Medical Device Alert

Ref: MDA/2012/079 Issued: 20 November 2012 at 14:00

Device

Samaritan public access defibrillator.

Model: PAD 300/PAD 300P.

Manufactured by HeartSine Technologies Ltd.

Specific serial numbers are affected.

Problem

Risk of failure to deliver therapy caused by two different faults:

1. Some defibrillators may repeatedly turn on and off when not in use, leading to unexpected battery depletion.
2. Defibrillators with early versions of the battery management software may switch off after delivering a single shock or give a premature low battery warning.

The manufacturer issued a Field Safety Notice (FSN) in September 2012, providing advice on management of the defibrillator.

Action by

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

Action

- Identify affected defibrillators (see below for serial numbers).
- Increase frequency of checks to daily.
- If the LED is red or unlit, contact the manufacturer immediately for a replacement defibrillator.
- Consider relocating the device so that faults are detected promptly.
- Return the confirmation request in the manufacturer's FSN issued September 2012 and HeartSine will send you an upgrade kit containing:

  1) reserve Pad-Pak (battery) and instruction 'hang tag'

  2) the software upgrade, USB cable and installation guide.

CAS deadlines

Action underway: 11 December 2012

Action complete: 07 January 2013

Note: These deadlines are for defibrillators to be identified and HeartSine contacted.

Contact

Manufacturer
HeartSine Technologies Ltd
Tel: 028 9093 9400
Email: data@heartsine.co.uk

Device

Samaritan PAD 300/300P distributed from August 2004 to December 2010 with a warranted life of up to seven years.

The following serial number ranges are affected with one or both of the identified faults.

0400000501 to 0700032917 inclusive

08A00035000 to 10A00070753 inclusive

10C00200000 to 10C00210318 inclusive **Note**: this range supersedes the one in the manufacturer's FSN.

Action

Once the upgrade pack is received follow the instructions to ensure that:

- a reserve battery pack is available in the carry case for emergency use
- the 'hang tag' with instructions for reserve battery use is attached to the device
- the software is updated.

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.

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
- 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
HeartSine Technologies Ltd
Canberra House
203 Airport Road West
Belfast
BT3 9ED

Tel: 028 9093 9400
Fax: 028 9093 9401

Email: www.heartsine.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/079** or **2012/009/011/081/001**

Technical aspects
Enitan Taiwo and Catriona Blake
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7122/7219
Fax: 020 8754 3965

Email: enitan.taiwo@mhra.gsi.gov.uk
catriona.blake@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare products Regulatory Agency
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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

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