Medical Device Alert

Ref: MDA/2014/040 Issued: 09 October 2014 at 14:00

Device

LIFEPAK® 1000 defibrillator.

Manufactured by Physio-Control.

All serial numbers.

Problem

Risk of failure to deliver a shock.
This is due to unexpected shut down of the defibrillator caused by a battery with very low charge.

Confusing instructions for use mean that batteries aren't always replaced when they have a low or very low charge.

See the Field Safety Notice for further details.

Action

- Identify all LIFEPAK 1000 defibrillators in your possession.
- Ensure users read the important information in the Field Safety Notice and follow the instructions on how to check if a new battery is required.
- Make sure that a spare, fully charged battery is always available.

Action by

All staff responsible for the use, maintenance and purchase of these devices.

CAS deadlines

Action underway: 23 October 2014

Action complete: 06 November 2014

Note: These deadlines are for operators to be aware of instructions and to check batteries.

Contact

Manufacturer

Olivier Anki
Physio-Control Operations
Tel: +33 695 475 522
Email: olivier.anki@physio-control.com

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 for information
- NHS trusts in England (chief executives)
- Special health authorities for information

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
- A&E directors
- A&E nurses
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Biomedical engineering staff
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Clinical governance leads
- EBME departments
- Health and safety managers
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Medical directors
- Medical physics departments
- Nursing executive directors
- Resuscitation officers and trainers
- Risk managers

Independent distribution

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

This alert should be read by:
- Hospitals in the independent sector
- Independent treatment centres

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

Olivier Anki
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Galjoenweg 68, 6222 NV
Maastricht
The Netherlands

Tel: +33 695 475 522

Email: olivier.anki@physio-control.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/040** or **2014/007/010/081/006**

Technical aspects
Paul Sandhu or Yasser Zayni
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7266 / 7238
Fax: 020 8754 3965

Email: paul.sandhu@mhra.gsi.gov.uk
yasser.zayni@@mhra.gsi.gov.uk

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

Tel: 020 3080 7128
Fax: 020 8754 3965
Email: mark.grumbridge@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

Email: improvingpatientsafety@wales.gsi.gov.uk

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