IMDRF International Medical Device Regulators Forum

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Considerations for the selection of IMDRF Adverse Event Terminology

A Guide for Industry Partners and Healthcare Providers.

AUTHORING GROUP

Adverse Event Terminology Working Group (AET WG)

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Preface

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1. Introduction

This document has been prepared by the International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology Working Group (AET WG), charged with developing a harmonized terminology for reporting adverse events related to medical devices including in vitro diagnostics (IVDs).

Since GHTF SG2/N54 (Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices) was published in 2006, most Global Harmonization Task Force (GHTF) members implemented adverse event reporting systems aligning with the general principles of N54. Building on the work of N54, the IMDRF AET WG developed globally harmonized terminology and codes for product problems, cause investigation, health effects, and components (IMDRF/N43). Widespread use of a single, appropriate adverse event terminology and coding system is expected to improve signal detection and validation by adverse event management systems enabling a faster response by both industry and regulatory authorities for public health safety.

As both regulators and industry work towards implementation of IMDRF terminology, an important next step 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 adverse events 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 e.g. some regions require the mandatory inclusion of some codes in the initial report and in the final report or some regions require the most relevant code in each terminology group to be highlighted. The aim of this document is solely to provide further guidance on the use of the IMDRF codes and terms.

2. Scope

This document is intended to provide guidance on the correct application and consistent use of the adverse event terminology. The document provides guidance for all stakeholders:

- providing general coding principles on reporting adverse events using IMDRF codes; and
- providing examples to address common coding challenges.

3. References

- GHTF/SG2/N54R8:2006 Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices.
- GHTF/SG2/N87:2012 Medical Devices: Post Market Surveillance: An XML Schema for the electronic transfer of adverse event data between manufacturers, authorized representatives and National Competent Authorities.
- GHTF/SG5/N5:2012 Reportable Events During Pre-Market Clinical Investigations
- GHTF/SG2/N54R6 Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices Appendix A.
- IMDRF/AE WG/N43 IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes.
- IMDRF/AE WG/N44 Maintenance of IMDRF AE Terminologies
- IMDRF CODE Browser: https://www.imdrf.org/working-groups/adverse-event-terminology/imdrf-adverse-event-terminology-web-browser.

4. Overview of IMDRF codes and coding practices for reports

Different regulatory authorities around the world require stakeholders (manufacturers, healthcare providers, etc.) to report adverse events involving medical devices marketed in their jurisdictions.

In general, a report contains free text that provides a narrative of what happened, informing about 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 and more coordinated response from both industry and regulatory authorities. More details can be found on the IMDRF website in IMDRF/AE WG/N43 (IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes).

Note: Throughout the document the term adverse event is used; however, it is understood that term is synonymous with incident or a serious incident in some jurisdictions.

Throughout this document the word '**device**' should be interpreted as meaning all or any of the following: medical device, in vitro diagnostic medical device, accessory to a medical device, medical device part and/or component.

Also, the word '**patient**' should be interpreted as meaning all or any of the following: user, operator, any other person affected by the incident.

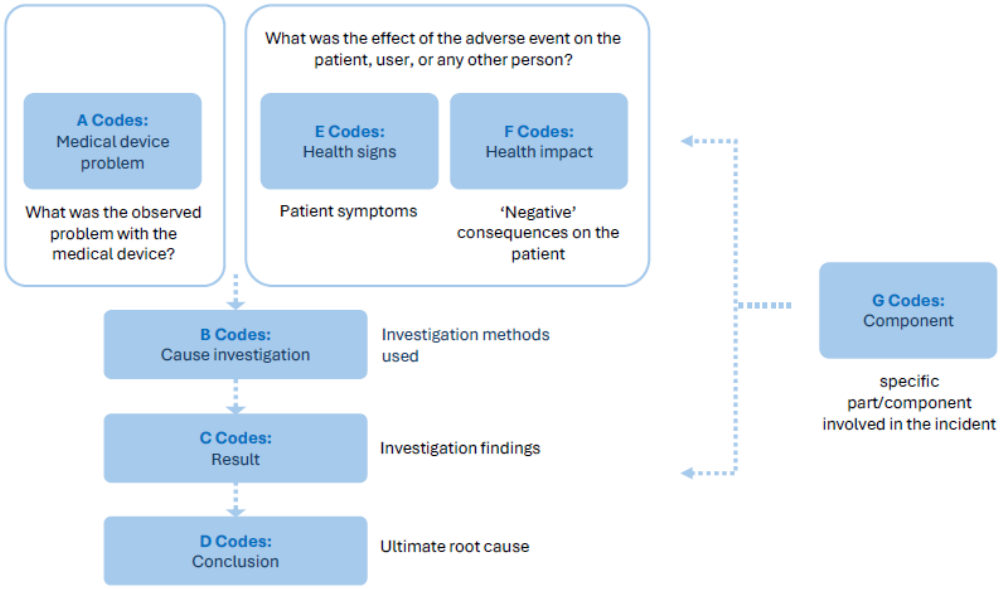
Completing an adverse event report involves coding free-text information describing a medical device incident using the standardized term(s) defined in the IMDRF codes. The complete IMDRF terminology is comprised of seven groupings within four distinct sets of terminologies and their associated alphanumeric 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.

