Medical Device Alert

Ref: MDA/2013/001 Issued: 10 January 2013 at 14:00

Device

External pacemaker:
MICRO-PACE REF 4580.

Manufactured by Pace Medical and distributed in the UK by APC Cardiovascular.

Problem

Further to MDA/2012/070 addressing the potential for loss of ventricular output or sensing failure, Pace Medical Inc has temporarily withdrawn the MICRO-PACE REF 4580 from sale.

Action by

All staff involved with the use of external pacemakers.

Action

Update to MDA/2012/070

- NEW UNITS: MICRO-PACE REF 4580 have been withdrawn from sale until further notice.
- UNITS ALREADY IN USE: if insufficient alternative devices are available, continued use should be based upon an individual risk assessment of the patient, taking account of factors such as:
  - degree of pacing dependency
  - arrhythmia history
  - the level of additional patient monitoring; in particular, for loss of ventricular sensing or capture.

  Units that have not been upgraded (see MDA/2012/070) should not be used with epicardial leads.
- Report all adverse incidents involving these pacemakers to the MHRA's Adverse Incident Centre and the manufacturer.

CAS deadlines

Action underway: 17 January 2013

Action complete: 24 January 2013

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Contact

Manufacturer's authorised representative

Steven Hanson or Catherine Rose
Devices Ltd

Tel: 01707 327 641
Fax: 01707 266 677
Email: pacemedicalpres@gmail.com

Problem

Subsequent to the publication of MDA/2012/070 on 9 October 2012 detailing three manufacturer Field Safety Corrective Actions (FSCAs), the MHRA has received a further incident report of loss of ventricular output due to a soldering failure in a fully upgraded MICRO-PACE REF 4580 pacemaker. After discussion with the MHRA, Pace Medical Inc has decided to remove the MICRO-PACE REF 4580 device from the market. They have confirmed that no further units will be sold until the MHRA has undertaken a review of manufacturing processes, and obtained sufficient evidence to support the safety of this external pacemaker. Specifically, the MHRA will be seeking reassurance that appropriate systems and controls are in place during both the manufacturing and post-production phases to ensure that consistent and safe products are produced.

MICRO-PACE REF 4580 pacemakers currently in use are not being recalled, as this could place patients at risk through lack of pacing provision, if alternative devices are not available. Instead, any risks associated with the continued use of these devices should be managed on an individual basis, with particular attention to the need for additional patient monitoring.

The MHRA will issue further advice on completion of this investigation.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards 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:

- A&E consultants
- Adult intensive care units
- All wards
- Cardiac laboratory technicians
- Cardiac pacing physiologists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Coronary care departments
- Coronary care nurses
- EBME departments
- Equipment stores
- Intensive care medical staff (adult and paediatrics)
- Intensive care nursing staff (adult and paediatrics)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Paediatric intensive care units
- Purchasing managers
- Resuscitation officers
- Risk managers
- Supplies managers
- Theatre managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector

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
Steven Hanson or Catherine Rose
Devices Ltd
28 Fiddlebridge Industrial Centre
Lemsford Road
Hatfield Hertfordshire AL10 0DE

Tel: 01707 327 641
Fax: 01707 266 677

Email: pacemedicalpres@gmail.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/001** or **2012/010/004/291/003**

Technical aspects
Guido Fumagalli or Simon Holmes
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7144 or 7240
Fax: 020 8754 3965

Email: guido.fumagalli@mhra.gsi.gov.uk
simon.holmes@mhra.gsi.gov.uk

Clinical aspects
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Medicines & Healthcare products Regulatory Agency
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151 Buckingham Palace Road
London SW1W 9SZ

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Fax: 020 8754 3965

Email: nicola.lennard@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:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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