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: 2024-05-29 (e.g. 2012-10-23)

b Date of incident (e.g. 2012-10-23): 2020-12-01 to 2020-12-01

c Manufacturer awareness date: 2024-02-26 (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

17916066

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: - NCA's local FSCA reference number - EUDAMED's FSCA reference number - 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	N/A	k	PO Box: N/A
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	N/A	k	PO Box: N/A
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: N/A	j	PO Box: N/A
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: 47267

2.3 Description of device and commercial information

a	Medical device name (brand/trade /proprietary or common name): PROPONENT MRI SR		
b	Nomenclature text/Description of the device and its intended use: Pacemaker, implantable, single-chamber, rate-responsive		
c	Model: L210	d	Catalogue/reference number: L210
e	Serial number: 813172	f	Lot/batch number: 813172
g	Software version:	h	Firmware version:
i	Device manufacturing date (e.g. 2012-10-23): 2020-05-25	j	Device expiry date (e.g. 2012-10-23): 2022-05-07
k	Date when device was implanted (e.g. 2012-10-23): 2020-06-30 to 2020-06-30	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 See section 3.4	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) 620231

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 2014 Month 9

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 this implantable pacemaker inappropriately recorded a signal artifact monitoring (SAM) episode. Analysis of the device performed and it was determined that this was due to minute ventilation (MV) oversensing and high out of range pacing impedance measurements on the right ventricular channel. Consequently, a lead safety switch was triggered. Reprograming of the device was performed and the patient will continue to be monitored. This device remains in service. No further adverse patient 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 A070909	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
- ☐ Patient/user
- ☐ In transit to manufacturer
- ☐ Manufacturer
- ☐ Distributor
- ☐ Discarded
- ☒ Remains implanted
- ☐ 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 reusable medical device
- ☐ Problem noted prior use
- ☐ Reuse of a single use medical device
- ☐ Re-serviced/refurbished/fully refurbished
- ☐ 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: F10	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

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:
With the available information, although no product was returned, Boston Scientific determined that this device likely exhibited oversensing of noise generated by the Minute Ventilation (MV)/Respiratory sensor that is related to a high impedance condition.

Device History Record (DHR) 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 product has not been returned to Boston Scientific, and as a result, laboratory analysis could not be conducted. Investigation of the available information determined this device exhibited oversensing of noise generated by the Minute Ventilation (MV)/Respiratory sensor that is related to intermittent increases in impedance measurements with no conclusive evidence of a product performance issue or inadequate lead-to-device connection; please refer to the Section 3.1: Nature of Incident, for more information regarding the specific circumstances of this event.

Device 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:
The investigation determined a compromised lead or inadequate device-lead connection has the potential to create a transient high impedance condition, which may alter the Minute Ventilation sensor signal such that it becomes visible on EGMs and potentially subject to oversensing on the RA or RV channels. An FSCA was communicated to physicians for this behavior in December 2017, and a software update was released in January 2019, which eliminates the risk of pacing inhibition due to MV sensor signal oversensing in pacemakers and cardiac resynchronization therapy pacemaker (CRT-P) systems.

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 MV/RRT Noise Or Oversensing 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 B17	Code B14	Code B15	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 D0101	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)

An FSCA was communicated to physicians for this behavior in December 2017 and Boston Scientific developed and released a software update in January 2019, which automatically eliminates the risk of pacing inhibition due to MV sensor signal oversensing in pacemakers and cardiac resynchronization therapy pacemaker (CRT-P) systems upon initial interrogation with the upgraded programmer software.

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) Year to date = incident year (e.g. 2012-10-23)		Time period (N-1) calendar year one year before incident (e.g. 2012-10-23)		Time period (N-2) calendar year two years before incident (e.g. 2012-10-23)		Time period (N-3) calendar year three years before incident (e.g. 2012-10-23)	
Start Date	2024-01-01		2023-01-01		2022-01-01		2021-01-01	
End Date	2024-04-30		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	24	546216	61	522500	41	454783	62	391524
World	174	1511831	526	1442262	465	1236153	380	1045991

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

If the device is received for analysis an investigation which involves altering the device will take place. Boston Scientific Corporation will assume destructive analysis can begin unless contacted immediately following submission of this report opposing the analysis.

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

Medical device name
PROPONENT MRI SR

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	F10							
IMDRF Medical device problem codes	A072201	A070909						
IMDRF Component codes	G07001							
IMDRF Cause investigation: Type of investigation	B17	B14	B15					
IMDRF Cause investigation: Investigation findings.	C19							
IMDRF Cause investigation: Investigation conclusion.	D0101							

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

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Date
2024-05-29

Signature/Digital Signature
CRM Division - Post Market Quality Assurance
Digitally signed by CRM Division - Post Market Quality Assurance
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