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| Working Group Draft Document |
| IMDRF/AET WG/N86 DRAFT: 2024 |
| Considerations for the Selection of IMDRF Adverse Event Terminology A Guide for Industry Partners and Healthcare Providers |
| Authoring Group |
| Adverse Event Terminology Working Group |

Preface

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**Jeffery Shuren, IMDRF Chair**

Contents

[1. Introduction 4](#_Toc172808215)

[1.1. Objective of this manual 4](#_Toc172808216)

[1.2. Overview of IMDRF codes and coding practices for reports 4](#_Toc172808217)

[2. General Term Selection Principles 7](#_Toc172808218)

[2.1. Select the most detailed level term. 7](#_Toc172808219)

[2.2. Include at least one code from each group of terms on all reports 7](#_Toc172808220)

[2.3. Codes May Change During the Investigation 8](#_Toc172808221)

[2.4. Quality Assurance 9](#_Toc172808222)

[2.5. Additional Codes and Terms 9](#_Toc172808223)

[3. Specific Term Selection 10](#_Toc172808224)

[3.1. Device Problem (A Codes) 10](#_Toc172808225)

[3.2. Medical Device Component (G Codes) 10](#_Toc172808226)

[3.3. Manufacturer's Cause Investigation (B, C & D Codes) 11](#_Toc172808227)

[3.4. Health Effects Codes (E & F Codes) 13](#_Toc172808228)

[4. Coding Examples from Case Description 17](#_Toc172808229)

[4.1. Broken hip stem implant (detailed illustrative example) 17](#_Toc172808230)

[4.2. ICD failure 18](#_Toc172808231)

[4.3. AED performed as intended 18](#_Toc172808232)

[4.4. No audible alarm on patient monitor 19](#_Toc172808233)

[4.5. Electrical supply issues with electric scalpel 19](#_Toc172808234)

[4.6. Surgical illuminator arm broke 20](#_Toc172808235)

[4.7. Fracture of microcatheter during surgery 20](#_Toc172808236)

[4.8. False negative test result 21](#_Toc172808237)

[4.9. Posterior capsule rupture in cataract surgery 21](#_Toc172808238)

[4.10. Broken Variable-Angle Compression Plate 22](#_Toc172808239)

[4.11. Fracture of a proximal femoral plate 23](#_Toc172808240)

[4.12. Blood glucose monitoring system discrepancies 23](#_Toc172808241)

[4.13. Patient monitoring unit telemetry issues 24](#_Toc172808242)

[4.14. Breast implant rupture 24](#_Toc172808243)

[4.15. Left ventricular assist device battery issue 25](#_Toc172808244)

[4.16. Balloon catheter failed to deflate 26](#_Toc172808245)

[4.17. Air bubbles in an infusion set 26](#_Toc172808246)

[4.18. Air-in-Line sensor in dialysis lines did not trigger alarm 26](#_Toc172808247)

[4.19. Uncontrolled movement of a powered wheelchair 27](#_Toc172808248)

[4.20. Hemolyzed plasma in blood collection tubes 28](#_Toc172808249)

[4.21. Breast implant removal 28](#_Toc172808250)

[4.22. Implanted port device fracture 29](#_Toc172808251)

[5. Frequently Misused/Misunderstood Codes 30](#_Toc172808252)

[6. Useful Links 31](#_Toc172808253)

[Definitions 32](#_Toc172808254)

# Introduction

Different Regulatory Authorities around the world require stakeholders (manufacturers, healthcare providers, etc.) to submit adverse event reports involving medical devices marketed in their jurisdictions.
In general, a report contains free text that provides a narrative of what happened, informing the identified problem and the immediate outcome. Each jurisdiction adopts a model form, in which the data of interest is inserted by the notifier. At the end of the investigation, the manufacturer/importer reports the findings and confirms, or not, the initial reason for the notification.
The use of harmonized coding aims to improve signal detection by adverse event management systems, enabling a faster response from both industry and regulatory authorities. More details can be found on the International Medical Device Regulators Forum (IMDRF) web site in IMDRF/AE WG/N43FINAL:2020 (Edition 4 IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes.

## Objective of this manual

The objective of this document is to provide further guidance on the correct application and consistent use of the terminology. The document provides guidance for all stakeholders:

* providing general coding principles on reporting incidents using IMDRF codes; and
* providing examples to address common coding challenges.

This document is not intended to address every potential code selection scenario. Medical judgement, related expertise, and common sense should also be applied.

**Regional specific regulatory reporting requirements will need to be considered in conjunction with this document**. The aim of this document is solely to provide further guidance on the use of the IMDRF Codes and Terms.

## Overview of IMDRF codes and coding practices for reports

Completing an adverse event report involves coding free-text information describing a medical device incident using the standardized term(s) defined in the IMDRF codes. The complete IMDRF terminology is comprised of seven groupings within four distinct sets of terminologies and their associated alphanumeric codes. A summary of the IMDRF groupings and their associated hierarchical structure (coding system) is presented in Table 1. Codes selected from each grouping when considered together provide a complete overview of the event and the related investigation.

### Table 1. Overview of the Four Sets of IMDRF Terminologies

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| No.  | Name of terminology | Description  | Code Prefix | Coding system |
| 1 | Medical device problem (A codes) | Terms/codes for describing problems (malfunction, deterioration of function, failure) of medical devices that have occurred in pre- or post-market contexts (e.g. clinical studies, clinical evaluation or post-market surveillance). | A | A|00[00][00] |
| 2 | Component (G codes) | Terms/codes for describing the component of the medical device involved in the adverse event/incident. | G | G|00[000][00] |
| 3 | Cause investigationType of Investigation (B Codes) | Terms/codes for describing the type of investigation of the device involved in the reported event.  | B | B|00 |
|  | Cause investigationInvestigation Findings (C codes) | Terms/codes for describing the findings of the device involved in the reported event. These are higher level codes to group device problems. | C | C|00[00][00] |
|  | Cause investigationInvestigation Conclusion (D Codes) | Terms/codes for describing the conclusion of the device involved in the reported event. They describe the root cause of the incident identified by the manufacturer once the investigation is completed. | D | D|00[00] |
| 4 | Health EffectsClinical Signs, Symptoms and Conditions (E codes) | Terms/codes for describing the clinical signs, symptoms and conditions of the affected person appearing as a result of the medical device adverse event/incident. | E | E|00[00][00] |
|  | Health EffectsHealth Impact (F Codes) | Terms/codes for describing the consequences of the medical device adverse event/incident on the person affected as a result of the incident.  | F | F|00[00][00] |

It is expected that all reports will include a minimum of one code from each of the 7 terminology groups. Case examples are provided in Section 4.

|  |
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# General Term Selection Principles

This section details the key coding principles that you must consider before starting to code an adverse event report. The choice should not be made from reading the term alone. Read the full definition of the possible code options before coding the report. It’s crucial to emphasize that coding is hierarchical, meaning that the selected code must not only match the definition but also align with the codes above it in the hierarchy.

