stryker

URGENT
MEDICAL DEVICE RECALL

# HeartSine® samaritan® PAD
# Pad-Pak-01, Pad-Pak-02, Pad-Pak-07

**Attn: AED Program Manager/Safety Manager**
**Recall number: PFA 4068245 - FA327**
**September 2025**

Please be advised, Stryker is issuing a voluntary medical device recall 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 patient expiry.

**Complaint information**

Since 2018, more than 1.4 million Pad-Paks have been used worldwide, with 120 complaints reported during that time. 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.

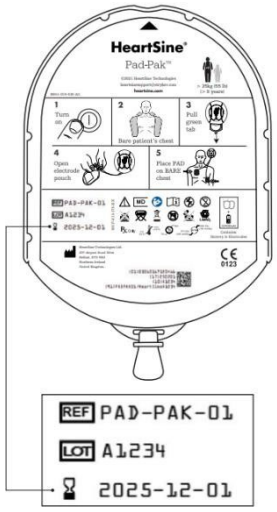
Please continue to next page for customer actions.

## 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.

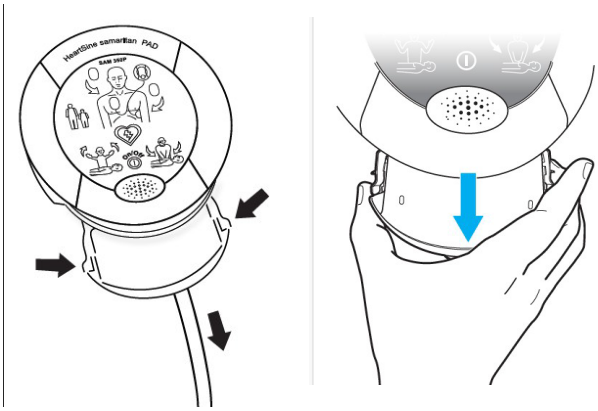
A. **Check the expiry date on your Pad-Pak:**
The expiry date can be found on the rear of the Pad-Pak (see diagram at right or refer to section "Set up your AED" in the IFU).

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



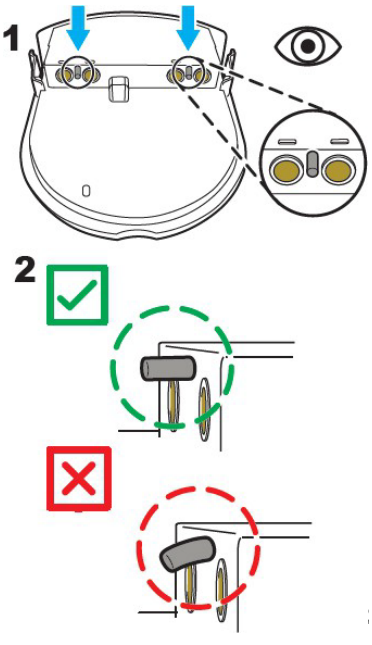

B. **Check for bent locator pins:**

- 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) 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 the 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:**

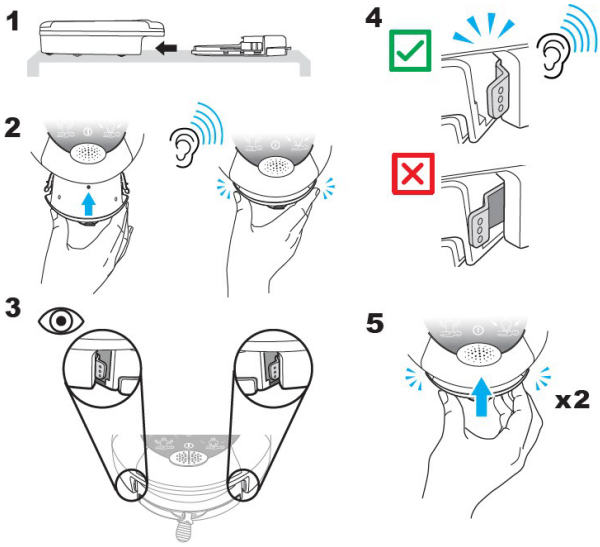
**Illustration 1:** Place your HeartSine samaritan PAD device and the Pad-Pak face up on a table or other flat surface.

**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 by completing the Appendix A – Business Reply Form and submit via email to: support@aedrecall.ca

E. If you report any pad-paks with bent locator pins, Rescue 7 Inc. will provide replacements. Once your acknowledgement form is received, Rescue 7 Inc. will contact you with next steps regarding the replacement process.

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

## Stryker's planned action:

Stryker is notifying all customers who have received affected Pad-Paks to perform the actions outlined above by September 28, 2025. On behalf of Stryker and Rescue 7 Inc., we thank you sincerely for your response and regret any inconvenience this may have caused.

If you have any questions or concerns, please contact AED recall team via email: support@aedrecall.ca or toll free number: 1-888-878-5094

# Appendix A

## Business Reply Form

### HeartSine® samaritan® PAD
### Pad-Pak-01, Pad-Pak-02, Pad-Pak-07
**Recall number: PFA 4068245 - FA327**
**September 2025**

**Response to this Notification is required. Please complete and sign this form.**
Email the completed form to support@aedrecall.ca by **26-09-2025.**

Company name: _____
Company address: _____

A. # of Pad-Paks with bent pins*:

| Product # | Quantity with Bent Pins |
|---|---|
| PAD-PAK-01 | |
| PAD-PAK-02 | |
| PAD-PAK-07 | |

* Rescue 7 Inc. *will be in contact with you to discuss next steps.*

B. Total # of Pad-Paks verified and properly inserted into the HeartSine Samaritan PAD device(s): _____

C. Have you distributed any Pad-Paks outside of your organization? ___YES ___NO

By signing and submitting this form, I acknowledge receipt of the medical device recall letter, agree I have provided accurate information and approve my responses.

**Form completed by:**

| | | | |
|---|---|---|---|
| **Printed name** | | **Title** | |
| **Signature** | | **Phone** | |
| **Date** | | **Email** | |