Medical Device Alert

Ref: MDA/2013/032 Issued: 10 May 2013 at 15:00

Device

Defibrillators/monitors used for external pacing with non-invasive transcutaneous pacemaker modules.

All manufacturers and all models.

Problem

Risk of inadequate external pacing, leading to potential periods of asystole, syncope and possible death.

Factory default start-up pacing current and rate settings on transcutaneous pacemaker modules vary and may be too low to ensure pacing capture.

Users should be aware of this and ensure settings are configured to meet their local protocols.

Transcutaneous pacing modules have factory defaults that initiate pacing with a low current and rate.

The MHRA has received a report that highlights the importance of raising awareness that the factory defaults can be configured to user presets.

Further guidance on trancutaneous pacing is being considered by Heart Rhythm UK (HRUK).

Action

Ensure that you:

- are aware of the pacing current and rate settings;
- follow recommendations in the manufacturer's instructions for use and local protocols within your trust.

Ensure those responsible for the devices:

- are aware that factory default pacing settings (for current and rate) can be configured to user presets;
- review and evaluate appropriateness of the factory defaults for pacing mode (demand or fixed).

Action by:
All medical, nursing and technical staff involved in the use and maintenance of these devices.

CAS deadlines

Action underway: 24 May 2013 Action complete: 07 June 2013

Note: These deadlines are for staff to be aware of the problem and to review settings.

Device

Transcutaneous pacing delivered by a defibrillator is also known as “external pacing”. It is the delivery of current via the external defibrillation pads. Successful delivery of this technique is reliant on sufficient current to stimulate the myocardium to contract (known as “capture”).

Transcutaneous pacing is sometimes used in the emergency setting to treat asystole or bradycardia. This is usually a temporary bridging measure prior to further treatment, such as temporary or permanent pacemaker implantation.

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)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS England area teams (chief executives)
- NHS England regional teams
- 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
- A&E departments
- All clinical departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Cardiac physiologists
- Cardiologists
- Cardiology departments
- Cardiothoracic departments
- Clinical governance leads
- Community defibrillation officers
- EBME departments
- Medical directors
- Nursing executive directors
- Outpatient theatre managers
- Resuscitation officers and trainers
- Risk managers
- Theatre managers

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/032** or **MHRA 2012/001/019/401/014**

Technical aspects
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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