Medical Device Alert

Ref: MDA/2014/015 Issued: 14 May 2014 at 15:00

Device

All temporary pacemakers and pacing system analysers (PSAs) manufactured by Pace Medical Inc.

Problem

These devices are currently not on the EU market. Their CE-marking has been suspended because of quality system failings.

Action by

All staff involved with the use of these external pacemakers.

Action

Be aware that as of 9 April 2014 this manufacturer is not able to sell these devices. However:

- any remaining Pace Medical devices purchased by distributors before this date can still be sold to UK hospitals
- servicing of Pace Medical devices can continue as before.

Be aware that Pace Medical reusable temporary pacing cables, which have been validated by the manufacturer for compatibility with their temporary pacemakers, remain available for purchase.

Be aware that the compatibility of alternative disposable or reusable cables with these pacemakers has not yet been fully validated by the manufacturer.

Consult with the manufacturer or relevant distributors for further information on cable availability, where necessary.

Consider the implications this has for the future provision of new devices within your hospital.

CAS deadlines

Action underway: 21 May 2014

Action complete: 30 May 2014

Contact

Manufacturer's authorised representative
Steven Hanson or Catherine Rose
Devices Ltd

Tel: 01707 327 641
Fax: 01707 266 677

Email: pacemedicalinfo@gmail.com

Problem

In April 2014 Pace Medical's subcontractor Devices Ltd, was audited by its notified body, BSI, with MHRA present as the observer. The audit found significant quality system failings relating to processes for complaint handling, post-market surveillance and vigilance, which included failures to implement corrective actions agreed at previous audits. As a result of this, on 9 April, the notified body suspended the EC-certification covering all devices manufactured by Pace Medical, except the pacing cables. Servicing of devices already in the field is unaffected by the suspension of the EC certificate.

We are aware that UK hospitals use a range of temporary pacing cables and heart wires with temporary pacemakers. However, Pace Medical only holds validation data to confirm compatibility of their own cables with their pacemakers. Hospitals should continue to make a risk-based decision on the use of alternative, reusable or disposable cables or heart wires, based on availability and clinical need.

The manufacturer is working with its notified body to prepare a corrective action plan to address the identified issues. The notified body will need to complete follow-up audits of Pace Medical's actions before the EC-certification can be restored. If the situation changes, the MHRA will issue further information.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (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 technicians
- 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/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Paediatric intensive care units
- Purchasing managers
- Resuscitation officers and trainers
- 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/2013/015** or **2014/002/027/401/003**

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
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7248
Fax: 020 8754 3965

Email: carol.lowry@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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 5801

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