stryker

Urgent: Medical Device Recall

HeartSine® samaritan® PAD

Pad-Pak-01, Pad-Pak-02, and Pad-Pak-07

Customer name: <<merge file>>

Customer #: <<merge file>>

Attn: AED Program Manager/Safety Manager

Recall number: PR4068245 - FA327

<<September 2025>>

This Urgent Medical Device voluntary recall is being issued to alert customers with Pad-Paks that have expiry date between April 17, 2025 – August 1, 2029, of a potential bent locator pin issue, and to provide instructions to ensure the Pad-Pak is properly inserted into the SAM PAD device.

Product description

Both the Adult and Pediatric Pad-Pak accessories to the HeartSine samaritan PAD device contain the battery to power the AED, and two electrode pads to provide the electrical connection to the patient's chest for delivery of defibrillation shock.

Product issue

Post-market surveillance has revealed that the Pad-Paks are not always inserted properly into the HeartSine samaritan PAD devices as outlined in the IFU, which can create failure during device use. In the event the device is unable to complete connection, the device will repeatedly prompt "Apply Pads to patient's bare chest". In some cases, the AED device may fail to power on entirely.

Upon investigation, two potential causes of the improper insertion of Pad-Paks include use error and bent locator pins, which may occur during the manufacturing process.

Potential risks

The connection issues that may arise from improper insertion of the Pad-Pak are not always obvious to the user when the Pad-Pak is inserted into the HeartSine samaritan PAD device. If the Pad-Pak is not properly inserted into the HeartSine samaritan PAD device, or if the Pad-Pak locator pins are bent, the device **may** fail to deliver the intended therapy during use, potentially leading to a delay in treatment or no treatment being delivered during use. A delay in treatment or no treatment may result in serious injury or death.

Complaint information

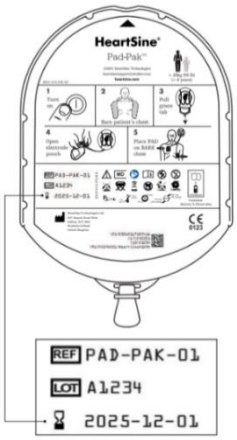
Since 2018, 120 complaints were reported among more than 1,447,266 Pad-Paks in service worldwide. Of these, there have been **36 adverse events** of which five were confirmed to be caused by bent locator pins, two devices were not returned for investigation and 29 were determined to be related to potential use error.

Customer actions needed:

To ensure the device works correctly in an emergency, follow the instructions below to ensure that the Pad-Pak is securely and correctly installed.

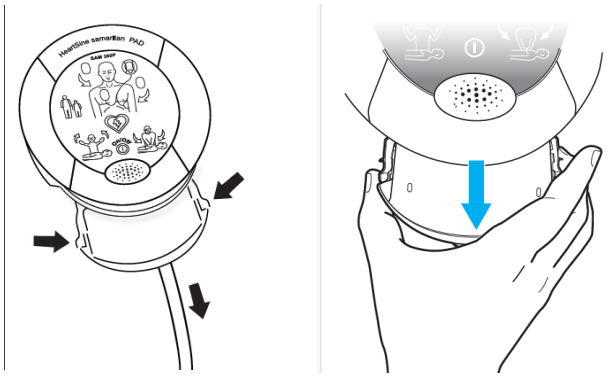
A. **Check the expiry date on your Pad-Pak:**
The expiry date can be found on the rear of the Pad-Pak (see diagram at right or refer to section "Set up your AED" in the IFU).

a. If your Pad-Pak expires between April 17, 2025 – August 1, 2029 proceed to ***Step B*** below.

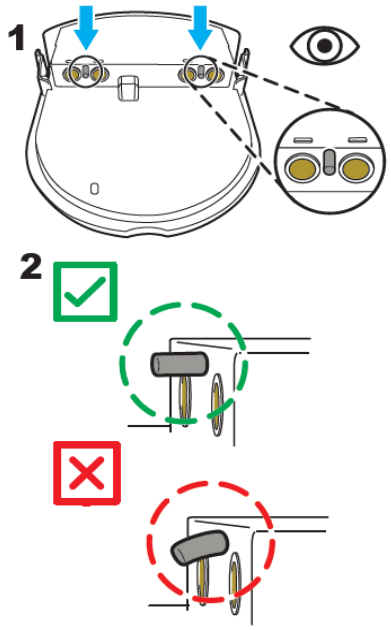


B. **Check for bent locator pins:**

- Place the HeartSine samaritan PAD device face up on a table or other flat surface.
- Squeeze the tab on each side of the Pad-Pak as shown on the right.
- Pull to remove the Pad-Pak from the device.



