



**IMDRF**

International Medical  
Device Regulators Forum

**APEC 2021 SCH Medical Device CoE Training**

**Adverse Event Terminology and Coding**  
**Generation of data related to the use of Medical Device**  
**Adverse Event (MDAE)**

**Sept 2021**

**IMDRF AE Working Group Chair:**

**H. Ishikawa**

**Pharmaceuticals and Medical Devices Agency**





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## Who am I

### Small self introduction

- 1972 Graduate Tohoku University
- 1972 Enter Toshiba Co. Medical Div.
- 1993 Join GHTF SG2 member
- 2001 Join GHTF SC member
- 2006 Publish N54 (team leader)
- 2008 Join APEC LSIF RHC
- 2009 Join APEC LSIF AHC Advisory (till 2011)
- 2011 Join PMDA
- 2012 IMDRF UDI WG member (UDI WG disbanded 2019)
- 2105 IMDRF AEWG Chair
- 2017 IMDRF Standards WG (Standards WG disbanded 2019)
- 2019 IMDRF GRRP member





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## **Adverse Event Terminology and Coding Generation of data related to the use of Medical Device Adverse Event (MDAE)**

### **Contents**

- 1. Background for creating IMDRF AE terminology and coding**
- 2. What terms that IMDRF AEWG set the harmonized terminology for AE Reporting with harmonized definition**
- 3. Explanation for 7 categories of Terms How to use**
- 4. How to use those terms (virtual case) and how regulator observe it**

**Assuming that understanding of GHTF N54 document and its related document**

This presentation includes personal opinion ,so that, some may not represent the PMDA opinion





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## 1. Background for creating IMDRF AE terminology and coding

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**IMDRF** International Medical  
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- ◆ Foundational **GHTF N54** document established the foundations for international harmonization of post-market reporting requirements and information.
- ◆ **GHTF N87** document established XML format for electrical reporting.
- ◆ Those are provide globally common use terms. **Appendix A for N54**
- ◆ Contents are
  - **What is an event?**
  - **What should be reported?**
  - **What is exempt?**
  - **To whom and when to report?**
  - **What information should be reported?**

Development of a **harmonized terminology for reporting adverse events** related to medical devices including in-vitro diagnostics (IVDs).

#### **Benefits;**

- Improved accuracy of capturing and reporting adverse events,
- Reduced ambiguity
- Better usability
- More sophisticated signal detection (i.e. the identification of potential novel risks), and
- Trending analysis

**For both regulatory agencies and device manufacturers.**





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## What happened since GHTF developed N54 document

- Actuary, GHTF SG2 activities is not create single document, there were so many documents had been published and 2006 ,**N54 was published as the summary of the document.**
- Leading by US FDA, other SG2 member country started to **implement their own Post Market regulation.**
- 2012 ,ISO, international Standard organization TC210 also try to establish “Event Type Code” and “Evaluation Code”. **Limited scope.**

### Medical Field **Rapid technical Innovation**

- During these 15 years, many innovative devices are developed.
- New technology provide new terms for the event.
- Necessity to corroborate with ICH in terms of Health Effect issue.(MedDRA)
- Some specific field such as Stand Alone Software becomes Medical Device





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## What happened since GHTF developed N54 document

### Regulators thoughts

Based on the situation that most of the jurisdiction applying **Electrical Form** for the ARE and necessity to exchange information for Signal detection purpose in a global manner.

- Required more specific information by text
- Also need to share the same understanding of the terminology
  - Standardized terms
  - Standardized definition of the relevant terms
  - Universal Coding system
- Frequent maintenance system (at least once a year)



2015, IMDRF AEWG has been set up to develop standardized terms which use for the ARE and its definition with IMDRF code.

- Product Problem and related components or parts
- Investigational terms and
- Health related terms





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- 2. What terms that IMDRF AEWG set the harmonized terminology for AE Reporting with harmonized definition**