##  Select the most detailed level term.

IMDRF codes are structured as a hierarchy. In the IMDRF coding structure, the more general terms comprise the entry level (i.e. Level 1). The more specific terms (Level 2, Level 3, etc.) nest within the Level 1 entries in that group.

In coding a report, the most detailed level term possible should always be selected for each of the groupings as this allows for capturing the term at its most precise level. Thoroughly review the code definitions prior to coding.

|  |  |  |  |
| --- | --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment | Best Choice  |
| False positive patient sample | Incorrect, Inadequate or Imprecise Result or Readings [A0908] |  |  |
|  | False Positive Result [A090804] | This is the more precise term; the parent term is too broad | ✓ |
| Little pieces of the device break off when adjusting the strap | Break [A0401] |  |  |
|  | Material Fragmentation [A040103] | As it is multiple small pieces breaking off, this may be better captured by a more specific term. | ✓ |

**Note**: that in both the above examples, the more precise term is a child of the other term; the parent term isn’t wrong, it simply lacks precision.

## Include at least one code from each group of terms on all reports

Where no exact match can be found within the IMDRF terminology, one of the following can be used as case description code:

* Appropriate Term/Code Not Available (A27/C22/D17/E2402/F28/G0702)
* Insufficient Information (A26/B22/E2401/F24/G0703)
* Part/Component/Sub-assembly Term not Applicable (G0701)

There are codes to indicate that it is not yet possible to provide information about the investigation.

This means that it is possible to submit a report which is fully and correctly coded even if the manufacturer knows nothing more than the name of the device which was involved in the incident. The benefit of providing these codes is that it makes it clear that the information is not known, whereas without the codes it is possible that the reporter overlooked those fields and submitted an incomplete report in error. The following illustrates how one can select a code from each section despite having insufficient information about the incident.

A26 - Insufficient Information

B21 - Type of Investigation Not Yet Determined

C21 - Results Pending Completion of Investigation

D16 - Conclusion Not Yet Available

E2401 - Insufficient Information

F24 - Insufficient Information

G07003 - Insufficient information

## Codes May Change During the Investigation

Changes in the patient’s condition, follow-up information, or investigation results might require an update of the reported coding. When this happens, a new report updating or complementing the codes previously submitted should be provided. For example:

1. If a submitted code was incorrect due to an error, the code should be removed or replaced.
2. If additional information becomes available, the codes assigned should be updated.

|  |  |  |  |
| --- | --- | --- | --- |
| **Reported narrative**  | **IMDRF terms [codes] Options** | **Comment**  | **Best Choice**  |
| The manufacturer received information alleging a ventilator inoperative condition occurred on a ventilator. Additionally, it was stated "Unable to write to Event Log" an error was observed in the device error log.**Follow-up information:** It was later clarified that the ventilator didn't start up properly but booted up endlessly instead. | **Initial:** Data Problem [A1107]Insufficient Information [A26] **Follow-up:**Data Problem [A1107]Failure to Power Up [A070803] | I**nitial:** Insufficient information can be used here in addition to coding the data problem, as without further information the inoperative condition can’t be accurately selected **Follow-up:** A26 was replaced by A070803 based on the additional information received from the field. |  ✓ |
|  | **Initial:** Data Problem [A1107]**Follow up:**Data Problem [A1107]Failure to Power Up [A070803] | Just coding the data problem doesn't capture the second problem, initially unspecified allegation of “inoperative condition”, so it should not stand alone even when the manifestation of “the inoperative condition” is yet unknown |   |

## Quality Assurance

Consistent coding practices are key in facilitating effective terminology standardization. It is recommended that anyone assigning the adverse events coding (manufacturers, healthcare providers, etc.) should have organization-wide term selection methods and quality assurance procedures in internal guidelines consistent with this document to ensure accurate, consistent coding.

## Additional Codes and Terms

If when coding, you regularly find that you are selecting “code not available” you may need to suggest a new term by submitting a change request. Please find further detail on this process in the [Maintenance of IMDRF AE Terminologies](https://www.imdrf.org/node/530)" (IMDRF/AE WG/N44) FINAL:2020). Before making such a request, it is important to check the latest version of the IMDRF codes on the IMDRF Website.

The terminology was developed to meet the needs of regulators. It is recognized that manufacturers may need more specific terms for coding their product post market surveillance data. These should be developed by the manufacturer for their own use. The additional terms should be child terms of existing IMDRF terms so that the IMDRF terms can be used for reporting.

Healthcare providers that use the IMDRF codes and terms may also consider a similar approach.

# Specific Term Selection

## Device Problem (A Codes)

The device problem terms/codes describe the problem (malfunction, deterioration of function, failure) associated with medical device adverse events.

The “A” term should be the answer to the question “what was the observed problem with the medical device?” Some device problems give an indication of the cause, but in general the terms are intended to be factual and not speculative.

### Avoid Coding the Normal Functions of the Device

When coding the device problem, care must be taken not to code the normal function of the device; for example, “infusion device alarmed because the infusion tank was empty.” In this scenario, the alarm is the normal function of the device, and therefore is not coded as a malfunction.

This principle emphasizes the importance of distinguishing between inherent device operations and genuine malfunctions. Often the reason for the alarm is the failure that should be coded (e.g. if the alarm code is for obstruction, the alarm is not the problem, the obstruction is).

|  |  |  |  |
| --- | --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment | Best Choice  |
| Device alarmed low battery and shut down, even though battery was freshly charged that morning | Device Alarm System [A1601]Premature Discharge of Battery [A070504]Unexpected Shutdown [A0719] | The alarm system did not malfunction, alarming is the intended protective measure to warn that battery is nearly discharged. |  |
|  | Premature Discharge of Battery [A070504]Unexpected Shutdown [A0719] | The battery discharged before it was expected to, and the system shut down unexpectedly.  | ✓ |

## Medical Device Component (G Codes)

The Medical Device Component codes describe the specific part or component that was involved in, or affected by, the medical device adverse event.

