stryker

Urgent:
Medical device field action

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

Attn: Safety Manager
Field action number:
PR3977961 – FA318
PR4280335 – FA319
PR4257283 – FA334
September 2026



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.	088582510021325S4

Stryker has initiated a serial-specific Urgent Recall and a Safety Notice for the devices listed in the table above. This device recall notification is being issued to alert customers with HeartSine® samaritan® PAD 350P/360P/500P devices of two potential device function problems (1) and a missing maintenance supplement (2) for a limited number of devices. Out of an abundance of caution, Stryker is issuing this notice.

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)(PR3977961 – FA318) 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.

(1)(PR4280335 – FA319) 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)(PR4257283 – FA334) 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) (PR3977961 – FA318 & PR4280335 – FA319) 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) (PR4257283 - FA334) The 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.

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. 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 fieldactionnby@stryker.com :
      - Subject: FA318/FA319/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 fieldactionnby@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 for all field actions via this link: https://heartsinerecall.com/HeartSineSamaritanPAD/LookUp and/or email fieldactionnby@stryker.com with the enclosed Business Reply Form.

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.

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 Stryker Customer Service at capitalorders@stryker.com, 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.

Sincerely,

Ramzi el Bawab

Manager, Regulatory Affairs
RAQA UK, Ireland, and Northern Europe

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:

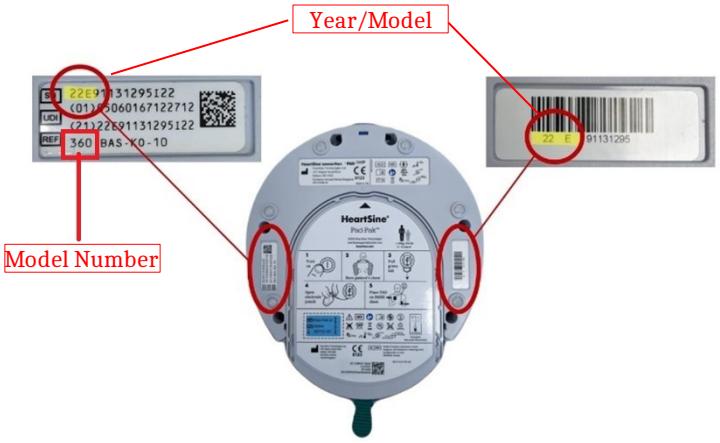


Figure 1 – Serial & Model Number location