GHTF N54 Appendix A 5.0

## Data Set Elements and Guidance

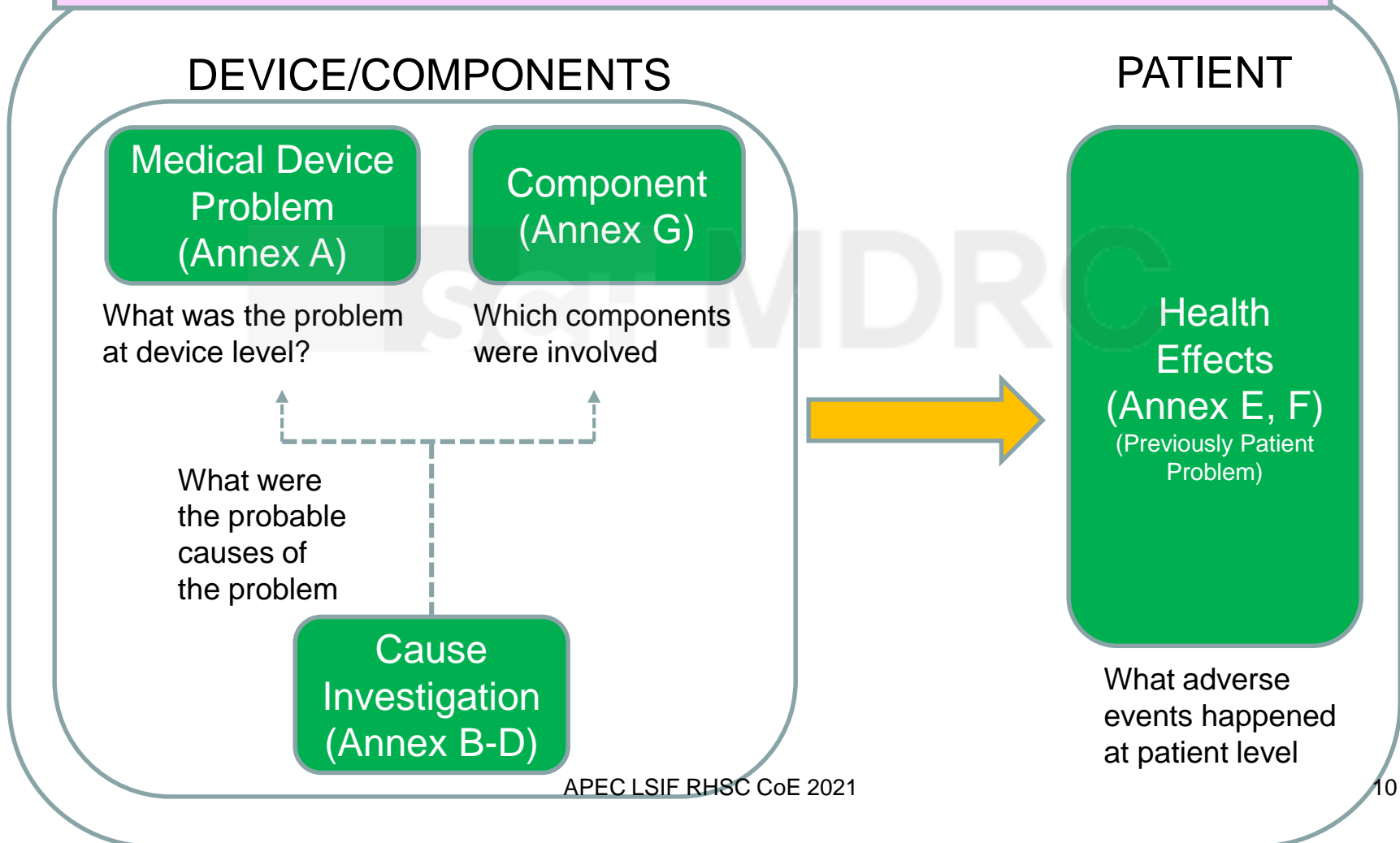
- I. Administrative Information**
- II. Clinical Event Information**
- III. Healthcare Facility Information
- IV. Device Information** (Repeat this section for each device involved)
- V. Results of Manufacturer's Investigation**
- VI. Patient information (Repeat this section for each patient involved)  
Includes any affected individual e.g. user, patient, or third party.
- VII Other Reporting Information (to be included in final reports only)
- VIII Comments
- IX Manufacturer Disclaimer

[GHTF Study Group 2 - Post-market Surveillance/Vigilance \(imdrf.org\)](https://imdrf.org)





### Selecting Term and Code for Adverse Event Reporting





## Title: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

**Started from 2015**

Main Body N43 (2017)

Annexes with IMDRF Terminology:  
Medical Device Problem

Annex A (2017)

Investigation

Annex B Type of Investigation (2017)

Annex C Investigation Finding (2017)

Annex D Investigation Conclusion (2017)

Health Effects

Annex E Clinical signs Symptoms and conditions (2019)

Annex F Health Impact (2019)

Component

Annex G (2020)

**All Annexes published (2020 July)**

Annex G

Annex E, F

Annex B - D

Annex A

Main Body  
N43





### Relation with GHTF N54 Appendix A and IMDRF Annex

GHTF Appendix A Data set contents

IMDRF Annex

#### **I Administrative Information**

E. Classification of event

Unanticipated Death, unanticipated Serious Injury,  
or Serious Public Health Threat

All other reportable events

F

#### **II Clinical Event Information**

A. Event description narrative

E

#### **IV Device Information**

F. Device Disposition/Current Location

e.g., device has been destroyed, remains implanted in patient,  
was returned to the manufacturer, remains under investigation,

A G  
B

#### **V. Results of Manufacturer's Investigation**

Manufacturers Device Analysis Results

Specify, for this event, details of investigation methods,  
results, and conclusions

B C D





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## 3. Explanation for 7 categories of Terms

Recommend to review definition of terms by yourself.

