# Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

## Reporting Template Version 7.2.1

### European Union Medical Devices Vigilance System

## Section 1: Administrative information

### 1.1 Corresponding competent authority

a Name of receiving national competent authority (NCA)

Ministero Della Salute

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident

Not Known

d Reference number assigned by EUDAMED for this incident

### 1.2 Date, type, and classification of incident report

a Date of submission: 2024-04-16 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2023-11-01 to 2023-11-01

c Manufacturer awareness date: 2024-02-22 (e.g. 2012-10-23)

d Type of report

- ☐ Initial
- ☐ Follow up
- ☐ Combined initial and final
- ☒ Final (Reportable incident)
- ☐ Final (Non-reportable incident)

e In case of initial and follow-up reports, please indicate the expected date of the next report (e.g. 2012-10-23)

f Classification of incident

- ☐ Serious public health threat
- ☐ Death
- ☐ Unanticipated serious deterioration in state of health
- ☒ All other reportable incidents

### 1.3 Submitter information

#### 1.3.1 Submitter of the report

a ☒ Manufacturer ☐ Authorised representative ☐ Other, please specify

b Manufacturer's reference number for this incident

17907248

c If this incident involves multiple devices from the same manufacturer, please list the respective reference numbers of the other MIR forms you have submitted

- NCA's local reference number
- EUDAMED's reference number

| | | |
|---|---|---|
| | - Manufacturer's reference number | |
| d | If this incident is covered under an FSCA, please provide the relevant numbers:<br>- NCA's local FSCA reference number<br>- EUDAMED's FSCA reference number<br>- Manufacturer's FSCA reference number | |
| e | Periodic Summary Report (PSR) ID | |
| f | If the incident occurred within a PMCF/PMPF investigation; please provide the Eudamed ID of that PMCF/PMPF investigation | |

| | | | | |
|---|---|---|---|---|
| **1.3.2** | **Manufacturer information** | | | |
| a | Manufacturer organisation name | Boston Scientific Corporation – CRM | | |
| b | Single registration number | N/A | | |
| c | Contact's first name | Rossana | d | Contact's last name: Perego |
| e | Email | MILBSCRegulatory@bsci.com, Giovanna.Pira@bsci.com | f | Phone: 1-651-582-4000 |
| g | Country | United States | | |
| h | Street | Hamline Avenue North | i | Street number: 4100 |
| j | Address complement | | k | PO Box |
| l | City name | Saint Paul, MN | m | Postal code: 55112 |
| **1.3.3** | **Authorised representative information** | | | |
| a | Authorised representative organisation name | Guidant Europe SA/NV- Boston Scientific | | |
| b | Single Registration Number | N/A | | |
| c | Contact's first name | Sophie | d | Contact's last name: Vaillot |
| e | Email | sophie.vaillot@bsci.com | f | Phone: N/A |
| g | Country | Belgium | | |
| h | Street | Green Square - Lambroekstraat 5D | i | Street number: N/A |
| j | Address complement | | k | PO Box |
| l | City name | Diegem | m | Postal code: 1831 |

| 1.3.4 | Submitter's details if not also manufacturer or authorised representative | | |
|---|---|---|---|
| a | Registered commercial name of company: Boston Scientific Corporation – CRM | | |
| b | Contact's first name: Rossana | c | Contact's last name: Perego |
| d | Email: MILBSCRegulatory@bsci.com, Giovanna.Pira@bsci.com | e | Phone: 1-651-582-4000 |
| f | Country: United States | | |
| g | Street: Hamline Avenue North | h | Street number: 4100 |
| i | Address complement: | j | PO Box: |
| k | City name: Saint Paul, MN | l | Postal code: 55112 |

## Section 2: Medical device information

### 2.1 Unique Device Identification (UDI)

| | | | |
|---|---|---|---|
| a | UDI device identifier/Eudamed ID: Unknown | b | UDI production identifier: Unknown |
| c | Basic UDI-DI/Eudamed-DI: Unknown | d | Unit of use UDI-DI: |

### 2.2 Categorisation of device

a Medical device terminology

☐ EMDN ☒ GMDN ☐ UMDNS(ECRI) ☐ GIVD/EDMS ☐ Other, please specify

b Medical device nomenclature code: 36241

### 2.3 Description of device and commercial information

a Medical device name (brand/trade /proprietary or common name): ENDOTAK RELIANCE

b Nomenclature text/Description of the device and its intended use: Defibrillator / Pacemaker Lead

| | | | |
|---|---|---|---|
| c | Model: 0148 | d | Catalogue/reference number: 0148 |
| e | Serial number: 102354 | f | Lot/batch number: |
| g | Software version: | h | Firmware version: |
| i | Device manufacturing date (e.g. 2012-10-23): 2000-10-01 | j | Device expiry date (e.g. 2012-10-23): 2002-10-01 |
| k | Date when device was implanted (e.g. 2012-10-23): 2000-12-01 to 2000-12-01 | l | Date when device was explanted (e.g. 2012-10-23): to |

m If precise implant/explant dates are unknown, provide the duration of implantation

| | | | |
|---|---|---|---|
| | Number of years | Number of months | Number of days |
| n | Implant facility: Istituto Per La Sicurezza Sociale | o | Explant facility |
| p | Notified body (NB) ID number(s) (if applicable): 1 2797; 2 | | Notified body (NB) certificate number(s) of device (if applicable): 54612 |

q Please indicate the date of one of the following:

- ☐ First declaration of conformity
- ☒ The device first CE marked
- ☐ First placed on the market
- ☐ First put into service
- ☐ If software, date first made available

Year 2000 Month 5

## 2.4 Risk class of device when placed on market

a ☐ This device has been placed on the market before the implementation of the MDD/AIMDD/IVDD

b

**MDD/AIMDD**

- ☒ active implant
- ☐ class III
- ☐ class IIb
- ☐ class IIa
- ☐ class I
- ☐ class Is
- ☐ class Im
- ☐ class Ism
- ☐ custom-made

**IVDD**

- ☐ IVD Annex II List A
- ☐ IVD Annex II List B
- ☐ IVD devices for self-testing
- ☐ IVD general

c

**MDR**

- ☐ class III
- ☐ class IIb
- ☐ class IIa
- ☐ class I

Type (Multiple choice)

- ☐ implantable
- ☐ active device
- ☐ intended to administer and/or remove a medicinal product
- ☐ sterile conditions
- ☐ measuring functions
- ☐ reusable surgical instruments
- ☐ software
- ☐ systems
- ☐ procedure packs
- ☐ custom-made
- ☐ non-medical purpose

**IVDR**

- ☐ class D
- ☐ class C
- ☐ class B
- ☐ class A

Type (Multiple choice)

- ☐ self-testing
- ☐ near-patient testing
- ☐ professional testing
- ☐ companion diagnostic
- ☐ reagent
- ☐ software
- ☐ instrument
- ☐ sterile conditions

## 2.5 Market distribution of device (region/country) (according to the best knowledge of the manufacturer)

a

☒ All EEA, Switzerland and Turkey

☐ AT ☐ BE ☐ BG ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GB

☐ GR ☐ HR ☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO

☐ PL ☐ PT ☐ RO ☐ SE ☐ SI ☐ SK ☐ TR

**Others:**

| 2.6 | Use of accessories, associated devices or other devices |
|---|---|
| a | Relevant accessories used with the device being reported on (please list with corresponding Manufacturer if different from device being reported on) |
| b | Relevant associated devices used with the device being reported on (please list with corresponding Manufacturer if different from device reported on) |

## Section 3: Incident information derived from healthcare professional/facility/patient/lay user/other

### 3.1 Nature of incident

a

Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), i.e. clinical signs, symptoms, conditions as well as the overall health impact (i.e. Death; life-threatening; hospitalization - initial or prolonged; required intervention to prevent permanent damage; disability or permanent damage; congenital anomaly/Birth defects; indirect harm; no serious outcome)

