

Urgent: Medical device recall

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

Attn: AED Program Administrator
Recall number: PR3977961-FA318



July 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 the following Technical Support Team that is handling your AED voluntary recall action at: info@think-safe.com.

Please continue to next page for customer actions.

Customer actions needed:

1. **Identify impacted devices** by verifying if your device serial numbers are included in the list we have received from Stryker. Instructions for where to locate device serial numbers on the device are found in Appendix A. **Please email us at info@think-safe.com with the AED serial numbers and the information noted in Step 2.**
2. **Submit your response:**
Response via Email to: info@think-safe.com (we are your AED technical support experts) including:
 - a. **Subject: FA 318 HeartSine T3 – Response from <<<Your Organization Name>>>**
 - b. **Email Body:**
 1. Dealer (if any), Your Organization name, Contact name, title, email address, phone
 2. The number of devices impacted & listed 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 & Your Technical Support Expert planned action:

Stryker and Think Safe are 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*, *Think Safe will be in contact to arrange the next steps for a replacement device*. Please mark your calendars with a reminder to check in after six (6) months, if you have not received any communication. Stryker anticipates being able to start shipping replacement devices in later Q4 2025 forward.

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. Think Safe is leading the communication and support for you.

If you have any questions or concerns, please contact Think Safe's Service Team at +1 888 473 1777, option 3, from 9:00 AM to 6:00 PM (Eastern Time), Monday – Friday, or email Think Safe's Technical Support at info@think-safe.com. We are your technical support assigned experts for this recall action.

On behalf of Stryker and Think Safe, we thank you sincerely for your help and support in submitting your response **ASAP**. 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 US 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:

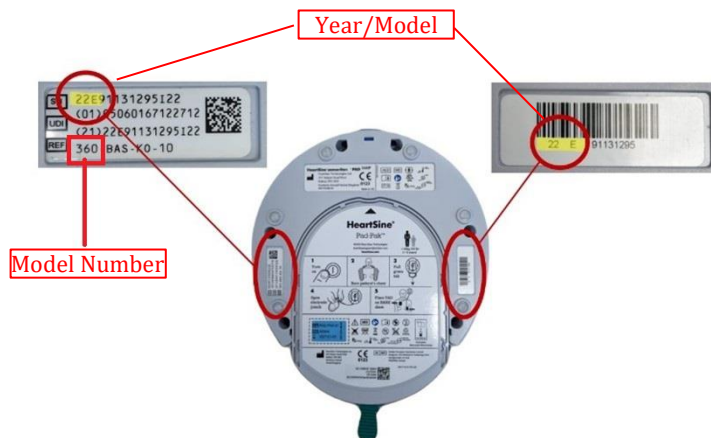


Figure 1 – Serial & Model Number location