HeartSine
Inventor. Innovator. Lifesaver.

URGENT FIELD SAFETY NOTICE

Date: 11th July 2014

Dear Owners of HeartSine® samaritan® PAD,

The purpose of this letter is to inform you of a voluntary corrective action that HeartSine Technologies Ltd. is introducing in relation to the HeartSine® samaritan® PAD (public access defibrillators). This notice affects you only if you have received a delivery from HeartSine since 15th May 2014.

In a small number of cases, the electrode/battery cartridges supplied for these devices have a foil pouch that contains the device electrodes which could be difficult to open. These affected cartridges need to be replaced immediately.

Name of affected product: Pad-Pak™ and Pediatric-Pak™, battery and electrode cartridges for the HeartSine® samaritan® PAD devices.

Identifier: FDA Recall#: 3004123209-06/30/2014-001R

Type of action: Device exchange

Details of affected devices:

The Pad-Pak and Pediatric-Pak are user-replaceable battery and electrode cartridges that are used with HeartSine samaritan public access defibrillators (SAM 300P and 350P). The following batches of the Pad-Pak and Pediatric-Pak are the subject of this recall:

- Pad-Pak: Batch numbers A1785 to A1805, inclusive.
- Pediatric-Pak: Batch numbers P433 to P445, inclusive.

Description of the problem:

In a small number of cases within the affected batches, the foil pouch that contains the single-use defibrillation electrodes may prove difficult to open. The extra effort required to open the foil pouch may cause an unacceptable delay in being able to administer therapy during a sudden cardiac arrest. Therefore, for safety reasons, the Company took the decision to voluntarily recall the affected batches as a matter of urgency.

The Pad-Pak and Pediatric-Pak cartridges have been supplied both as replacement consumables and with new HeartSine® samaritan® PAD devices.

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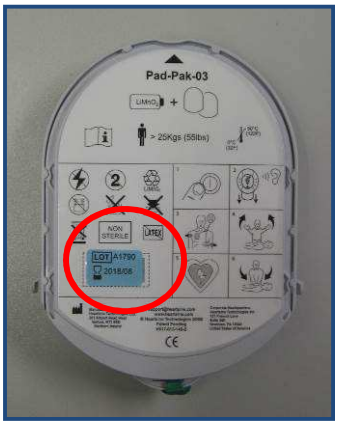
Action to be taken by the user:

If you were supplied with an affected Pad-Pak or Pediatric-Pak you should have been contacted directly by your distributor/supplier. This Field Safety Notice enables you to check independently to see if you have any affected cartridges.

- Identification: If you have received a new Pad-Pak or Pediatric-Pak or a new HeartSine samaritan PAD since 15th May 2014, then please check to see if you have an affected battery/electrode cartridge. The batch/lot number is on the labels, shown below.

Pad-Pak Box label

Pad-Pak Label



Pediatric-Pak Label

- Action. If you have an affected, Pad-Pak or Pediatric-Pak **do not take your device out of service.** Please contact your distributor/supplier for a free replacement Pad-Pak or Pediatric-Pak. They will issue you with a replacement and arrange for the return of the affected cartridge. The retrieval of the affected cartridge will only happen after you have received and fitted the replacement; so your defibrillator will remain available for therapy throughout.

Please note that no other HeartSine product is affected by this issue.

Issued by:

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