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 7.

4.1.1. Table 1. Overview of the four sets of IMDRF terminologies

No.	Name of terminology	Description	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|00[00][00]
2	Medical Device Component (G Codes)	Terms/codes for describing the component of the medical device involved in the adverse event/incident.	G|00[000][00]
3	Health Effects - Clinical Signs and Symptoms or Conditions (E Codes)	Terms/codes for describing the clinical signs and symptoms or conditions of the affected person appearing as a result of the medical device adverse event/incident.	E|00[00][00]
	Health Effects - Health 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|00[00][00]
4	Cause Investigation - Type of Investigation (B Codes)	Terms/codes used to describe the type or scope of investigation activities performed in relation to the reported event.	B|00
	Cause Investigation - Investigation Findings (C Codes)	Terms/codes used to describe the actual condition, defect, or malfunction identified as the cause of the reported device behavior. The codes are structured at a higher level to group related device problems.	C|00[00][00]
	Cause Investigation - Investigation Conclusion (D Codes)	Terms/codes used to describe the identified root cause of the event, as determined by the manufacturer upon completion of the device investigation.	D|00[00]

4.1.2. Figure 1: A diagram illustrating the sequence in which the IMDRF codes should be used



5. 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.

5.1. Select the most detailed level term

IMDRF codes follow a hierarchical structure where higher-level terms describe general issues, and lower-level terms provide specific details. Select the lowest-level term that accurately describes the issue. 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) nest within the Level 1 entries in that group.

In coding a report ('initial,' 'follow-up,' and 'final'), 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.

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

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.	✓

When coding an adverse event, always aim to select the most specific (lowest-level) term that accurately reflects the issue. However, sometimes the most appropriate term available is a higher-level (Level 1 or Level 2) parent term. If a parent term is selected, then all child terms nested under that term should be considered similar types of events. This hierarchical structure allows for consistent grouping and analysis of adverse events, even when varying levels of detail are available. For example, if multiple reports are coded under different child terms of the same parent, they can be aggregated for broader analysis, enabling the earlier identification of trends and safety signals.

The general principle is that the 'most relevant' code should be listed first. Additional codes can complement this to provide a more informative, comprehensive understanding of the element being described. However, as this may vary in different jurisdictions it is important that the approach taken should be confirmed with the specific regulator.

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

Where no exact match can be found within the IMDRF terminology or there is not enough information provided to determine the correct code, one of the following can be used as case description code:

- Appropriate Term/Code Not Available (A27/C22/D17/E2402/F28/G07002)
- Insufficient Information (A26/B22/E2401/F24/G07003)
- Part/Component/Sub-assembly Term not Applicable (G07001)

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 that 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 a code can be selected from each section despite having insufficient information about the incident:

- A26 - Insufficient Device Problem Information
- B21 - Type of Investigation Not Yet Determined
- C21 - Results Pending Completion of Investigation
- D16 - Conclusion Not Yet Available
- E2401 - Insufficient Information
- F24 - Insufficient Health Impact Information
- G07003 - Insufficient Component Information

5.3. 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 from the field becomes available, the codes assigned should be updated.

It should be noted that the Problem Codes provided in a follow up report should always reflect the problems that were observed at the time of the adverse event.

5.3.1. Example: Inoperable ventilator

Reported narrative

Initial information: The manufacturer received information alleging an inoperative condition occurred on a ventilator. Additionally, it was stated that "Unable to write to Event Log" was observed in the device error log.

Follow-up information: Additional information from the field later clarified that the ventilator didn't start up properly but booted up endlessly instead.

IMDRF terms [codes] options	Comment	Best choice
Initial report: Data Problem [A1107] Insufficient Device Problem Information [A26] **Follow-up report:** Data Problem [A1107] Failure to Power Up [A070803]	**Initial report:** 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 report:** A26 was replaced by A070803 based on the additional information received from the field.	✓
Initial report: Data Problem [A1107] **Follow-up report:** Data Problem [A1107] Failure to Power Up [A070803]	**Initial report:** 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.	

5.4. 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.

5.5. 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. Further details on this process can be found on the IMDRF website at “Maintenance of IMDRF AE Terminologies" (IMDRF/AE WG/N44). Before making such a request, please check the latest version of the IMDRF codes on the IMDRF website.

The terminology was developed to meet the needs of regulators. It is recognised that manufactures may need more specific terms for coding their product post market surveillance data. These should be developed by manufacturers 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.

6. Specific term selection

6.1. Medical Device Problem (A Codes)

The Medical 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.

