

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/26

Issued: 21 March 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: External defibrillators: Samaritan AED manufactured by HeartSine. Models SAM001, SAM002 and SAM003.</p>	▶ ①
<p>Problem: In semi-automatic mode the device incorrectly recognises an unusual ECG rhythm. The rhythm is non-shockable but the device can advise to shock. The manufacturer has advised users not to use these devices in automatic modes until the software has been updated. A copy of the manufacturer's advisory notice is on the field safety notice section of the MHRA website.</p>	▶ ②
<p>Action by: All engineering and clinical staff involved in the use or maintenance of these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify whether your organisation has any of the above devices. SAM002 and SAM003 models should be withdrawn from use and quarantined. Ensure that users are aware that SAM001 models should only be used in manual mode. Contact HeartSine Technologies (tel: 028 9093 9400) to arrange for a software update. After the update has been carried out the devices can be returned to unrestricted use in automatic mode. 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p>For onward distribution see Section 5</p> <p style="text-align: right;">General Medical Practitioners</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niac>

1. DEVICE/EQUIPMENT:

External defibrillators: Samaritan AED manufactured by HeartSine. Models SAM001, SAM002 and SAM003.

2. PROBLEM:

In semi-automatic mode the device incorrectly recognises an unusual ECG rhythm. The rhythm is non-shockable but the device can advise to shock.

The manufacturer has advised users not to use these devices in automatic modes until the software has been updated.

A copy of the manufacturer's advisory notice is on the field safety notice section of the MHRA website.

3. ACTION BY:

All engineering and clinical staff involved in the use or maintenance of these devices.

4. ACTION:

- Identify whether your organisation has any of the above devices.
- SAM002 and SAM003 models should be withdrawn from use and quarantined.
- Ensure that users are aware that SAM001 models should only be used in manual mode.
- Contact HeartSine Technologies (tel: 028 9093 9400) to arrange for a software update. After the update has been carried out the devices can be returned to unrestricted use in automatic mode.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- All Clinical Departments
- All Wards
- Directors of Cardiology
- Trust Dental Departments
- Outpatient Clinics
- Theatre Managers
- Practice Managers
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Resuscitation Officers

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Gary Johnston
Quality Manager
HeartSine Technologies Ltd
Canberra House, 203 Airport Road West,
Belfast
BT3 9ED

Tel: 028 9093 9400

Fax: 028 9093 9401

E-mail: support@heartsine.com

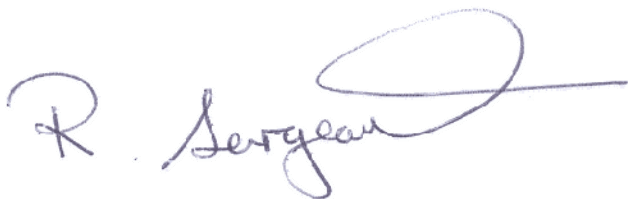
Enquires to NIAIC should quote reference number MDEA(NI)2007/26 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 23 March 2007
Deadline (action underway)	: 23 March 2007
Deadline (action complete)	: 10 April 2007



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety