HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Samaritan PAD 300 / PAD 300P Public Access Defibrillators

Part Numbers: PAD 300/PAD 300P
Serial numbers:
0400000501 to 0700032917;
08A00035000 to 10A0070753;
10C00200000 to 10C002108200

Priority 2 – Warning

HPRA Safety Notice: SN2014(43)
Update to SN2012(19)

Issue Date: 26 November 2014

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Manufacturer: HeartSine Technologies Ltd.	V15772

ISSUE
Certain PAD 300 / PAD 300P devices may experience On/Off Issues and battery management software issues that could affect the ability to deliver therapy to a patient in a sudden cardiac arrest event. This was highlighted in field safety notice (FSN) that was circulated by the manufacturer in September 2012 and a IMB/HPRA Safety Notice SN2012(19).

ACTION OR RECOMMENDATIONS

HPRA advises users to:

1. Ensure that you have read and followed the instructions that were provided in the manufacturer's field safety notice (FSN) that was circulated in September 2012.
2. Complete and return the Response Form included with the FSN if you have not already done so.
3. Arrange for your device to be upgraded if it has not already been completed.
4. Ensure relevant personnel receive a copy of the attached FSN.
5. Forward the FSN and this safety notice to any other persons/organisations where these devices have been transferred.

TARGET GROUPS

HSE Hospital Staff	Community First Responder schemes
Private Hospital Staff	General Practitioners
Nursing Home Staff	Schools
Hospital Chief Executive Officers	Sports clubs
Risk Managers	Nursing Homes
Clinical Engineering/ Medical Physics	
Purchasing Managers	
Supplies Managers	

BACKGROUND

Certain PAD 300 / PAD 300P devices may experience the following conditions that could affect your ability to deliver therapy to a patient in a sudden cardiac arrest (SCA) event, if needed:.

Issue 1 (On/Off Issue): The device may turn itself on without input from the user. If the device does not detect that the audible prompts emitted after the device turns on are followed the device will automatically switch off after 10 minutes to save power. If this sequence of events occurs repeatedly, the battery of the device may deplete below the minimum battery capacity required for the delivery of therapy.

Issue 2 (Battery Management Software Issue):
Certain PAD 300/PAD 300P devices containing early versions of the battery management software may misinterpret a temporary drop in battery voltage as signalling a low battery. If the low battery warning is triggered due to this issue the device may turn itself off.

Please refer to the attached FSN for additional details on the issues affecting the devices, the list of affected serial numbers and the actions proposed by the manufacturer.

The HPRA are circulating this Safety Notice at this time as a reminder to ensure that all users of the device are aware of the issue. The HPRA issued a Safety Notice, SN2012(19), in December 2012 to highlight this issue. The HPRA understand from HeartSine that despite their communication to customers, there remain a large number of these devices that have not yet had the necessary actions completed.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

HeartSine® Technologies Ltd.
203 Airport Road West
Belfast, Northern Ireland
BT3 9ED

Telephone: +44 (0) 28 9093 9401
Fax: +44 (0) 28 9093 9401
E-mail: data@heartsine.co.uk
Website: www.heartsine.com

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace , Dublin 2

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