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### Annex A: Medical Device Problem Terms and Codes

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)

<b>A01</b>	Patient Device Interaction Problem	<b>A15</b>	Activation, Positioning or Separation Problem
<b>A02</b>	Manufacturing, Packaging or Shipping Problem	<b>A16</b>	Protective Measures Problem
<b>A03</b>	Chemical Problem	<b>A17</b>	Compatibility Problem
<b>A04</b>	Material Integrity Problem	<b>A18</b>	Contamination /Decontamination Problem
<b>A05</b>	Mechanical Problem	<b>A19</b>	Environmental Compatibility Problem
<b>A06</b>	Optical Problem	<b>A20</b>	Installation-Related Problem
<b>A07</b>	Electrical /Electronic Property Problem	<b>A21</b>	Labelling, Instructions for Use or Training Problem
<b>A08</b>	Calibration Problem	<b>A22</b>	Human-Device Interface Problem
<b>A09</b>	Output Problem	<b>A23</b>	Use of Device Problem
<b>A10</b>	Temperature Problem	<b>A24</b>	Adverse Event Without Identified Device or Use Problem
<b>A11</b>	Computer Software Problem	<b>A25</b>	No Apparent Adverse Event
<b>A12</b>	Connection Problem	<b>A26</b>	Insufficient Information
<b>A13</b>	Communication or Transmission Problem	<b>A27</b>	Appropriate Term/Code Not Available
<b>A14</b>	Infusion or Flow Problem	469 terms could be selectable	





### Annex G Components

Describing the **parts and components** which were **involved in**, or affected by, the medical device adverse event/incident.

G01	Biological and Chemical
G02	Electrical and Magnetic
G03	Measurement
G04	Mechanical
G05	Optical
G06	Safety
G07	Others

**Seven categorized terms(G01-G07) could not be used for Reporting. Use L2/L3 (288terms) for reporting**

When select Product Problem and then Component will associate with that term.

i.e.

When select under A05 Mechanical problem  
Select appropriate term from G04 Mechanical  
Category L2/L3.

There are several measurement by using  
mechanical or electrical, so Safety related  
Components could select from G06 L2/L3





## Annex E Clinical Signs, Symptoms and Conditions Terms and Codes

Describe the **observed condition of the affected persons** after the medical device adverse event occurs.

As a reference **Mapping Information with MedDRA** are including.

1. Nervous System	13. Kidney and Urinary Tract
2. Mental, Emotional and Behavioural Disorders	14. Reproductive System and Breast
3. Blood and Lymphatic System	15. Pregnancy, Childbirth and the Puerperium
4. Immune System	16. Musculoskeletal System
5. Vascular System	17. Skin and Subcutaneous Tissue
6. Heart	18. Neoplasms Benign, Malignant and Unspecified
7. Respiratory System	19. Infections
8. Eye	20. Injury
9. Ear and Labyrinth	21. Procedural Complications
10. Gastrointestinal System	22. Investigations and Diagnostic Tests
11. Hepatic and Biliary System	23. General Disorders
12. Endocrine, Metabolism and Nutrition	24. Others

**Note: Those 24 category indicated in L1 could not use for the report.**







### Annex E: Special case for coding

◆ One term has one code.

- Some terms belong to two categories. In such case, the only code assigned to the term in the category taking priority is also applied to the same term in the other category.
- Other applicable category for the term is shown in the term list and the prioritized category is written in red and bold.

e.g.  
Category 17. Skin and Subcutaneous Tissue

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Skin Erosion	<u>E17XX</u>	20. Injury	3				

Category 20. Injury

Level 2 Term	Level 2 Code	Other Applicable Category	Level	Level 3 Term	Level 3 Code	Other Applicable Category	Level
Erosion	E20YY			Skin Erosion	<u>E17XX</u> Not E20YYZZ	<b>17. Skin and Subcutaneous Tissue</b>	<b>2</b> 17





## Annex F: Health Impact Terms and Codes

Describing the **consequences of the medical device adverse event/incident on the person affected.** (e.g., death, hospitalization, unexpected medical intervention, wrong intervention due to incorrect diagnosis)

F01	Change in Therapeutic Response	F15	Recognized Device or Procedural Complication
F02	Death	F16	Reduction in Life Expectancy
F03	Brain Death	F17	Sedation
F04	Delay to Diagnosis	F18	Rehabilitation
F05	Delay to Treatment/ Therapy	F19	Surgical Intervention
F06	Disruption of Subsequent Medical Procedure	F20	Serious Public Health Threat
F07	Exacerbation of Existing Condition	F21	Unexpected Deterioration
F08	Hospitalization or Prolonged Hospitalization	F22	Unexpected Diagnostic Intervention
F09	Fetal Harm	F23	Unexpected Medical Intervention
F10	Inadequate/Inappropriate Treatment or Diagnostic Exposure	F24	Insufficient Information
F11	Minor Injury/ Illness / Impairment	F25	Unanticipated Adverse Device Effect
F12	Serious Injury/ Illness/ Impairment	F26	No Health Consequences or Impact
F13	Misdiagnosis/ Misclassification	F27	No Patient Involvement
F14	Prolonged Episode of Care	F28	Appropriate Term/Code Not Available