The G terms should be the answer to the question “what part or component of the medical device was involved in or suspected to have been involved in or affected by the adverse event?” It is intended that the G terms can be used in combination with both the device problem codes (A) and the investigation codes (B, C, D). The design of adverse event reporting systems should facilitate the linking of the G terms with terms from the other groupings.

|  |  |  |  |
| --- | --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment | Best Choice |
| Initial: The device was explanted because of premature battery depletion. | Battery [G02002]Premature Discharge of Battery [A070504] |  | ✓ |
|  | Premature Discharge of Battery [A070504] | While it may seem obvious that the battery was a problem, having the parts coded using DCC terms can allow detection of trends affecting components. |  |
| Follow-up: Analysis of the device identified an anomalous capacitor as root cause of the increased current consumption that caused the premature battery depletion. | Capacitor [G0201201]Electrical/Electronic Component Problem Identified [C0201]Cause Traced to Component Failure [D02] | Without the inclusion of the capacitor term from DCC terms it wouldn’t be obvious what the problematic electronic component was.  | ✓ |
|  | Electrical/Electronic Component Problem Identified [C0201]Cause Traced to Component Failure [D02] |  |  |

## Manufacturer's Cause Investigation (B, C & D Codes)

The B, C and D terms together detail the Cause Investigation coding. These terms can be thought of as coding the manufacturer’s investigation, broken down into the method, the results, and the conclusion.

### Manufacturer Investigation Types (B codes)

Manufacturer type of investigation terms/codes are used to describe the types of investigation related to the adverse event that has been undertaken.

The B terms should be the answer to the question “what methods have been or will be used to investigate the incident?”

If the methods of investigation have not been determined when submitting the Initial report, the term **Type of Investigation Not Yet Determined [B21]** can be used.

Multiple codes may need to be selected to comprehensively explain all the methods of evaluation in addition to the availability of the device for testing.

|  |  |  |
| --- | --- | --- |
|  Reported narrative | IMDRF terms [codes] Options | Comment |
| The device has been returned for analysis. Based on the problem description, photos provided, and testing performed, a likely cause is a heat exchanger leak in the port area. A review of the batch record found no deviations that could have caused or contributed to the reported malfunction. No trends for this type of failure have been observed. | Trend Analysis [B12]Analysis of Production Records [B14]Testing of Actual/Suspected Device [B01]Analysis of Information Provided by User/Third Party [B15] | Multiple types of investigations occurred so each investigation type has been coded. |

### Manufacturer Investigation Findings (C codes)

Manufacturer investigation findings terms/codes are used to describe the findings of the investigation relating to the reported event.

The C terms should be the answer to the question “what are/were the results of the manufacturer’s investigation of the adverse event/incident?”

An appropriate number of C codes should be selected to enable the findings from the investigation to be clearly identified. It is possible that the result codes assigned may not align with the initial reported device problem codes.

|  |  |  |  |
| --- | --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment | Best Choice |
| The device had displayed a critical error code. On examination water damage and corrosion was found on the PCBA. Cracks were found in the waterproofing/case. | Degradation Problem Identified [C0601] Leakage/Seal [C0703] | The finding of cracks in the waterproofing suggests a reason for the degradation problem and should also be included. | ✓ |
|  |  |  |

### Manufacturer Investigation Conclusions (D codes)

Manufacturer investigation conclusion terms/codes are used to describe the conclusion of the adverse event investigation, indicating the root cause.

The D terms should be the answer to the question “what was concluded as the root cause of the reported event?”

The D terms are designed to be broad, as the detail is added, detailing the findings in the context of the reported device problems. Regulators may require more detail regarding the exact root cause and corrective action in the report text. However, it is not appropriate for the IMDRF to include sub-terms in D terms to cover every stage of the design process nor every type of manufacturing process and associated machinery.

Example: If the root cause was traced to a loose nozzle on a widget extrusion system on production line 3, then the appropriate D code would be D03 - Cause Traced to Manufacturing.

Typically, there are only a few root cause codes that are applicable. Please select the most appropriate code or codes.

|  |  |  |
| --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment |
| Upon device return and inspection, some spline deformation was observed on the catheter. While moving the slider switch, the spline cage remained undeployed. It was noted that the guidewire lumen was no longer adhered to the tip of the spline cage. The spline cage of the catheter was examined under a microscope to look for any potential causes for the spline inversion. It was observed that the welding of the splines was visibly damaged by the melting/ overheating during the procedure. Dissection of the catheter was performed to look for any abnormalities that could have contributed to the delamination of the guidewire lumen, but no other anomalies were noted. The reported event was confirmed. | Cause Traced to Device Design [D01]Cause Traced to Component Failure [D02] | Multiple causes were found so each investigation type has been coded. |

## Health Effects Codes (E & F Codes)

Together the Health Effect terms (E and F terms) should be the answer to the question “what happened to the patient (or other person affected) as a result of the incident or use of the device?”

The relevant terms should be selected even if it is not confirmed that the harm was caused by the device. The health effect codes should not be selected for any harm that cannot be confirmed to be related to the device. The exception to this is F29 - Death not related to reported adverse event. This code has been specifically added to enable reports to record the fact that a death has occurred without linking it to the incident. This is to avoid the apparent ambiguity caused by incidents being initially reported as “death”, then being concluded as “No Health Consequences or Impact”. Use of medical judgement is important for accurate term selection.

The IMDRF E terms are harmonized with a subset of the Medical Dictionary for Regulatory Activities (MedDRA) terms, except for some specific cases. When coding you may wish to consult the most current [MedDRA® TERM SELECTION: POINTS TO CONSIDER document](https://admin.meddra.org/sites/default/files/guidance/file/000571_termselptc_r4_21_mar2021.pdf).

### Health Effect – Clinical Signs, Symptoms and Conditions Terms and Codes (E codes)

E terms/codes are used to describe the clinical signs, symptoms, and conditions that manifest in the affected person as a result of the medical device adverse event. These terms are organized into categories based on organ systems and physiological problems.

Some terms appear in more than one category for ease in finding the proper term. In these cases, each repeated term will only have one unique code assigned based on its primary category.

**It is important to note that these terms should not be used to describe the patient history and/ or signs, symptoms, and conditions that existed prior to the adverse event (e.g. conditions that the device is intended to treat).**

The terminology was developed to meet the needs of regulators. It is recognized that manufacturers may need more specific terms for coding their product post market surveillance data. These should be developed by the manufacturer for their own use. The additional terms should be child terms of existing IMDRF terms so that the IMDRF terms can be used for reporting.

