Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2016/018 Issued: 13 October at 11:00

Automatic external defibrillator (AED) LIFEPAK CR Plus and LIFEPAK EXPRESS – risk of failure to deliver a shock.

Summary

Manufactured by Physio-Control – risk of delay to defibrillation due to an intermittent component failure. Specific serial numbers are affected.

Action

- Ensure that all those responsible for the AED follow the instructions in the manufacturer's Field Safety Notice (FSN).
- To check if your AED is affected call Physio-Control customer support or visit their website and go to 'Search Affected Devices' and enter the serial numbers.
- If the AED is faulty, remove the unit from service and contact Physio-Control to arrange for it to be corrected.
- If you have already acted on this FSN, no further action is required.

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

Deadlines for actions
Actions underway: 27 October 2016
Actions complete: 17 November 2016

NOTE: These deadlines are for systems to be in place to take actions and not for completion of the repair.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

The AED can be found in hospitals and in public places (eg railway stations, village halls and supermarkets).

Problem / background

LIFEPAK CR Plus AEDs or LIFEPAK EXPRESS AEDs may fail to initiate voice prompts when the ON/OFF button is pressed and the lid is opened. The problem is due to an internal component (reed switch) that can intermittently become fixed in the closed position. A defibrillator in this condition will fail to deliver a shock.

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
- Clinical governance leads
- Community defibrillation officers
- Community hospitals
- 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
- Purchasing managers
- Resuscitation officers and trainers

- Risk managers
- School nurses
- Supplies managers
- Walk-in centres

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)
- Education departments for equipment held in schools
- Equipment stores
- Equipment supplies managers
- In-house residential care homes

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only
- Adult placement
- 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 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/2016/018** or **2016/008/003/299/011.**

Technical aspects
Hiten Patel and Paul Sandhu, MHRA

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Email: hiten.patel@mhra.gsi.gov.uk and paul.sandhu@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge, MHRA
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Email: mark.grumbridge@mhra.gsi.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).