Medical Device Alert

Ref: MDA/2011/060 Issued: 02 June 2011 at 11:00

Device

Dual Chamber Pacemakers.

Medtronic models:
Kappa 600, 700, 800 and 900; EnPulse; Adapta; Versa; Sensia; Relia.

Vitatron models:
E50A1, E60A1 and G70A1.

Problem

The manufacturer issued a Field Safety Notice (FSN) – Medtronic Reference: FA507 – for these devices on 4 April 2011, but has not had sufficient confirmation from users that they have received and acted on this information.

A copy of the FSN is in the appendix of this Alert, and it is also available on the MHRA website.

Action

- Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.

Action by

Cardiologists, Cardiac physiologists who implant these pacemakers or who manage implanted patients.
Physiological measurement technicians.

CAS deadlines

Action underway: 16 June 2011

Action complete: 23 June 2011

Contact

Manufacturer
Lezlie Bridge
Medtronic Ltd

Tel: 07740 899 216
Fax: 01923 225 273

Email: lezlie.j.bridge@medtronic.com

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)
- NHS boards and trusts in Wales (Chief Executives)
- 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 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

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

Manufacturer

Lezlie Bridge
Medtronic Ltd
Building 9
Croxley Green Business Park
Hatters Lane
Watford
WD18 8WW

Tel: 07740 899 216
Fax: 01923 225 273

Email: lezlie.j.bridge@medtronic.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/060** or **2011/004/004/081/023**

Technical aspects
Miss Feza Haque or Mr Simon Holmes
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7066 / 7240
Fax: 020 8754 3965

Email: feza.haque@mhra.gsi.gov.uk
simon.holmes@mhra.gsi.gov.uk

Clinical aspects
Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7126
Fax: 020 8754 3965

Email: nicola.lennard@mhra.gsi.gov.uk

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
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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

MHRA is an executive agency of the Department of Health
© Crown Copyright 2011
Addressees may take copies for distribution within their own organisations

Appendix

Medtronic Limited
Building 9
Croxley Green Business Park
Hatters Lane
Watford
Hertfordshire
WD18 8WW

Tel:01923 212213
Fax:01923 241004

URGENT FIELD SAFETY NOTICE

Dual Chamber Models of Pacemakers:
Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia,
Vitatron Models E50A1, E60A1, and G70A1

4 April 2011

Medtronic Reference: FA507

Dear Doctor,

Attached is a Performance Note that explains a rare measurement lock-up condition that may (at a rate of approximately 1 in 18,000 devices) inappropriately trigger ERI/RRT in the Medtronic Dual Chamber Pacemakers listed above. This is caused by a random lock-up of the measurement system hardware that may result in an incorrect battery voltage reading of zero. **This issue does NOT impact battery longevity and does NOT require device explant. Currently, the device can be reset to normal operation by a Medtronic representative.** Reset devices are no more likely to experience a recurrence of this issue. In late 2011, pending regulatory approval, Medtronic is planning to release a programmer software update that will allow the clinician to reset the device.

Medtronic has received 101 reports worldwide of this issue out of an estimated 1.8 million devices. Seventy devices have been explanted due to this issue, with most explants occurring prior to Medtronic's development of a method to reset devices.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of this action. We request that you inform others within your organization of this notice as appropriate.

If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services on 01923 212 213.

Yours sincerely,

Lezlie Bridge
Senior Regulatory Affairs Specialist – UK & Ireland

Performance Note

Dual Chamber Pacemakers with Measurement Lock-up ERI

Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia, and Vitatron Models E50A1, E60A1, and G70A1

Purpose of this Information

This Performance Note describes a rare measurement lock-up issue that impacts the Medtronic **Dual Chamber** pacemakers listed above. If this measurement lock-up occurs, the device will trigger a false Elective Replacement Indicator (ERI). A reset is available to clear this condition and there is no need to explant the device. This issue does not impact battery longevity.

Background

If this rare measurement lock-up occurs in the pacemaker, it causes the device to read a value of zero for battery voltage. After four measurements of zero, the device will trigger ERI and revert to a VVI pacing mode at 65 bpm. There is no loss of ventricular pacing and the output voltage will remain the same.

The issue can be uniquely identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values. Medtronic has developed a method for clearing the ERI condition through the use of a specially configured programmer. There is no impact to the device functionality or longevity after this reset is complete.