Where a provisional diagnosis is presented and no definitive diagnosis is known, the provisional diagnosis should be coded. Should a different diagnosis be reached at a later time, this can be corrected with a follow up report.

|  |  |  |  |
| --- | --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment | Best Choice |
| The wheelchair of the paraplegic patient malfunctioned.The patient suffered a fall and was admitted to the hospital with a suspected intracranial hemorrhage.Follow-up: The patient was later diagnosed with a concussion while an intracranial hemorrhage could not be confirmed | Fall [E2007]**Initial:** Intracranial Hemorrhage [E0118]**Follow-up:** Concussion [E0108] | E0118 should be coded initially but corrected to E0108 after the final diagnosis becomes available. | ✓ |
|  | Paraplegia [E012203]Fall [E2007] **Initial:** Intracranial Hemorrhage [E0118]**Follow-up:** Concussion [E0108] | Being a precondition, paraplegia should not be coded. |  |

#### Combination Terms

There may be situations where two terms can be used in combination to describe a condition. The use of multiple terms to capture an adverse event is acceptable, provided that the terms are still individually accurate. Where a single term captures both the site of and the type of problem, the single term should be selected.

|  |  |  |  |
| --- | --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment | Best Choice |
| The patient developed a fungal eye infection | Fungal Infection [E1902]Eye Infections [E0818] | The combination of terms captures information that neither term would capture on their own | ✓ |
| Fungal Infection [E1902] |  |  |
| Eye Infections [E0818] |  |  |
| The patient’s cornea was punctured | Corneal Perforation [E0811] | In this case, a single term can be used | ✓ |
| Eye Injury [E0819]Perforation [E2114] |  |  |

#### Test results

A narrative may describe test results presented in the form of a number and units, interpretation of this value should be undertaken according to local guidance and in line with using medical judgement. The approach taken can be confirmed with the appropriate regulator.

|  |  |  |
| --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment |
| Reduced blood cell count and hematocrit. | Anemia [E0301] | The definition of anemia is deliberately broad.  |
| RBC was 3.6 [10^12/L] | Anemia [E0301] | There is no way to express test results without this interpretation; for both men and women this is below the normal range; check with the regulator. |
| Unsure of insulin pump delivery (possible over delivery), blood glucose levels were 2.8 mmol/L. No patient consequences. | Hypoglycemia [E1206] | Although it is stated that there are no patient consequences, the fact that blood glucose levels are lower than normal levels, hypoglycemia could be coded as a health effect; check with the regulator. |

#### Death as the only reported patient information

Death is not considered a clinical sign, symptom, or condition, and is instead captured in the F terms as a Health Impact (as well as possibly being a field required on the reporting forms of many regulators). Ideally, additional information would be sought to allow selection of codes in E terms, but the code E2401 (Insufficient Information) can be used if necessary.

### Health Effect – Health Impact Terms and Codes (F codes)

F terms/codes are for describing the consequences of the medical device adverse event on the person affected. The resulting consequences can include final patient outcomes and/or interventions or procedures required as a result of the clinical signs, symptoms and conditions captured using E terms or to deal with a medical device problem captured using A terms.

Do not select every applicable term; if for example there were both a minor injury and a serious injury, only the more serious should be coded. Nonetheless, multiple codes can be selected where they do not imply one another. Please strive for consistency with other fields on the report related to reporting outcomes.

For most codes, the health impact should have followed the adverse event, and the device should have contributed to or potentially contributed to the health impact. The exception to this is the use of F29 (Death not related to the reported adverse event).

It is important to be mindful of the difference between “no patient involved “(F27 - problem identified during non-clinical procedure) and “no patient consequence” (F26 – no health consequences or impact) when deciding on the best code to choose. If you have coded any clinical signs or symptoms, then “no patient consequence” should not be used.

|  |  |  |
| --- | --- | --- |
| Reported narrative | IMDRF terms [codes] Options | Comment |
| No patient consequences. | No Health Consequences or Impact [F26] | If there was no impact to the health outcomes of the patient, this term should be selected to satisfy E/F terms.This code should not be used if there were consequences such as delays in treatment, extended surgery, or additional medical intervention. |
| An issue with the device was identified during maintenance | Problem identified during non-clinical procedure [F27] | Only choose when no patient (sample) was present when the incident happened. This applies for incidents with quality assessment samples or during cleaning and maintenance. |

# Coding Examples from Case Description

The coding examples in this section are not intended to address every potential code selection scenario. Users of IMDRF codes should rely on their expertise and judgement to determine the most appropriate codes to apply in each scenario. The examples serve as a guide, but medical judgement, related expertise, and common sense should also be applied.

## Broken hip stem implant (detailed illustrative example)

Narrative:

A patient with a hip implant fell to the ground during an intensive sport activity, complaining of pain. The patient was taken by ambulance to an Emergency Department for an x-ray. The hip stem was found to be broken due to the fall and patient required hospitalization. During surgery, the device was explanted, and a new hip implant was implanted. The affected device was returned to the manufacturer for investigation. The manufacturer evaluated the returned device and conducted a review of the production record of the lot. The manufacturer confirmed the breakage of the stem but could not identify any issue associated with the production of the device. However, the manufacturer noted that the Instructions for Use clearly indicates that patients with the implant should not participate in any heavy-duty labour work or sport activities.

The following table shows the appropriate codes selected for the incident described above.

|  |  |  |
| --- | --- | --- |
| Text | IMDRF Code Set | Code  |
| complaining of pain | Signs and Symptoms  | Pain [E2330] |
| hip stem was found to be broken  | Device Problem  | Break [A0401] |
| required hospitalization | Health Impacts  | Hospitalization or prolonged hospitalization [F08]Serious Injury/illness/Impairment [F12] |
| During surgery, the device was explanted, and a new hip implant was implanted. | Health Impacts | Device Revision or Replacement [F1905]Unexpected Medical Intervention [F23] |
| manufacturer evaluated the returned device | Investigation Type | Testing of actual/suspected device [B01] |
| conducted a review of the production record of the lot | Investigation Type | Analysis of Production Records [B14] |
| The manufacturer confirmed the breakage of the stem | Investigation Findings | Fracture Problem [C070603] |
| The Instructions for Use clearly indicates that patients with the implant should not participate in any heavy-duty labour work or sport activities. | Investigation Conclusion | Failure to Follow Instructions [D1101] |
|  | Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |

**Note:** In the incident, “fall” is not coded as it is not the result of the incident.

## ICD failure

During an in-clinic follow-up of a patient with an ICD, noise resulting in oversensing was observed on the device. A device header problem was suspected. The device was explanted and replaced to resolve the event. The patient was stable. The reported event of noise was confirmed via review of the device data. However, the noise was determined to have been caused due to non-device related factors. The device behaved as expected and according to its programmed settings. The reported event of header anomaly could not be confirmed. Interrogation of the device revealed the device was above elective replacement indicator (ERI) when received. Telemetry, impedance, sensing, pacing and high voltage (HV) output functions of the device were tested and found to be normal which indicated no anomalies were found.

|  |  |
| --- | --- |
| **IMDRF Code Set** | **Code**  |
| Device Problem  | Over-Sensing [A070909] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001]Header [G04064] |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | Device revision or Replacement [F1905] |
| Investigation Type | Event History Log Review [B24]Testing of Actual/Suspected Device [B01] |
| Investigation Findings | No Device Problem Found [C19] |
| Investigation Conclusion | Device problem excluded [D1402] |

**Note:** Only “Over-sensing” is coded as device problem as the “header” problem is only suspected. Other codes are applicable as well as Health impact codes (i.e. 1901 - Additional Surgery or 1903 - Device Explantation). When a manufacturer is coding multiple reports for similar health impacts with similar devices, every effort should be made to be consistent by using the same health impact code (i.e. always 1905 or always 1901 for surgical revision).

The analysis was deemed sufficient to exclude a device malfunction with high certainty. Therefore, D1402 was picked.

## AED performed as intended

Patient collapsed and an AED was applied on the patient, who then passed away. The manufacturer reviewed the event data and confirmed the device performed as expected. There was no evidence to suggest any device malfunction or performance deficiency. The device correctly classified each ECG signal as non-shockable. Afterwards, the field representative tested the device, and it performed as intended.

|  |  |
| --- | --- |
| **IMDRF Code Set** | **Code**  |
| Device Problem  | No Apparent Adverse Event [A25] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | Death not related to reported adverse event [F29] |
| Investigation Type | Testing of Actual/Suspected Device [B01] |
| Investigation Findings | No Device Problem Found [C19] |
| Investigation Conclusion | Device problem excluded [D1402] |

## No audible alarm on patient monitor

It was reported that there was no audible alarm on a patient monitor. Only a visual alarm was displayed when the SpO2 signal was lost. The device was in use on a patient and there was no reference to patient harm. The review of the device log and its evaluation by the manufacturer did not confirm the customer’s allegations. The device was confirmed to be operating per specifications and no failure was identified.

|  |  |
| --- | --- |
| **IMDRF Code Set** | **Code**  |
| Device Problem | No Audible Prompt/Feedback [A090103] |
| Component Problem  | Alarm [G06001]  |
| Signs and Symptoms  | Insufficient Information [E2401] |
| Health Impacts  | Insufficient Information [F24] |
| Investigation Type | Event History Log Review [B24] |
| Investigation Findings | No Device Problem Found [C19] |
| Investigation Conclusion | Device problem excluded [D1402] |

## Electrical supply issues with electric scalpel

A customer reported that he was experiencing problems with the electric scalpel, the device does not turn on. It was noted that the connection to the electrical supply network (socket melting the base of the fuse) made it unavailable for use. The investigation showed that the scalpel's fuse holder was disconnected and improperly removed by the customer. Pointed and cutting tools were used to force the edges and contours of the fuse holder box, thereby destroying the support locks, and these locks support the fuses that are being pressed by safety springs, which guarantee electrical contact to meet the electrical parameters declared by the manufacturer. The customer did not follow the instructions for correctly disconnecting the fuse box, as printed on the external box.

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| **IMDRF Code Set** | **Code**  |
|  Device Problem   |  Activation Failure [A150101] Thermal decomposition of device [A1006] |
|  Component Problem   |  Part/Component/Sub-assembly Term not Applicable [G07001] |
|  Signs and Symptoms  |  No Clinical Signs, Symptoms or Conditions [E2403] |
|  Health Impacts   |  No Health Consequences or Impact [F26] |
|  Investigation Type |  Testing of Actual/Suspected Device [B01] |
|  Investigation Findings |   Stress Problem Identified [C0706] |
|  Investigation Conclusion |  Failure To Follow Instructions [D1101] |

##  Surgical illuminator arm broke

The arm of the surgical illuminator broke, and the head suddenly fell. As the product is used outside the surgical field, there was no health hazard to the patient; and since it was replaced with an alternative product, there was no impact on the surgery. After inspecting the item, it was suspected that the cause was deterioration over time in the parts that fix the arm.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem  | Break [A0401] |
| Component Problem  | Retainer [G0405211] |
| Signs and Symptoms | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | No Health Consequences or Impact [F26] |
| Investigation Type | Testing of Actual/Suspected Device [B01] |
| Investigation Findings | Degradation Problem Identified [C0601] |
| Investigation Conclusion | End of Life Problem Identified [D1105]Cause traced to component failure [D02] |

## Fracture of microcatheter during surgery

Manufacturer was advised by the surgeon that upon retraction of the microcatheter at completion of 360 degrees canaloplasty procedure, the microcatheter component broke, leaving a ~12mm section of microcatheter within and partially extended from the Schlemm's canal. The surgeon noticed the fragment and removed it intra-operatively using micro-grasping forceps.

An in-depth visual and functional inspection of the returned device, including all components and the detached material removed from the patient's eye was carried out. No manufacturing or device problem was identified. The catheter shaft appeared to have been damaged in an exogenous manner. The most likely cause of damage is other surgical instrumentation used during surgery unrelated to the device.

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| **IMDRF Code Set** | **Code**  |

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| Device Problem  | Break [A0401]Material separation [A0413] |
| Component Problem  | Catheter [G04023]  |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | Unexpected medical intervention [F23]Prolonged surgery [F1908] |
| Investigation Type | Testing of Actual/Suspected Device [B01] |
| Investigation Findings | Fracture Problem [C070603] |
| Investigation Conclusion | Adverse Event Related to Procedure [D1002] |

## False negative test result

It was reported that several testing sites participating in the same round of external quality assessment via proficiency testing reported a false negative result for the same single specimen of a multi-specimen panel. The testing sites all identified the result as non-reactive for the pathogen, which would lead to false negative misdiagnosis. The panel was comprised of positive sera sourced commercially. As the specimen was tested for external quality assessment purposes, no patient was involved. The provider of the external quality assessment scheme provided a sample of the specimen which was referred to a specialist laboratory for sequencing. The specimen contained an uncommon but documented genetic variant of the pathogen. The investigation showed that the target sequence did not account for all variants of the pathogen.