When coding the medical 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 medical 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 the problem).

6.1.1. Example of A Codes

Reported narrative

Device alarmed low battery and shut down, even though battery was freshly charged that morning.

IMDRF terms [codes] options	Comment	Best choice
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 the 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.	✓

6.2. Medical Device Component (G Codes)

The Medical Device Component terms/codes describe the specific part or component that were 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 to support the initial observations at the time of the adverse event and/or later to support the investigation findings. Therefore, the G terms can be used in combination with both the device problem codes (A) and/or the investigation codes (B, C and D). The design of adverse event reporting systems should facilitate the linking of the G terms with terms from the other groupings.

6.2.1. Example of G Codes

Reported narrative

Initial information: The device was explanted because of premature battery depletion.

Final information: Analysis of the device identified an anomalous capacitor as root cause of the increased current consumption that caused the premature battery depletion.

Report type	IMDRF terms [codes] options	Comment	Best choice
Initial report	Battery [G02002] Premature Discharge of Battery [A070504]	While it may seem obvious that the battery was a problem, having the parts coded using Medical Device Component terms can allow detection of trends affecting components.	✓
	Premature Discharge of Battery [A070504]		
Final report	Capacitor [G0201201] Electrical/Electronic Component Problem Identified [C0201] Cause Traced to Component Failure [D02]	Without the inclusion of the capacitor term from Medical Device Component terms it wouldn’t be obvious what the problematic electronic component was.	✓
	Electrical/Electronic Component Problem Identified [C0201] Cause Traced to Component Failure [D02]		

6.3. Health Effects (E & F Codes)

Together the Health Effect terms in E and F 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 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 Death Not Related to Reported Adverse Event [F29]. 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 [F02] then being concluded as No Health Consequences or Impact [F26]. Use of medical judgement is important for accurate term selection.

6.3.1. Health Effect – Clinical Signs and Symptoms or Conditions (E Codes)

E terms/codes are used to describe the clinical signs and symptoms or 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 recognised that manufactures 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 later, this can be corrected with a follow up report.

The IMDRF E terms are harmonised 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, please also see https://www.meddra.org/how-to-use/support-documentation/english?current=true.

6.3.2. Examples for E Codes

Preexisting conditions

Initial information: 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 information: The patient was later diagnosed with a concussion while an intracranial hemorrhage could not be confirmed.

IMDRF terms [codes] options	Comment	Best choice
Initial report: Fall [E2007] Intracranial Hemorrhage [E0118] Follow-up report: Fall [E2007] Concussion [E0108]	E0118 should be coded initially but corrected to E0108 after the final diagnosis becomes available.	✓
Initial report: Paraplegia [E012203] Fall [E2007] Intracranial Hemorrhage [E0118] Follow-up report: Fall [E2007] 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.	✓
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, hypo-glycemia 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.

6.3.3. Health Effect – Health Impact (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 and symptoms or 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.

When using a term/code like Device Revision or Replacement [F1905] adding Serious Injury/Illness/Impairment [F12] is not needed if you have coded No Clinical Signs/Symptoms or Conditions [E2403]. In this case F1905 is considered serious so F12 is implied.

It is important to be mindful of the difference, where a patient has not been involved, between Problem Identified During Non-Clinical Procedure [F27] and No Health Consequences or Impact [F26] when deciding on the best code to choose. If you have coded clinical signs and symptoms, F26 should not be used.

If the health impact is found to be unrelated to the adverse event during investigation, this code should be removed accordingly.

Where additional signs and symptoms have been coded, for example an infection or bone fracture led to the decision to explant or revise the device, it would be relevant to code additional health impact terms related to those.

Reported	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 the F26 code should be selected and No Clinical Signs, Symptoms or Conditions [E2403] should also be coded. 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 or patient sample was present, when the incident happened. This applies for incidents with quality assessment samples or during cleaning and maintenance.

6.4. 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.

6.4.1. Type of Investigation (B Codes)

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 or a follow up report, the term Type of Investigation Not Yet Determined [B21] can be used. However, this code should not be used for the final report.

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.

6.4.2. Example of B Codes

The reported narrative is provided in the example below, illustrating that with the multiple types of investigations occurring, each investigation type is required to be coded.

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.	Testing of Actual/ Suspected Device [B01]	
No trends for this type of failure have been observed.	Historical Data Analysis [B11]	
Because the information obtained from the healthcare professionals in the first report was insufficient, we asked the user again to explain the details of the case. A healthcare facility that owns multiple medical devices of the same batch investigated the occurrence of malfunction other than the malfunction device and shared this data with the manufacturer.	Analysis of Information Provided by User/Third Party [B15]	It is recommended to use B15 for any exchange of information (communication, interviews, data, images, etc.) with third parties.
A review of the batch record found no deviations that could have caused or contributed to the reported malfunction.	Analysis of Production Records [B14]	

6.4.3. 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 terms 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.

