Medical Device Alert

Ref: MDA/2012/070 Issued: 09 October 2012 at 15:30

Device

External pacemaker used with temporary endocardial pacing leads or epicardial pacing wires.

MICRO-PACE 4580.

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

Problem

Risk of under-sensing or output failure when used on patients with epicardial pacing wires.

Action by

All staff involved with the use of these devices.

Action

- Do not use these pacemakers with epicardial pacing wires until they have undergone all three upgrades notified in the manufacturer's Field Safety Notices of April, June and September 2012;
- Arrange, as soon as possible, for the pacemakers to be returned to the manufacturer to be upgraded. Contact the manufacturer to obtain loan units or to agree a return timetable that ensures continued availability of devices;
- Report all adverse incidents involving these pacemakers to the MHRA's Adverse Incident Centre and the manufacturer.

CAS deadlines

Action underway: 12 October 2012

Action complete: 16 October 2012

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

APC Medical

Tel: 01707 327 641
Fax: 01707 333 117

Email: pacemedicalpres@gmail.com

Problem

In April 2012, Pace Medical issued a Field Safety Notice (FSN) due to a risk of inadequate output from these pacemakers, which they now understand to arise from damage caused by application of direct heart defibrillation when the pacemaker is used with epicardial pacing wires. The manufacturer then began action aimed at solving the output problem by replacing an electronic component in devices in the field.

At the end of June 2012, the manufacturer issued a second FSN due to reports of under-sensing, once again when the pacemaker was used with epicardial pacing wires following surgery. A further schedule of field up-grades began for all 4,580 pacemakers in use.

In September 2012, the manufacturer issued a third FSN to implement a further hardware upgrade to these temporary pacemakers, introducing a component to provide greater protection in the event of defibrillation. This action arose from their continued investigations, which had improved their understanding of the root cause of the failures.

To date there have been no reported problems when these pacemakers have been used with temporary endocardial pacing leads.

Copies of all three FSNs are available on the MHRA website.

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/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
- Risk managers
- Supplies managers
- Theatre managers

Health Protection Agency
Directors for onward distribution to:
- Divisional directors

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

APC Medical Ltd

68 Tewin Road, Welwyn Garden City, AL7 1BD

Tel: 01707 327641
Fax: 01707 333117

Email: pacemedicalpres@gmail.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/070** or **[2012/009/019/081/021]**

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
Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7126
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