

**Table 1. IMDRF Annex A Breakdown for Fatal Defibrillator Adverse Incident Reports Received
Between 1 January 2023 to 31 December 2023**

Annex A	Number of Cases reported
A0203-Defective Device	1
A07-Electrical /Electronic Property Problem	1
A0705-Battery Problem	1
A070603-Failure to Charge	2
A070903-Failure to Analyze Signal	1
A070908-Failure to Sense	3
A070912-Incorrect Interpretation of Signal	2
A071204-No Pacing	1
A071301-Failure to Deliver Shock/Stimulation	4
A0719-Unexpected Shutdown	2
A090402-Failure to Deliver Energy	1
A090811-Unable to Obtain Readings	3
A10-Temperature Problem	1
A12-Connection Problem	1
A150302-Difficult or Delayed Separation	1
A23-Use of Device Problem	2

**Table 2. IMDRF Annex A Breakdown for Fatal Defibrillator Adverse Incident Reports
Received Between 1 January 2024 to 31 December 2024**

Annex A	Number of cases reported
A0203-Defective Device	2
A020501-Difficult to Open or Remove Packaging Material	1
A07-Electrical /Electronic Property Problem	4
A0705-Battery Problem	1
A0707-Failure to Discharge	3
A070803-Failure to Power Up	3
A070903-Failure to Analyze Signal	5
A070912-Incorrect Interpretation of Signal	4
A0713-Defibrillation/Stimulation Problem	1
A071301-Failure to Deliver Shock/Stimulation	8
A0719-Unexpected Shutdown	1
A0721-Circuit Failure	1
A090801-Signal Artifact/Noise	1
A090811-Unable to Obtain Readings	1
A23-Use of Device Problem	3
A2302-Use of Incorrect Control/Treatment Settings	1
A24-No Apparent Device Problem	1
A25-No Apparent Adverse Event	1

**Table 3. IMDRF Annex A Breakdown for Fatal Defibrillator Adverse Incident Reports Received
Between 1 January 2025 to 31 December 2025**

Annex A	Number of Cases reported
A01-Patient Device Interaction Problem	2
A0101-Patient-Device Incompatibility	2
A010101-Biocompatibility	1
A010102-Device Appears to Trigger Rejection	1
A010103-Inadequacy of Device Shape and/or Size	1
A0102-Osseointegration Problem	1
A0203-Defective Device	1
A0505-Firing Problem	1
A07-Electrical /Electronic Property Problem	4
A0705-Battery Problem	1
A070503-Failure to Run on Battery	1
A070803-Failure to Power Up	2
A0709-Device Sensing Problem	2
A070903-Failure to Analyze Signal	1
A070912-Incorrect Interpretation of Signal	3
A0713-Defibrillation/Stimulation Problem	2
A071301-Failure to Deliver Shock/Stimulation	10
A0719-Unexpected Shutdown	2
A090402-Failure to Deliver Energy	1
A090811-Unable to Obtain Readings	7
A110201-Application Program Freezes or Fails to Launch	2
A1301-Failure to Read Input Signal	1
A150104-Self-Activation or Keying	1
A150105-Key or Button Unresponsive/not Working	1
A210103-Inaccurate Information	1
A2105-Inadequate or Insufficient Training	1
A2303-Improper or Incorrect Procedure or Method	2
A25-No Apparent Adverse Event	1
A26-Insufficient Device Problem Information	1