If the investigation is incomplete at the time of submission of the initial report or a follow up report, and the findings are not yet available, the term Results Pending Completion of Investigation [C21] can be used. However, this code should not be used for the final report.

6.4.4. Example of C Codes

The reported narrative is provided in the example below, with the findings from the multiple types of investigations that occurred, requiring each finding to be coded.

Reported narrative	IMDRF terms [codes] options	Comment
The device had displayed a critical error code. On examination water damage and corrosion was found on the Printed Circuit Board Assembly (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.

6.4.5. Investigation Conclusions (D Codes)

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?”

If the conclusions of investigation have not yet been established as the investigation is incomplete when submitting the initial or a follow up report, the term Conclusion Not Yet Available [D16] can be used. However, this code should not be used for the final report.

The D terms are designed to be broad. 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.

For example, if the root cause was traced to a loose nozzle on a widget extrusion system on a certain product line, then the appropriate D term would be Cause Traced to Manufacturing [D03].

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

6.4.6. Example of D Codes

The reported narrative is provided in the example below, with the conclusion from the multiple types of investigations that occurred, each conclusion needs to be coded.

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. This was a design issue, as the device needed to be deployed several times and did not have the required durability. 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 conclusion has been coded.

7. 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.

In assigning the codes in the examples provided the assignment is based on the narrative text. The severity of the actual event is not considered.

7.1. Example 1: Broken hip stem implant

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. 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 labor work or sport activities.

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

Text	Terminology group	**Code**
Complaining of pain.	Clinical Signs and Symptoms or Conditions	E2330 – Pain
Hip stem was found to be broken.	Medical Device Problem	A0401 – Break
During surgery, the device was explanted, and a new hip implant was implanted.	Health Impacts	F1905 – Device Revision or Replacement
Manufacturer evaluated the returned device.	Type of Investigation	B01 – Testing of actual/ suspected device
Conducted a review of the production record of the lot.	Type of Investigation	B14 – Analysis of Production Records
The manufacturer confirmed the breakage of the stem.	Investigation Findings	C070603 – Separation Problem

The Instructions for Use clearly indicates that patients with the implant should not participate in any heavy-duty labor work or sport activities.	Investigation Conclusions	D1101 – Failure to Follow Instructions
N/A	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

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

7.2. Example 2: An implantable cardioverter-defibrillator failure

During an in clinic follow up of a patient with an implantable cardioverter-defibrillator 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.

Text	Terminology group	Code
Noise resulting in oversensing was observed on the device.	Medical Device Problem	A070909 – Oversensing
The device was explanted and replaced to resolve the event.	Health Impact	F1905 – Device revision or Replacement
The patient was stable.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions
The reported event of noise was confirmed via review of the device data.	Type of Investigation	B24 – Event History Log Review
The noise was determined to have been caused due to non-device related factors.	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

The device behaved as expected and according to its programmed settings.	Investigation Conclusions	D15 – Cause Not Established C1902 – Device Problem Excluded
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.	Type of Investigation	B01 – Testing of Actual/Suspected Device

Note: Only "Over-sensing" is coded as device problem as the "header" problem is only suspected. Other codes may seem relevant for example, F1901 (Additional Surgery) or F1903 (Device Explanation), but they are implied by the code F1905 which is more precise.

The analysis was deemed sufficient to exclude a device malfunction with high certainty. Therefore, C1902 was selected.

As the header problem was only a suspicion, no matching G code exists.

7.3. Example 3: An automated external defibrillator performed as intended

Patient collapsed and an automated external defibrillator 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 electrocardiogram signal as non-shockable. Also, the field representative tested the device, and it performed as intended.

Text	Terminology group	Code
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.	Medical Device Problem	A25 – No Apparent Adverse Event
There was no evidence to suggest any device malfunction or performance deficiency.	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

N/A	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions [That the patient collapsed is not coded since it happened prior to the use of the device and is therefore not considered a symptom of the event]
Patient who then passed away There was no evidence to suggest any device malfunction or performance deficiency.	Health Impacts	F29 – Death not related to reported adverse event
The manufacturer reviewed the event data and confirmed the device performed as expected.	Type of Investigation	B24 – Event History Log Review
	Investigation Conclusions	D15 – Cause Not Established
The device correctly classified each electrocardiogram signal as non-shockable.	Investigation Findings	C1902 – Device Problem Excluded

7.4. Example 4: 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 patient harm. The review of the device log by the manufacturer did not confirm the customer's allegations. The device was examined by the manufacturer and was confirmed to be operating per specifications and no failure was identified.

