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14th September 2012

URGENT FIELD SAFETY NOTICE
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 signaling 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

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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 Field Safety Notice. 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 Field Safety Notice and download the HeartSine Technologies Ltd. Samaritan PAD Universal Updater at http://www.heartsine.com/recall/software_updates. 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 Field Safety Notice 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 Field Safety Notice 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.

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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 Field Safety Notice.

Please also complete and return the response card provided in **Annex II** of this Field Safety Notice 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 HeartSine Technologies Ltd. c/o HTM Medico Pte Ltd at (65) 6744-5911.

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, these corrective actions are implemented with the knowledge of the Health Science Authority Singapore.

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,

W.S. McChesney
President and CEO
HeartSine Technologies Ltd.

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ANNEX I

Instructions to be followed by users of the PAD 300 and PAD 300P

1. **DO NOT** remove your device(s) from service.

2. If necessary, relocate the PAD 300/PAD 300P to an area where the audible prompts would be heard if initiated. If the device turns itself on and off OR if your device displays a Low Battery Warning before the expiry date labeled on the PAD-PAK in the device, contact HeartSine Technologies, at c/o HTM Medico Pte Ltd at (65) 6744-5911 immediately so that we may make sure that you have the ability to provide therapy in the future.

3. Immediately increase the frequency of your device checks to daily to confirm that the PAD 300/PAD 300P is operable and in ready standby mode as indicated by a flashing green LED (see the HeartSine Samaritan® PAD SAM 300/300P User Manuals).

4. Confirm that the LED light is flashing green. If the LED is red or unlit, contact HeartSine Technologies c/o HTM Medico Pte Ltd at (65) 6744-5911 immediately so that we may send you a replacement unit.

5. When you receive the 1500 mAh PAD-PAK, insert it in the zippered pouch on the back of the PAD 300/PAD 300P soft carrying case so that it may be held in reserve if needed.

   MAKE SURE YOU ALWAYS HAVE A RESERVE PAD-PAK ON HAND.

6. When you receive the hang-tag, attach it to the handle of the PAD 300/PAD 300P soft carrying case to alert a first responder that they may need to replace the installed depleted PAD-PAK with the reserve PAD-PAK contained in the zippered pouch. Instructions for replacing the PAD-PAK are provided on the hang-tag.

7. When you receive the CD, data cable and User Manual, your device must be connected to a USB port in your computer so that the current version of the software can be downloaded. The software can also be downloaded from http://www.heartsine.com/recall/software_updates. Either the CD or the link will automatically update your device to the appropriate version of the battery management software. Replace the originally supplied User Manual, stored in the soft carry case, with the new copy supplied with this field action.

8. If your device LED is red or unlit and you need the device in a sudden cardiac arrest event, replace the PAD-PAK battery with the reserve PAD-PAK battery that has been provided to you following the instructions on the hang tag. Once the reserve PAD-PAK battery has been inserted you will have more than sufficient power to deliver therapy.

   Following the event, contact HeartSine Technologies c/o HTM Medico Pte Ltd at (65) 6744-5911 immediately so that we may send you a replacement unit that will ensure that you have the ability to provide therapy in the future

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ANNEX II
Response Card **SG**

Please assist us in making this corrective action process efficient and convenient for you by completing and returning this card to HTM Medico Pte Ltd via mail, email, or fax. This card serves as a confirmation that you have received and understand this notification. Also, please indicate the address to which you would like your equipment shipped.

A cover sheet is not required for this Response Card.

ADDRESS: HTM Medico Pte Ltd
625 Aljunied Road #04-05A
Aljunied Industrial Complex
Singapore 389836

FAX: (65) 6748-2718
MAIL: sophia.wan@htmmedico.com.sg

If you have questions, please call HTM Medico Pte Ltd at (65) 6744-5911 between 9:00 am to 6:00 pm Monday to Friday.

Please complete this form by checking the applicable boxes indicating that you understand and have taken the recommended actions.

- ☐ We have checked our device(s) and it is/they are not displaying a low battery warning.
- ☐ We have relocated the device to an area where the audible prompts would be heard if initiated.
- ☐ We are increasing our device status checks to a daily occurrence.
- ☐ Upon receipt, we will:
  - o Place the reserve mAh 1500 PAD-PAK™ battery in the zippered portion of the soft carrying case.
  - o Place the hang tag on the soft carrying case handle.
  - o Update the device(s) software using the supplied CD or the website download, using the data cable supplied.
  - o Replace the originally supplied User Manual, stored in the soft carry case, with the new copy supplied with this field action.

Device serial number(s)	
Facility Name:	
Facility Address:	
Identify where you would like the battery shipped	
Completed By:	
Title:	
Signature:	
Date:	
Phone:	
Facsimile:	
Email:	
Preferred form of contact	☐ Email ☐ Phone ☐ Fax

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ANNEX III
Hang Tag

Attach this hang tag to the handle of the soft carrying case so that it is readily visible to a first responder.

IF YOUR DEVICE LED IS RED OR UNLIT AND YOU NEED IT IN A SUDDEN CARDIAC ARREST EVENT, REPLACE THE INSTALLED PAD-PAK WITH THE RESERVE PAD-PAK PER THE INSTRUCTIONS ON THE REVERSE.

If you need to use the reserve PAD-PAK™ to treat a patient, contact HeartSine (data@heartsine.com or +800 1212 5555), immediately after so that we may make sure that you have the ability to provide therapy in the future.

Instructions for installing Reserve PAD-PAK

Remove Reserve Pad-Pak™ from its packaging.

Remove installed Pad-Pak™ by depressing the clips on either side and sliding it out from the device.

Place the samaritan® PAD and Pad-Pak™ on a flat surface.

Push Pad-Pak™ into the opening and listen for the "click" sound to ensure it is properly inserted

Once the Pad-Pak™ is installed properly the PAD STATUS INDICATOR will begin to blink Green every 5 seconds

☞ Do not open the Pad-Pak™ tray or open the defibrillation pads protective packaging until the time of emergency use when they are applied to a patient.

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