It was reported that the right ventricular (RV) lead exhibited high out of range pacing impedance measurements of greater than 2000 Ohms along with increasing threshold measurements. The patient underwent provocation maneuvers and no oversensing or noise was observed. It was believed that the change in values is due to the age of the lead as it has been implanted for 24 years. The output was increased to maximum value. Data was sent into Technical Services (TS) for review. Upon review TS noted that the increase in impedance measurement has been gradual. TS discussed higher thresholds need to be evaluated for appropriate programming of outputs to ensure appropriate capture. TS indicated that this could be a symptom of encapsulation or ionization, but further testing would need to occur. No noise episodes have been stored, however TS observed greater than three thousand counters that were greater than 250 minutes during a six-month time frame. TS discussed troubleshooting the lead to determine the reason for the high counters. The RV lead remains in service and no adverse effects were reported.

### 3.2 Medical device problem information

a

IMDRF Medical device problem codes (Annex A)
Coding with IMDRF terms is a mandatory requirement.

| | Choice 1 (most relevant) | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
|---|---|---|---|---|---|---|
| IMDRF 'Medical device problem codes' | Code A072201 | Code | Code | Code | Code | Code |

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b

Number of patients involved
1

c

What is the current location of the device?

- ☐ Healthcare facility/carer
- ☐ Distributor
- ☐ Patient/user
- ☐ Discarded
- ☐ In transit to manufacturer
- ☒ Remains implanted
- ☐ Manufacturer
- ☐ Unknown
- ☐ Other:

d

Operator of device at the time of the incident

- ☐ Healthcare professional
- ☒ Patient/lay user
- ☐ Other, please describe

e

Usage of device (as intended)

- ☒ Initial use
- ☐ Reuse of a single use medical device
- ☐ Reuse of a reusable medical device
- ☐ Re-serviced/refurbished/fully refurbished
- ☐ Problem noted prior use
- ☐ Other:

f

Remedial actions taken by healthcare facility, patient or user subsequent to the incident

See Incident Narrative.

## 3.3 Patient information

a

IMDRF 'Health Effect' terms and codes (Annex E,F)
Coding with IMDRF terms is a mandatory requirement.

| | Choice 1 (most relevant) | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
|---|---|---|---|---|---|---|
| IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E) | Code: E2403 | Code | Code | Code | Code | Code |
| IMDRF 'Health impact' codes (Annex F) | Code: F26 | Code | Code | Code | Code | Code |

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

b

Age of patient at the time of the incident
years | months | days

c

Gender ☐ Female ☐ Male ☒ Unknown ☐ Not applicable

d

Body Weight (kg)

e

List any of the patient's prior health condition or medication that may be relevant to this incident

## 3.4 Initial reporter (can be healthcare professional of facility, patient, lay user)

a

Role of initial reporter
☒ Healthcare professional ☐ Patient ☐ Lay user ☐ Other, please specify

b

Name of healthcare facility where incident occurred
ISTITUTO PER LA SICUREZZA SOCIALE

c

Healthcare facility report number (if applicable)

d

Contact's first name
Roberto

e

Contact's last name
Tomassoni

f

Email
rtomassoni@omniway.sm

g

Phone
+011(378)0549994111

h

Country
San Marino

i

Street
VIA SCIALOIA, 20

j

Street number

k

Address complement

l

PO Box

m

City name
BORGO MAGGIORE

n

Postal code
47893

## Section 4: Manufacturer analysis

### 4.1 Manufacturer's preliminary comments

a For **initia**l and **follow-up** reports: preliminary results and conclusions of manufacturer's investigation

N/A

b Initial actions (corrective and/or preventive) implemented by the manufacturer

N/A

c What further investigations do you intend in view of reaching final conclusions?

Boston Scientific will continue to monitor field performance to detect similar events should they occur.