- Once the Pad-Pak is removed from the device, check the locator pins (blue arrows in Step 1 at the right) to ensure they are straight and not bent, as shown in Step 2 at the right.
  - If locator pins are straight, proceed to ***Step C*** below to follow Pad-Pak insertion instructions.
  - If pins are bent:
    - Remove that Pad-Pak from your device, and set it aside. Pull another Pad-Pak from your inventory, verify locator pins are straight, then proceed to ***Step C*** below, to properly insert the Pad-Pak into the device.
    - If you do not have an additional Pad-Pak in your inventory, remove the device from service and proceed to ***Step D*** below.



C. **Follow Pad-Pak insertion instructions:**

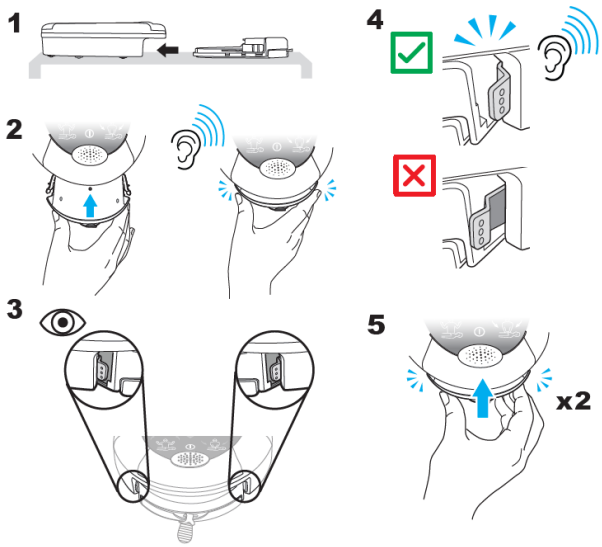
Illustration 1: Place your HeartSine samaritan PAD device and the Pad-Pak face up on a table or other flat surface.

Illustration 2: Slide the Pad-Pak into bottom of the AED as shown until you hear the "double click" and look at both clips to ensure they are correctly engaged.

Illustration 3: Look at both clips to ensure they are correctly engaged.

Illustration 4: Correctly engaged clips will click in and sit snugly/tightly against the AED with no gap as per the green tick. Incorrectly engaged clips will not click and will have a gap as shown in the image with the red x.

Illustration 5: Push the Pad-Pak in one last time to ensure correct engagement. Once you've verified proper insertion, return the device to its storage location for use.



Proceed to ***Step D*** – submit your response.

D. **Submit your response:**
Submit your response online at: heartsinerecall.com. **A response is required in all instances.**
   - **a.** Follow the online instructions to acknowledge receipt of this information, confirm that you've completed the required actions, and indicate whether any locator pins may be bent.
   - **b.** If you report any pad-paks with bent locator pins, Stryker will provide replacements. Once your acknowledgement form is received, Stryker will contact you with next steps regarding the replacement process.

E. **Maintain awareness:** Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility.

F. If you have further distributed affected product(s), please forward a copy of this notice to the new responsible party and email RSRecall@stryker.com with both the location to which the product(s) was/were further distributed to and the quantity and lot number for any Pad-Paks that have been disposed of.

Stryker's planned action:

Stryker is notifying all customers who have received affected Pad-Paks to perform the actions outlined above by <<DD-MON-YYYY>>. On behalf of Stryker, we thank you sincerely for your response and regret any inconvenience that may be caused.

If you have any questions or concerns, please contact Stryker Customer Service at +1 800 787 9537, option 2, from 8:00 AM to 7:00 PM (Eastern Time), Monday–Friday, or HeartSine Technologies Technical Support at heartsinesupport@stryker.com.

The U.S. Food and Drug Administration has been notified of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.