PO Box 2059
281 Heads Road
Wanganui 4543

H017-201-336-0

5 March 2014

Customer Name details here
City

MEDICAL DEVICE RECALL FOR PRODUCT CORRECTION
HeartSine 500P Samaritan Defibrillator
Manufactured between February 2010 and January 2014

Dear Customer,

The purpose of this letter is to inform you of a corrective action that HeartSine Technologies is introducing in relation to Samaritan PAD 500P Defibrillator.

The corrective action is intended to address an issue with the secondary function of the PAD500P with regard to its CPR feedback function. The issue requires a software upgrade and is compulsory.

We need your help and cooperation to deal with this field action with you or your customers that may have one.

Issue:
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 notice 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.

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

Amtech Medical records indicate that you have received a Samaritan PAD 500P device which is affected by this action.

Action:

- To address the issue described in this 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 1 of this notice and fill out the acknowledgement form.

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- If you do not have a HeartSine data cable or internet access, you should ask Amtech Medical, using the Acknowledgement Form, 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.

- To confirm you have received this notice, please complete the attached acknowledgement form and return it to us by fax (06 3447150) or by scanning and email to sales@amtech.co.nz

- If you have further distributed your Samaritan PAD 500P, please notify your customers at once of this communication.

If you do have a query, please phone 0800 268 324 and ask for '500P modification support staff.'

This action has being conducted following consultation with Medsafe, Ministry of Health.

Yours faithfully,

Jeremy Anderson
Quality Control Officer
Amtech Medical
www.amtech.co.nz

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Acknowledgement Form.

(Please send this form to Amtech Medical as soon as you get this, and even before you do the upgrade).

I confirm that I have received and read the recall for product correction notice regarding the HeartSine Samaritan 500P.

Please check the appropriate response:

[ ] We have the data cable and will upgrade our device

[ ] Please contact me to arrange to upgrade our device

[ ] We no longer have this device

Your Name	
Your Signature	
Date	
Your Facility or Company Name	
Your Contact Ph. Number	
Your Email address	
The serial number on the back of the defib	

Please send this form to either of the following:

sales@amtech.co.nz
Fax to 06 3447150
Mail to PO Box 2059, Wanganui Postal Code 4543

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281 Heads Road
Wanganui 4543

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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 sales@amtech.co.nz

Email to: sales@amtech.co.nz
Post to: Amtech Medical, PO Box 2059, Wanganui. Postal Code 4543.
Fax to: +64 6 3447150

5. Insert the User Manual update (see Annex ll) into the originally supplied User Manual, stored in the soft carry case of the Samaritan PAD 500P.

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

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Annex II

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*

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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% Specificity > 90%	96.05 93.01
CPR force: adequate	Sensitivity > 90% Specificity > 90%	99.91 97.95

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