### 4.2 Cause investigation and conclusion

a **For Final (Reportable incident):** Description of the manufacturer's evaluation concerning possible ro causes/causative factors and conclusion

Investigation Summary:
Based on the available information, although no product has been returned as it remains implanted and in-service, we have determined that the clinically observed high impedance measurements are a known inherent risk with use of this product.

Device History Review:
A review of the Device History Record (DHR) was performed. The review of the DHR identified that there were no process related non-conformances, scrap, or rework performed during the production that could explain the event. The reviews ensure each device meets specification prior to release for use. There is no indication the device manufacturing process contributed to the reported complaint.

Device Technical Analysis:
This device was not returned as it remains implanted and in-service. As such, physical analysis has not been conducted in our laboratory. However, labeling review was conducted. This review determined that the clinically observed high impedance measurements are a known inherent risk of with use of this product.

Labeling Review:
Review of labeling determined that the complaint situation was listed in the manual. There was no indication in the complaint that the product was not used in accordance to labeling. The manual was unlikely to be the cause of the reported complaint; translation, wording, or graphics does not require further review.

Investigation Conclusion:
Based on all available information, Boston Scientific concludes that the high impedance measurements observed with this device are due to a known inherent risk of device use. High impedances are known to occur with use of this product and is listed as a potential adverse event in the product's labeling.

b **For Final (Non-reportable incident):** Fill out rationale for why this is considered not reportable

c Is root cause confirmed?

☒ Yes ☐ No

d Has the risk assessment been reviewed?

☒ Yes

☐ No If 'No', rationale for no review required:

If the risk assessment has been reviewed, is it still adequate?

☒ Yes

☐ No

Results of the assessment:

A Risk Review was completed and confirmed that the event of Pacing Impedance High Out Of Range was defined in the risk documentation. This event type has been accounted for during product risk analysis to support acceptable risk benefit for the product.

e

IMDRF 'Cause Investigation' terms and codes (Annex B, C, D)

| Coding with IMDRF terms is a mandatory requirement. | Choice 1 (most relevant) | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | Choice 7 | Choice 8 |
|---|---|---|---|---|---|---|---|---|
| IMDRF Cause investigation: Type of investigation (Annex B) | Code B14 | Code B17 | Code | Code | Code | Code | Code | Code |
| IMDRF Cause investigation: Investigation findings (Annex C) | Code C19 | Code | Code | Code | Code | Code | | |
| IMDRF Cause investigation: Investigation conclusion (Annex D) | Code D12 | Code | Code | Code | Code | Code | | |

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

f

IMDRF Component codes (Annex G)

Coding with IMDRF terms is a mandatory requirement.

| | Choice 1 (most relevant) | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
|---|---|---|---|---|---|---|
| IMDRF 'Component' codes (Annex G) | Code G07001 | Code | Code | Code | Code | Code |

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:

g

Description of remedial action/corrective action/preventive action/field safety corrective action (FSCA)

(For a FSCA, fill in the FSCA form )

None

h

Time schedule for the implementation of the identified actions

N/A

i

Final comments from the manufacturer on cause investigation and conclusion

N/A

## 4.3 Similar incidents (for Final (Reportable incident))

### 4.3.1 Use of IMDRF terms and codes for identifying similar incidents

a

Identification of similar incidents using IMDRF Adverse Event Reporting terms and codes

Tick-mark which code or combination of codes were used for identifying similar incidents.

| | Choice 1 |
|---|---|
| IMDRF code relating to most relevant 'Medical device problem' (Annex A) | ☒ |
| IMDRF code relating to most relevant 'Investigation finding' (Annex C, 'Cause investigation' | ☒ |

☐ Other - enter description of what similar incidents are based on and the rationale why the above IMDRF codes were not used

### 4.3.2 Use of in-house terms/codes for identifying similar incidents (only for transition period)

a

If similar incident were not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

| | Choice 1 | |
|---|---|---|
| Code/term for most relevant medical device problem | Code | |
| | Term | |
| Code/term for most relevant root cause evaluation | Code | |
| | Term | |