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| **IMDRF Code Set** | **Code**  |
|  Device Problem  | False Negative Result [A090803] |
|  Component Problem  | Device Ingredient or Reagent [G01003] |
|  Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
|  Health Impacts  | Problem identified during non-clinical procedure [F27] |
|  Investigation Type | Testing of Device from Same Lot/Batch Retained by Manufacturer [B02]Historical Data Analysis [B11]Analysis of Production Records [B14]Analysis of Information Provided by User/Third Party [B15] |
|  Investigation Findings | Change in Target Marker/Variant/ Mutant [C1403] |
|  Investigation Conclusion | Cause Traced to Device Design [D01] |

## Posterior capsule rupture in cataract surgery

It was reported that a patient suffered from posterior capsule rupture as the lens was not stable in the eye. An explant was performed, and the patient recovered well. There was no delay in treatment or other interventions provided. No further information was provided.

A product evaluation was not performed because the product was not returned. As per complaint investigation results, the product was released within specifications. No product deficiency or product malfunction could be identified. A search of complaints related to the production order for the specific serial number was performed in the system. The search revealed that no other complaints were received for the production order of reported serial number.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem  | Patient Device Interaction Problem [A01] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | Capsular Bag Tear [E0801] |
| Health Impacts  | Device Explantation [F1903] |
| Investigation Type | Device Not Returned [B17]Analysis of Production Records [B14] |
| Investigation Findings | No findings available [C20] |
| Investigation Conclusion | Cause Not Established [D15] |

## Broken Variable-Angle Compression Plate

A patient with trauma after a serious accident underwent revision surgery due to a broken Variable-Angle Compression Plate. The patient underwent a revision with a Retrograde/Antegrade Femoral Nail. The explanted device was returned to the manufacturer and the evaluation process was completed. Visual analysis of the photo revealed that the plate was broken across the shaft. No other issues were found.

The product was returned to the manufacturer for evaluation including visual inspection of the returned device. The observed condition of the device was consistent with a random component failure that may have been caused by exposure to unintended forces. There is no indication that a design or manufacturing issue has caused the complaint condition and hence the root cause cannot be determined. Based on the investigation findings, it has been determined that no corrective and/or preventative action is proposed.

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| **IMDRF Code Set** | **Code**  |

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| Device Problem | Break [A0401] |
| Component Problem  | Plate [G04097]  |
| Signs and Symptoms  | Failure of Implant [E2107] |
| Health Impacts  | Device Revision or Replacement [F1905] |
| Investigation Type | Testing of Actual/Suspected Device [B01] |
| Investigation Findings | Fracture Problem [C070603] |
| Investigation Conclusion | Cause Traced to Component Failure [D02] |

## Fracture of a proximal femoral plate

The patient underwent surgical treatment for fractures of the proximal femur and a proximal femoral plate was implanted on January 30, 2002. The patient was instructed by the surgeon to apply lower loads to the fracture, using a support to walk. After about 5 months, the plate broke, and the patient felt pain around joints. Revision surgery to remove the broken implant was performed on June 19, 2002.

The investigation of the production process did not identify any problems and revealed that they were in accordance with regulatory standards. The product was returned for analysis, and it was identified that the product was in accordance with specifications. Scratches were identified on the top of the plate, indicating fatigue failure. Based on the topography of the fracture surface, we can conclude/assume that the implant was subjected to dynamic bending loads. Constantly alternating load cycles (during walking) led to material fatigue and then first cracking and finally overload, respectively, and fatigue fracture of the plate. The plate could not withstand the applied force, which finally led to material overload/fatigue failure. The patient's postoperative activities (physical activity, exertion, possible fall) may have played a significant role as well.

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| --- | --- |
| **IMDRF Code Set** | **Code**  |
|  Device Problem   |  Fracture [A040101] |
|  Component Problem   |  Part/Component/Sub-assembly Term not Applicable [G07001] |
|  Signs and Symptoms  |  Arthralgia [E1601] |
|  Health Impacts   |   Device Explantation [F1903] |
|  Investigation Type |  Testing of Actual/Suspected Device [B01] Analysis of Production Records [B14] |
|  Investigation Findings |  Fracture Problem [C070603] |
|  Investigation Conclusion |  Reasonably Foreseeable Misuse [D1108] |

## Blood glucose monitoring system discrepancies

According to the instructions for use for the blood glucose monitoring system, a patient compared the readings from their blood glucose monitoring system against their blood glucose meter. The patient reported a discrepancy between the estimated glucose value displayed on their blood glucose monitoring system and their blood glucose meter. According to the patient, the blood glucose monitoring system displayed 9.0 mmol/L, while the blood glucose meter displayed 21.0 mmol/L. A second measurement from the blood glucose meter, also indicated value of 21.0 mmol/L. It was reported that the patient had symptoms of hyperglycemia and it was later confirmed at the lab that the blood monitoring system was incorrect. It was reported that the patient’s blood glucose levels were later stabilized by additional medication.

The product was not returned for investigation and lot number was not provided so evaluation of the device is not possible for this complaint. A data investigation was performed, and the complaint was confirmed, however the root cause could not be determined.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem | Low Test Results [A090810] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms | Hyperglycemia [E1205] |
| Health Impacts  | Unexpected Medical Intervention [F23]Medication Required [F2303]Minor Injury / Illness / Impairment [F11] |
| Investigation Type | Device Not Returned [B17]Analysis of Information Provided by User/Third Party [B15] |
| Investigation Findings | Malfunction Observed Without Conclusive Finding [C24] |
| Investigation Conclusion | Cause Linked to Device but Unable to Trace More Specifically [D1501] |

**Note:** Hyperglycemia was selected as a health effect code since the high blood glucose level was not detected by the blood glucose monitoring system and was confirmed with the blood glucose meter. The patient experienced this health effect, and the device was unable to perform its function. The health outcome code of “No Health Consequences or Impact” were not selected because the patient required a lab draw and additional medication even though he stabilized without any further health complications.

