



Medical Device Alert

MDA/2018/036

Issued: 29 November 2018 at 14:30

Valid until: November 2019

Batteries for the HeartStart MRx monitor/defibrillator may fail to charge or to provide power.

Summary

Philips M3538A lithium-ion batteries manufactured from 28 December 2017 to 20 March 2018 inclusive for the HeartStart MRx monitor/defibrillator may have an internal component failure.

Action

- Identify affected batteries highlighted in the manufacturer's [Field Safety Notice](#) and remove them from service.
- Ensure alternative devices are available as defined in local risk assessment procedures until you can source a new battery.
- Follow the manufacturer's instructions for use on battery management to keep your existing batteries in the best possible condition.
- Ensure there are systems in place to replace affected batteries as a priority when supplies are resumed.

Action by

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

Deadlines for actions

Actions underway: 13 December 2018

Actions complete: 28 December 2018

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.

Problem / background

This MDA is related to our previous alert, [MDA/2018/002](#), advising users of a significant delay in the supply of batteries for the HeartStart MRx monitor/defibrillator.

The supply of batteries for these devices has been halted again due to further manufacturing problems. There is likely to be an ongoing significant delay in the fulfilment of outstanding orders.

Manufacturer contacts

Clare Fripp
 Head of Q&R
 Philips UK&I
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 Email: clare.fripp@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:

- 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
- Audiology departments
- Biomedical engineering staff
- Cardiac laboratory technicians
- Cardiac pacing technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chiropodists
- Clinical governance leads
- Clinical perfusionists
- Colposcopy departments
- Community children's nurses
- Community defibrillation officers

- Community dental practices
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- Dental nurses
- Dentists
- Diabetes clinics/outpatients
- EBME departments
- Endocrinology units
- Endocrinology, directors of
- 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
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Health visitors
- 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
- Medical physics departments
- 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
- Palliative care teams
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Physiotherapists
- Purchasing managers
- Radiation & medical oncology departments
- 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
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments
- Walk-in centres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only) Hospitals in the independent sector

- Independent treatment centres
- Private medical practitioners
- Hospices

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/2018/036** or 2018/010/031/487/020

Technical aspects

Paul Sandhu, MHRA

Tel: 020 3080 7266

Email: paul.sandhu@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: 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 [NICAS 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

<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

Email: 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

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 and Social Care.

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