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Urgent:
Medical device recall

HeartSine® samaritan® PAD
SAM 350P/SAM 360P/SAM 450P

Customer Name: Pam Foster
Customer Mail ID#: 504
Attn: Safety Manager
Recall Number: PR3977961-FA318

June 2025

This device recall notification is being issued to alert customers with HeartSine samaritan PAD SAM 350P/SAM 360P/SAM 450P devices of a potential device malfunction issue. Out of an abundance of caution, Stryker is completing a voluntary recall of these devices.

Product description

The HeartSine samaritan PAD is a small, lightweight, portable, battery operated Automated External Defibrillator (AED) designed to treat victims of cardiac arrest.

Product issue

It was determined during extensive quality testing that a manufacturing process issue related to a circuit board component **may** impair the device's ability to function or cause failure. This failure could occur at any point when the device is holding a charge in preparation to deliver therapy, while delivering a shock, or after shock delivery. The device becomes inoperable after the failure occurs.

Potential risks

If this issue occurs, 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. **The issue was observed during quality testing, not during patient use. There have been no adverse events reported related to this product issue.**

If your device experiences this issue during use, please seek an alternative defibrillator and contact your Authorized Distributor or HeartSine Technologies Technical Support at: heartsinesupport@stryker.com.

Please continue to next page for customer actions.

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Customer actions needed:

1. **Identify impacted devices** by verifying if your device serial numbers are included in the list at the link below. Instructions for where to locate device serial numbers on the device are found in Appendix A.

   https://www.stryker.com/us/en/emergency-care/product-notices/heartsine/index.html

2. **Submit your response:**
   Electronically via QR Code scan or link: https://bit.ly/fa318-heartsine

   OR

   Response via Email to: RSRecall@stryker.com, including the following:
   a. **Subject:** FA 318 HeartSine T3 – Response from <<<Company Name>>>
   b. **Email Body:**
      1. Customer ID, Customer name, your name, title, email address
      2. The number of devices impacted by model, and serial numbers
      3. Inform us if any of these devices have been distributed to other organizations. We will work with you on how to inform the recipients appropriately.

3. Until a replacement is available, Stryker recommends keeping your HeartSine samaritan PAD in service if you do not have an alternative public access defibrillator. This recommendation is based on internal testing demonstrating a low probability of failure due to this product manufacturing issue.

4. Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility and the unit has been replaced.

Stryker's planned action:
Stryker is notifying all customers who have received affected HeartSine samaritan PAD devices to perform the actions outlined above. Once your response is received and a replacement is available, Stryker will be in contact to arrange the next steps for a replacement device.

Please note that the HeartSine AED is a Class III medical device in the U.S. and requires regulatory approval before a component change can be implemented on the device. Stryker is working diligently with the FDA to ensure a timely approval of the changes.

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.

On behalf of Stryker, we thank you sincerely for your help and support in submitting your response by **August 15, 2025.** We regret any inconvenience that may be caused and would like to reassure you that we are committed to meeting our high internal quality standards and your expectations.

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.

Appendix A

HeartSine® Samaritan® PAD 350P/360P/450P

Instructions to identify impacted devices

1) To find your device serial number and model number, see the labels on the rear of your device as shown below:

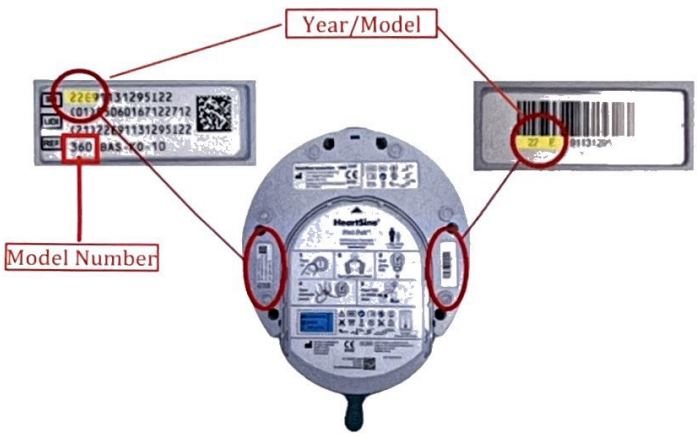

Figure 1 – Serial & Model Number location