## Patient monitoring unit telemetry issues

A nurse in a critical care unit was sitting at the central station and noticed a patient, who was being monitored on a bedside monitor (not telemetry), going into Asystole. After roughly four seconds the central unit identified the asystole, as it is supposed to, and gave the visual asystole red alarm. However, it was noticed that roughly five seconds later the audible alarm kicked in. The staff are concerned it took so long for the audible alarm to kick in. There was no adverse event or harm reported. The investigation highlighted a software problem caused by erroneous coding.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem | Delayed Alarm [A160104] |
| Component Problem  | Alarm, Audible [G0600101] |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | No Health Consequences or Impact [F26] |
| Investigation Type | Testing of Actual/Suspected Device [B01] |
| Investigation Findings | Software Problem Identified [C10] |
| Investigation Conclusion | Cause Traced to Software Coding [D18] |

## Breast implant rupture

A patient with breast implants experienced bilateral rupture and capsular contracture. The patient’s implants were revised and replaced with similar prostheses. The explanted devices were returned, and the complaint of device rupture was confirmed from the samples. Rupture and capsular contractures are known inherent risks associated with these devices. No definitive root cause was identified. The event of Capsular Contracture is a physiological complication and analysis of the device generally does not assist in determining a probable cause for this event.

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| --- | --- |
| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem  | Material Rupture [A0412]Patient Device Interaction Problem [A01] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | Capsular Contracture [E2303] |
| Health Impacts  | Device Revision or Replacement [F1905] |
| Investigation Type | Testing of Actual/Suspected Device [B01] |
| Investigation Findings | Stress Problem Identified [C0706] |
| Investigation Conclusion | Known Inherent Risk of Device [D12]Cause Not Established [D15] |

## Left ventricular assist device battery issue

It was reported to the company that in October 2022, the left ventricular assist device system began emitting a visual and audible alarm. The patient checked the battery connection, which was intact. The patient then switched power from the battery to the mobile power unit, but the alarm continued. The emergency backup battery was then changed, and the alarm continued. Finally, the controller was replaced by the patient at home and the alarm was resolved. The patient later went to the hospital and reported the event.

The system controller was not returned for analysis. It was reported that the backup batteries were in use with the system controllers. These batteries were manufactured in May 2019 and therefore would have expired at the time of the reported event (October 2022). The root cause of the backup battery failure alarm was determined to be the use of batteries that were past their expiration date. Review of the device history record for the system controller showed that the device was manufactured in accordance with manufacturing and quality control specifications. The Instructions for Use (IFU) informs users that backup batteries expire 36 months after the date of manufacture.

|  |  |
| --- | --- |
| **IMDRF Code Set** | **Code**  |
|  Device Problem  |  Battery problem [A0705] |
|  Component Problem   |  Battery [G02002] |
|  Signs and Symptoms  |  No Clinical Signs, Symptoms or Conditions [E2403] |
|  Health Impacts   |  No Health Consequences or Impact [F26] |
|  Investigation Type |  Analysis of Production Records [B14] |
|  Investigation Findings |  No Device Problem Found [C19] |
|  Investigation Conclusion |  Reasonably Foreseeable Misuse [D1108] |

##  Balloon catheter failed to deflate

During surgery, a balloon catheter inserted into the patient failed to deflate. In order to remove the catheter, the surgeon introduced a guide wire to pierce and deflate the balloon. This extended the patient’s surgery time. There was no patient injury.

The device was received by the manufacturer, but due to extensive device damage the actual device could not be tested. Therefore, the manufacturer conducted testing on retained samples from the same lot and found that the balloon catheter material was out of specifications for material stiffness.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem  | Failure to Deflate [A140101] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | Prolonged Surgery [F1908]Modified Surgical Procedure [F1906] |
| Investigation Type | Testing of Device from Same Lot/Batch Retained by Manufacturer [B02] |
| Investigation Findings | Inadequate Physicochemical Properties [C0603] |
| Investigation Conclusion | Quality Control Deficiency [D0302] |

## Air bubbles in an infusion set

It was reported that air bubbles were observed within the tubing of an infusion set. The user was unable to remove the air, the user had to stop the infusion and change the infusion set. No other patient effects noted. The device was returned. An investigation found an inadequate sealing of the device. The issue was the result of an error during the manufacturing step with the supplier. The manufacturer will continue to monitor for trends as more definitive data is collected.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem | Air/Gas in Device [A1415]Improper flow or Infusion [A1405] |
| Component Problem  | Tube [G04134] |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts  | Additional Device Required [F2301]Prolonged Episode of Care [F14] |
| Investigation Type | Testing of Actual/Suspected Device [B01]Trend Analysis [B12] |
| Investigation Findings | Leakage/Seal [C0703] |
| Investigation Conclusion | Manufacturing Deficiency [D0301] |

## Air-in-Line sensor in dialysis lines did not trigger alarm

A large gap of air in the line was observed during dialysis. The lines moved past the Air-in-Line sensor without triggering an alarm. The event was reported to the associate during a site visit. The patient was anxious to see the air, impact is unknown. The root cause was not determined because no products or device logs were returned. Complaints are monitored and trended with further investigation. No device history search was performed since the serial number was unreadable. A review of the Complaint Review Board did not find an increasing trend for the reported issue of “Air-in-Line alarms”. Based on the Complaint Review Board review and the limited information provided no further investigation actions will be performed.

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| --- | --- |
| **IMDRF Code Set** | **Code**  |

|  |  |
| --- | --- |
| Device Problem | Air/Gas in Device [A1415]Device Alarm System [A1601] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | Anxiety [E020201] |
| Health Impacts  | Insufficient Information [F24] |
| Investigation Type | Device Not Returned [B17]Trend Analysis [B12] |
| Investigation Findings | No Findings Available [C20] |
| Investigation Conclusion | Cause Not Established [D15] |

## Uncontrolled movement of a powered wheelchair

An elderly user of a powered wheelchair was waiting at a street corner for a red light to turn green. The user claims that the powered wheelchair started moving out into the busy intersection without being prompted to by the user. The user tried to turn the wheelchair to avoid moving into the intersection and ended up going over the curb. The user was propelled forward out of their seat and suffered bruises and a cut to the skin. She was treated in hospital with stitches and has since recovered.

A service technician inspected the device at the user’s home. Historical adverse event analysis and trend analysis were also performed. No specific device issue was identified that would have contributed to spontaneous forward propulsion. However, it was revealed that the device had not been serviced as specified in the manufacturer’s instructions for use. As a result, the wheelchair’s brakes required maintenance which had not been performed according to the maintenance schedule.

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| **IMDRF Code Set** | **Code**  |

|  |  |
| --- | --- |
| Device Problem | Unintended Movement [A0512] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms | Bruise/Contusion [E2002]Laceration(s) [E2009] |
| Health Impacts | Unexpected Medical Intervention [F23]Minor Injury/Illness/Impairment [F11] |
| Investigation Type | Testing of Actual/Suspected Device [B01]Historical Data Analysis [B11]Trend Analysis [B12] |
| Investigation Findings | No Device Problem Found [C19] |
| Investigation Conclusion | No Problem Detected [D14] |

**Note:** The missed maintenance was not coded as it was an independant finding which was not directly related to the root cause.

## Hemolyzed plasma in blood collection tubes

Upon using a brand of sodium fluoride, potassium oxalate collection tubes, the user was experiencing many tubes with hemolyzed plasma, from orange to red plasma. Patient re-draw of blood specimen was required with new collection tubes. There was no patient injury. Unused samples of tubes from the same lot were returned for analysis. Manufacturer’s investigation determined that an improper composition of chemicals used during the manufacturing process resulted in hemolyzed plasma.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem | Improper Chemical Reaction [A0303] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | No Clinical Signs, Symptoms or Conditions [E2403] |
| Health Impacts | Additional Device Required [F2301]Unexpected Medical Intervention [F23] |
| Investigation Type | Testing of Device from Same Lot/Batch Returned from User [B03] |
| Investigation Findings | Improper Composition/ Concentration [C060201] |
| Investigation Conclusion | Cause Traced to Manufacturing [D03] |

**Note:** Given the nature of the device type and the description of the report, hemolysis was not coded in the health effects code as the term refers to observations made on the device itself.

##  Breast implant removal

Manufacturer received an e-mail from company sales representative on behalf of a doctor’s office reporting a possible breast implant associated anaplastic large cell lymphoma (BIA-ALCL). Healthcare professional reported patient experienced "a swollen breast about 3x normal side." Healthcare professional reported left side textured implant removal and a "good possibility [the patient] has BIA-ALCL." Healthcare professional later reported left side "confirmed BIA-ALCL." The device has been explanted. Healthcare professional reported that pathology report is pending. Histopathological markers have not been received.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem  | Patient Device Interaction Problem [A01] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms | Swelling/Edema [E2338]Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA ALCL) [E180102] |
| Health Impacts | Device Explantation [F1903]Unexpected Diagnostic Intervention [F22]Serious Injury/Illness/Impairment [F12] |
| Investigation Type | Communication/Interviews [B13] Type of Investigation Not Yet Determined [B21] |
| Investigation Findings | Results Pending Completion of Investigation [C21] |
| Investigation Conclusion | Conclusion Not Yet Available [D16] |

##  Implanted port device fracture

Ten months after the implantation of a port device, a dye study confirmed a port catheter fracture and a leak of normal saline. The patient had experienced a sharp pain episode in the area of the catheter during use that week, leading to treatment interruption and the ordering of a dye test. Reportedly, there was extravasation of the contrast medium as well. The catheter was subsequently returned for evaluation. Unfortunately, a Device History Record Review could not be conducted for the investigation due to the unknown lot number.

The visual and microscopic evaluation of the tube displayed a distinctive curvature, and a partial circumferential break with jagged and rounded edges was noted. Multiple bends were also observed along the length of the catheter. Consequently, the investigation confirmed the reported port catheter fracture. Two medical images were provided for review, further supporting the investigation’s findings.

Although a definitive root cause could not be determined, various physiological, placement, usage, and mechanical factors could have potentially caused or contributed to the reported event. The observed characteristics align with damage caused by flexural fatigue, characterized by breaking, splitting, and partially smoothed edges – a result of repetitive kinking of the catheter. There has been no increased rate of flexural fatigue observed for this device compared to similar devices.

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| **IMDRF Code Set** | **Code**  |

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| --- | --- |
| Device Problem  | Fracture [A040101]Fluid/Blood Leak [A050401] |
| Component Problem  | Part/Component/Sub-assembly Term not Applicable [G07001] |
| Signs and Symptoms  | Implant Pain [E2109]Extravasation [E0504] |
| Health Impacts  | Unexpected Diagnostic Intervention [F22] or Imaging Required [F2203]Device Explantation [F1903] |
| Investigation Type | Testing of Actual/Suspected Device [B01]Analysis of Information Provided by User/Third Party [B15] |
| Investigation Findings | Stress Problem Identified [C0706]Fracture Problem [C070603]Fatigue Problem [C070602] |
| Investigation Conclusion | Cause Linked to Device but Unable to Trace More Specifically [D1501]ORCause Traced to component Failure[D02] |

**Note:** D02 was chosen based on the findings that the observed characteristics align with damage caused by flexural fatigue.

# Frequently Misused/Misunderstood Codes

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| --- | --- |
| **IMDRF Code Set** | **Comment** |

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| --- | --- |
| A0203 – defective device:  | Not to be used as a general term for any type of defect. Using it like this goes without regard to the parent term (manufacturing packaging or shipping problem) and the definition (Problem associated with having flaws or dimensional deviations greater than acceptable for the intended use of the device). If the device initially worked when the user started to use the device, an out of the box problem that would qualify for the use of a A02 code does not apply |
| D15 Vs D1401 | *Specify when to use “Cause not established” and when to use “unable to exclude device problem*”As there is an overlap in these codes D1401 – “unable to exclude device problem” (and requires an investigation). D15 - “Cause not established”, also unable to exclude device problemSo it is recommended that D15 should be the preferred choice.  |

# Useful Links

**IMDRF documents**
<http://www.imdrf.org/documents/documents.asp>

**IMDRF maintenance**
<http://www.imdrf.org/workitems/wi-aet-maintenance.asp>

**MedDRA documents**
<https://www.meddra.org/how-to-use/support-documentation>

**IMDRF AET terminologies**

<https://www.imdrf.org/working-groups/adverse-event-terminology>

# Definitions

### Abbreviations

|  |  |
| --- | --- |
| Abbreviations  | Meaning  |
| **AER** | Adverse Event Reporting |
| **AET WG**  | Adverse Event Terminology Working Group |
| **CRB** | Complaint Review Board |
| **DA** | Data Acquisition |
| **DHR** | Device History Record |
| **IFU** | Instructions for Use |
| **IV** | Intravenous |
| **IMDRF** | International Medical Device Regulators Forum |
| **MedDRA** | Medical Dictionary for Regulatory Activities |
| **MRSA** | Methicillin-resistant Staphylococcus aureus |
| **PCBA** | Printed circuit board assembly |
| **RA** | Right Atrial |
| **RV** | Right Ventricular |
|  |  |

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