Text	Terminology group	Code
It was reported that there was no audible alarm on a patient monitor.	Medical Device Problem	A160102 – No Audible Alarm
	Medical Device Component	G0600101 – Alarm, Audible
There was no patient harm.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions

	Health Impacts	F26 – No Health Consequences or Impact
Review of the device log.	Type of Investigation	B24 – Event History Log Review
The device was examined by the manufacturer.	Type of Investigation	B01 – Testing of Actual/Suspected Device
The device was confirmed to be operating per specifications and no failure was identified.	Investigation Findings	C1902 – Device Problem Excluded
The device was confirmed to be operating per specifications and no failure was identified.	Investigation Conclusions	D15 – Cause Not Established

7.5. Example 5: Electrical supply issues with electric scalpel

A customer reported that he was experiencing problems during surgery with the electric scalpel, the device does not turn on. It was noted that there was heat damage to the power supply near the base of the fuse, making 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. 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.

Text	Terminology group	Code
The device does not turn on.	Medical Device Problem	A150101 – Activation Failure
Heat damage to the power supply near the base of the fuse.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions
	Health Impacts	F26 – No Health Consequences or Impact
	Medical Device Component	G02027 – Power Supply
	Type of Investigation	B01 – Testing of Actual/Suspected Device

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.	Investigation Findings	C0706 – Stress Problem Identified
	Medical Device Component	G04068 – Holder
The customer did not follow the instructions.	Investigation Conclusions	D1101 – Failure to Follow Instructions

7.6. Example 6: 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, given the age of the device (15 years), it was suspected that the cause was deterioration over time in the parts that fix the supporting arm.

Text	Terminology group	Code
The arm of the surgical illuminator broke.	Medical Device Problem	A0401 – Break
There was no health hazard to the patient, and since it was replaced with an alternative product.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions
	Health Impacts	F26 – No Health Consequences or Impact F2301 – Additional Device required
After inspecting the item.	Type of Investigation	B01 – Testing of Actual/Suspected Device
It was suspected that the cause was deterioration over time in the parts that fix the retainer arm.	Investigation Findings	C0601 – Degradation Problem Identified
	Investigation Conclusions	D1105 – End of Life Problem Identified D02 – Cause traced to component failure
	Medical Device Component	G04068 - Holder

7.7. Example 7: 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, thereby extending the original procedure by several minutes.

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.

Text	Terminology group	Code
The microcatheter component broke, leaving a ~12mm section of microcatheter within.	Medical Device Problem	A0401 – Break A0413 – Material Separation
	Medical Device Component	G04023 – Catheter
N/A	Clinical Signs and Symptoms or Conditions	E2401 – Insufficient Information
The surgeon noticed the fragment and removed it intra-operatively using micro-grasping forceps, thereby extending the original procedure by several minutes.	Health Impacts	F23 – Unexpected medical intervention F1908 – Prolonged surgery
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.	Type of Investigation	B01 – Testing of Actual/Suspected Device
The catheter shaft appeared to have been damaged in an exogenous manner.	Investigation Findings	C070603 – Separation Problem
	Medical Device Component	G04112 – Rod/Shaft
No manufacturing or device problem was identified.	Investigation Conclusion	D20 – Cause Traced to Another Device

The most likely cause of damage is other surgical instrumentation used during surgery unrelated to the device.		

7.8. Example 8: False negative test result identified through external quality assessment scheme (proficiency testing)

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 one specimen of a multi-specimen panel. The testing sites all identified the result as non-reactive for the pathogen, this 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 known variants of the pathogen at the time of product development.

Text	Terminology group	Code
False negative result for the same one specimen of a multi-specimen panel.	Medical Device Problem	A090803 – False Negative Result
As the specimen was tested for external quality assessment purposes, no patient was involved.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions
	Health Impacts	F27 – Problem identified during non-clinical procedure
The provider of the external quality assessment scheme provided a sample of the specimen which was referred to a specialist laboratory for sequencing.	Type of Investigation	B02 – Testing of Device from Same Lot/Batch Retained by Manufacturer B15 – Analysis of Information Provided by User/Third Party
The specimen contained an uncommon but documented genetic variant of the pathogen.	Investigation Findings	C1403 – Problem Related to Variant/Mutant.
	Medical Device Component	G01003 – Device Ingredient or Reagent

The target sequence did not account for all known variants of the pathogen at the time of product development.	Investigation Conclusion	D01 – Cause Traced to Device Design

7.9. Example 9: Posterior capsule rupture in cataract surgery

It was reported that a patient suffered from posterior capsule rupture following initial treatment as the lens was not stable in the eye. An explant was performed, and 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. 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.

Text	Terminology group	Code
A patient suffered from posterior capsule rupture following initial treatment.	Clinical Signs and Symptoms or Conditions	E0801 – Capsular Bag Tear
The lens was not stable in the eye.	Medical Device Problem	A01 – Patient Device Interaction Problem
An explant was performed, and patient recovered well.	Health Impacts	F1903 – Device Explantation
A product evaluation was not performed because the product was not returned.	Type of Investigation	B17 – Device Not Returned
As per manufacturing records, the product was released within specifications.	Type of Investigation	B14 – Analysis of Production Records
The product was released within specifications.	Medical Device Component	G05006 – Lenses
	Investigation Conclusions	D15 – Cause Not Established
A search of complaints related to the production order for the specific serial number.	Type of Investigation	B11 – Historical Data Analysis

The search revealed that no other complaints were received for the production order of reported serial number.	Investigation Findings	C20 – No Findings Available
	Investigation Conclusions	D15 – Cause Not Established

7.10. Example 10: Broken variable-angle compression plate

A patient with trauma, after 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 device revealed that the plate was broken across the shaft. No other issues were found.

