IRISH MEDICINES BOARD
SAFETY NOTICE

SAFETY NOTICE

samaritan® PAD 500P (Public Access Defibrillator)

IMB Safety Notice: SN2014(12)
Circulation Date: 18 March 2014

MANUFACTURER/IRISH DISTRIBUTOR
HeartSine Technologies/Heartsafety Solutions

TARGET GROUPS
Paramedics
Emergency Medical Technicians
Ambulance Headquarters
Community First Responder Schemes
Medical Directors
Risk Managers
Supplies Managers
General Practitioners
Private medical practitioners
Clinics
Hospitals
Nursing Homes
Schools
Sports clubs

Please bring this safety notice to the attention of all who need to be aware of it.

ISSUE
HeartSine Technologies is issuing a Software Upgrade to address an issue that could affect the accuracy of the CPR (cardiopulmonary resuscitation) instructions provided to rescuers by the samaritan® PAD 500P during a sudden cardiac arrest situation.

BACKGROUND
HeartSine Technologies has recently issued a Field Safety Notice advising customers that the software in the samaritan® PAD 500P public access defibrillators may miscalculate the 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, in fact, the CPR rate is at an acceptable level.

Any samaritan® PAD 500P device manufactured between February 2010 and January 2014 with the following serial numbers inclusive are affected by this issue:

10B0010001 to 14B00461703

SAFETY NOTICE

HeartSine Technologies have developed a software upgrade to correct the issue.

The Irish Medicines Board recommends customers to contact the Irish distributor and/or manufacturer to perform the software upgrade on affected devices if a date has yet to be scheduled.

For additional details, please see field safety notice attached.

ACTION OR RECOMMENDATIONS

The IMB recommends that:

1. Relevant personnel in your organisation are made aware of this potential issue.
2. Ensure that this IMB Safety Notice and the attached field safety notice is passed on to any organisation or end user where the potentially affected devices have been transferred.
3. Customers should contact either the local distributor or the manufacturer to schedule a service call out to upload the software upgrade to affected devices if a date has yet to be scheduled.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Manufacturer

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

Telephone:	+44 (0) 28 9093 9404
Fax:	+44 (0) 28 9093 9401
Contact:	HeartSine Technical Support
Email:	support@heartsine.com

Enquiries to the distributor should be addressed to:

Irish Distributor

Heartsafety Solutions
Unit 17
Kilcarbery Business Park
Nangor Road
Dublin 22

Telephone:	+353 1 457 8719
Fax:	+353 1 457 7659
Contact person:	David Greville
Email:	info@hearts.ie

SAFETY NOTICE

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie