Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/018 Issued: 30 June 2020 at 10:00

Philips HeartStart XL Defibrillator/Monitor – therapy selector switch may fail

Summary

Manufactured by Philips – the rotary therapy selector switch may fail resulting in unexpected device behaviours which could lead to a delay or failure in delivering therapy.

Action

Note: This is a targeted MDA, sent via the Central Alerting System (CAS), to organisations in England supplied with these devices.

Different distribution arrangements may apply in the Devolved Administrations.

- Follow the instructions in the manufacturer's Field Safety Notice (FSN).
- Continue to perform shift checks and operational checks as recommended in the instructions for use.
- If a device exhibits any of the behaviours described below and in the FSN, or fails shift or operational checks, immediately remove it from service.
- Ensure alternative devices are available as defined in the local risk assessment procedures if an affected device is removed from service.
- Retire all HeartStart XL Defibrillator/Monitors from service as soon as practicable, as they have been discontinued and are no longer supported by the manufacturer.
- Insert a copy of the FSN into each copy of the HeartStart XL instructions for use.
- Contact Philips to confirm receipt of their Field Safety Notice if your device is affected.

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

Deadlines for actions
Actions underway: 14 July 2020
Actions complete: 28 July 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 rotary therapy selector switch (energy select knob) on this device may fail, resulting in unexpected device behaviour including:

- not switching on
- not performing the selected function
- delivering a shock with an energy level different from that selected.

Philips discontinued this device in December 2013. As accessories and servicing are no longer provided by the manufacturer, devices should be retired as soon as practicable.

Manufacturer contacts

Philips Customer Care Service Centre

Tel: 0870 532 9741

Email: safetynoticeuki@philips.com

Quote Philips reference number: FCO86100213

Distribution

Note: This is a targeted MDA, sent via the Central Alerting System (CAS), to organisations in England supplied with these devices.

Different distribution arrangements may apply in the Devolved Administrations.

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:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments

- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Colposcopy departments
- Community defibrillation officers
- Community dental practices
- Community hospitals
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- Dental nurses
- Dentists
- EBME departments
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- Fracture clinics
- Gastroenterology departments
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haemodialysis units
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maintenance staff
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Midwifery departments
- Midwifery staff
- MRI units, directors of
- Neonatology departments
- NHS walk-in centres
- Nursing executive directors
- Obstetrics and gynaecology departments
- Occupational health departments
- Operating department practitioners
- Ophthalmology departments
- Oral surgeons
- Outpatient clinics
- Outpatient theatre managers
- Paediatric intensive care units
- Paediatric medicine, directors of

- Paediatric surgery, directors of
- Paediatric wards
- Paediatrics departments
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Radiation & medical oncology departments
- Radiology departments
- Renal medicine departments
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Urology departments
- Walk-in centres

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number MDA/2020/018 or 2020/004/016/291/001.

Technical aspects

Paul Sandhu, 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).