HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

VALITUDE™ CRT-P, ACCOLADE™ Pacemakers, ESSENTIO™ Pacemakers, VISIONIST™ CRT-P, PROPONENT™ Pacemakers, ALTRUA™ 2 Pacemakers

and

VALITUDE™, VISIONIST™ CRT-P and CHARISMA™ , MOMENTUM™, RESONATE™, VIGILANT™, AUTOGEN™, DYNAGEN™, INOGEN™, ORIGEN™ CRT-D

Priority 2 – Warning

HPRA Safety Notice: SN2017(43) **Issue Date: 20th December 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Boston Scientific	V34084, V34085

ISSUE

The HPRA is aware that Boston Scientific is launching 2 Field Safety Corrective Actions, to address 2 potential issues with certain CRT-P and CRT-D devices.

FSCA 92179817-FA: Technical programming information – Left Ventricular (LV) Offset interaction on Cardiac Resynchronization Therapy (CRT-Ps) and defibrillators (CRT-Ds)

Boston Scientific has discovered that an unintended asynchronous biventricular pacing behavior can occur when tracking elevated atrial intrinsic rhythms in certain CRT-D and CRT-P devices, when certain infrequent programming parameters are programmed, which may cause the need for early device replacement. Boston Scientific has given programming recommendations to eliminate the risk of premature device replacement until a software upgrade is available. Boston Scientific has estimated that the probability of occurrence is low. For further details on the affected device models and risk mitigations, please see the attached

Field Safety Notice (FSN) "*Left Ventricular (LV) Offset interaction on Cardiac Resynchronization Therapy pacemakers (CRT-Ps) and defibrillators (CRT-Ds)*"

FSCA 92186345-FA: Pacemakers – Technical programming information on Minute Ventilation Sensor

Boston Scientific has received reports of intermittent oversensing of the Minute Ventilation (MV) sensor signal with certain Boston Scientific pacemaker and cardiac resynchronisation systems (pacemakers). This may cause pacing inhibition and syncope or pre-syncope due to periods of pacing inhibition. This MV oversensing behaviour may occur with any manufacturer's pacing lead system, however Boston Scientific has determined it to be more likely for affected Boston Scientific pacemakers using Medtronic or Abbott/St. Jude (Abbott) leads implanted in either the right atrium (RA) or right ventricle (RV). Boston Scientific is developing a software upgrade to resolve this oversensing behaviour, and has developed recommendations to mitigate the risk of this occurring. Boston Scientific has estimated that the probability of occurrence is low. Please see the attached FSN *"Pacemakers – Technical Programming information on Minute Ventilation Sensor"* for information on the affected device models and risk mitigations.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSNs and follow the instructions provided by the manufacturer.

2. Acknowledge receipt of the FSNs to the manufacturer.

3. Forward a copy of this Safety Notice and FSNs to all relevant personnel within your organisation, or any person/s or organisation to whom/which this device has been transferred.

4. Report any adverse events associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Cardiac pacemaker/ICD technicians	Medical Directors
Cardiologists in pacing and electrophysiology	Nursing Staff
Clinical Engineers / Biomedical Engineers	Private Hospital Staff
HSE Hospital Staff	Purchasing / Procurement / Material Managers
Hospital Managers	Risk Managers
Surgeons	Theatres
Supplies Managers	

BACKGROUND

Please see the attached FSNs for detailed information on the affected device models, background to the issue, and risk mitigations.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Boston Scientific Ltd
Breakspear Park, Breakspear Way,
Hemel Hempstead,
United Kingdom, HP2 4TZ

Telephone: + 44 (0) 1442 411 600
Fax: + 44 (0) 1442 411 816
E-mail: : UK-Quality@bsci.com
Website: https://www.bostonscientific.com/

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to the manufacturer and:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
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