

URGENT RECALL FOR PRODUCT CORRECTION**HeartSine Technologies samaritan® PAD 500P (Public Access Defibrillator)
Software upgrade**

TGA Reference Number: RC-2014-RN-00243-1

Dear Owners of the samaritan® PAD 500P,

The purpose of this letter is to inform you of a corrective action that HeartSine Technologies Ltd. is introducing in relation to samaritan® PAD 500P public access defibrillators.

The corrective action is intended 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.

HeartSine Technologies' records indicate that you have received a samaritan® PAD 500P device which is affected by this action.

Issue identified

The samaritan® PAD 500P is intended, where appropriate, to deliver shocks to victims of a sudden cardiac arrest and has a secondary function to provide feedback to rescuers concerning the effectiveness of the CPR they are providing. The corrective action described in this Urgent Recall for Product Correction relates to this secondary function.

The software in your samaritan® PAD 500P 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. There are reports of death and serious injury during the use of the samaritan PAD 500P devices, and in two cases the incorrect CPR feedback given to the user cannot be eliminated as being a contributory factor to the patient outcome.

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

- 10B0010001 to 14B00461703

Corrective action related to the samaritan® PAD 500P

To address the issue described in this Field Safety Notice, an updated version of the software (3.4.0) for the samaritan® PAD 500P is now available. The updated software has been posted on the HeartSine Technologies website ready for download.

If you already have a HeartSine data cable and internet access, please follow the instructions in **Annex I** of this Recall for Product Correction and fill out the response card in **Annex II**.

If you do not have a HeartSine data cable or internet access, you should ask Aero Healthcare, using the Response Card in **Annex II**, to send you an upgrade kit. When you receive the upgrade kit, follow the instructions provided, in order to upgrade your device software.

Do not remove the device from service.

If you have any questions, please call Aero Healthcare at 1800 628 881.

If you have further distributed your samaritan® PAD 500P, please notify your customers at once of this communication. Please also provide Aero Healthcare with the customer's contact information so that we can follow-up with the current owner of the device.

This action has been undertaken after consultation with the Therapeutic Goods Administration (TGA)

We appreciate your understanding as we work to ensure that we are providing you with the most up to date and reliable devices you have come to trust.

Sincerely,

Tim Ovenden
Managing Director
Aero Healthcare

ANNEX I Upgrade Instructions

If you have a HeartSine data cable and access to the internet you can execute the upgrade immediately.

1. Go to www.HeartSine.com/500P/system-updates.
2. Click on the link "PAD 500P Upgrader User Instructions" to download the instructions to your desktop.
3. Follow the instructions to complete the software download.
4. On completion of each device upgrade return the upgrade certificate to Aero Healthcare via web upload, email or post as per the on screen instructions.

Email to: data@aerohealthcare.com

Post to: Aero Healthcare
63 Seaton Street
Armidale
NSW 2350
Australia

Fax to: 02 6771 3369

5. Insert the User Manual update (see **Annex III**) into the originally supplied User Manual, stored in the soft carry case of the samaritan® PAD 500P.
6. Fill out the response card in **Annex II**.

It is critical that you return the upgrade certificate as it enables HeartSine Technologies Ltd. to update its records for your device and confirms that the upgrade has been successfully carried out.

ANNEX II Response Card

Please assist us in making this corrective action process efficient and convenient for you by completing and returning this Response Card to Aero Healthcare via mail, email, or fax. This card serves as a confirmation that you have received and understood this notification. Please also indicate the address to which you would like the upgrade kit to be shipped if required.

A cover sheet is not required for this Response Card.

ADDRESS: Aero Healthcare
63 Seaton Street
Armidale
NSW 2350
FAX: 02 6771 3369
EMAIL: data@aerohealthcare.com

If you have questions, please call Aero Healthcare at 1800 628 881 between 9:00 am to 5:00 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 a HeartSine data cable and internet access. We shall update the device(s) software by accessing the relevant HeartSine Technologies web link.
- We do NOT have a data cable and/or internet access. Please supply us with a HeartSine data cable and software CD. Upon receipt of these we shall update the device(s) software using the HeartSine data cable supplied and either the CD supplied or by accessing the relevant HeartSine Technologies web link.
- We shall return the upgrade certificate.
- We shall place the User Manual update with the originally supplied User Manual.

Device serial number(s)

Facility Name:

Facility Address:

Identify where you would like the upgrade kit shipped if different from above.

Completed By:

Title:

Signature:

Date:

Phone:

Fax:

Email:

Preferred form of contact Email Phone Fax

Upon receipt of the software upgrade certificate we do not anticipate needing to contact you again regarding this action. We will not use this information for any other reason.

Annex III
User Manual Update.

This sheet contains updates made after the publication of the User Manual for the samaritan® PAD 500P.

Product Family: HeartSine samaritan® PAD 500P

Date: 20th February 2014

Manual: User Manual

Please replace the table in Section titled “ECG Arrhythmia Analysis Algorithm” with the table below



Rhythm Class	Sample Size (sec.)	Required Performance	Performance Results (%)	90% One-Sided Lower Confidence Limit
Shockable Rhythm: Ventricular Fibrillation (VF)	13341	Sensitivity > 90%	96.97	96.72
Shockable Rhythm: Ventricular Tachycardia (VT)	1946	Sensitivity > 75%	91.36	90.25
Non-Shockable Rhythm: Combined Non-Shockable Rhythms	286056	Specificity > 95%	99.04	99.01
Non-Shockable Rhythm: Asystole	10839	Specificity > 95%	100*	99.97*

Please replace the table in Section titled “CPR Advisor Analysis Algorithm” with the table below



CPR Criteria	Performance Specifications	Performance Results (%)
CPR speed: good	Sensitivity > 90%	96.05
	Specificity > 90%	93.01
CPR force: adequate	Sensitivity > 90%	99.91
	Specificity > 90%	97.95