Medical Device Alert

Ref: MDA/2014/024 Issued: 26 June 2014 at 15:00

Device

HeartStart MRx defibrillator/monitor.

Model numbers M3535A and M3536A with Q-CPR™ meter option B08.

Manufactured by Philips.

Specific serial numbers affected.

Problem

Risk of delay in delivering CPR.

When the HeartStart MRx is used with the Q-CPR meter in defibrillation mode, the meter may incorrectly display the 'Do Not Touch the Patient' icon.
Consequently, the user might not resume chest compressions in a timely manner, which could affect patient outcome.

This problem can occur in AED or manual modes.

Philips issued a Field Safety Notice dated April 2014 (reference FSN86100128A).

Action by

Staff responsible for the use, maintenance and purchase of these devices.

Action

- Identify any affected devices in your possession, using the Field Safety Notice.
- You can continue to use your HeartStart MRx without the Q-CPR meter attached.
- If you use the HeartStart MRx with the Q-CPR meter attached and the Q-CPR meter displays the 'Do Not Touch the Patient' icon at an unexpected time, follow the MRx instructions for use and remove the meter from the patient and continue CPR according to local protocol.
- Philips will contact you to arrange to install the software upgrade.

CAS deadlines

Action underway: 10 July 2014

Action complete: 24 July 2014

Contact

Manufacturer

UK Philips Customer Care Service Centre

Tel: 0870 532 9741

Device

Affected MRx units have to meet **all** of the three criteria below:

1. serial numbers from US00100153 to US00571587 inclusive
2. the Q-CPR Meter Option B08 installed
3. Software revision F.xx, R.xx, T.00.00 or T.00.01 installed.

Problem

When the HeartStart MRx is in AED mode, the Q-CPR meter is designed to display the 'Do Not Touch the Patient' icon during the shock advisory analysis period. If the user continues to deliver chest compressions when the shock advisory analysis begins, the 'Do Not Touch the Patient' icon may incorrectly remain on the screen after analysis or shock delivery is complete.

When the HeartStart MRx is in Manual Mode, the Q-CPR meter is designed to display the 'Do Not Touch the Patient' icon when the device is charging to the selected energy. If the clinician continues to provide chest compressions while the device is charging, the Q-CPR meter 'Do Not Touch the Patient' icon may incorrectly remain on the screen after shock delivery is complete.

Note:

- The MRx shock advisory decision and shock delivery continue to be executed correctly in all modes.
- In AED Mode the MRx continues to re-analyze for the shock advisory decision every two minutes.
- With the exception of CPR meter feedback, all other MRx voice prompts including 'Resume CPR' and 'Pause, Analyzing' operate as intended.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities for information

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

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
- Ambulance services directors
- Ambulance staff
- Biomedical engineering staff
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Clinical governance leads
- EBME departments
- Health and safety managers
- Intensive care units
- Intensive care, directors of
- Maintenance staff

- Medical directors
- Medical physics departments
- Nursing executive directors
- Resuscitation officers and trainers
- Risk managers

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

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 and requesting this facility.

Contacts

Manufacturer
UK Philips Customer Care Service Centre
Philips Centre
Guildford Business Park
Guildford GU2 8XH

Tel: 0870 532 9741

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/024** or **2014/003/010/081/007**

Technical aspects
Paul Sandhu or Eni Taiwo
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7266 / 7122
Fax: 020 8754 3965

Email: paul.sandhu@mhra.gsi.gov.uk
enitan.taiwo@mhra.gsi.gov.uk

Clinical aspects
Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6097
Fax: 020 8754 3965

Email: camilla.fleetcroft@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre
Health Estates Investment Group, Room 17
Annex 6
Castle Buildings
Stormont Estate,
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Email: improvingpatientsafety@wales.gsi.gov.uk