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Urgent:
Medical device recall

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

Attn: Safety Manager
Recall number: PR3977961–FA318/FA319/FA334

This device recall notification is being issued to alert customers with HeartSine samaritan PAD SAM 350P/SAM 360P/SAM 450P devices of (1) two potential device malfunctions and (2) a missing maintenance insert. Out of an abundance of caution, Stryker is completing a voluntary recall/removal 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

(1) Stryker informed customers in May 2025 of a manufacturing process issue related to a circuit board component that **may** impair the device's ability to function and/or cause failure. This issue was identified during extensive quality testing.

In addition, Stryker has recently identified an issue with the membrane tail, an internal component, which could cause an intermittent fault. 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.

(2) Stryker has also identified that a limited number of HeartSine samaritan PAD devices were distributed without the required maintenance supplement. This supplement contains periodic maintenance instructions implemented as an additional risk-control measure. While most devices contain the maintenance supplement, this voluntary correction is being initiated to ensure all end users have access to the supplemental maintenance information. This issue was identified through a customer complaint.

Potential risks

(1) Due to internal component issues, 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. These issues were observed during non-standard rework process and quality testing, not during patient use.

(2) The omission of this insert may result in users not performing the recommended quarterly power-cycle check. If the check is not performed, the device may have an undetected audio-prompt failure that could result in reduced device readiness and user confusion. This issue was identified through a customer complaint.

There have been no adverse events reported related to this device recall notification.

If your device experiences any of the above issues during use, please seek an alternative defibrillator and contact your Authorized Distributor or HeartSine Technologies Technical Support at heartsinesupport@stryker.com.

Customer actions needed:

1. **Identify impacted devices** by verifying if your device serial numbers are included in the list at the link below. For this field action notice, please select "AED + Pad-Pak".

   https://heartsinerecall.com/HeartSineSamaritanPAD/LookUp

   a. Instructions for where to locate device serial numbers on the device are found in Appendix A*.

2. **Download** a copy of the missing maintenance supplement when acknowledging the recall and store with your device's user manual until a replacement is received.
3. **Submit your response/acknowledgement** to Stryker electronically for all field actions via this link: https://heartsinerecall.com/HeartSineSamaritanPAD/LookUp
4. 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 these product manufacturing issues.
5. 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 actions:

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 as soon as possible to arrange the next steps for a replacement device.

If you have any questions or concerns, please contact Stryker Recall Support at 1-866-891-0586 from 8:00 AM to 5:00 PM (Eastern Time), Monday – Friday, your Authorized Distributor, 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. 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.

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.

- *Complete and submit the report online.*
- *Regular mail or fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.*

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Appendix A

HeartSine samaritan PAD SAM 350P/SAM 360P/SAM 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:

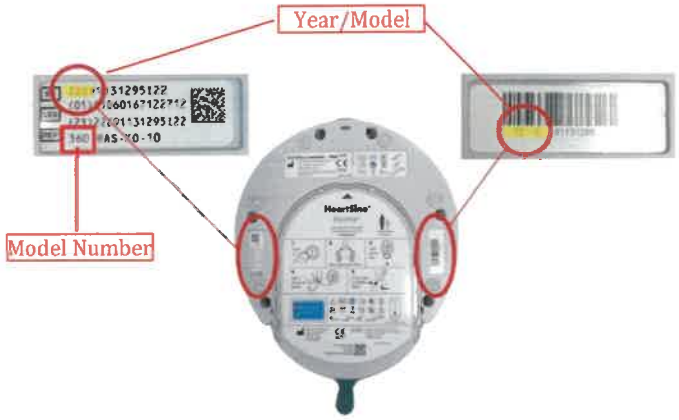

Figure 1 – Serial & Model Number location