



Llywodraeth Cymru
Welsh Government

Medical Device Alert

16th January 2018

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

Pacemakers and CRT-P - oversensing of minute ventilation sensor signal leading to risk of syncope and pre-syncope

1. Read the manufacturer's [Field Safety Notice \(FSN\)](#)
2. Identify all patients implanted with the affected devices listed below.
3. Schedule a follow-up of pacemaker-dependent patients as soon as possible, within 6 weeks, with priority to those with pacemakers connected to competitors' pacing leads (see Problem/background). This should include reassessment of patients whose current degree of pacemaker-dependency is uncertain.
Turn off the minute ventilation (MV) sensor for all pacemaker-dependent patients.
4. Evaluate the risks of pacing inhibition against the benefits of MV based rate adaptive pacing (and other MV based diagnostic functions) within 6 months for patients not considered to be pacemaker-dependent. Prioritise those with pacemakers connected to competitors' pacing leads (see Problem/background).
5. Consider the following for patients left with the MV sensor "ON":
 - monitoring for signs of MV oversensing, such as transient, abrupt changes or out-of-range RA/RV pacing impedance measurements, or MV sensor signal artefacts on ECGs.
 - increasing the frequency of patient follow-ups to assess for future pacemaker dependency.

Sent to:

NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

This document is available online at:
<https://www2.nphs.wales.nhs.uk/contacts.nsf>

Ffôn/Tel: 029 2082 3624/029 2082 5510
Eboost/Email: Haz-Aic@wales.gsi.gov.uk

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

**Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ**



Medical Device Alert

MDA/2018/001

Issued: 12 January 2018 at 11:00

Pacemakers and CRT-P - oversensing of minute ventilation sensor signal leading to risk of syncope and pre-syncope

Summary

Manufactured by Boston Scientific: specific models only – risk of syncope or pre-syncope due to periods of pacing inhibition from oversensing of the minute ventilation sensor signal

Action

1. Read the manufacturer's [Field Safety Notice \(FSN\)](#)
2. Identify all patients implanted with the affected devices listed below.
3. Schedule a follow-up of pacemaker-dependent patients as soon as possible, within 6 weeks, with priority to those with pacemakers connected to competitors' pacing leads (see Problem/background). This should include reassessment of patients whose current degree of pacemaker-dependency is uncertain.
Turn off the minute ventilation (MV) sensor for all pacemaker-dependent patients.
4. Evaluate the risks of pacing inhibition against the benefits of MV based rate adaptive pacing (and other MV based diagnostic functions) within 6 months for patients not considered to be pacemaker-dependent. Prioritise those with pacemakers connected to competitors' pacing leads (see Problem/background).
5. Consider the following for patients left with the MV sensor "ON":
 - monitoring for signs of MV oversensing, such as transient, abrupt changes or out-of-range RARV pacing impedance measurements, or MV sensor signal artefacts on ECGs.
 - increasing the frequency of patient follow-ups to assess for future pacemaker dependency.
6. Adopt increased vigilance and report any suspected incidents to the MHRA and Boston Scientific

Action by

All cardiologists and cardiac physiologists who manage patients implanted with pacemakers and CRT-P

Deadlines for actions

Actions underway: 19 January 2018

Actions complete: 12 July 2018

Device details

Product name	Models
VALITUDE™ CRT-P	U125, U128
ACCOLADE™ Pacemakers	L300, L301, L310, L311, L321, L331
ESSENTIO™ Pacemakers	L100, L101, L110, L111, L121, L131
VISIONIST™ CRT-P	U225, U226, U228
PROPONENT™ Pacemakers	L200, L201, L209, L210, L211, L221, L231
ALTRUA™ 2 Pacemakers	S701, S702, S722

In addition to the [FSN](#) which details affected product, please refer to the Excel spreadsheet which accompanies this MDA for additional unique device identification information.

Problem / background

Boston Scientific issued an [FSN](#) on the 19 December 2017, following reports of pacing inhibition due to oversensing of the MV sensor signal. Note that the nominal setting for MV sensor in affected Boston Scientific pacemakers is "Passive", which presents the same patient risk of oversensing as when it is reprogrammed to "ON".

There are approximately 32,500 affected patients at 308 centres in the UK. To date there have been 184 reported oversensing events worldwide (22 in the UK) representing 0.05% of sales of these device models. These include 31 known incidents of serious injury or death (8 in the UK) including patient dizziness, syncope or falls. The true prevalence of the MV oversensing is, however, unknown as it can go undetected if the patient remains asymptomatic.

Intermittency related to the lead or pacemaker-lead connection can lead to transient high impedance conditions, which can alter the MV sensor signal which can become visible on an electrogram and potentially cause oversensing on the right atrial or right ventricular channels. Further information is provided in the [FSN](#).

Based upon data from reported events, and testing of competitors' leads, Boston Scientific has indicated that the issue tends to be more prevalent in leads with greater terminal ring motion within the pacemaker header such as Medtronic or Abbott leads. Boston Scientific has also indicated that over 60% of MV oversensing reports have involved their devices connected to Medtronic or Abbott leads, despite only around 12% of the affected models being implanted with these competitors leads (based on US data).

A software fix mitigating the risk of MV oversensing is currently being developed by the manufacturer and is planned to be released by October 2018. In the meantime, an accelerometer based rate response function can be programmed for these pacemakers where deemed clinically necessary. Further information is available from Boston Scientific.

Note that some patients affected by this MV field action may also be affected by a second [FSN](#) issued simultaneously by Boston Scientific on left ventricular offset interaction, which provides separate patient management recommendations not covered by this MHRA alert.

Manufacturer contacts

Technical Enquires:
 Boston Scientific
 Tel: +32 2 416 7222
 Email: intltechservice@bsci.com

Non-Technical Enquiries:
 Boston Scientific
 Your local Boston Scientific representative or
 Email: UK-Quality@bsci.com, Tel: +44 (0)1442 411 731

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- EBME departments
- Medical directors
- Medical libraries
- Radiology departments
- Risk managers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners
- General practice managers
- General practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/001** or **2017/012/019/291/016**.

Technical aspects

Jillan Hussein, MHRA

Tel: 020 3080 7148

Email: jillan.hussein@mhra.gov.uk

Simon Holmes, MHRA

Tel: 020 3080 7240

Email: simon.holmes@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

Northern Ireland

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
<https://www.health-ni.gov.uk/niaic>

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.irc@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to [Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to [Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

Single Registration Number (SRN) Reference
Company Name
Company Global Location Number (GLN)
Company FSN Reference
Issue Date

EUDAMED not yet available - N/A
Boston Scientific Corporation
191506000004 & 8714729000006
92186345-FA
19-Dec-17

