HeartSine
Inventor. Innovator. Lifesaver.

URGENT FIELD SAFETY NOTICE

HeartSine Technologies Ltd. Samaritan® PDU 400

[XX October 2013]

Dear Owners of the Samaritan® PDU 400,

The purpose of this letter is to inform you that HeartSine Technologies Ltd. has identified a potential issue with the software in the Samaritan® PDU 400 device that you own.

The software of your Samaritan® PDU 400 device may fail to accurately determine the remaining capacity of the device battery. Rather than emitting an alarm warning you that the device has insufficient battery to deliver therapy the device may simply shut down. If your PDU 400 device has a serial number falling within the sequence listed below it may be affected by this issue. In such circumstances, your device may be unable to operate during a sudden cardiac arrest (SCA).

The PDU 400 devices affected by this issue have serial numbers between:

08P00001003 to 11P00007347

Following discovery of this defect HeartSine Technologies Ltd. has decided to recall all PDU 400 devices with the serial numbers listed above that are currently on the EU market.

No PDU 400 devices other than those with the serial numbers listed are affected by this action.

Instructions for owners of PDU 400 devices affected by this issue

If your PDU 400 device has a serial number falling within the sequence listed above please take the following steps:

1. Locate your PDU 400 device and complete the Recall Response Form that you will find at the end of this Notice.

2. Contact HeartSine Technologies Ltd. immediately by telephone on 008800 1212 5555 or by email on recallpdu@heartsine.com. You will be asked to provide the serial number of your device. This serial number can be found at the back of the device as shown in the image below.

   Alternatively you can contact the authorised distributor for Denmark who is:
   Lotek A/S
   Tel: 0045 70 13 52 00
   Email: hec@lotek.dk

   and they will contact HeartSine Technologies Ltd. on your behalf.

U.S./Americas 121 Friends Lane, Suite 400, Newtown, PA 18940 • P: 215.860.8100 • F: 215.860.8192
EMEA/ASP 203 Airport Road West, Belfast, Northern Ireland BT3 9ED • P: +44 (0) 28 90 93 94 00 • F: +44 (0) 28 90 93 94 01
www.heartsine.com

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Serial Number Location:

FRONT

REAR

3. Even if you cannot locate your PDU 400 device, or if your PDU 400 device is no longer in your possession, please complete the Recall Response Form in any event. In the Comments section of the Form, please include any information that you can provide regarding the current whereabouts of the missing PDU 400 device. For example, has the device been discarded, lost, destroyed, or given or sold to a third party?

4. If you know anybody who may have a PDU 400 device affected by the present action, please inform this person of the current Field Safety Corrective Action and ask them to contact HeartSine Technologies Ltd. directly using the contact details provided in Paragraph 2 above.

5. Upon hearing from you, whether directly or through your supplier/distributor, HeartSine Technologies Ltd. will immediately send you a replacement PDU 400 device. Along with the replacement device HeartSine Technologies Ltd. will send you instructions and packaging so that your original device may be returned to the Company at no cost to you.

6. Place the Recall Response Form and your original PDU 400 device in the packaging provided. Then contact the courier who delivered the replacement device and they will arrange to collect the package from you and return it to HeartSine Technologies Ltd..

7. To permit HeartSine Technologies Ltd. to keep current files concerning the location of all affected devices, if you no longer have the PDU 400 device in your possession, please fax or email the Recall Response Form to the following number/email to the attention of "Recall Samaritan® PDU 400":

   FAX: +44 (0)28 9093 9401

   Email: recallpdu@heartsine.com

In accordance with applicable rules, Danish Health and Medicines Authority has been notified of this Field Safety Corrective Action.

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We apologise for any inconvenience this action may cause you. If you have any questions or concerns, please contact us using the contact details provided in Paragraph 2 above

Thank you for your continued support.

Yours sincerely,

Declan O'Mahoney

HeartSine Technologies Ltd.

203 Airport Road West

Belfast, Northern Ireland

BT3 9ED

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Recall Response Form

HeartSine Technologies Ltd. Samaritan® PDU 400

Please assist us in making this corrective action process efficient and convenient for you by completing and returning this Recall Response Form with your PDU 400 device to HeartSine Technologies Ltd. This will serve as confirmation that you have received a replacement PDU 400 device and have understood the Notice. It will allow us to ensure that we have reached all owners who may be affected by this action.

PDU 400 Device Serial Number	Date Purchased	Date Returned	Other Comments *

* please include any information you can provide regarding the whereabouts of a missing PDU 400 device (for example, was it discarded, lost, destroyed, or given or sold to a third party); please also include contact details of persons who may be in possession of a PDU 400 device that is affected by the present action.

* If you have more than one affected PDU 400 please complete a separate line for each device.

Person Completing Form		
Name	**Address**	**Signature**
Telephone number	**Email address**	**Date**

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