Medical Device Alert

Ref: MDA/2011/097 Issued: 28 September 2011 at 12:00

Device

Implantable pacemakers manufactured by Medtronic.

EnRhythm®:
Model P1501DR is a dual chamber rate responsive pacemaker.

EnRhythm MRI™ SureScan:
Model EMDR01 IPG is a modified EnRhythm® P1501DR which is MR Conditional.

Problem

Following a software update the new battery impedance elective replacement indicator (ERI) threshold may trigger an unexpected ERI in some EnRhythm® and EnRhythm MRI™ devices.

Action by

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

Action

- Schedule all patients who have received the software update for a follow-up visit to identify devices that triggered ERI shortly after the software update.
- Patients who have not yet received the software update should be reviewed, and then again within 90 days after the software update to identify if ERI is triggered.
- Continue to follow up until device is ready for replacement:
  - every three months if patient is pacemaker dependent, and
  - every six months (or at individual physician's discretion) if patient is not pacemaker dependent.
- Schedule device replacement when ERI is triggered.

CAS deadlines

Action underway: 12 October 2011

Action complete: 30 December 2011

Contact

Manufacturer
Dr David Dunham / Mrs Lezlie Bridge
Medtronic Limited

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Problem

The manufacturer issued a Field Safety Notice (FSN) in August 2011 with patient management recommendations updated from a previously issued FSN (in February 2010), which informed healthcare professionals about a software update.

The software update adds a battery impedance ERI threshold that may trigger an unexpected ERI in some devices. Medtronic's modelling from collected data estimates that approximately 6–10% of devices may reach ERI within 5 years of implantation.

When ERI is triggered, the device reverts to VVI back-up pacing mode (65 beats per minute) which may not be adequate treatment and may cause symptoms associated with pacemaker syndrome for some patients.

These pacemakers are no longer sold in the UK and all devices supplied in the UK reached their use by date by 14 August 2011.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- General practitioners (for information)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiac physiologists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Risk managers

Primary care trusts

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

- General practitioners (for information)

Independent distribution

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

This alert should be read by:

- 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.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/097** or **2010/002/010/081/003**

Technical aspects
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

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

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
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Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

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