



# Medical Device Alert

MDA/2017/014

Issued: 24 May 2017 at 14:30

All HeartStart MRx defibrillators – possible failure to deliver a shock, cardioversion, pacing or monitoring

## Summary

Manufactured by Philips Healthcare – two battery-related problems: 1) may fail to power on or reboots repetitively, 2) after unplugging from AC mains, may fail to deliver a shock or undertake pacing.

## Action

- Identify affected devices.
- Ensure alternative devices are available as defined in local risk assessment procedures.
- Follow the instructions in the [Field Safety Notice \(FSN\)](#) for both problems.
- Contact Phillips Healthcare to confirm receipt of their FSN.

### Action by

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

### Deadlines for actions

Actions underway: 09 June 2017

Actions complete: 23 June 2017

## Problem / background

The two problems affecting the HeartStart MRx, may result in a failure to treat cardiac arrest.

When the manufacturer has a solution to the problems they will issue another FSN.

## Manufacturer contacts

Philips Customer Care Service Centre

Tel: 0870 532 9741

Email: [mike.turvey@philips.com](mailto:mike.turvey@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 SABS (NI) 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
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Biomedical engineering staff
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Clinical perfusionists
- Colposcopy departments
- Community defibrillation officers
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units

- Dental departments
- Dermatologists
- Diabetes clinics/outpatients
- EBME departments
- Endocrinology units
- Endocrinology, directors of
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment libraries and stores
- Equipment 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
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- 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
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Midwifery departments
- Midwifery staff
- Minor injury units
- 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
- Occupational health departments

- Oncology nurse specialists
- Ophthalmic nurses
- Ophthalmologists
- 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
- Palliative care teams
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Pharmaceutical advisors
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Renal medicine departments
- Renal medicine, directors of
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Virologists
- Walk-in centres

**Public Health England**

Directors for onward distribution to:

- Heads of department
- Heads of health, safety and quality
- Risk manager

- Safety officers

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

- Clinics
- 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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Enquiries

**England**

Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/014** or **2017/003/015/291/022**.

**Technical aspects**

Hiten Patel or Paul Sandhu, MHRA

Tel: 020 3080 6115 or 020 3080 7266

Email: [hiten.patel@mhra.gsi.gov.uk](mailto:hiten.patel@mhra.gsi.gov.uk) or [paul.sandhu@mhra.gsi.gov.uk](mailto:paul.sandhu@mhra.gsi.gov.uk)

**Clinical aspects**

MHRA Devices Clinical Team

Tel: 020 3080 7124

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

**Reporting adverse incidents in England**

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

**Northern Ireland**

Alerts in Northern Ireland are distributed via the [NI SABS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
CMO Group,  
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto:niaic@health-ni.gov.uk)  
<https://www.health-ni.gov.uk/niaic>

**Reporting adverse incidents in Northern Ireland**

Please report directly to NIAIC using the [forms on our website](#).

**Scotland**

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

**Reporting adverse incidents in Scotland**

NHS Boards and Local Authorities in Scotland – [report to Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – [report to Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

**Wales**

Enquiries in Wales should be addressed to:

Healthcare Quality Division

Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

**Reporting adverse incidents in Wales**

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> 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  
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