Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2016/019 Issued: 17 October 2016 at 14:00

Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) – risk of loss of therapy due to rapid battery depletion

Summary

Manufactured by St Jude Medical – risk of unpredictable, rapid battery depletion leading to potential device failure and loss of therapy.

Action

1. Identify all affected devices supplied to your hospital by checking: www.sjm.com/batteryadvisory
2. Do not implant affected devices; quarantine them and contact St Jude Medical to arrange return.
3. Identify all patients already implanted with an affected device.
4. Prophylactic replacement of these devices is **not** recommended except in exceptional circumstances.
5. Replace all implanted devices that reach ERI as quickly as possible, prioritising pacing dependent patients, as time remaining to EOL is unpredictable and may be no more than a day.
6. Undertake the following steps to help ensure early ERI identification:
    a. review the most recent programmed parameter print-outs where possible to verify whether the **'Device at ERI'** parameter under the **'Trigger Alerts When'** section is programmed '**ON**' for both '**Show on FastPath**' and '**Notify Patient**' selections
    b. follow up as soon as possible any patient for whom this is programmed **'OFF'** or it is not possible to verify the alerts status, to ensure both parameters are programmed **'ON'**
    c. ensure as many patients as possible are enrolled in Merlin.net remote monitoring with the 'Direct Alerts' feature enabled
    d. at the next scheduled in-clinic follow-up:
        i. evaluate battery status
        ii. ensure patients can feel their vibratory alert and know to call their cardiac centre immediately if this is triggered.
        iii. remind patients of the importance of using their remote monitoring
7. Consider providing patients with the St Jude Medical patient advisory letter or one produced locally.

Action by
All cardiologists and cardiac physiologists who manage patients implanted with ICDs and CRT-Ds.

Deadlines for actions
Actions underway: 24 October 2016
Actions complete: 17 April 2017

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Models containing the affected battery design are:
Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura and Unify Quadra, ICD and CRT-D.

Family	UK model numbers	UK launch
Fortify	CD1233-40, CD1233-40Q, CD1235-40, CD1235-40Q	Q1 2010
	CD2233-40, CD2233-40Q, CD2235-40, CD2235-40Q	
Unify	CD3235-40, CD3235-40Q, CD3251-40, CD3251-40Q	Q1 2010
Assura	CD3267-40, CD3267-40Q, CD3261-40, CD3261-40Q	Q1 2012
	CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC	
	CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC	
	CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC	
	CD2259-40, CD2259-40Q, CD1259-40, CD1259-40Q	
	CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC	
	CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC	

Problem

St Jude Medical issued a Field Safety Notice addressing this issue on 10th October 2016.

Approximately 350,000 devices are estimated to remain implanted worldwide, manufactured between January 2010 and 23 May 2015, with just under 9,000 sold in the UK.
Devices manufactured after 23 May 2015 are not affected due to a design improvement.

Lithium clusters can occur in any high voltage device battery with lithium based chemistries. Factors such as the specific battery design and charge density can determine whether cluster formation presents a risk to battery performance. These clusters can induce a short circuit that causes premature battery depletion, depending on their location. The shorts are unpredictable, can drain the battery in days to a few weeks, and tend to occur during high voltage charging. Under this fault condition the ICD will not meet its nominal 3 months safety margin between ERI (elective replacement indicator) and EOL (end of life) and instead this has been reported to be as short as 24 hours.

To date only 0.2% of affected devices are reported to have experienced premature battery depletion due to this mechanism. However, the failure rate as implant duration increases beyond 6 years is as yet unknown. Worldwide there have been 10 reported incidents of syncope (fainting) and 2 deaths (1 of which was in the UK) from lack of defibrillation therapy that may have been linked to lithium cluster induced short circuits.

Although most devices will reach ERI due to normal battery depletion, it is not possible for centres to quickly differentiate these from the few that are affected by this failure mechanism. There is no way to predict which devices will suffer a lithium cluster induced short circuit and so it is important to detect ERI as soon as it occurs and replace the device as quickly as possible. At present, the risk of patient harm from revision surgery is generally greater than that of device failure, so prophylactic explant is **not** recommended. The relative risks, however, should be assessed on an individual patient basis taking account of their unique clinical circumstances. If the decision is made to replace an affected device St. Jude Medical will provide a replacement device at no cost.

Manufacturer contacts

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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 SABS (NI) 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

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

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/2016/019** or **2016/009/012/291/008**.

Technical aspects
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Clinical aspects
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Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS 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
Fax: 0131 314 0722

Email: nss.iric@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).