

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/95

Issued: 23rd December 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Medtronic Sigma [®] implantable pacemakers:	▶ ①
Problem: Failure of interconnecting wires within the pacemakers may cause: <ul style="list-style-type: none"> • loss of pacing output from atrial and/or ventricular ports • premature battery depletion • intermittent or total loss of telemetry • undersensing • high lead impedance values • loss of rate response device reset to manufacturer's default settings.	▶ ②
Action by: All cardiologists and cardiac physiologists who manage patients implanted, or to be implanted with any of these devices.	▶ ③
Action: See detailed actions on page 2 and 3.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts Details of manufacturer/National Pacing & ICD Database, and NIAIC contacts.	▶ ⑥
Feedback Requirements to NIAIC	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Medtronic Sigma[®] implantable pacemakers: Model Numbers

SD203	SDR203	SS203	SSR203
SD303	SDR303	SS303	SSR303
SS103	SS106	SDR306	SVDD303

see list of affected serial numbers distributed in the UK on our website at

<http://www.dhsspsni.gov.uk/niaic/mdea.asp>

2. PROBLEM:

Medtronic has advised MHRA that some Sigma[®] pacemakers from the listed model ranges may be subject to failures which could result in any of the behaviours listed on page 3. Medtronic issued letters to clinicians about this issue in November 2005 (see Appendices 1).

Medtronic's analyses of 19 returned Sigma[®] pacemakers has identified a failure mode where separation of interconnecting wires between certain electronic components, can seriously affect the performance of the device.

Analysis has identified that the wire separation is associated with the use of an incorrect cleaning solvent during circuit board manufacturing that contained an antioxidant. The solvent, which was only used for a limited manufacturing period, resulted in surface contamination of electrical connection areas prior to wire bond connection. Extensive testing and analysis by Medtronic has now confirmed that use of this cleaning solvent can lead to a reduction in strength of the wire bond connections and these connections may separate over time. No mean time to failure has been established for this failure mode. However, there have been no failures less than 17 months post implant.

There is no provocative testing that can be performed to identify when any of the affected devices may fail.

Failure rates are currently low at approximately 0.05%. To date, 19 Sigma[®] failures have been confirmed where wire bond connections have separated. Medtronic estimates that approximately 28,000 devices remain implanted worldwide. In the UK 1 failure by this mode has been confirmed to date out of an estimated 1,700 devices that remain implanted. The UK failure occurred at implant duration of 36 months with the patient presenting with shortness of breath. Subsequent clinical checking confirmed no pacing output or telemetry.

Medtronic has received no reports of serious injuries or deaths due to this problem.

Affected Sigma[®] pacemakers may be identified by accessing the Medtronic website

<http://SigmaSNList.medtronic.com>

3. ACTION BY:

All cardiologists and cardiac physiologists who manage patients implanted, or to be implanted with any of these devices

4. ACTION:

- Identify and return to Medtronic all un-implanted devices that are potentially affected
<http://www.mhra.gov.uk>
- Identify all patients that have affected pacemakers and where last follow-up was longer than six months, arrange for pacemaker follow-up as soon as possible, giving priority to pacemaker dependant patients.
- At follow-up confirm that the device is performing as expected. Abnormal device behaviours may

include:

- intermittent or total loss of pacing output in either or both of the atrial/ventricular ports
 - intermittent or total loss of telemetry
 - unanticipated premature battery depletion
 - unexplained increases in lead impedance(s) in unipolar or bipolar mode
 - undersensing
 - loss of rate response function (where applicable and programmed on)
 - 'power on reset' - return to manufacturer's default settings
- Advise patients to contact their follow-up clinic immediately if they experience a return of symptoms (e.g. syncope / light-headedness or shortness of breath).
 - Consider elective device replacement if any of the above device behaviours are detected, especially for pacemaker dependant patients giving consideration to each patient's medical history, degree of pacemaker dependency and the relative risks of an invasive procedure.
 - Consider scheduling subsequent pacemaker follow-up at intervals no longer than six months, for all potentially affected pacemakers, to monitor for signs of device degradation.
 - Report all incidents of device failure to the MHRA and Medtronic.
 - Report explants to the National Pacing and ICD Database (see Contacts).

