

Urgent:
Medical device field action**HeartSine® samaritan® PAD**
SAM 350P/SAM 360P/SAM 450P/SAM 500P**Customer name:** <<merge file>>**Customer #:** <<merge file>>**Attn: Safety Manager****Field action number: PR4257283 – FA334****<Month DD, YYYY/ DD Month YYYY>**

Model	Serial Numbers	UDI-DI
350P 360P 500P	A subset of serial numbers has been affected by this notice. Please check if your AED serial number is affected by visiting the HeartSine PFA Global Landing Page below: https://heartsinerecall.com/HeartSineSamaritanPAD/LookUp If your device is listed, please follow the instructions provided in this letter.	08858251002132S4

Stryker has initiated a serial-specific Safety Notice for the devices listed in the table above. This device notification is being issued to alert customers with HeartSine samaritan PAD SAM 350P/SAM 360P/SAM 450P/SAM 500P devices of a missing maintenance supplement. Out of an abundance of caution, Stryker is completing a voluntary **correction** 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. Affected devices were received by customers within March 11, 2024 – February 18, 2025.

Product issue Stryker has identified a limited number of HeartSine samaritan PAD devices that 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 supplemental maintenance information. This issue was identified through a customer complaint.

Potential risks Omission of this supplement 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.

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. For devices available in your inventory & Stryker direct customers/distributors:

- a. Instructions for where to locate device serial numbers on the device are found in Appendix A*.
- b. If you have more than 15 devices and would like a list of impacted serial numbers, please email <Insert Local Email>@stryker.com:
 - Subject: FA334 - Impacted device list - <<your company name>>
 - Be sure to include your name and phone number in case we need to reach out to you.

B. For devices you have transferred to other users (Non-Stryker direct customers/distributors):

- a. Instructions for where to locate device serial numbers on the device are found in Appendix A*.
- b. If you have further distributed any affected product, please provide this notification to the relevant recipients. **Recipients who are not direct Stryker customers should respond to the facility or organization from which they receive this notification and **not directly to Stryker**.*
- c. Email your Stryker representative at xxxxx@stryker.com when you have collected all the responses from your end-users.

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 via this link: <https://heartsinerecall.com/HeartSineSamaritanPAD/LookUp> and/or email xxxxxx@stryker.com the enclosed Business Reply Form by [<Insert Date>](#).
4. Maintain awareness of this communication internally and near the affected unit until all required actions have been completed within your facility.

Stryker's planned actions:

Stryker is notifying all customers who have received affected HeartSine samaritan PAD devices to perform the actions outlined above.

If you have any questions or concerns, please contact Stryker Customer Service at [<Insert Info Here>](#), your Authorized Distributor, or HeartSine Technologies Technical Support at heartsinesupport@stryker.com.

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.

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.

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:

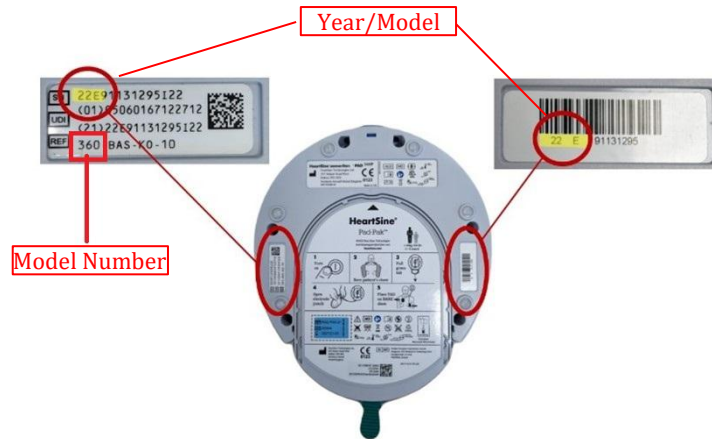


Figure 1 – Serial & Model Number location