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.

Text	Terminology group	Code
A patient with trauma, after serious accident, underwent revision surgery due to a broken Variable-Angle Compression Plate.	Health Impacts	F1905 – Device Revision or Replacement
	Medical Device Problem	A0401 – Break
	Medical Device Component	G04097 – Plate
The explanted device was returned to the manufacturer, and the evaluation process was completed.	Type of Investigation	B01 – Testing of Actual/Suspected Device
Visual analysis of the device revealed that the plate was broken across the shaft.	Medical Device Component	G04112 – Rod/Shaft
The observed condition of the device was consistent with a random component failure that may have been caused by exposure to unintended forces.	Investigation Findings	C070603 – Separation Problem.

There is no indication that a design or manufacturing issue has caused the complaint condition and hence the root cause cannot be determined.	Investigation Conclusions	D02 – Cause Traced to Component Failure
N/A	Clinical Signs and Symptoms or Conditions	E2401 – Insufficient Information

7.11. Example 11: 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 surgeon instructed the patient to avoid excessive weight-bearing and to use walking support. However, the patient did not adhere to these medical instructions and continued to place high loads on the operated leg during daily activities.

After about 5 months, the patient experienced pain around the joints. Imaging revealed that the proximal femoral plate had fractured. Revision surgery to remove the broken implant was performed on June 19, 2002.

The investigation of the manufacturing process did not identify any issues, and the returned product met all technical and regulatory specifications. Examination of the implant revealed scratches and a fatigue fracture pattern consistent with repeated overloading. The analysis concluded that the implant was subjected to excessive dynamic bending loads due to the patient's non-compliance with postoperative restrictions.

Text	Terminology group	Code
Imaging revealed that the proximal femoral plate had fractured.	Medical Device Problem	A040101 – Fracture
The patient experienced pain around the joints.	Clinical Signs and Symptoms or Conditions	E1601 – Arthralgia
Revision surgery to remove the broken implant was performed.	Health Impacts	F1903 – Device Explanation
The investigation of the manufacturing process.	Type of Investigation	B14 – Analysis of Production Records
Examination of the implant.	Type of Investigation	B01 – Testing of Actual/Suspected Device

Revealed scratches and a fatigue fracture pattern consistent with repeated overloading.	Investigation Findings	C070602 – Fatigue Problem
The implant was subjected to excessive dynamic bending loads due to the patient's non-compliance with postoperative restrictions.	Investigation Conclusions	D1108 – Reasonably Foreseeable Misuse
N/A	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

7.12. Example 12: Glucose monitoring system measurement discrepancies

The patient reported a discrepancy between the estimated glucose value displayed by their continuous glucose monitoring system (CGM) and the blood glucose value provided by their blood glucose meter. According to the patient, the CGM 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 by a healthcare professional that the CGM 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. The investigation was conducted based on log data in the CGM app provided by the user, and the complaint was confirmed, however the root cause could not be determined.

Text	Terminology group	Code
The CGM system displayed 9.0 mmol/L while the blood glucose meter displayed 21.0 mmol/L. It was later confirmed by a health care professional that the CGM system was incorrect.	Medical Device Problem	A090810 – Low Test Results
A second measurement from the blood glucose meter, also indicated value of 21.0 mmol/L.	Health Impacts	F2204 – IVD testing
The patient had symptoms of hyperglycemia.	Clinical Signs and Symptoms or Conditions	E1205 – Hyperglycemia

The patient's blood glucose levels were later stabilized by additional medication.	Health Impacts	F2303 – Medication Required
The product was not returned.	Type of Investigation	B17 – Device Not Returned
The investigation was conducted based on app history data provided by the user, and the complaint was confirmed.	Type of Investigation	B15 – Analysis of Information Provided by User/Third Party *or* B24 – Event History Log Review
The root cause could not be determined.	Investigation Findings	C24 – Malfunction Observed Without Conclusive Finding
	Investigation Conclusions	D1501 – Cause Linked to Device but Unable to Trace More Specifically
	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

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.

