

Medical Device Alert

Ref: MDA/2011/079 Issued: 13 July 2011 at 11:30

Device

Implantable Pulse Generators (IPGs) – Neurostimulators.

Eon Mini™ (Model 65-3788) and Brio™ (Model 65-6788).

Manufactured by St Jude Medical.



Problem	Action
<p>Faulty battery components have resulted in some IPGs losing the ability to communicate with the programmer or recharge. In the cases reported, the duration between recharges became progressively shorter until the IPG failed to charge or there was a sudden loss of power, which resulted in the need for device replacement. The time from manufacture of affected devices to explant has so far ranged from 8 months to 2 years.</p>	<ul style="list-style-type: none"> • Read the manufacturer's Field Safety Notice (FSN). • Identify affected patients using the list of serial numbers within the FSN. • Review affected patients and advise them to contact their clinician immediately in the event of a sudden loss of device power. • Patients fitted with devices that are noted to have a shorter duration between recharges should be considered for a replacement device on an individual basis.
<p>Action by</p> <p>Implanting surgeons and clinicians involved in the management and follow-up of patients with these devices.</p> <p>Neurologists. Neurological Surgeons. Chronic pain consultants.</p>	
CAS deadlines	Contact
<p>Action underway: 20 July 2011</p> <p>Action complete: 03 August 2011</p>	<p>Manufacturer St Jude Medical UK Ltd UK contact: Sean Hogarth Tel: 01789 207 611 Fax: 01789 207 601 Email: SHogarth@SJM.com</p>

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local Authorities 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:

- Chronic pain consultants
- Medical directors
- Neurological surgeons
- Neurologists
- Nursing executive directors

For information only

- General practitioners

Independent distribution

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

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Email: SHogarth@SJM.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/079** or **2011/005/024/081/002**

Technical aspects

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Clinical aspects

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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.irc@nhs.net
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

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
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