Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/016 Issued: 17 June 2020 at 14:00

Philips HeartStart MRx Monitor/Defibrillators may fail to deliver therapy without alerting the user to a fault in the event of internal damage.

Summary

The Philips HeartStart MRx Monitor/Defibrillator MRx may fail to identify a fault and alert the user in the event of internal damage suffered during a drop or due to severe mechanical shock.

Action

- Identify monitors/defibrillators affected by the manufacturer's Field Safety Notice.
- Perform a manual operational check immediately if the monitor/defibrillator is dropped or subject to severe mechanical shock.
- Ensure alternative devices are available as defined in the local risk assessment procedures if an affected device is removed from service.
- Insert a copy of the Field Safety Notice into each copy of the HeartStart MRx instructions for use.
- Contact Philips to confirm receipt of their Field Safety Notice if your device is listed as being affected.

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

Deadlines for actions
Actions underway: 01 July 2020
Actions complete: 15 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

Manufacturer contacts

Philips Customer Care Service Centre
Tel: 0870 532 9741
Email: safetynoticeuki@philips.com
Quote Philips reference number: FCO86100198

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:

- 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
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haemodialysis 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
- IV nurse specialists
- Maintenance staff
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Midwifery departments
- Midwifery staff
- MRI units, directors of
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Occupational health departments
- Occupational therapists
- Operating department practitioners
- Ophthalmology departments
- Ophthalmology, directors of
- Oral surgeons
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of

- Paediatric wards
- Paediatricians
- Paediatrics departments
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Physiotherapists
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Rehabilitation engineers
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number MDA/2020/016 or 2020/003/005/291/012.

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).