7.13. Example 13: 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.

Text	Terminology group	Code
A patient with breast implants experienced bilateral rupture and capsular contracture.	Clinical Signs and Symptoms or Conditions	E2303 – Capsular Contracture
	Medical Device Problem	A01 – Patient Device Interaction Problem

The patient's implants were revised and replaced with similar prostheses.	Health Impacts	F1905 – Device Revision or Replacement
The explanted devices were returned.	Type of Investigation	B01 – Testing of Actual/Suspected Device
The complaint of device rupture was confirmed from the samples.	Medical Device Problem	A0412 – Material Rupture
No definitive root cause was identified.	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable
The event of capsular contracture is a physiological complication.	Investigation Conclusions	D12 – Known Inherent Risk of Device
Analysis of the device generally does not assist in determining a probable cause for this event.	Investigation Findings	C24 – Malfunction Observed Without Conclusive Finding

7.14. Example 14: A 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.

Text	Terminology group	Code
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 then switched power from the battery to the mobile power unit, but the alarm continued.	Medical Device Problem	A0705 – Battery problem
	Medical Device Component	G0600101 – Alarm, Audible
The system controller was not returned for analysis.	Type of Investigation	B17 – Device Not Returned
The root cause of the backup battery failure alarm was determined to be the use of batteries that were past their expiration date.	Medical Device Component	G02002 – Battery
Review of the device history record for the system controller.	Type of Investigation	B14 – Analysis of Production Records
The device was manufactured in accordance and quality control specifications.	Investigation Findings	C19 – No Device Problem Found
The Instructions for Use (IFU) informs users that backup batteries expire 36 months after the date of manufacture.	Investigation Conclusions	D1105 – End of Life Problem Identified
N/A	Clinical Signs and Symptoms or Conditions	E2401 – Insufficient Information
N/A	Health Impacts	F24 – Insufficient Health Impact Information

7.15. Example 15: 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.

Text	Terminology group	Code
A balloon catheter inserted into the patient failed to deflate.	Medical Device Problem	A140101 – Failure to Deflate
	Medical Device Component	G04010 – Balloon
The surgeon introduced a guide wire to pierce and deflate the balloon.	Health Impacts	F1906 – Modified Surgical Procedure
This extended the patient's surgery time.	Health Impacts	F1908 – Prolonged Surgery
There was no patient injury.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions
The manufacturer conducted testing on retained samples from the same lot.	Type of Investigation	B02 – Testing of Device from Same Lot/Batch Retained by Manufacturer
And found that the balloon catheter material was out of specifications for material stiffness.	Investigation Findings	C0603 – Inadequate Physicochemical Properties
N/A	Investigation Conclusions	D03 – Manufacturing Deficiency

7.16. Example 16: 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 until the doctor visit. The impact of the air on the patient 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 'Missing Air-in-Line alarms'. Based on the Complaint Review Board review and the limited information provided no further investigation actions will be performed.

Text	Terminology group	Code
A large gap of air in the line was observed during dialysis.	Medical Device Problem	A1415 – Air/Gas in Device
The lines moved past the Air-in-Line sensor without triggering an alarm.	Medical Device Problem	A1601 – Device Alarm System
The impact of the air on the patient is unknown.	Clinical Signs and Symptoms or Conditions	E2401 – Insufficient Information
The impact of the air on the patient is unknown.	Health Impacts	F24 – Insufficient Health Impact Information
The root cause was not determined.	Investigation Conclusions	D15 – Cause Not Established
Because no products or device logs were returned.	Type of Investigation	B17 – Device Not Returned
A review of the Complaint Review Board did not find an increasing trend for the reported issue of 'Missing Air-in-Line alarms'.	Type of Investigation	B11- Historical Data Analysis
	Investigation Findings	C20 – No Findings Available
	Investigation Conclusions	D15 – Cause Not Established
N/A	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

7.17. Example 17: 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.

Text	Terminology group	Code
The user claims that the powered wheelchair started moving out into the busy intersection without being prompted to by the user.	Medical Device Problem	A0512 – Unintended Movement
The user was propelled forward out of their seat and suffered bruises and a cut to the skin.	Clinical Signs and Symptoms or Conditions	E2002 – Bruise/Contusion E2009 – Laceration(s)
She was treated in hospital with stitches and has since recovered.	Health Impacts	F23 – Unexpected Medical Intervention F11 – Non-Serious Injury/Illness/Impairment
A service technician inspected the device at the user's home.	Type of Investigation	B01 – Testing of Actual/Suspected Device
Historical adverse event analysis and trend analysis were also performed.	Type of Investigation	B11 – Historical Data Analysis

No specific device issue was identified that would have contributed to spontaneous forward propulsion.	Investigation Findings	D15 – Cause Not Established D15 – Cause Not Established
N/A	Medical Device Component	G07001 – Part/Component/Sub-assembly Term not Applicable

Note: "The wheelchair's brakes required maintenance which had not been performed according to the maintenance schedule" was not coded as it was an independent finding which was not directly related to the root cause.

7.18. Example 18: 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 for an IVD test 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.

