Medical Device Alert

MDA/2015/038   Issued: 09 December 2015 at 14:30

Cardiac Resynchronization Therapy Pacing (CRT-P) – Risk of loss of pacing therapy
Medtronic InSync III

Summary
Manufactured by Medtronic – battery voltage may reduce to a point where the device is no longer able to provide patient pacing therapy.

Action
1. Identify all affected patients.
2. Schedule an early follow up to discuss this issue with the patient, with priority given to pacing dependent patients.
3. Compare the risk presented by device failure against that associated with device replacement on an individual patient basis. Patient assessment should include review of the:
   a. degree of pacing-dependency;
   b. estimated remaining device longevity/time to ERI;
   c. applicability of the average mortality risk associated with device failure and device replacement, given by Medtronic (see background).
4. Be aware that the low risk of device failure does not justify prophylactic replacement for the majority of non-pacing dependent patients.
5. Repeat the above assessment at each follow-up appointment (intervals of 6 months or less)
6. Remind patients to contact their follow-up centre if they experience increased symptoms of bradycardia or heart failure (including breathlessness) as this may be an indication of device failure.

Action by
All cardiologists and cardiac physiologists who manage patients implanted with Cardiac Resynchronization Therapy Pacing devices

Deadlines for actions
Actions underway: 23 December 2015
Actions complete: 09 June 2016

Device details
InSync III Models  8042U:

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Unique Device Identifier</th>
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</thead>
<tbody>
<tr>
<td>IPG 8042U INSYNC III UNI INTL</td>
<td>00613994322524</td>
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<tr>
<td>IPG 8042U INSYNC III DC UNI EAME</td>
<td>00681490993364</td>
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<tr>
<td>IPG 8042U INSYNC III DC UNI INTL</td>
<td>00681490993425</td>
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</tbody>
</table>
Problem / background

Medtronic has identified that an unpredictable, but very small, subset of InSync III devices may develop unexpectedly high and variable battery impedances, which can reduce the battery voltage to a point where the current is insufficient to support pacing output. Reported harms to date include bradycardia, dyspnoea, complete heart block, weakness and dizziness. Medtronic has received one report of a patient death where it is possible, but unconfirmed, that this issue was a contributing factor.

There is no provocative testing that can predict which specific devices may fail, and there is no programming that can mitigate this issue. The failure results from the development of a resistive film on the cathode current collector. Development of the film is erratic and it is, therefore, not possible to identify a specific current drain above which the film will not develop and hence at which the devices are not at risk.

To date Medtronic has received 30 reports of devices affected by this issue, which represents 0.03% of those distributed worldwide, all of which have involved devices with implant duration over 53 months. Medtronic predicts the failure rate will be between 0.16% and 0.6% for the remaining active devices, with an associated mortality risk of 0.007-0.02%. This should be compared to Medtronic’s estimated average mortality risk presented by early device replacement of around 0.005%, although clearly this will vary significantly depending upon the patient circumstances.

Unfortunately the InSync III models are not supported by Medtronic’s Carelink network, and so it is not possible to review patients remotely.

In the UK nearly 6,000 potentially affected devices have been supplied between June 2001 and October 2010 when this product was discontinued, and therefore most devices can be expected to have exceeded 4 years implant duration. To date there have been two incidents associated with this problem reported within the UK.

Medtronic issued a FSN to affected hospitals on 10 November 2015 which includes patient management recommendations to mitigate the risk associated with this issue.

Manufacturer contacts

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Watford
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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
• Adult intensive care units
• Ambulance services directors
• Ambulance staff
• Anaesthesia, directors of
• Anaesthetic medical staff
• Anaesthetic nursing staff
• Anaesthetists
• Biomedical engineering staff
• Biomedical science departments
• 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
• Intensive care nursing staff (adult)
• Intensive care units
• Intensive care, directors of
• Medical directors
• MRI units, directors of
• Nursing executive directors
• Outpatient clinics
• Outpatient theatre managers
• Outpatient theatre nurses
• Renal medicine departments
• Renal medicine, directors of
• Risk managers
• Theatre managers
• Theatre nurses
• Theatres

Public Health England
Directors for onward distribution to:
• Risk manager

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
• General practitioners
• General practice managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
• Hospitals in the independent sector
• Independent treatment centres
• Private medical practitioners

Establishments registered with OFSTED
• Children’s services
• Educational establishments with beds for children
• Residential special schools

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/2015/038 or 2015/011/010/131/003.

Technical aspects
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Clinical aspects
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Email: camilla.fleetcroft@mhra.gsi.gov.uk

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  Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk
http://www.dhsspsni.gov.uk/index/hea/niaic.htm

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
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

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health
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