Medical Device Alert

Ref: MDA/2013/052 Issued: 11 July 2013 at 15:00

Device

HeartStart MRx Monitor/Defibrillator.

Manufactured by Philips Healthcare.

Model numbers: M3535A, M3536A, M3536J, M3536M, M3536MC, M3536M2, M3536M4, M3536M5, M3536M6.

Affected serial numbers from US00100100 to US00565942 inclusive.

Problem

The Philips HeartStart MRx Monitor/Defibrillator may fail to deliver defibrillation therapy in either “Manual Defib”, “AED” or “Sync Cardioversion” mode.

If this occurs, the MRx will simultaneously display the following:

- Flat line ECG.
- “Device error. Service required” message.
- “Shock Equip Malfunction” INOP.
- Red “X” in the RFU indicator.

If the problem occurs it can impact either cardioversion or defibrillation therapy within the specified modes. Pacing is not affected.

Action by

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

CAS deadlines

Action underway: 18 July 2013

Action complete: 01 August 2013

Note: These deadlines are for identification of device, staff to be aware and availability of a backup.

Action

- Identify affected devices.

Ensure that:

- staff are aware of the recommended actions in the FSN;
- you have ready access to an alternative defibrillator until the software upgrade has been undertaken;
- Philips contact you to arrange installation of the software upgrade.

Contact

Manufacturer
Philips Customer Care Service Centre
Tel: 0870 532 9741
Email: ph.pmuk.support@philips.com

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- 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)

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 departments
- All clinical departments
- All clinical staff
- All wards
- Ambulance services directors
- Ambulance staff
- Biomedical engineering staff
- Cardiology departments
- Cardiothoracic departments
- Clinical governance leads
- EBME departments
- Health and safety managers
- Maintenance staff
- Medical directors
- Nursing directors
- Resuscitation officers
- 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

Philips Customer Care Service Centre

Tel: 0870 532 9741

Email: ph.pmuk.support@philips.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/052** or **2013/005/007/081/025**

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

Tel: 020 3080 6648
Fax: 020 8754 3965

Email: jonathan.plumb@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

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

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk