Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 17, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: HeartSine Technologies, Ltd. Recall [Medical Device]

AFFECTED PRODUCT: **Samaritan® 300/300P PAD devices; Serial #'s 0400000501 to 0700032917, 08A00035000 to 10A00070753, and 10C00200000 to 10C00210106.**

SUMMARY: **Unclassified Recall; HeartSine Technologies, Ltd. initiated a voluntary global correction of certain Samaritan® 300/300P PAD public access defibrillators to address two separate issues that may affect the ability to deliver therapy to a patient in a sudden cardiac arrest (SCA) event, if needed.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. Be aware of this recall in case of consumer concern and refer affected consumers to the company. Refer consumers to contact the company at 1-877-877-0147 Mon - Fri between the hours of 8:00am and 5:00 pm ET or email at heartsine6265@stericycle.com for an upgrade kit. Furthermore, if any recalled devices are identified please contact this office at 317-233-3213.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company

HeartSine Technologies, Ltd. Issues Global Correction of Samaritan® 300/300P PAD

Contact
Consumer:
1-877-877-0147
heartsine6265@stericycle.com

FOR IMMEDIATE RELEASE - September 13, 2013 - HeartSine Technologies, Ltd. initiated a voluntary global correction of certain Samaritan® 300/300P PAD public access defibrillators to address two separate issues that may affect the ability to deliver therapy to a patient in a sudden cardiac arrest (SCA) event, if needed.

Because HeartSine is committed to reaching every customer and upgrading affected devices, it is reissuing an updated press release. If you have a device that is affected by this issue and you **HAVE NOT** contacted the company to receive a free upgrade kit, please do so immediately.

Certain Samaritan® 300/300P PAD devices manufactured before December 2010 have been found to intermittently turn on and off, which may eventually deplete the battery. In addition and separately, certain Samaritan 300/300P PAD devices containing early versions of the battery management software may misinterpret a temporary drop in battery voltage as signaling a low battery and subsequently turn the device off. In certain instances, a device experiencing either condition could be unable to deliver therapy during a cardiac event.

The potentially affected Samaritan 300/300P PADs were manufactured from August 2004 to December 2010 and have a warranted life of 7 years. Potentially affected devices were distributed globally. Samaritan® 300/300P PAD devices with the following serial numbers inclusive are affected by one or both these issues:

- 0400000501 to 0700032917
- 08A00035000 to 10A00070753
- 10C00200000 to 10C00210106

The serial number is located on the bottom of the device under the bar code. Because a device experiencing the on/off issue will function appropriately if it has an adequate power source, HeartSine is sending affected customers a new PAD-PAK to be held in reserve and an accompanying hang tag with instructions for when and how to insert the reserve PAD-PAK so that the customer always has the ability to deliver therapy in a rescue attempt. In addition, HeartSine is providing a software upgrade (with a CD, data cable and associated User Manual) to bring all users up to a more recent version of the software that the company's data shows is no longer susceptible to the secondary issue.

HeartSine has requested that customers take the following actions to ensure that they are able to provide therapy in the event that a sudden cardiac arrest event occurs:

1. Keep the device(s) in service.

2. If necessary, relocate the Samaritan® 300/300P PAD to an area where the audible prompts would be heard if initiated.
3. Immediately increase device check frequency to daily to confirm that the Samaritan 300/300P PAD is operable and in ready standby mode.
4. If the device is not in ready standby mode, contact HeartSine Technologies at 1-877-877-0147 (Mon-Fri between the hours of 8:00am and 5:00pm ET) immediately so that a replacement unit can be sent.
5. Always have a reserve PAD-PAK on hand. Place the supplied reserve PAD-PAK in the zippered pouch on the back of the Samaritan 300/300P PAD soft carrying case and attach the provided hang-tag to the handle of the Samaritan 300/300P PAD soft carrying case to alert a first responder when and how to insert the reserve PAD-PAK if the installed PAD-PAK appears to have been depleted and the device is needed in a rescue attempt. Instructions for replacing the PAD-PAK are provided on the hang-tag.
6. Update the device software using the supplied data cable and CD (or via the company's website at http://www.heartsine.com/recall/software_updates). Replace the originally supplied User Manual, stored in the soft carry case, with the new copy supplied with this field action.

   NOTE: A small number of users have reported a difficulty with performing the software Upgrade. If you encounter any issues, please contact HeartSine immediately by telephone at 1-866-478-7463 (toll-free) Mon-Fri 8:00am - 9:00pm ET.

7. If the device is needed in a sudden cardiac arrest event and the LED is red or unlit, replace the PAD-PAK with the reserve PAD-PAK according to the instructions on the hang tag. Once the reserve PAD-PAK has been inserted, therapy can be delivered. Following the event, HeartSine Technologies should be contacted immediately at 1-877-877-0147 (Mon - Fri between the hours of 8:00am and 5:00 pm ET).

The firm voluntarily issued a correction for this product after becoming aware of the above issue. FDA is aware of the action and the steps the company is taking. No deaths or injuries have been reported to date associated with the on/off issue. To date, HeartSine has received six reports of death for which the company has not been able to rule out the possibility that the events may have been related to the battery management software issue.

Consumers with questions may contact the company at 1-877-877-0147 Mon - Fri between the hours of 8:00am and 5:00 pm ET and email at heartsine6265@stericycle.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm[1] (form available to fax or mail), or
- Call FDA 1-800-FDA-1088

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