REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥٠
رقم الصادر: ١٢/١/٢٥٢٢٢
بيروت، في: ٣١ تشرين الأول ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Defibrillators, Samaritan PDU 400

الجهاز المعني بالمتابعة:

- Defibrillators, Samaritan PDU 400
- Trade Mark: Heartsine Technologies
- Local Representative:

نرجو الاطلاع على التوصية الصادرة عن وكالة
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى خلل في عمل الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:
- التوصية الصادرة عن الشركة المصنعة

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قلم الديوان
وزارة الصحة العامة

Museum Street - Hussein Mansour Blg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

URGENT FIELD SAFETY NOTICE

HeartSine Technologies Ltd. Samaritan® PDU 400

4th 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 [The Toll-Free Telephone Number will be communicated to the MHRA on Thursday 10 October 2013] 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 authorized distributor for [COUNTRY] who is:
   [NAME]
   [TEL]
   [EMAIL]

U.S./Americas: 121 Friends Lane, Suite 400, Newtown, PA 18940 • P: 215.860.8100 • F: 215.860.8132
EMEA/ASP: 209 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

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

Serial Number Location:

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 you 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, [NATIONAL AUTHORITY] has been notified of this Field Safety Corrective Action.

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We apologize 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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