Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/003 Issued: 28 January 2020 at 12:30 Valid until January 2021

Professional use defibrillator/monitor: all HeartStart XL+ (Model number 861290) - risk of failure to deliver therapy

Summary

Manufactured by Philips – due to hardware or software issues (described in two separate FSNs) the device may fail to start, unexpectedly restart or deliver defibrillation therapy at the wrong energy level.

Action

- Identify affected devices in your organisation.
- Ensure that:
  - staff are aware of the recommended actions in the manufacturer's two (2) Field Safety Notices issued 30 October 2019 and 31 October 2019
  - if possible, you have ready access to a backup defibrillator until the corrective actions have been undertaken
  - you have systems in place to arrange for the upgrades to be implemented.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

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

Deadlines for actions
Actions underway: 11 February 2020
Actions complete: 25 February 2020

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

The potential problems include:

- failure of the therapy selector switch
- defect in the memory management software
- malfunction of the System On Module (SOM) installed on the processor printed circuit assembly (PCA)

Manufacturer contacts

For technical queries call UK Philips Customer Care Service Centre on 0870 532 9741 quoting FCO86100203 or FCO86100208

To confirm receipt of the FSN, email safetynoticeuki@Philips.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 NICAS liaison officers for onward distribution to all relevant staff including:

- All departments
- All staff
- All wards

Independent distribution

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

- Clinics
- Further education colleges registered as care homes
- Hospices
- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2020/003** or **2019/010/029/291/007**

Technical aspects

Paul Sandhu or Jillan Hussein, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).