## Annex B-D: Cause Investigation Terms and Codes

Those terms are used any type of report and not only for the Final ARE report

### **Annex B: Type of Investigation** (1 level)    **For finding Root Cause**

- What was investigated
- What kind of investigation was conducted

(e.g., **Testing of Actual/Suspected Device, Testing of Device from Same Lot/Batch, Trend Analysis**)

### **Annex C: Investigation Findings** (3 levels)    **Keys to identify Root Cause**

- finding the specific investigation

Jurisdictions allow to choose the level of coding to use.

(e.g., **Biological Problem Identified, Cytotoxicity Problem Identified, Microbial Contamination**)

### **Annex D: Investigation Conclusion** (2 levels)

#### **Conclusions delivered from the investigation**

Jurisdictions allow to choose the level of coding to use.

(e.g., **Cause Traced to Device Design, Cause Traced to Manufacturing, Quality Control Deficiency**)





## Annex B-D: Cause Investigation Terms and Codes

### B=23 terms

### C= 149 terms

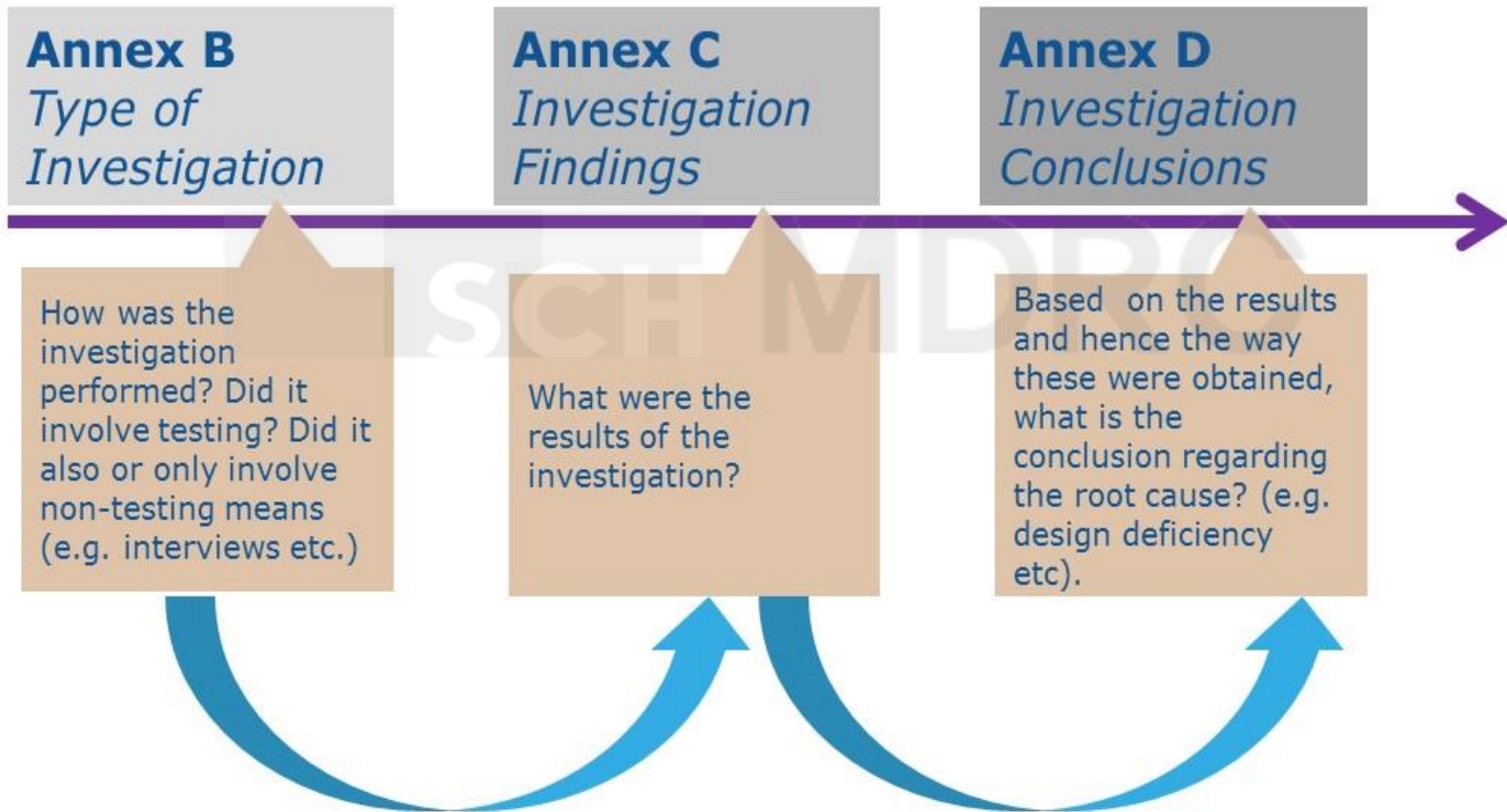
### D= 39terms

B01	Testing of Actual/Suspected Device	C01	Biological Problem Identified	D01	Cause Traced to Device Design
B02	Testing of Device from Same Lot/Batch Retained by Manufacturer	C02	Electrical Problem Identified	D02	Cause Traced to Component Failure
B03	Testing of Device from Same Lot/Batch Returned from User	C03	Electromagnetic Compatibility Problem Identified	D03	Cause Traced to Manufacturing
B04	Testing of Device from Other Lot/Batch Retained by Manufacturer	C04	Interoperability Problem Identified	D04	Cause Traced to Transport/Storage
B05	Testing of Device from Other Lot/Batch Returned From User	C05	Labeling and Instructions for Use/Maintenance	D05	Cause Traced to Infrastructure
B06	Testing of Model Variant	C06	Material and/or Chemical Problem Identified	D06	Cause Traced to Environment
B07	Testing of Raw/Starting Materials	C07	Mechanical Problem Identified	D07	Cause Traced to Maintenance
B08	Testing of Patient Sample or Reference Material Using Manufacturer's Device	C08	Optical Problem Identified	D08	Cause Traced to Training
B09	Testing of Patient Sample or Reference Material Using Reference Method	C09	Clinical Imaging Problem Identified	D09	Cause Traced to Labeling
B10	Testing of Patient Sample or Reference Material Using Competitor's Device	C10	Software Problem Identified	D10	Cause Traced to Non-Device Related Factors
B11	Historical Data Analysis	C11	Thermal Problem	D11	Cause Traced to User
B12	Trend Analysis	C12	Protective System Problem Identified	D12	Known Inherent Risk of Device
B13	Communication/Interviews	C13	Operational Problem Identified	D13	Falsified Device
B14	Analysis of Production Records	C14	Patient Sample Problem	D14	No Problem Detected
B15	Analysis of Data Provided by User/Third Party	C15	Environment Problem Identified	D15	Cause Not Established
B16	Device Not Manufactured by Reporting Manufacturer	C16	Manufacturing Process Problem Identified	D16	Conclusion Not Yet Available
B17	Device Not Returned	C17	Maintenance Problem Identified	D17	Appropriate Term/Code Not Available
B18	Device Discarded	C18	Transport/Storage Problem Identified	D18	Cause Traced to Software Coding
B19	Incomplete Device Returned	C19	No Device Problem Found		
B20	Device Not Accessible for Testing	C20	No Findings Available		
B21	Type of Investigation Not Yet Determined	C21	Results Pending Completion of Investigation		
B22	Insufficient Information Available	C22	Appropriate Term/Code Not Available		
B23	Specimen Requested But Not Provided	C23	Usage Problem Identified		





## Concept of Annex B-D: Cause Investigation Terms and Codes





### Annex B: Cause Investigation Terms and Codes

#### Type of Investigation

<b>B01</b>	Testing of Actual/Suspected Device
<b>B02</b>	Testing of Device from Same Lot/Batch Retained by Manufacturer
<b>B03</b>	Testing of Device from Same Lot/Batch Returned from User
<b>B04</b>	Testing of Device from Other Lot/Batch Retained by Manufacturer
<b>B05</b>	Testing of Device from Other Lot/Batch Returned From User
<b>B06</b>	Testing of Model Variant
<b>B07</b>	Testing of Raw/Starting Materials
<b>B08</b>	Testing of Patient Sample or Reference Material Using Manufacturer's Device
<b>B09</b>	Testing of Patient Sample or Reference Material Using Reference Method
<b>B10</b>	Testing of Patient Sample or Reference Material Using Competitor's Device
<b>B11</b>	Historical Data Analysis
<b>B12</b>	Trend Analysis
<b>B13</b>	Communication/Interviews
<b>B14</b>	Analysis of Production Records
<b>B15</b>	Analysis of Data Provided by User/Third Party
<b>B16</b>	Device Not Manufactured by Reporting Manufacturer
<b>B17</b>	Device Not Returned
<b>B18</b>	Device Discarded
<b>B19</b>	Incomplete Device Returned
<b>B20</b>	Device Not Accessible for Testing
<b>B21</b>	Type of Investigation Not Yet Determined
<b>B22</b>	Insufficient Information Available
<b>B23</b>	Specimen Requested But Not Provided

**B01 Use Actual Device** suspected

**B02-B10 Use NOT Actual Device** suspected

- same Lot/Bach
- other Lot Bach
- tested at sight/ manufacturer site
- testing use sample or reference material

**B11-B15 Use NOT Device** suspected but  
**other data**

- Historical Data/Record
- information from user
- Analysis

**B16** could use C20and D14

**B17,B19,B23** use when still **waiting for return**

**B18.B20,B22** move back to B02-B15

**B21 Could not start investigation** in any reasons







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## Annex C: Cause Investigation Terms and Codes Investigation Finding

23 categories and 149 terms

C01	Biological Problem Identified
C02	Electrical Problem Identified
C03	Electromagnetic Compatibility Problem Identified
C04	Interoperability Problem Identified
C05	Labeling and Instructions for Use/Maintenance
C06	Material and/or Chemical Problem Identified
C07	Mechanical Problem Identified
C08	Optical Problem Identified
C09	Clinical Imaging Problem Identified
C10	Software Problem Identified
C11	Thermal Problem
C12	Protective System Problem Identified
C13	Operational Problem Identified
C14	Patient Sample Problem
C15	Environment Problem Identified
C16	Manufacturing Process Problem Identified
C17	Maintenance Problem Identified
C18	Transport/Storage Problem Identified
C19	No Device Problem Found
C20	No Findings Available
C21	Results Pending Completion of Investigation
C22	Appropriate Term/Code Not Available
C23	Usage Problem Identified

Some terms related with D conclusion terms

C01–C04,C06-C09

C05–D09

C10–D18

C15–D06

C16–D03

C23–D05-D10

C17 –D07

C20 –D15,D16

C18 –D04

C21 –D15,D16

C19 –D10,D14

Relation with D is private comments and Not official





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### Annex D: Cause Investigation Terms and Codes Investigation Conclusion

Many finding selections but Root Cause is defined around 40 selection.  
To reach to the conclusion, there are lots of **scientific rational** are required.

#### 18 categories and **39 terms**

<b>D01</b>	Cause Traced to Device Design
<b>D02</b>	Cause Traced to Component Failure
<b>D03</b>	Cause Traced to Manufacturing
<b>D04</b>	Cause Traced to Transport/Storage
<b>D05</b>	Cause Traced to Infrastructure
<b>D06</b>	Cause Traced to Environment
<b>D07</b>	Cause Traced to Maintenance
<b>D08</b>	Cause Traced to Training
<b>D09</b>	Cause Traced to Labeling
<b>D10</b>	Cause Traced to Non-Device Related Factors
<b>D11</b>	Cause Traced to User
<b>D12</b>	Known Inherent Risk of Device
<b>D13</b>	Falsified Device
<b>D14</b>	No Problem Detected
<b>D15</b>	Cause Not Established
<b>D16</b>	Conclusion Not Yet Available
<b>D17</b>	Appropriate Term/Code Not Available
<b>D18</b>	Cause Traced to Software Coding

D01-04 ,09 Find Root Cause

- Design / Manufacturing/ package/transportation

D05-06 Related to the **user side**

- Infrastructure/ envelopment

Related outside of factory  
but real root cause may  
happen to original manufacturer

D07,08 **Supporting system**

- Training/Maintenance

D10 Other reasons and **NOT this device is the cause.**

D11 **Caused by User**

D12 **Known Risk Labeled**

D13 **No more my Product**

D14 **Root Cause could not find** based on the several Investigation methods and their findings

D15-16 **Still Investigating** ant NOT reach to the conclusion.







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As of Sept 2021

Annex	Title	Version	L1	L2	L3	Total	Approved
A	Medical Device Problem	3.0	27	171	271	469	21 Jan 2021
B	Cause Investigation - Type of Investigation	3.0	23	NA	NA	23	21 Jan 2021
C	Cause Investigation - Investigation Findings	3.0	23	90	36	149	21 Jan 2021
D	Cause Investigation – Investigation Conclusion	3.0	18	21	NA	39	21 Jan 2021
E	Health Effects - Clinical Signs and Symptoms or Conditions	3.0	(24)	550 (96)	225 (68)	775 (164) <b>611</b>	21 Jan 2021
F	Health Effects - Health Impact	3.0	28	34	2	64	21 Jan 2021
G	Medical Device Component	2.0	(7)	220	68	288 (7)	21 Jan 2021
G Total						1799 (171) <b>1628</b>	





