Medical Device Alert

Ref: MDA/2012/014 Issued: 16 March 2012 at 12:00

Device

Implantable cardioverter defibrillators (ICD).

EnTrust VR/DR/AT.

Models: D153ATG, D153DRG, D153VRC, D154ATG, D154DRG, and D154VRC.

Manufactured by Medtronic.

Problem

Risk of loss of ICD/pacing therapy after elective replacement indicator (ERI) is reached, due to rapid battery depletion occurring approximately 2½ years after implantation.

Action by

All cardiologists and cardiac physiologists who manage patients implanted with ICDs

Action

1. Follow-up all patients with EnTrust ICDs urgently:
   - within 1 month if the device has been implanted for more than 28 months;
   - within 3 months in other cases; in order to:
     > ensure audible alerts for 'Low Battery Voltage ERI' and 'Excessive Charge Time EOL' are programmed ON (status can be viewed over CareLink)
     > advise patients to contact centres immediately if the alert sounds
     > compare battery voltage with values from previous follow ups for evidence of rapid battery voltage drop (see Fig 1).
2. Replace ICDs where ERI has been reached in the presence of rapid battery voltage drop, within 2 weeks.
3. Continue to review all patients every 3 months.
4. Ensure all patients are enrolled on CareLink, in discussion with the manufacturer.
5. Prophylactic replacement of these devices is not recommended except in exceptional circumstances.

CAS deadlines

Action underway:
22 March 2012

Action complete:
22 June 2012

Contact

Manufacturer
Mrs Lezlie Bridge
Medtronic Limited
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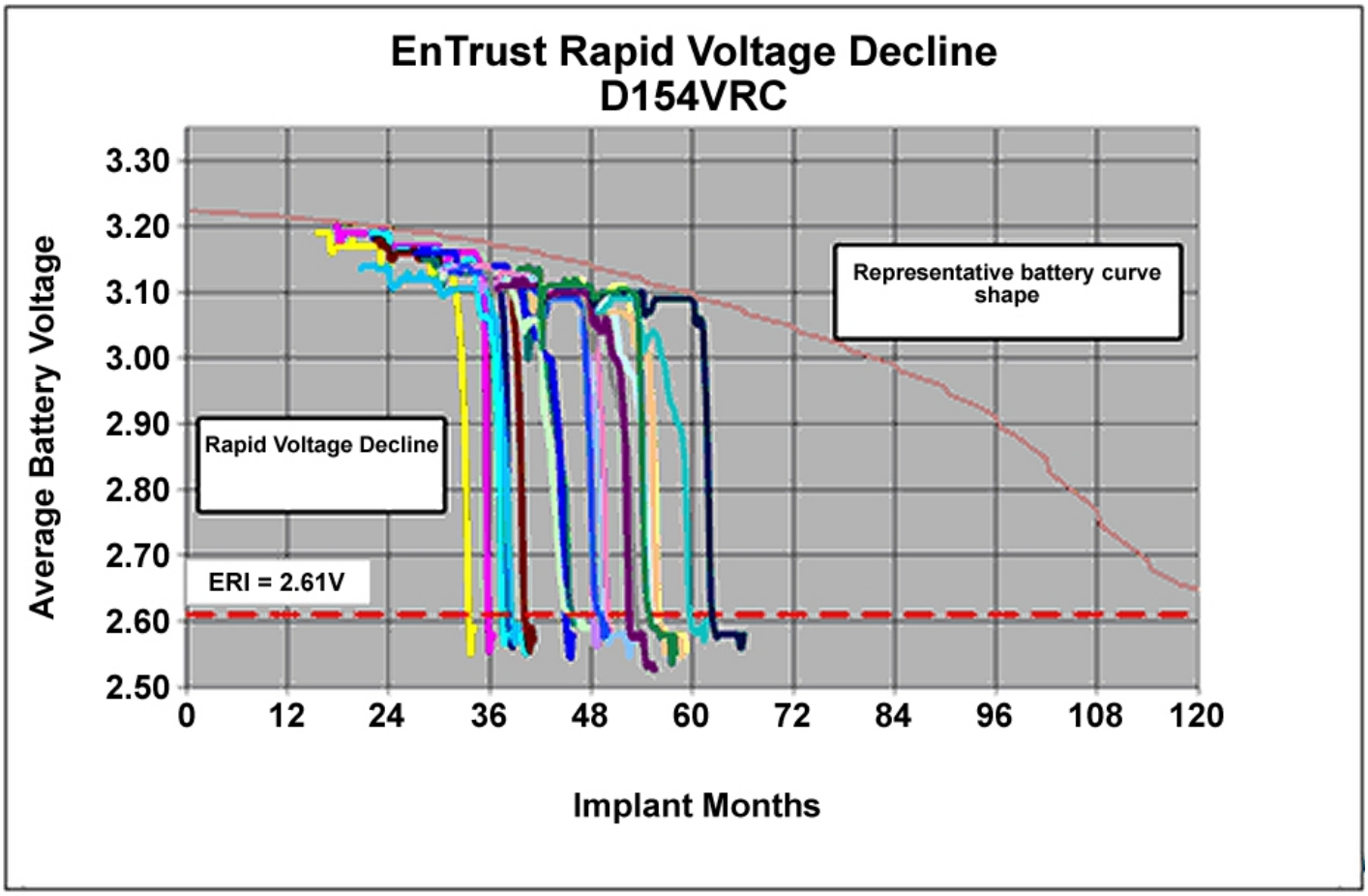
Email: lezlie.j.bridge@medtronic.com