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Clinical Directors
- Nurse Directors
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Accident & Emergency Departments
- Cardiac Pacemaker/ICD Physiologists
- Cardiologists with Pacemaker/ICD Responsibilities

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

David G Dunham BSc PhD
Regulatory Affairs Manager – UK & Ireland
Medtronic Ltd
Suite One Sherbourne House
Croxley Business Centre
Watford WD18 8WW

Tel: 01923 212 213

E-mail: david.dunham@medtronic.com

Enquiries to the National Pacing and ICD Database should be addressed to:

National Pacing and ICD Database
PO Box 9205
Bridge of Weir
Strathclyde
PA11 3DZ

Tel: 01505 612 829

Fax: 01505 612 829

E-mail: mwc@btconnect.com

Enquires to NIAIC should quote reference number MDEA(NI)2005/95 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

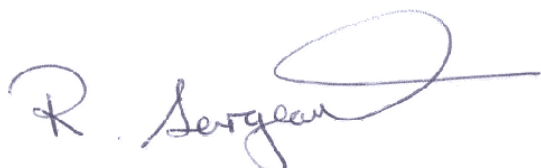
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2005/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Appendix 1 to MDEA(NI)2005/95

Medtronic's letter to clinicians **with** affected devices



Medtronic[®]

Medtronic Limited
Suite One
Sherbourne House
Croxley Business Centre
Watford, Herts WD18
8WW
Telephone: 01923 212213
Facsimile: 01923 241004

IMPORTANT PATIENT MANAGEMENT INFORMATION

November 2005

Dear Doctor (*With affected devices*)

In accordance with Medtronic's commitment to keeping you informed about the performance of our products, we write to advise you about an issue observed during ongoing returned product analysis. This concerns a specific subset of Sigma® series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit. This failure mechanism may present clinically as loss of rate response, premature battery depletion, high lead impedance, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Medtronic has advised the Medicines and Healthcare products Regulatory Agency (MHRA) and the action Medtronic is taking.

Affected Devices

There are approximately 28,000 active implants worldwide with approximately 1700 in the UK. A list of affected devices is attached or you can check affected serial numbers online at <http://SigmaSNList.medtronic.com>.

Root Cause

Separation of interconnect wires has been observed on hybrid terminal blocks. In October 2005, we completed testing and analysis identifying the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Low Probability of Occurrence

As part of the ongoing returned product analysis, Medtronic has observed 19 devices (approximately 0.05%) that have exhibited this failure mechanism. There is no provocative testing that can predict which devices may fail. Implant duration for the 19 failures ranged from 17-38 months. Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers.

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Recommendations

We realise that each of your patients is unique, and we support your clinical judgment in caring for them. To assist physicians in their patient care and after discussion with our physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow up in accordance with standard practice or at least every six months and inform patients to seek immediate attention if they experience return of symptoms (e.g. syncope or light headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient's medical history and consideration of the relative risks of an invasive procedure.

Physician Support

We regret the difficulties this may cause you and your patients. The information in this letter will be posted on Medtronic.com on December 5, 2005. We will provide you with regular updates on the ongoing actual performance in our Product Performance Report, available at www.medtronic.com/crm/performance.

Should you elect to replace a device for a specific patient, Medtronic will provide a replacement device in accordance with the terms of the applicable product warranty.

Your Medtronic representative will evaluate and replace any inventory in your center(s) affected by this action.

If you have any questions, or if we can be of assistance, please contact your local Medtronic Representative.

Yours sincerely

David G. Dunham BSc. PhD
Regulatory Affairs Manager – UK & Ireland

Attachment - Serial number listing of affected devices distributed in the UK

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Dear Doctor (Without affected devices),

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These affected pacemakers may fail due to separation of interconnect wires from the hybrid circuit. This failure mechanism may present clinically as loss of rate response, premature battery depletion, high lead impedance, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

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