Example

Two examples of images from the Medtronic 2090 programmer are shown below. Example 1 shows what a normal ERI condition looks like. Example 2 shows what will be displayed if the ERI is triggered due to the measurement lock-up condition.

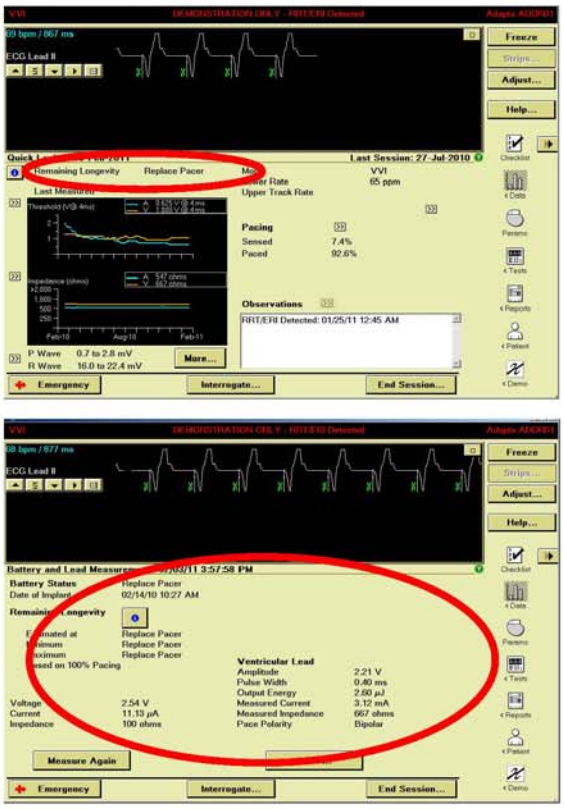
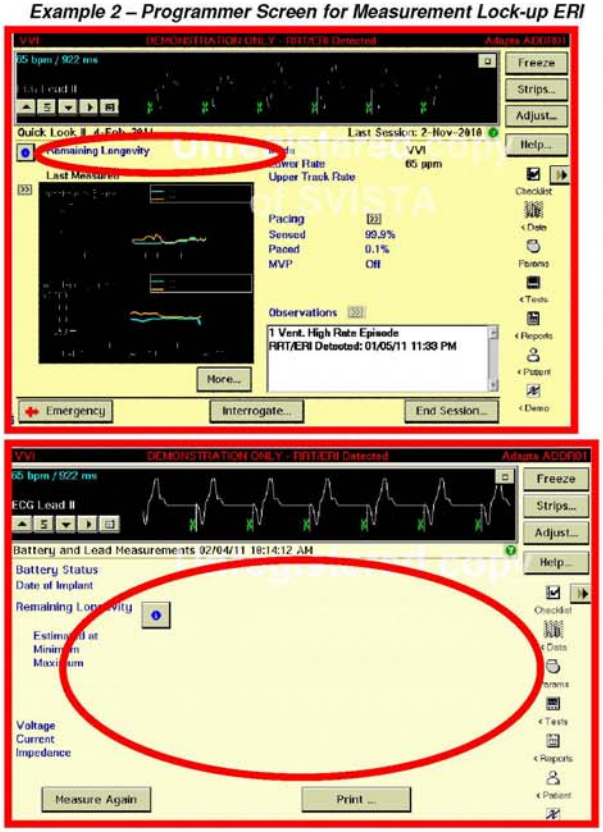
A device that has experienced a measurement lock-up ERI will present ALL of the following symptoms:

- Device declaring ERI/RRT
- Remaining Longevity = <Blank> on the programmer (and CareLink where available)
- Battery Voltage = <Blank> on the programmer (and CareLink where available)
- If the user attempts to take a Battery and Lead Measurement, a pop up window will indicate that it cannot estimate remaining battery life.

Recommendation

This condition can be reset and does not require device explant. If this measurement lock-up occurs, obtain a save-to-disk file and contact your local Technical Consultant or Medtronic Technical Services on 01923 212 213 for assistance. Reset devices are no more likely to experience a recurrence of this issue.

Example 1–Programmer Screen for Typical Pacemaker at ERI



Example 2 – Programmer Screen for Measurement Lock-up ERI