stryker

Urgent: Medical device recall

HeartSine® Samaritan® PAD
SAM 350P/SAM 360P/SAM 450P/SAM 500P

Customer name: <<merge file>>
Customer #: <<merge file>>
Attn: Safety Manager
Recall number: RA2025-3977961 (FA318)
<Month DD, YYYY/ DD Month YYYY>

This device recall notification is being issued to alert customers with HeartSine Samaritan PAD SAM 350P/SAM 360P/SAM 450P/SAM 500P 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

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 HeartSine Technologies Technical Support at heartsinesupport@stryker.com.

Please continue to next page for customer actions.

Customer actions needed:

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

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

2. **Submit your response:**

   a. **Complete the Business Reply Form below & email to** <<<emailaddr>>>

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 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.

Please note that the HeartSine AED is a Class III medical device.
In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

If you have any questions or concerns, please contact Customer Service +1 800 XXX XXXX.

On behalf of Stryker, we thank you sincerely for your help and support in submitting your response by <MMM DD YYYY. 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.

Business Reply Form

Customer number:
Account name:
Account Address:

HeartSine® Samaritan® PAD
SAM 350P/SAM 360P/SAM 450P/SAM 500P

Recall Number: RA2025-3977961 (FA318)
<Month DD, YYYY/ DD Month YYYY>

Product affected:
Serial Numbers: Please refer to this site, or scan the QR code for list of SNs impacted by this recall:

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

Response is required: Complete and sign this form, then email the completed form to <<<emailaddr>>>, by **<MMM DD YYYY>**.

Identify the affected devices below.
Appendix A provides instructions on where to locate Serial Number/Model information.

Product	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
SAM 350P						
SAM 360P						
SAM 450P						
SAM 500P						

Have you further distributed any affected product: _____ YES _____ NO
Please send an email to <<<emailaddr>>>, *notifying Stryker of further distribution. Stryker will work with you to ensure recipients are notified appropriately.*

Form completed by:

Company Name		**Your Name & Title**	
Signature		**Phone**	
Date		**Email**	

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Appendix A

HeartSine Samaritan PAD SAM 350P/SAM 360P/SAM 450P/SAM 500P

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:

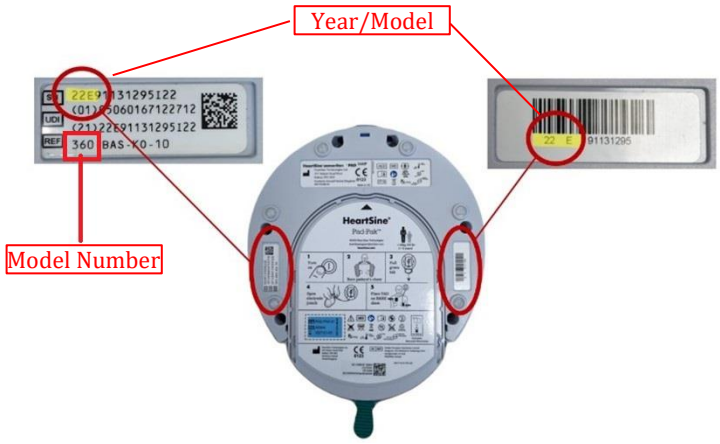

Figure 1 – Serial & Model Number location