Medical Device Alert

Ref: MDA/2013/036 Issued: 31 May 2013 at 13:30

Device

External pacemaker:
MICRO-PACE REF 4580.

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

Problem

Update to MDA/2013/001 and MDA/2012/070 on the return to market of the MICRO-PACE REF 4580.

Action

Remove from service any devices still awaiting any of the 3 modifications detailed in MDA/2012/070, until these have been completed.

Ensure continued, heightened vigilance in monitoring the safe operation of these pacemakers in use, and in reporting any new incidents to both Pace Medical and the MHRA.

Review routine pacemaker servicing schedules, taking account of the ten year service life for all Pace Medical devices.

Action by

All staff involved with the use of these external pacemakers.

CAS deadlines

Action underway: 07 June 2013

Action complete: 14 June 2013

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

In January 2013 the MHRA issued Medical Device Alert MDA/2013/001 advising that Pace Medical had decided to cease further sales of MICRO-PACE REF 4580 external pacemakers in response to safety concerns. The MDA also gave advice on risk management for units already in use.

We have since carried out an audit of both Pace Medical's US manufacturing site and the UK authorised representative's premises. Following this audit the manufacturer provided satisfactory responses in the areas of post-market surveillance where deficiencies had been found.

Although the MHRA has received a small number of adverse incident reports involving this external pacemaker model, since our last MDA in January 2013, the manufacturer has provided sufficient feedback during our investigations to reassure us that these were not related to any new root causes. Nevertheless, clinicians should continue to closely monitor the safe operation of these devices and to report any new incidents to both the MHRA and the manufacturer.

In consultation with the MHRA, Pace Medical has now decided to resume sales of MICRO-PACE REF 4580 external pacemakers in the UK and elsewhere. We will continue to scrutinise the safety of these devices and review the appropriateness of this decision in light of any new information arising from further reported incidents, or other sources.

In addition, we have asked Pace Medical to remove all affected devices from UK hospitals which still require any one of the 3 modifications described in MDA/2012/070. The company has already confirmed that they now have enough loan units available to allow this process to take place without service disruption.

Pace Medical has also recently confirmed that their products are currently sold with a statement that their expected service life is ten years from the date of purchase, and that they will not service or repair product returned after this time. Although this information was not provided when older devices were sold, they have confirmed that this condition for servicing or repair applies retrospectively to all Pace Medical devices.

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's authorised representative
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/2013/036** 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
Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 6648 Fax: 020 8754 3965

Email: jonathan.plumb@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