Urgent Field Safety Notice: RA2024-3540155 FA305

Recall Number: RA2024-3540155 FA305
April 2024

Affected Products: HeartSine® Samaritan® PAD 350P/360P/450P/500P, Omron HDF-3500

Product Model	Serial Numbers
SAM 300P SAM 350P SAM 360P SAM 450P SAM 500P OMRON HDF-3500	Device serial numbers consist of a 2-digit prefix, device model code and 8-digit serial number string. Please see *Appendix A* for instructions on identifying your device Serial Number. The prefix (device identifier) consists of the manufacturing year (**YY**) and the device model (**B, C, D, E, G, or H**). See example below: **16B00001234** Devices affected by this notification begin with the following prefixes and device codes: 16B, 16C, 16D, 16E, 16G, 16H 17B, 17D, 17E, 17G, 17H 18B, 18D, 18E, 18G, 18H 19B, 19D, 19E, 19G, 19H 20B, 20D, 20E, 20G, 20H 21B, 21D, 21E, 21G, 21H 22B, 22D, 22E, 22G, 22H 23B, 23D, 23E, 23G, 23H 24B, 24D, 24E, 24G, 24H

Product description

The HeartSine Samaritan PAD and Omron HDF-3500 are small, lightweight, portable, battery operated Automated External Defibrillators (AEDs) designed to treat victims of cardiac arrest.

Product issue

We have determined that a manufacturing related issue may impair device audio prompts. Stryker is issuing a customer notification to remind customers to follow the User Manual and power the device upon receipt to ensure the audio prompts function as intended.

Potential risks

The issue could prevent the device from delivering instructional voice prompts to the user during use of the device. The device has visual instructional icons still present and is functional, but if the issue is not identified by the customer prior to use, it could potentially lead to no therapy or a delay in therapy. In addition, there may be risk of shock to the user due to the absence of the "stand clear" voice prompt. **There has been one reported serious incident to date in which the device failed to deliver audio prompts.** Serious incidents or quality problems experienced with the use of this product may be reported to the Stryker Representative.

Stryker's planned actions:

The company is notifying all customers that have HeartSine Samaritan PAD & Omron HDF-3500 devices within the identified range of potentially affected devices to perform the actions outlined below.

Customer actions needed:

1. Inspect your device inventory to identify if you have any of the devices with affected serial numbers listed on page 1.
    a. If devices with the specified serial number prefixes are found, please follow the instructions to power cycle your device listed in *Appendix A.*
    b. HeartSine Technologies recommends that the user carries out the check in *Appendix A*, Step 6-Step 8, **once every three months**. This can be carried out quickly without removing the AED from its case.
2. Complete *Appendix B* – Business Reply Form and return to nina.goddard@stryker.com
3. Create awareness of this communication internally.
4. If you have further distributed this product to other organizations, proceed to inform them about the present Field Safety Notice.
5. If your device does not deliver any voice prompts:
    a. Please remove the device from use and segregate it immediately.
    b. On receipt of *Appendix B – Business Reply Form*, the Stryker Representative below will contact you to organize return and replacement of the device to Stryker.

We request that you respond to this notice within 60 calendar days from the date of receipt.

Please respond even if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

The Stryker Representative for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Aman Auluck
Position: Associate Manager, Post Market Surveillance
Email: amandip.auluck@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 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 completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

Nina Goddard
Regulatory Affairs and Quality Assurance

Attachment:
Appendix A – Instructions to Identify and Power Cycle Device
Appendix B – Business Reply Form

Appendix A

HeartSine Samaritan PAD 350P/360P/450P/500P, Omron HDF-3500 RA2024-3540155 FA305

Instructions to Identify Serial Number and Power Cycle Device

1) To find your device serial number, see the labels on the rear of your device as shown below:

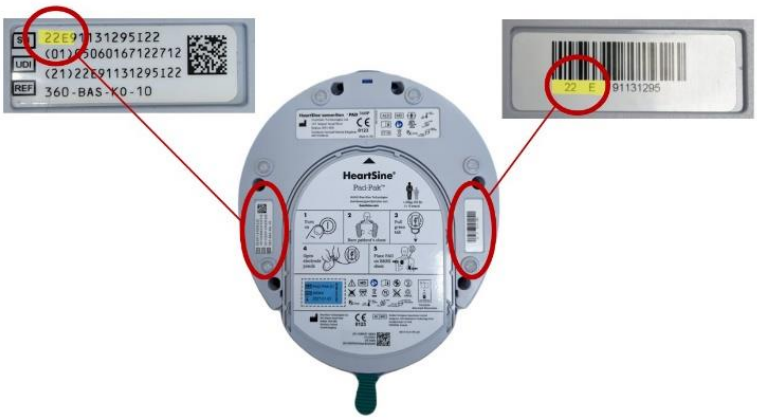

Figure 1 – Locating the device Serial Number & Prefix

The prefix of your device will depend on the year and device model. Please check your prefix against the table in this letter to determine if your device is affected.

