Medical Device Alert

Ref: MDA/2014/014 Issued: 28 April 2014 at 15:00

Device

Samaritan® public access defibrillator

Model: PAD 500P

Manufactured by HeartSine Technologies

Specific serial numbers affected

Problem

Risk of failure to deliver therapy.

The software in the samaritan® PAD 500P may miscalculate the cardiopulmonary resuscitation (CPR) rate of compression per minute being administered to the patient.

The rescuer may, therefore, be incorrectly advised by the device to 'Push Slower' when the CPR rate is actually at an acceptable level.

The manufacturer issued a Field Safety Notice in February 2014 providing advice on this problem

Action

- Identify any affected devices.
- Follow the manufacturer's instructions in the Field Safety Notice to update to software version 3.4.0.
- Return the confirmation request to the manufacturer when the software has been updated.

Action by:
Community defibrillation officers and staff responsible for the use, maintenance and purchase of these devices.

CAS deadlines

Action underway: 13 May 2014

Action complete: 28 May 2014

Note: These deadlines are for systems to be in place to take actions.

Contact

Manufacturer
Mr James McGuinness
Heartsine Technologies Ltd
Tel: 028 9093 9400
Email: james.mcguinness@heartsine.com

Device

The affected devices were manufactured between February 2010 and January 2014 and have a serial number in the range 10B0010001 to 14B00461703 inclusive.

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 trusts in England (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:

- Ambulance services directors
- Ambulance staff

Primary Care Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

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

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- 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
Mr James McGuinness
Heartsine Technologies Ltd
203 Airport Road West
Belfast
Antrim
BT3 9ED
Northern Ireland

Tel: 028 9093 9400
Fax: 028 9093 9401

Email: james.mcguinness@heartsine.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/014** or 2014/001/027/081/044

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

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128 Fax: 020 8754 3965

Email: mark.grumbridge@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

Tel: 029 2082 5801 Email: Haz-Aic@wales.gsi.gov.uk

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