# URGENT:
# MEDICAL DEVICE RECALL

## HeartSine® Samaritan® PAD 350P/360P/500P

**Attn: Safety Manager**
**PFA 3977961**
**May 14, 2025**
**FIRST NOTICE**

This device recall notification is being issued to alert customers with HeartSine® Samaritan® PAD 350P/360P/500P devices of a potential device function issue. Out of an abundance of caution, Stryker is completing a voluntary removal of these devices.

Review the information in this letter, collect a count of your devices per model (details below), and then submit your response to Stryker by June 14, 2025.

**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 rigorous quality testing that a manufacturing process-related issue **may** impair the device's ability to function or cause failure. The likelihood of this occurring is 0.0128% (low/remote).

**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. 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 your Authorized Distributor.

Once your response is received, Stryker will be in contact within the next 90 days to arrange next steps for device replacement. Note that the HeartSine AEDs are Class III and Class IV medical devices in Canada and require regulatory approval before changes can be implemented on the devices. Stryker is working diligently to ensure a timely approval of the changes.

In the interim, it is recommended by Stryker to keep your HeartSine® Samaritan® PAD in service until a replacement device is available. The likelihood of an occurrence is low/remote widespread deployment of public access defibrillators results in an overall benefit to society as in most instances, the device will function without failure.

## Stryker's Planned Actions:

The company is notifying all customers who have received HeartSine® Samaritan® PAD devices within the identified range of potentially affected devices to perform the actions outlined below. Once your response is received, Stryker will be in contact within 90 days to arrange the next steps for a replacement device.

## Customer Actions needed

1. Identify impacted devices:
    a. Check your internal inventory using the instructions in Appendix A to locate model and serial numbers of impacted products:
        - Affected Serial Numbers begin with **22, 23, 24**, followed by letter **B, D, E, or G**.
        - Collect the total number of impacted devices, grouped by model number, you will need this information for your response. Example: Model 350=7, Model 500=10

2. Submit your Response via email to postmarket.canada@stryker.com and include the following:
    - Subject: PFA 3977961 HeartSine T3 – Response from <<<Company Name>>>
    - Email body:
        - Customer ID
        - Customer Name, Your Name, Title, Email Address
        - The number of impacted devices by model
        - 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.

In the interim, Stryker recommends keeping your HeartSine® Samaritan® PAD in service, and maintain awareness of this communication internally until all required actions have been completed within your facility.

If you have any questions or concerns, please contact Customer Service +1 800 668 8323.

On behalf of Stryker, we thank you sincerely for your help and support in submitting your response by **June 14, 2025**. 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.

stryker

# Business Reply Form

**Customer number:**_____
**Account name:**_____
**Account Address:**_____

## HeartSine® Samaritan® PAD 350P/360P/500P

**PFA 3977961**
**May 14, 2025**

### Product affected

| Model | Serial Numbers |
|---|---|
| SAM 350P<br>SAM 360P<br>SAM 500P | Device serial numbers consist of 2-digit year prefix, a letter for device model code and 8-digit serial number string.<br>• Impacted devices begin with 22,23,24<br>• Followed by model reference B, D, E, or G<br>Example: **22D00001234** |

**Response is required:** Complete and sign this form, then email the completed form to postmarket.canada@stryker.com by **June 14, 2025**.

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

| Product | Quantity on hand |
|---|---|
| 350P | |
| 360P | |
| 500P | |

**Have you further distributed any affected product:** _____ YES _____ NO

*Please send an email to postmarket.canada@stryker.com, 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 350P/360P/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:

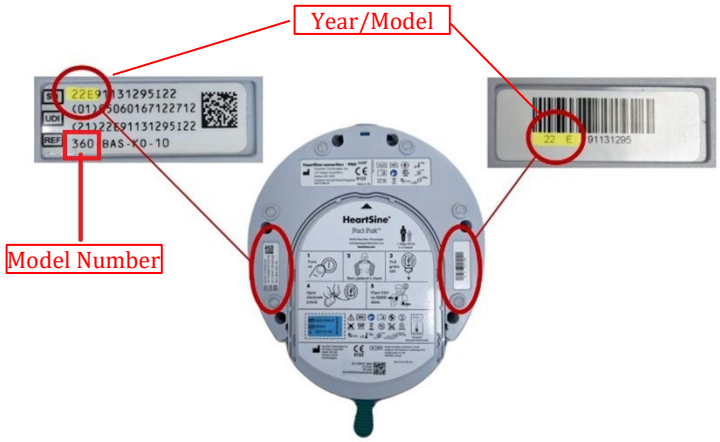


*Figure 1 – Serial & Model Number location*

Impacted devices are:

- Model number 350P, 360P, 500P
- Serial numbers beginning with 22,23,24, then followed by letter B, D, E, or G