2nd October 2012

URGENT RECALL FOR PRODUCT CORRECTION

Reserve battery and new instructions for users of the PAD 300/PAD 300P (Public Access Defibrillator)

Dear Sir or Madam,

The purpose of this letter is to inform you of a voluntary correction that HeartSine Technologies Ltd. is introducing in relation to the PAD 300/PAD 300P public access defibrillators. The correction is intended to address two issues that could affect the device battery and hence your ability to deliver therapy using the device when needed. HeartSine Technologies Ltd.'s records indicate that you have received a PAD 300 and/or PAD 300P that is affected by this action.

Issues identified

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. When this occurs, the normal sequence of audible prompts will be emitted from the device. If the device does not detect that the audible prompts are followed (e.g., that a patient is connected to the electrodes to allow the device to read the patients' ECG and start the normal sequence of events), the device will automatically switch off after 10 minutes to save power. This sequence of events can happen repeatedly or intermittently. If this condition continues undetected, the battery will eventually become completely depleted. In worst-case situations the battery could, within a week, be depleted below the minimum battery capacity necessary to allow for the delivery of therapy. In such, circumstances, the device will subsequently be capable of delivering therapy if an adequate power supply is provided. Devices potentially affected by the On/Off Issue were manufactured between August 2004 and December 2010 and have a warranted life of up to 7 years.

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. The issue will result in the device prematurely displaying the low battery warning and turning itself off even though sufficient battery capacity remains. This may occur when the device performs its weekly self-test, or when the device is turned on, or when the device is preparing to deliver a shock, or after delivering a shock. If the low battery warning is triggered due to this issue, the device will have sufficient power to deliver multiple shocks but it is possible that the device will only deliver one shock before turning itself off. If this occurs, delivery of any subsequent shocks may be delayed and would likely only be

delivered at the lowest energy level of 150 Joules. Once the device has experienced this condition, it is more likely to experience it again.

This condition can occur where the installed PAD-PAK has already been partially depleted due to normal battery depletion or where the installed PAD-PAK is an 800 mAh capacity battery. This software version was distributed until end December 2010. Devices containing software version 1.4.2 / 3.2.0 or higher are not susceptible to this issue.

PAD 300/PAD 300P with the following serial numbers inclusive are affected by one or both of these issues:

- 0400000501 to 0700032917
- 08A00035000 to 10A00070753
- 10C00200000 to 10C00210318

No other HeartSine Technologies Ltd. automated external defibrillator products are affected by either issue addressed in this letter.

Corrective actions related to the PAD 300/PAD 300P

Issue 1 (On/Off Issue): To ensure that you will have sufficient power to deliver therapy during a sudden cardiac arrest event, we will be shipping you a reserve 1500 mAh PAD-PAK battery as soon as possible after we receive the response card that is included with this Urgent Recall for Product Correction. This reserve PAD-PAK battery is to be held in reserve in the zippered pouch on the back of your PAD 300/PAD 300P carry case. Do not install this battery. It is simply provided as a precaution in case the battery in your existing PAD-PAK expires earlier than anticipated.

Issue 2 (Battery Management Software Issue): To ensure that your device does not issue a premature / inadvertent low battery warning, we will be shipping you a data cable that will allow you to download the current version of the device's battery management software. When you receive this data cable, connect your device to a USB port in your computer following the instructions in Annex I of this Urgent Recall for Product Correction and download the HeartSine Technologies Ltd. Samaritan PAD Universal Updater at **http://heartsine.com/recall/**. This link will automatically update your device to the most current version of the software. We will also be supplying a copy of the software on CD in case you do not have web access and a new user manual to reflect the software version you will now be using.

In addition, in **Annex III** of this Urgent Recall for Product Correction we have shown a graphic of a hang tag for your device. This hang tag will instruct users how to install the reserve PAD-PAK battery should the existing battery appear to lack sufficient battery power during a patient event and will be provided to you at the same time as the Reserve Battery inside your upgrade kit.

As a user of the PAD 300 or PAD 300P the actions outlined in **Annex I** to this Urgent Recall for Product Correction need to be implemented by you at user level. Your assistance is appreciated and necessary to ensure that you are able to deliver therapy to sudden cardiac arrest patients using the PAD 300/ PAD 300P.

Therefore, HeartSine Technologies Ltd. asks all users of the PAD 300/PAD 300P to immediately follow the instructions laid down in Annex I of this Urgent Recall for Product Correction.

Please also complete and return the response card provided in **Annex II** of this Urgent Recall for Product Correction as soon as possible confirming that you have received and understand this communication and indicating to where you would like HeartSine to ship your equipment (i.e., reserve PAD-PAK, CD, data cable, user manual and hang tag). If you have any questions, call either HeartSine Technologies Ltd. at 00800 1212 5555 or our designated distributor Aero Healthcare on 1800 628 881.

If you have further distributed this product, please identify your customers and notify them at once of this communication. Please also provide HeartSine Technologies Ltd. with the customer's contact information so that we can follow-up with the current owner of the device.

In accordance with applicable rules, this action has been undertaken after consultation with the Therapeutic Goods Administration (TGA).

We apologise for the inconvenience these corrective actions may cause you. We value you and your patients and appreciate your understanding as we work to ensure that we are providing you with the reliable devices you have come to trust.

Sincerely,

Tim Ovenden
Managing Director
Aero Healthcare