

Medical Device Alert

Ref: MDA/2012/043 Issued: 11 July 2012 at 15:00

Device

Schiller electrodes: silver packet, manufactured by Nessler Medizintechnik.

All (Paediatric and Adult) electrodes are affected.

Distributed by Amazon Medical Ltd.



Example of one of the electrodes.

Problem	Action
<p>Premature drying up of electrodes due to a manufacturing quality problem.</p> <p>This may prevent shock delivery, which may result in failure to defibrillate and a reduced chance of survival for the patient.</p>	<ul style="list-style-type: none"> • See manufacturer's Field Safety Notice, issued May 2012 by Amazon Medical Limited. MDA/2012/042 and MDA/2012/043 refer to this Field Safety Notice. • Check inventory and identify affected electrodes. • If affected, immediately contact Amazon Medical Limited for replacement electrodes. • Return the fax back confirmation form in the FSN to Amazon Medical Limited.
Action by	
<p>All clinical, medical and ambulance staff who use these devices and those responsible for their maintenance.</p>	
CAS deadlines	Contact
<p>Action underway: 01 August 2012</p> <p>Action complete: 22 August 2012</p> <p>Note: These deadlines are for systems to be in place for the replacement of electrodes.</p>	<p>Supplier Amazon Medical Limited</p> <p>Tel: 0161 776 4336</p> <p>Fax: 0161 776 4339</p> <p>Email: sally@amazonmedical.co.uk</p>

Device

The electrodes are supplied with the FRED defibrillators or can be acquired as an accessory. All those electrodes produced before January 2011 are affected.

SCHILLER FRED AED: Defibrillation Electrodes – Nessler Medizintechnik

Product	Part number
FRED defibrillation electrodes Adult	REF W1410241
FRED defibrillation electrodes Child Same packet – labelled Child	REF W1404262

Schiller Fred easyport, APLC1 & APLC2 Defibrillation Electrodes – Nessler Medizintechnik

Product	Part number
FRED easyport defibrillation electrodes - Adult Same size packet as 2.155057	REF 2.155056
FRED easyport defibrillation electrodes - Child	REF 2.155057
APLC1 & APLC2 defibrillation electrodes Adult	REF 0-21-0024

Schiller Fred easy Defibrillation Electrodes – Nessler Medizintechnik

Product	Part number
FRED easy defibrillation electrodes	REF 0-21-0003
FRED easy	REF 0-21-0020
FRED easy	REF 0-21-0000
FRED easy	REF 0-21-0021

The Schiller electrodes are used with the following defibrillators/monitors manufactured by Schiller.

Products
FRED easy Basic
FRED easy ECG on-screen
FRED easy Manual
FRED AED
FRED easyport APLC1
FRED easyport APLC2
AT101 easy
Argus Pro Lifecare 1
Argus Pro Lifecare 2

Problem

Users have reported that these electrodes partially dry up before their expiry date, possibly due to variations in the manufacturing process. If the electrodes partially dry up, there is a risk that they will not be detected by the defibrillator, as their impedance is too high.

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
- Maintenance staff
- Minor injury units
- NHS walk-in centres
- Practice managers
- Practice nurses

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

Manufacturer

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/2012/043** 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.irc@nhs.net

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

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

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