Medical Device Alert

Ref: MDA/2012/077 Issued: 08 November 2012 at 14:00

Device

Batteries for HeartStart XL defibrillator/monitor.

Battery part number M3516A.

Batch labelled ‘Made in Taiwan’ with ‘Date of Manufacture’ code ‘R-2011-12’.

Manufactured by Philips and distributed by Philips and Cardiac Services UK & Ireland.

Problem

Risk of immediate and unexpected loss of critical monitoring, defibrillation or non-invasive pacing.

If a HeartStart XL defibrillator/monitor is not connected to the mains and is used with a battery from the affected batch, it may shut down unexpectedly without providing the user with a low battery warning or audible alarm.

The manufacturer published a Field Safety Notice in September 2012 to notify users and prompt them to take action. The manufacturer has not received sufficient confirmation that this FSN had been received and acted upon.

Action

- Identify HeartStart XL defibrillator/monitors with affected batteries and affected spare batteries.
- If you have affected batteries, follow the guidance given in the Field Safety Notice. In particular;
  - do not use device on battery power alone, and
  - ensure you have access to an appropriate alternative device.
- Contact the manufacturer to arrange for a replacement battery.

Action by

All those responsible for the use or maintenance of the devices.

CAS deadlines

Action underway: 15 November 2012

Action complete: 06 December 2012

Note: These deadlines are for devices to be identified and arrangements made to replace the battery.

Contact

Manufacturer
Customer Care Service Centre
Philips Healthcare
Tel: 0870 532 9741

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)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)
- Local authorities in Scotland (Equipment Co-ordinators)

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 departments
- All departments
- All wards
- Ambulance staff
- Clinical governance leads
- EBME departments
- Medical directors
- Nursing executive directors
- Outpatient theatre managers
- Resuscitation officers and trainers
- Risk managers
- Theatre managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community defibrillation officers
- Minor injury units
- NHS walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- Education departments for equipment held in schools
- Equipment supplies 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)
- Care homes providing personal care (adults)
- Clinics
- Further education colleges registered as care homes
- 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.

Contacts

Manufacturer
Philips Healthcare
Philips Centre
Guildford
GU2 8XH

Tel: 0870 532 9741

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/077** or **2012/009/026/291/006**

Technical aspects
Ian Sealey and Paul Sandhu
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6691/7266
Fax: 020 8754 3965

Email: ian.sealey@mhra.gsi.gov.uk
paul.sandhu@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

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