

URGENT:
MEDICAL DEVICE CORRECTION

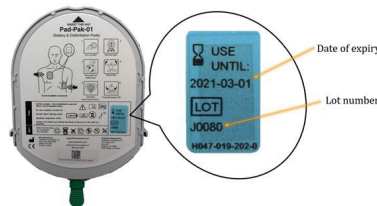
HeartSine samaritan® PAD-PAK

Attn: Risk Management/Recall Coordinator
Product Field Action Number: 2922086
May 3, 2023



Affected Product:

Product Number	Lot Number			
PAD-PAK-01	A3634	A3632	A3681	A3834
	A3636	A3635	A3805	J0801
	A3633	A3657	A3833	



Product description

The Pad-Pak is a single use battery and electrode cartridge containing the battery to power the HeartSine samaritan PAD (LiMnO2 (18V – 1500mAh) non-rechargeable battery) and two electrode pads to provide the electrical connection for delivery of defibrillation to the patient’s chest.

Product issue

Stryker has determined that the affected Pad-Paks may be rendered inoperable due to depleted battery cells. As a result, the affected Pad-Paks could potentially fail to power on the device if needed for use.

Potential risks

The issue could prevent device from analyzing patient condition or delivering therapy correctly. **There have been no reports of adverse events to date.**

Stryker’s planned actions:

The company is notifying all customers that have received HeartSine devices that may have the affected Pad-Paks.

Customer actions needed:

1. Inspect your Pad-Pak inventory to identify if you have any of the affected lot numbers listed on page 1.
 - a. If affected Pad-Paks are found, please request replacement through your original distributor Rescue 7 by emailing support@rescue7.net.
2. Complete the attached acknowledgment form below and return it by email to original distributor Rescue 7 email: support@rescue7.net confirming your receipt and understanding of this information.
 - a. Upon receipt of the acknowledgment form, arrangements will be made for the shipment of replacement Pad-Pak(s) at no charge to you.
3. In the interim, please continue monitoring the AED to ensure the status indicator is flashing green every 5 to 10 seconds. Please contact your Authorized Distributor or HeartSine Technologies immediately if you identify either of the following situations:
 - a. If the status indicator is flashing red or you hear continuous beeping.
 - b. If there is no status indicator operative.
4. Once you receive the replacement Pad-Paks, please destroy the affected Pad-Paks per local disposal guidelines.
5. Maintain awareness of this communication internally until the required action has been completed within your facility.
6. Inform your authorized distributor if any of the subject Pad-Paks have been distributed to other organizations.
 - a. If further distributed, please send an email to Rescue 7 at support@rescue7.net notifying them of further distribution.

We thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

Bhumil Shah
Rescue 7 Inc.

Acknowledgement Form

Attn: Risk Management/Recall Coordinator
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Customer Name: _____
 Customer Address: _____

Response is required:

Please complete and sign this form. Return the completed form by email to support@rescue7.net

The quantities indicated below will be replaced upon receipt of this acknowledgment form. This form must be returned in order to receive replacement product.

Product Number	Lot Number	Quantity

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed			
Facility Name		Contact Person	
Full Address			

Form completed by:

Printed Name		Title	
Signature		Phone	
Date		Email	

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.