Medical Device Alert

Action

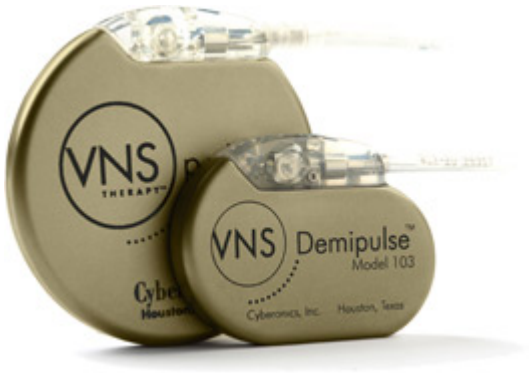
Ref: MDA/2010/050 Issued: 15 June 2010 at 15:00

Device

Implantable vagus nerve stimulators (VNS):

- Pulse and Pulse Duo Generators (Models 100, 101, 102 and 102R)
- Demipulse and Demipulse Duo Generators (Models 103 and 104)
- Model 250 programming software.

Manufactured by Cyberonics VNS Therapy.



Problem

- Premature battery depletion (models 103 and 104).
- Inaccurate battery life projection (models 103, 104 and 250).
- Loss of therapy (all models).
- Painful, erratic or atypical stimulation (all models).

Action by

Implanting surgeons and clinicians involved in the management and follow-up of patients with these devices.

Action

- Follow the advice in the manufacturer's Field Safety Notices (FSNs) issued in:
  July 2009
  November 2009
  April 2010
- Ensure that you acknowledge each FSN that applies to your organisation by returning the receipt to the manufacturer.

CAS deadlines

Action underway: 14 July 2010
Action complete: 09 September 2010

Contact

Manufacturer
Cyberonics
UK contact: John Forsey
Tel: 01246 261 397
Fax: 0870 166 0501
Email for clinical and technical queries:
europeclintechservices@cyberonics.com

Problem

The MHRA has issued this Medical Device Alert (MDA) to support Cyberonics' corrective actions, as they have informed us that to date there has been a low level of response to their Field Safety Notices (FSNs) listed below.

In July 2009 Cyberonics issued a FSN concerning Model 250 Programming software when used with Pulse and Pulse Duo Generators (Models 100, 101, 102 & 102R) and Demipulse and Demipulse Duo Generators (Models 103 and 104).

In November 2009 Cyberonics issued a FSN concerning the Demipulse and Demipulse Duo Generators (Models 103 and 104).

In April 2010 Cyberonics issued a FSN concerning Model 250 Programming software when used with Demipulse and Demipulse Duo Generators (Models 103 and 104).

Cyberonics has requested that clinicians contact them as soon as possible if they should have received any of the above FSNs but did not.

It is important to follow the actions advised in FSNs, and for your organisation to acknowledge receipt of FSNs. The receipt provides the manufacturer, and subsequently the MHRA, with the means to monitor the progress of Field Safety Corrective Actions. It also minimises the need for the MHRA to issue MDAs, which otherwise place an additional burden on the health service because of the broadcast nature of the MDA and the extra administrative work required.[1]

[1] Reporting Adverse Incidents and Disseminating Medical Device Alerts - DB 2010(01)

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

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

Trusts to:

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
- All departments
- All staff
- All wards
- Anaesthetists
- Clinical governance leads
- Day surgery units
- Equipment stores
- General surgeons
- General surgery
- General surgical units, directors of
- Health and safety managers
- In-house maintenance staff
- Medical directors
- Medical oncologists
- MRI units, directors of
- Nursing executive directors
- Neurological surgeons
- Neurology and neurosurgery departments
- Occupational therapists

- Oncology nurse specialists
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Palliative care teams
- Purchasing managers
- Radiation and medical oncology departments
- Radiation oncology, directors of
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Primary care trusts to:

CAS liaison officers for onward distribution to all relevant staff including:

- Directors of public health
- Palliative care team
- Practice managers
- Practice nurses

Contacts

Manufacturer/Supplier
John Forsey
Cyberonics Europe
Unit 4 Dunston Innovation Centre
Dunston Road
Chesterfield
S41 8NG

Tel: 01246 261 397
Fax: 0870 166 0501
Email: europeclintechservices@cyberonics.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/050**.

Technical aspects
Simon Holmes or Feza Haque
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3240 / 3066
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Email: simon.holmes@mhra.gsi.gov
feza.haque@mhra.gsi.gov.uk

Clinical aspects
Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123
Fax: 020 7084 3111
Email: susanne.ludgate@mhra.gsi.gov.uk

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 Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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