Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/013 Issued: 18 May 2017 at 14:30

All LIFEPAK 1000 automatic external defibrillators (AEDs) - risk of device shutting down unexpectedly during patient treatment and possible failure to deliver therapy

Summary

Manufactured by Physio-Control – risk of unexpected device shutdown due to an intermittent connection between the battery and device contacts.

Action

1. Identify all LIFEPAK 1000 defibrillators in your possession.
2. Ensure that all those responsible for the AED follow the instructions in the manufacturer's Field Safety Notice (FSN).
3. If you have already acted on this FSN, no further action is required.

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

Deadlines for actions
Actions underway: 05 June 2017
Actions complete: 19 June 2017

NOTE: These deadlines are for systems to be in place to take actions and not for completion of the manufacturer's corrective action. These deadlines are only for users registered with the Central Alerting System.

Device details

The LIFEPAK 1000 defibrillator can be found in hospitals and in public places.
The manufacturer's logo on the front cover may vary, displaying 'Medtronic' or 'Physio-Control'.

Manufacturer contacts

Physio-Control Operations, Netherlands

Tel: 0808 258 0094

Email: RS.EMEArecall@physio-control.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All departments
- All staff
- All wards
- Ambulance services directors
- Biomedical engineering staff
- Biomedical science departments
- Cardiology, directors of
- Chief pharmacists
- Clinical governance leads
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Health and safety managers
- In-house maintenance staff
- Maintenance staff
- Medical directors
- Medical libraries
- Medical physics departments
- NHS walk-in centres
- Paramedics
- Patient transport managers
- Purchasing managers

- Resuscitation officers and trainers
- Risk managers
- School nurses
- Supplies managers
- Walk-in centres

Public Health England
Directors for onward distribution to:
- Heads of department
- Heads of health, safety and quality
- Risk manager
- Safety officers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
- General dental practitioners
- General practitioners
- General practice managers
- General practice nurses

Social services
Liaison officers for onward distribution to all relevant staff including:
- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Disability equipment stores
- Education departments for equipment held in schools
- Equipment stores
- Equipment supplies managers
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Establishments registered with OFSTED
- Children's services
- Educational establishments with beds for children
- Residential special schools

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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/013** or **2017/001/019/291/001**.

Technical aspects
Paul Sandhu, MHRA
Tel: 020 3080 7266
Email: paul.sandhu@mhra.gov.uk

Clinical aspect
Mark Grumbridge, MHRA
Tel: 020 3080 7128
Email: mark.grumbridge@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Tel: 0131 275 7575
Fax: 0131 314 0722
Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.
Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.
Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division
Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).