☐ Other - enter description of what similar incidents are based on and the rationale why the above codes were not used

### 4.3.3 Number of similar incidents and devices on the market

a

Indicate on which basis similar incidents were identified regarding the device or device variant:

☐ Model ☐ Software ☐ Lot/Batch ☒ Product platform ☐ Other variant

Details of the selection made above

b

Indicate to what criteria the number of devices on the market (also known as denominator data) is based o
(tick the most appropriate):

- ☐ Devices placed on the market or put into service
- ☐ Units distributed within each time period
- ☐ Number of tests performed
- ☐ Number of episodes of use (for reusable devices)
- ☐ Active installed base
- ☒ Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
- ☐ Number of devices implanted
- ☐ Other -describe

c

Enter the number of similar incidents and devices on the market for the indicated time periods
You must use yearly time periods unless:
A: a different time period has been specified by the European vigilance Working Group
B: the device has not been on the European market for more than three years

| | Time period (N)<br>Year to date = incident year<br>(e.g. 2012-10-23) | | Time period (N-1)<br>calendar year one year before incident<br>(e.g. 2012-10-23) | | Time period (N-2)<br>calendar year two years before incident<br>(e.g. 2012-10-23) | | Time period (N-3)<br>calendar year three years before incident<br>(e.g. 2012-10-23) | |
|---|---|---|---|---|---|---|---|---|
| Start Date | 2024-01-01 | | 2023-01-01 | | 2022-01-01 | | 2021-01-01 | |
| End Date | 2024-03-31 | | 2023-12-31 | | 2022-12-31 | | 2021-12-31 | |
| | Number of similar incidents | Number of devices on market | Number of similar incidents | Number of devices on market | Number of similar incidents | Number of devices on market | Number of similar incidents | Number of devices on market |
| Country of incident | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| EEA + CH + TR | 11 | 6562 | 26 | 6562 | 27 | 6561 | 38 | 6561 |
| World | 20 | 118097 | 71 | 118097 | 65 | 118094 | 85 | 118089 |

d

Comments on how similar incidents and associated number of devices on the market were determinec

Please note that all-time sales data was provided for this active implantable device. The use of all-time sales data provides a relevant occurrence rate for active implantable devices, as it accounts for sales volume variability and latent issues that may occur many years post-implant.

## Section 5: General Comments

Local Affiliate Contact Information:
Name: Boston Scientific S.p.A.
Contact Name: Rossana Perego
Address: Viale Forlanini 23
City/Postal Code: Milano, 20134
Country: Italy
Phone Number: +39(02)26983225
Fax Number: +39(02)26983230
Email: MILBSCRegulatory@bsci.com, Giovanna.Pira@bsci.com

## Coded summary of report (will be auto populated from previous selections)

Medical device name
ENDOTAK RELIANCE

| | |
|---|---|
| Basic UDI-DI | Unknown |
| UDI device identifier | Unknown |
| UDI productior identifier | Unknown |

IMDRF adverse event reporting terms and codes
IMDRF=International Medical Device Regulators Forum. Coding with IMDRF terms is a mandatory requirement.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| IMDRF clinical signs, symptoms, conditions codes | E2403 | | | | | | | |
| IMDRF health impact codes | F26 | | | | | | | |
| IMDRF Medical device problem codes | A072201 | | | | | | | |
| IMDRF Component codes | G07001 | | | | | | | |
| IMDRF Cause investigation: Type of investigation | B14 | B17 | | | | | | |
| IMDRF Cause investigation: Investigation findings. | C19 | | | | | | | |
| IMDRF Cause investigation: Investigation conclusion. | D12 | | | | | | | |

Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

I affirm that the information given above is correct to the best of my knowledge.

Before signing and submitting

Check the form | Save as PDF

Date
2024-04-16

Signature/Digital Signature
CRM Division - Post Market Quality Assurance
Digitally signed by CRM Division - Post Market Quality Assurance
Date: 2024.04.16 16:30:40 -06'00'

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