Problem

Approximately 69,000 EnTrust devices have been sold worldwide since 2005, with just over 1,000 sold in the UK. To date only 0.15% of single chamber EnTrust ICDs and 0.04% of dual chamber EnTrust ICDs worldwide are reported to have experienced rapid voltage decline. Although the issue does not appear to affect devices implanted for less than 30 months, the failure rate as implant duration increases is as yet unknown.

Medtronic issued a Field Safety Notice addressing this issue on 6 March 2012.

Fig 1: Medtronic's analysis of ICD failures
The graph shows examples of a number of ICDs which have experienced rapid voltage drop from 3.0V to 2.61V over a time period ranging from approximately 1 week to 6 months.
Note: This graph may not be characteristic of every possible voltage curve drop due to this issue. The sole purpose of this graph is to illustrate rapid voltage decline to 2.61V (ERI), not the duration of time between ERI and EOL.



End of life (EOL) is triggered 90 days after ERI or after 2 excessive charge time events (>16 seconds) or if the battery voltage is 2.55V.

In EnTrust devices that experienced rapid voltage decline, time between measurements of approximately 3.0V and 2.61V (ERI) ranged from 4 to 198 days (mean 71, median 56).

In EnTrust devices that experienced rapid voltage decline, time between ERI and EOL ranged from 6 to 96 days (mean 41, median 26), based upon data available from the 9 ICDs that experienced charge circuit timeout events during automatic capacitor formation prior to device explant.

In the event of a battery short circuit the ICD may not be able to provide the required therapy for the 3 month period generally expected post ERI. Although incidents of charge circuit timeout have occurred, there have been no reports to date of death or serious injury associated with this failure.

The rapid voltage drop has been linked to an internal short circuit within the ICD battery. Although the exact root cause is still being investigated by the manufacturer, the issue appears to be specific to EnTrust devices. Failure rate data for other Medtronic ICD models incorporating the same battery model currently indicate that they are not affected. Furthermore, these batteries are not used by other manufacturers.

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)

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
- Cardiothoracic surgeons
- Clinical governance leads
- Medical directors
- Nursing executive directors

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- 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/2012/014** or **2012/002/029/291/009**

Technical aspects
Simon Holmes or Hazel Randall
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Floor 4
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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 Chris Jones
Medical Director
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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