Text	Terminology group	Code
The user was experiencing many tubes with hemolyzed plasma, from orange to red plasma.	Medical Device Problem	A0303 – Improper Chemical Reaction
	Medical Device Component	G04134 – Tube
Patient re-draw of blood specimen was required with new collection tubes.	Health Impacts	F2201 – Patient Sample
There was no patient injury.	Clinical Signs and Symptoms or Conditions	E2403 – No Clinical Signs, Symptoms or Conditions
Unused samples of tubes from the same lot were returned for analysis.	Type of Investigation	B03 – Testing of Device from Same Lot/Batch Returned from User
Manufacturer's investigation determined that an improper composition of chemicals used.	Investigation Findings	C060201 – Improper Composition/ Concentration
	Medical Device Component	G01003 - Device Ingredient or Reagent
During the manufacturing process.	Investigation Conclusions	D03 – Cause Traced to Manufacturing

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.

7.19. Example 19: 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 cancellation 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.

Text	Terminology group	Code
A dye study confirmed a port catheter fracture.	Medical Device Problem	A040101 – Fracture
	Medical Device Component	G04023 – Catheter
And a leak of normal saline.	Medical Device Problem	A050401 – Fluid/Blood Leak
The patient had experienced a sharp pain episode in the area of the catheter during use that week.	Clinical Signs and Symptoms or Conditions	E2109 – Implant Pain
Leading to treatment cancellation.	Health Impacts	F31 – Cancelled/Aborted Treatment/Therapy or F05 Delay to Treatment/ Therapy
And the ordering of a dye test.	Health Impacts	F2203 – Imaging Required
There was extravasation of the contrast medium as well.	Clinical Signs and Symptoms, or Conditions	E0504 – Extravasation

	Medical Device Problem	A050401 – Fluid/Blood Leak
The catheter was subsequently returned for evaluation.	Health Impacts	F1903 – Device Explantation
	Type of Investigation	B01 – Testing of Actual/Suspected Device
The visual and microscopic evaluation of the tube displayed a distinctive curvature, and a partial circumferential break with jagged and rounded edges was noted.	Investigation Findings	C070603 – Separation Problem
Two medical images were provided for review, further supporting the investigation's findings.	Type of Investigation	B30 – Analysis of Images
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.	Investigation Findings	C070602 – Fatigue Problem
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.	Investigation Conclusions	D1501 – Cause Linked to Device but Unable to Trace More Specifically

7.20. Example 20: Artificial intelligence software failure in chest X-ray

The manufacturer reported an issue with his artificial intelligence software system designed to analyze chest X-rays for early detection of pneumonia. The respective software is integrated into hospital radiology information systems and automatically flags suspected pneumonia cases for prioritized review.

The AI system failed to flag a case of pneumonia in an elderly patient with a pre-existing lung condition, leading to delayed diagnosis and treatment. The 73-year-old patient with COPD experienced significant clinical deterioration requiring ICU admission due to the delayed pneumonia diagnosis. This worsened the patient's pneumonia symptoms.

Investigation of device data and information provided by the hospital revealed that the algorithm had a systematic bias in its training data, with underrepresentation of elderly patients with co-morbidities. The software misclassified certain opacity patterns common in COPD patients as normal variations rather than potential pneumonia.

The problem that occurred was only identified with version 2.3 of the software after an update to improve detection of other conditions.

Text	Terminology group	Code
The AI system failed to flag a case of pneumonia in an elderly patient.	Medical Device Problem	A090803 – False Negative Result
	Medical Device Component	G02008 – Computer Software
Investigation of device data and information provided by the hospital.	Type of Investigation	B24 – Event History Log Review B15 – Analysis of Information Provided by User/Third Party
The software misclassified certain opacity patterns common in COPD patients as normal variations rather than potential pneumonia.	Investigation Findings	C1010 – Artificial Intelligence Training/Validation Problem Identified
Investigation revealed that the algorithm had a systematic bias in its training data, with underrepresentation of elderly patients with co-morbidities.	Investigation Conclusions	D19 – Cause Traced to Artificial Intelligence Training/Validation Process
This worsened the patient's pneumonia symptoms.	Clinical Signs and Symptoms or Conditions	E0733 – Pneumonia
The 73-year-old patient with COPD experienced significant clinical deterioration requiring ICU admission due to the delayed pneumonia diagnosis.	Health Impacts	F13 – Misdiagnosis/ Misclassification F04 – Delay to Diagnosis F05 – Delay to Treatment/Therapy F30 – Disease Progression F07 – Exacerbation of Existing Condition

Test Your Understanding

To test your understanding of this document an online quiz is available the IMDRF Website Training | International Medical Device Regulators Forum

8. Useful Links

IMDRF documents
http://www.imdrf.org/documents/documents.asp

IMDRF maintenance
https://www.imdrf.org/working-groups/adverse-event-terminology/imdrf-adverse-event-terminology-maintenance

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

IMDRF Adverse Event Terminology terminologies
https://www.imdrf.org/working-groups/adverse-event-terminology

Please visit our website for more details.

www.imdrf.org