

**Table 1. Anonymised Summary of the First 10 Adverse Event Reports Received Between 1 January 2023 and 31 December 2023
(Including IMDRF Annex A, E and F Classifications)**

Case number	Annex A	Annex E	Annex F
1	A110201-Application Program Freezes or Fails to Launch		F26-No Health Consequences or Impact
2	A090811-Unable to Obtain Readings	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact
3	A0719-Unexpected Shutdown	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
4	A070803-Failure to Power Up	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
5	A0708-Power Problem	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
6	A0719-Unexpected Shutdown	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact
7	A0719-Unexpected Shutdown	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
8	A0705-Battery Problem		F26-No Health Consequences or Impact
	A09-Output Problem		F26-No Health Consequences or Impact
9	A071204-No Pacing	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
10	A070803-Failure to Power Up	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure

**Table 2. Anonymised Summary of the First 10 Adverse Event Reports Received Between 1 January 2024 and 31 December 2024
(Including IMDRF Annex A, E and F Classifications)**

Case number	Annex A	Annex E	Annex F
1	A070903-Failure to Analyze Signal	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact
	A070908-Failure to Sense	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact
2	A071302-Inappropriate/Inadequate Shock/Stimulation	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
3	A071301-Failure to Deliver Shock/Stimulation	E0602-Cardiac Arrest	F24-Insufficient Health Impact Information
4	A070504-Premature Discharge of Battery	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
5	A071301-Failure to Deliver Shock/Stimulation	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact
6	A070912-Incorrect Interpretation of Signal	E0602-Cardiac Arrest	F24-Insufficient Health Impact Information
7	A070803-Failure to Power Up	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
8	A0712-Pacing Problem	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
9	A0705-Battery Problem	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
10	A070603-Failure to Charge	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact
	A070908-Failure to Sense	E2403-No Clinical Signs, Symptoms or Conditions	F26-No Health Consequences or Impact

**Table 3. Anonymised Summary of the First 10 Adverse Event Reports Received Between 1 January 2025 and 31 December 2025
(Including IMDRF Annex A, E and F Classifications)**

Case number	Annex A	Annex E	Annex F
1	A0203-Defective Device		F26-No Health Consequences or Impact
	A05-Mechanical Problem		F26-No Health Consequences or Impact
2	A150105-Key or Button Unresponsive/not Working	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
3	A070803-Failure to Power Up	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
4	A0501-Detachment of Device or Device Component	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
	A070803-Failure to Power Up	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
5	A090103-No Audible Prompt/Feedback	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
6	A070803-Failure to Power Up	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
7	A0203-Defective Device	E0602-Cardiac Arrest	F02-Death F05-Delay to Treatment/ Therapy
	A070503-Failure to Run on Battery	E0602-Cardiac Arrest	F02-Death F05-Delay to Treatment/ Therapy
	A070803-Failure to Power Up	E0602-Cardiac Arrest	F02-Death F05-Delay to Treatment/ Therapy
8	A0906-Gas Output Problem	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure
9	A070912-Incorrect Interpretation of Signal	E0602-Cardiac Arrest	F02-Death
10	A150105-Key or Button Unresponsive/not Working	E2403-No Clinical Signs, Symptoms or Conditions	F27-Problem Identified During Non-Clinical Procedure

**Table 4. Number of Defibrillator Adverse Incident Reports
Relating to Battery or Power Failure by Calendar Year
(identified Using IMDRF Annex A Medical Device Problem Codes)**

Year	Clinical Event as Reported	Number of Cases reported
2023	A0405-Degraded	1
	A0705-Battery Problem	14
	A0707-Failure to Discharge	1
	A0708-Power Problem	10
	A070802-Intermittent Loss of Power	3
	A070803-Failure to Power Up	83
	A070804-Unintended Power Up	1
2024	A020602-Component Missing	1
	A0705-Battery Problem	9
	A070503-Failure to Run on Battery	1
	A0707-Failure to Discharge	2
	A0708-Power Problem	6
	A070802-Intermittent Loss of Power	17
	A070803-Failure to Power Up	62
2025	A0405-Degraded	1
	A0705-Battery Problem	12
	A070503-Failure to Run on Battery	2
	A0707-Failure to Discharge	1
	A0708-Power Problem	3
	A070802-Intermittent Loss of Power	3
	A070803-Failure to Power Up	48