



# 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.

## Manufacturer contacts

Philips Customer Care Service Centre  
Tel: 0870 532 9741  
Email: [safetynoticeuki@philips.com](mailto: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](mailto:DSS-TM@mhra.gov.uk)

### Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto: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](mailto: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.irc@nhs.net](mailto:nss.irc@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](mailto: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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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