Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/008 Issued: 13 February 2019 at 14:30

Implantable cardiac pacemakers: specific brands of dual chamber pacemakers - risk of syncope due to pause in pacing therapy

Summary

Manufactured by Medtronic Inc – a subset of dual chamber pacemakers may experience a loss of pacing therapy when programmed to a dual chamber mode with atrial-sensing.

Action

Actions

1. Read the manufacturer's Field Safety Notice (FSN)
2. Identify all affected devices supplied to your hospital between March 2017 and January 2019 using the serial number look-up tool on Medtronic's Product Performance website: http://wwwp.medtronic.com/productperformance
   Additional support in identifying affected devices is available from Medtronic - see details in 'Manufacturer contact'.
3. Do not implant affected devices; quarantine them and contact Medtronic to arrange return.
4. Identify all patients already implanted with an affected device and verify the programmed pacing mode for their pacemaker.
5. Arrange an in-clinic assessment for all patients with a pacemaker programmed to a susceptible pacing mode (see FSN). Prioritise patients without an underlying escape rhythm to prevent syncope who should be seen as soon as possible and ideally within 1 month. Be aware that if these patients are also in atrial fibrillation, this increases the risk of a circuit error occurring.
6. Follow the recommendations for pacemaker reprogramming included in the FSN.
7. Consider pacemaker replacement for patients without an underlying ventricular escape rhythm who are unable to tolerate a non-susceptible pacing mode, taking account of their individual procedure-related risk.

Report adverse events involving these devices either directly or through your local incident reporting system to your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to the manufacturer.

Action by

All cardiologists and cardiac physiologists who manage patients implanted with pacemakers.

Deadlines for actions
Actions underway: 20 February 2019
Actions complete: 13 May 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Device details

Brands distributed in the UK	Models
ADAPTA™	ADD01, ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1, ADVDD01
SENSIA™	SEDR01, SEDRL1
ATTESTA™	ATDR01
SPHERA™	SPDR01, SPDRL1
VITATRON™ E, G, Q series	E60A1, G70A2, Q70A2

Problem / background

Medtronic issued a Field Safety Notice on 17 January 2019 addressing the potential risk of loss of pacing therapy in a specific subset of dual chamber pacemakers. The problem is limited to these pacemakers when programmed to a dual chamber mode with atrial-sensing.

156,957 potentially affected devices were distributed worldwide from March 2017 to January 2019 inclusive, with around 7,400 sold in the UK. Devices distributed before March 2017 are not affected.

These pacemakers are at risk of experiencing a circuit error following an atrial sensed event, that may result in a device lock-up condition. During the lock-up condition, the pacemaker will not provide atrial or ventricular pacing, neither will it initiate a session with the programmer or CareLink remote monitor or respond to a magnet.

For most patients the chance of device circuit error is low, estimated by Medtronic to be around 2.8% per month. This, however, increases significantly for patients in atrial fibrillation, whose pacemaker is atrial sensing, due to the high number of atrial sensed events.

The pacemaker will resume normal pacing therapy as soon as an intrinsic ventricular event is detected. **Therefore, patients with no ventricular escape rhythm are at greatest risk, as the cessation of pacing will be prolonged**. Attention should also be paid to patients previously suspected to have experienced ventricular over-sensing, especially if this resulted in programming changes to ventricular sensing threshold.

As of the date of the FSN, there had been 4 non-UK events of clinically apparent pause in 2 patients ranging from 6 to 61 seconds. However, according to the analysis performed by Medtronic using CareLink data, for most patients the duration of the pacing pause would be clinically insignificant in the event of a circuit error, due to the detection of a ventricular sensed event.

A software fix mitigating the risk of circuit error is currently being developed by the manufacturer and is estimated to be released in the second half of 2019.

Manufacturer contacts

Medtronic Inc.
Keith Taverner, Regulatory Affairs Manager UK and Ireland
Tel: 01923 212 213
Email: Vigilance.eu@medtronic.com

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
- Adult intensive care units
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Community defibrillation officers
- Community hospitals
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units

- Intensive care, directors of
- Medical directors
- Medical physics departments
- NHS walk-in centres
- Outpatient clinics
- Paediatric intensive care units
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Walk-in centres

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

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/008** or **2019/001/018/291/003**.

Technical aspects

Kristine Perovica and Hazel Randall, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

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

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

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

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).