Medical Device Alert

Ref: MDA/2012/042 Issued: 11 July 2012 at 14:00

Device

FRED easy Defibrillators manufactured by Schiller.

All devices are affected.

Devices are distributed by Amazon Medical Ltd

Problem

A false defibrillator error message, "transistor error", displays on screen and requires the device to be re-started.

This problem may prevent shock delivery, which may result in failure to defibrillate and a reduced chance of survival for the patient.

Action by

All clinical, medical and ambulance staff who use and those responsible for maintenance of these devices.

Action

- Identify affected defibrillators; see manufacturer's Field Safety Notice. MDA/2012/042 and MDA/2012/043 refer to this Field Safety Notice.
- If affected, contact Amazon Medical Ltd immediately for software upgrade deployment details.
- Provide Amazon Medical Ltd with up to date contact details via return of the fax back confirmation form in the FSN.
- Until software update is deployed, be aware of this problem which, if it occurs, can be rectified by a restart.

CAS deadlines

Action underway: 01 August 2012

Action complete: 22 August 2012

Note: These deadlines are for systems to be in place for the installation of the updated software or further actions.

Contact

Supplier
Amazon Medical Limited
Tel: 0161 776 4336
Fax: 0161 776 4339
Email: sally@amazonmedical.co.uk

Device

Affected defibrillators:

Product All models	Article number
FRED easy Basic	REF BR-FREDEASY
FRED easy ECG on-screen	REF BR-FREDEE
FRED easy Manual	REF BR-FREDEEM

Problem

Restarting of the defibrillator after display of a false error message may result in a delay to defibrillation. A software solution is either already available or under development, depending on the age of device.

The older 1G units with serial numbers of 8 and 9 digits (manufactured from 2003 to 2006 inclusive) currently cannot be upgraded, as the software is under development. Amazon Medical will contact affected customers to provide further information, at a later date.

For the remaining devices, the software will be deployed via a SD card for installation by users or the manufacturer.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care 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

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community defibrillation officers
- Community hospitals
- General practitioners
- Practice nurses
- Practice managers
- Maintenance staff
- Minor injury units
- NHS walk-in centres

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- 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 and requesting this facility.

Contacts

Supplier

Sally Turner
Amazon Medical Limited
Carrington Business Park, Carrington,
Manchester, M31 4XL

Tel: 0161 776 4336
Fax: 0161 776 4339

Email: sally@amazonmedical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/042** or **2012/005/011/081/009**

Technical aspects

Enitan Taiwo or Paul Sandhu
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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

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