



Medicines & Healthcare products Regulatory Agency

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Our Ref: **FOI2026/00903**

10 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 13 August. You wrote:

Under the Freedom of Information Act 2000, please provide:

- 1. The number of adverse incident reports received by the MHRA relating to defibrillators, including automated external defibrillators, manual defibrillators and monitor-defibrillators, in each of the calendar years 2023 to 2025 inclusive. Please state which field or device category was used to identify them.*
- 2. Of those reports, the number in which the patient outcome was recorded as death.*
- 3. Anonymised summaries of the first 10 of those reports in each year, to the level of detail routinely provided in response to similar requests, with nothing identifying the patient, the reporter or the organisation.*
- 4. If the MHRA holds a breakdown by fault type, the number of reports attributed to battery or power failure, and the number attributed to missing or expired consumables such as defibrillation pads, then please provide this as well broken down by calendar year.*

If any part of this request would exceed the appropriate limit, please say which part and answer the remainder.

MHRA Response

We confirm that we hold the information you have requested.

As such please find data relating to your query below:

We conducted a search of the MHRA adverse incident database for reports relating to defibrillators received between 1 January 2023 to 31 December 2025.

Defibrillator-related reports were identified using the Global Medical Device Nomenclature (GMDN) Collective Term (CT) codes listed below. These codes were selected because they represent the device categories under which external defibrillators, automated external defibrillators (AEDs), public access defibrillators, manual defibrillators and monitor-defibrillators are routinely classified within the MHRA adverse incident database.

The following GMDN CT codes were used:

- CT269 – External defibrillators

- CT299 – Public access defibrillators

Using these search criteria, the MHRA identified **1,409 adverse incident reports** relating to defibrillators received between 1 January 2023 and 31 December 2025, inclusive. Of these, 478 reports were received in 2023, 595 reports were received in 2024, and 336 reports were received in 2025.

With regard to your request for “*the number in which patient outcome was recorded as death*”, we searched for records where either:

- “Death” was recorded as the reported patient outcome; or
- International Medical Device Regulators Forum (IMDRF) Annex code F02 (Death) was assigned during case assessment.

These criteria were used to ensure that both reporter-submitted outcome information and MHRA-coded patient impact assessments were captured.

Using this methodology, the MHRA identified **86 adverse incident reports** received between 1 January 2023 and 31 December 2025 in which a fatal outcome was recorded. Of these, 19 reports were received in 2023, 38 reports were received in 2024, and 29 reports were received in 2025.

In relation to your query regarding the “*Anonymised summaries of the first 10 of those reports in each year*”, we have provided anonymised summaries derived from information routinely recorded during MHRA case assessment.

The anonymised summaries can be found in the accompanying PDF document under **Annex A**, with reference to Table 1 – 3:

- *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)*
- *Table 2. Anonymised Summary of the First 10 Adverse Event Reports Received 1 January 2024 and 31 December 2024 (Including IMDRF Annex A, E and F Classifications)*
- *Table 3. Anonymised Summary of the First 10 Adverse Event Reports Received 1 January 2025 and 31 December 2025 (Including IMDRF Annex A, E and F Classifications)*

The summaries have been prepared using the IMDRF Adverse Event Terminology, which provides a consistent and internationally recognised method for classifying medical device incidents. The summaries include information on the reported device problem, clinical effects and patient outcome, while excluding any information that could identify individual patients, reporters, healthcare organisations or manufacturers.

The following IMDRF classifications have been included:

- Annex A – Medical device problems
- Annex E – Health Effects – clinical signs and symptoms or conditions
- Annex F – Health Effects – health impacts or patient outcome

The tables contain anonymised summaries of the first 10 reports received in each calendar year (2023, 2024 and 2025), together with the associated IMDRF Annex A, E and F classifications.

With regard to your request of reports attributed to “*battery or power failure*”, we searched for records assigned the following IMDRF Annex A (Medical Device Problem) codes. These codes were selected because they relate to battery malfunctions, power supply failures, charging issues or loss of device power functionality.

The following Annex A codes were used:

- A0705 – Battery Problem
- A0707 – Failure to Discharge
- A0708 – Power Problem
- A0718 – Failure to Shut Off
- A1910 – Electrical Power Problem
- A0405 – Degraded
- A020602 – Device Misassembled During Manufacturing/Shipping

Reports assigned one or more of the above codes were extracted and grouped by calendar year.

The breakdown of reports relating to battery or power failure can be found in the accompanying PDF under **Annex A**:

- *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)*

When reviewing Adverse incident data please note:

- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues.
- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of dermal fillers and on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- The numbers may include reports where the incident has been taken from published literature.
- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.
- The inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. The data provided, therefore, is not a summary of known or

proven adverse reactions to the device and must not be interpreted and used as such.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](https://ico.org.uk/for-the-public/foi/) or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>

Annex A



TABLES 1 2 3 4.pdf