### Annex A~G Display (Excel File)

**Annex Name:**

**Annex Title:** Medical Device

**Annex Version:** 1.1

**Annex Description:**

**Annex Instructions:**

**Administrative Information about the Annex**

**Annex Approval Date:** 25 June 2020

**Terms**  
**Hierarchical structure**

**Annex E only**

**Just for information for Browser**  
**change Information**

Level 1 Term	Level 2 Term	Level 3 Term	Term Code	Definition	Non-IMDRF Code	Primary Secondary	Status	Status Description	Code Hierarchy
XX			AXX	AAAAAAA					AXX
	XY		AXXY	BBBBBBB			modify	20' editorial	AXX,XXYY
		YZ	AXXYZA	CCCCCCC					AXX XXYY XXYYZA
		ZX	AXXYZB	DDDDDDD					AX XXYY XXYYZB





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## **4. How to use those terms (virtual case) and how regulator observe it**

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## Virtual Case and Kye Point

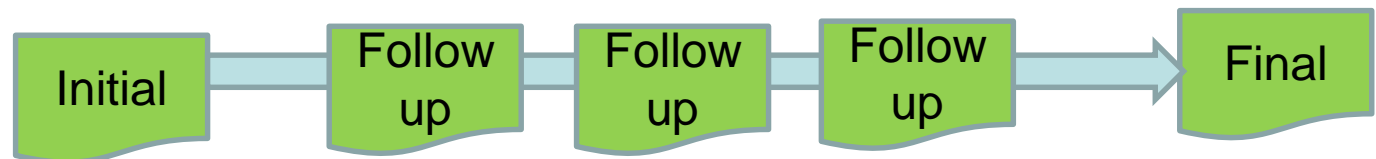
Report Type

GHTF N54 Appendix A

**Initial Report** : defined as the **first information** submitted by the manufacturer about a reportable event, but the **information is incomplete and supplementary information will need to be submitted**. This includes immediate notification

**Follow-up Report** : defined as a report that provides **supplemental information** about a reportable event that was not previously available

**Final Report** : defined as **the last report** that the manufacturer expects to submit about the reportable event. A final report may also be the first report



**Nature of  
Information**

Very Limited

Supplemental and adding cause analysis

Conclusive  
Results of  
cause analysis





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## Virtual Case and Kye Point

**This is my personal observation and not official**

### **Manufacturer Received AE information from User**

- Device stopped during the normal operation
- This is Not a new device and using 1 years but nothing happened like this
- Patient health impact and current situation is as follows . . . . .

### **Manufacturer response**

- Ask User by phone and try to find the more details ,such as “ normal operation”
- Any sound or noise come out when it stopped
- How the device stopped suddenly or gradually.

**Manufacturer investigate** to find the root cause and make report within regulated Period with text description.

- Device provided the safety lock, so something happened for fail that function.
- So the something electrical parts may have damage
- But need to investigate more intensively.





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Some virtual example for utilize AE terms for your e-MDAR

In case Initial Report

Not real report

		Situation	Selecting Term	Selecting Code
<b>Problem</b>	A	Device stopped suddenly in normal procedure	Fail-Safe Problem	A1602
<b>Parts and Components</b>	G	Looks electronic parts	Switch/Relay	G02034
<b>Type of Investigation</b>	B	Ask user to find the details by phone	Communication/Interviews	B13
<b>Results of Investigation</b>	C	Under investigation	Results Pending Completion of Investigation	C21
<b>Investigation Conclusion</b>	D	Not reached to the conclusion	Conclusion Not Yet Available	D16
<b>Clinical signs</b>	E	Vomiting brood from mouth	Hematemesis	E1016
<b>Health Impact</b>	F	In hospitalization	Hospitalization or Prolonged Hospitalization	F08





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## Virtual Case and Kye Point

This is my personal observation and not official

### Manufacturer investigate to find the root cause continue

- Ask user to send back the device
- At the interview with the operator and found that they hard some noise, when the device stopped.
- They use almost 3 times a week in average.
- Investigate actual suspected device and try to find the real root cause

### Manufacturer investigate to find the root cause

- Looks electrical function may have a problem and then mechanically stopped.
- Fail safe function dose not operate because of activation part looks stacked.
- Actually inverter seems to have some problem
- But still not reached to the conclusion because need to investigate other device which has same mechanism such as different Lot/Butch device, because of the noise.





In case Follow up Report (not reached to the conclusion to find the root cause)

More		Situation	Selecting Term	Selecting Code
Problem	A	Device electronic stopper function dose not operate	Activation Problem	A1501
Parts and Components	G	Seems electrical inverter	Inverter	G02022
Type of Investigation	B	Investigate the problemed device itself at our factory	Testing of Actual/Suspected Device	B01
Results of Investigation	C	Still need more investigation	Device Difficult to Operate	C1303
Investigation Conclusion	D	Not reached to the conclusion	Conclusion Not Yet Available	D16
Clinical signs	E	Vomiting brood from mouth	Hematemesis	E1016
Health Impact	F	Still in hospitalization	Hospitalization or Prolonged Hospitalization	F08







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## Virtual Case and Kye Point

This is my personal observation and not official

### Manufacturer investigate to find the root cause continue

- Investigate the other device with different Lot use with factory stocked
- From section to section quality inspection process, electrical safety function  
has no problem and could not find significant root cause.

### Manufacturer investigate to find the root cause and **made final decision**

- Actually electrical function may not have a problem.
- Investigate mechanical fail safe function, because noise comes first before stopped and find mechanical stopper such as open/close function cause damage  
to electrical portion.
- Actually mechanical stopper has not tightened enough  
according to the manufacturing process specification.
- The same lot device behave similar
- Reproducibility experiment shows the manufacturing process is the cause





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In case Final Report

		Situation	Selecting Term	Selecting Code
<b>Problem</b>	A	Device Mechanical stopper failure	Activation Failure	A150101
<b>Parts and Components</b>	G	Stopper	Stopper	G04124
<b>Type of Investigation</b>	B	Investigated at our Factory	Testing of Device from Other Lot/Batch Returned From User	B05
<b>Results of Investigation</b>	C	Mechanical parts that is function to open and close has been damaged	Assembly Problem Identified	C1601
<b>Investigation Conclusion</b>	D	Root cause is the mechanical stopper has not been tightened enough under less torque during manufacturing process	Manufacturing Deficiency	D0301
<b>Clinical signs</b>	E	Vomiting brood from mouth	Hematemesis	E1016
<b>Health Impact</b>	F	In hospitalization but now back to home	Hospitalization or Prolonged Hospitalization	F08





# IMDRF

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More		Situation	Selecting Term	Selecting Code
Problem	A	Device stopped suddenly in normal procedure Device electronic stopper function dose not operate Device Mechanical stopper failure	Fail-Safe Problem Activation Problem Activation Failure	A1602 A1501 A150101
Parts and Components	G	Looks electronic parts Seems electrical inverter Stopper	Switch/Relay Inverter Stopper	G02034 G02022 G04124
Type of Investigation	B	Investigate the problemed device itself at our factory  Investigated at our Factory	Communication/Interviews Testing of Actual/Suspected Device Testing of Device from Other Lot/Batch Returned From User	B13 B01 B05
Results of Investigation	C	Under investigation Still need more investigation  Mechanical parts that is function to open and close has been damaged	Results Pending Completion of Investigation Device Difficult to Operate Assembly Problem Identified	C21 C1303 C1601
Investigation Conclusion	D	Not reached to the conclusion  Root cause is the mechanical stopper has not been tightened enough under less torque during manufacturing process	Conclusion Not Yet Available  Manufacturing Deficiency	D16 D16 D0301
Clinical signs	E	Vomiting brood from mouth	Hematemesis	E1016
Health Impact	F	In hospitalization Still in hospitalization	Hospitalization or Prolonged Hospitalization	F08





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## Virtual Case and Kye Point

From regulator side observation and consideration

**This is my personal observation and not official**

### Manufacturer investigation conclusion

- Use real device and same lot device and different lot device
- Find the cause by reproducibility and lead to make occlusion that root cause is manufacturing process deficiency.

Regulator side question from the view of “Prevention from the same event”.

- Root cause is “Manufacturing deficiency” such as person who assemble the device did not follow the manufacturing specification. QMS issue.
- The torque gauge is well maintained? Or specified the specification?
- Specification of torque force is suitable to this Device?
- Is there any thought about the design specification is suitable or not because event happened just a year. And probably same thing will happen.
- Once manufacturing process has been improved and then nothing happened in future? And Manufacture assure to prevent the same event?
- **Is't it design problem and need to review design specification?**





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## Summary

Investigation terms are very important.

Manufacturer know everything about their Product through development stage to manufacturing process. On the other hand , User or Regulator has no knowledge how the device was developed and manufactured.

In that sense, Regulator could only make observation like third party review.

Lets take a look back why we have the AER system. Both party wants to use Device for Patient and keep their health in good condition by using the most sophisticated technology.

AE Report and its investigational information might help for both party to make sure that the corrective action should be the best preventive action.

Simply User do not want to be suffered by the same event to the patient, and believe that Regulator dose not want to take same legal action repeatedly. So that both Manufacturer and Regulator should work together to keep patient safety.





## Resources

When preparing AER, find terms from IMDRF WEB site.

### IMDRF Terminology

- [IMDRF AE WG Webpage](#) (Includes links to the terminology web browser)
- [IMDRF AE Terminology \(Current Version\)](#)
- [IMDRF AE Terminology \(Archived Versions\)](#)

### IMDRF Terminology Maintenance

- [IMDRF Terminology Maintenance Webpage](#)
- [Change Request Form](#)

### Related Documents

- [IMDRF AE Terminology Guideline Main Body \(N43 Document\)](#)
- [IMDRF Terminology Maintenance \(N44 Document\)](#)





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Thank you