2) If your device serial number prefix is present within the table on this letter, please perform the following steps to check your device delivers audio prompts.

3) Check the expiration date (YYYY-MM-DD) on the rear of the Pad-Pak (Figure 2). If the expiration date has passed, do not use and immediately replace the expired Pad-Pak.

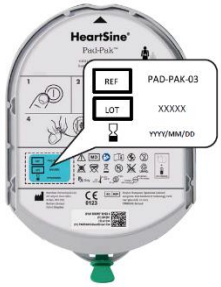

Figure 2 – Pad-Pak Expiry

4) Place the HeartSine Samaritan PAD face up on a flat surface and slide the Pad-Pak into the HeartSine Samaritan PAD until you hear the “double click” to indicate that the tabs on the right and left sides of the Pad-Pak are fully engaged.

Figure 3 – Inserting a Pad-Pak

5) Verify that the green Status indicator is blinking to indicate the initial self-test routine has been performed and the device is ready for use.

6) Press the On/Off button to turn on the HeartSine Samaritan PAD.

7) Listen for, but do not follow, the voice prompts to ensure you can hear the prompts and no warning messages are played.

   a) If you hear the message "Adult patient,'' or ''Call for medical assistance'" no further action is needed.

b) If you do not hear a prompt:

- Please remove the device from use and segregate it immediately.
- On receipt of *Appendix B – Business Reply Form*, the Stryker Representative below will contact you to organize return and replacement of the device to Stryker.

Name: Aman Auluck
Position: Associate Manager, Post Market Surveillance
Email: amandip.auluck@stryker.com

8) Press the On/Off button to turn off the HeartSine 4Samaritan PAD. Verify that the status indicator is flashing green. If you have not heard a warning message and the status indicator continues to flash green, the device is ready for use.

9) HeartSine Technologies recommends that the user carries out this check (Step 6- Step 8) **once every three months**. This can be carried out quickly without removing the AED from its case.

10) Although this audio issue will not cause a warning message, if any other warning messages are played, or you see a red flashing status indicator, please refer to User Manual (General Troubleshooting).

Appendix B

Business Reply Form

HeartSine Samaritan® PAD (Public Access Defibrillator) 350P/360P/450P/500P, Omron HDF-3500

Recall Number: RA2024-3540155 FA305
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Affected Products:

Product Description	Serial Numbers
SAM300P SAM 350P SAM 360P SAM 450P SAM 500P OMRON HDF-3500	Device serial numbers consist of a 2-digit prefix, device model code and 8-digit serial number string. Please see Appendix A for instructions on identifying your device Serial Number. The prefix (device identifier) consists of the manufacturing date (**YY**) and the device model (**B, C, D, E, G, or H**). See example below: **16B00001234** Devices affected by this notification begin with the following prefixes and device codes: 16B, 16C, 16D, 16E, 16G, 16H 17B, 17D, 17E, 17G, 17H 18B, 18D, 18E, 18G, 18H 19B, 19D, 19E, 19G, 19H 20B, 20D, 20E, 20G, 20H 21B, 21D, 21E, 21G, 21H 22B, 22D, 22E, 22G, 22H 23B, 23D, 23E, 23G, 23H 24B, 24D, 24E, 24G, 24H

Response is required: Please complete and sign this form. Return the completed form by email to nina.goddard@stryker.com

☐ **I confirm that I have checked all my inventory and power cycled the devices to check the presence of voice prompts.**

☐ **I have no devices in my inventory. (**please fill in the Table 2 if you have further distributed**)**

Table 1:

Note: Please fill in the next table to add the **devices without voice prompts.**

Part Number	Serial Number of the device without voice prompts

Table 2:

If you have further distributed subject devices, please provide information below:

Product code	Serial Number

Note: *I have read and understand the instructions provided and acknowledge receipt of the subject Field Safety Notice. I will carry out the check in Appendix A, Step 6 – Step 8, once every three months. I also agree to further distribute and communicate this important information from this letter to those to whom I distributed any of the subject devices noted in this letter and perform at least 3 attempts to non-responsive end customers. Please collect all forms from your customers and provide Stryker a collective form.*

Form completed by:

Company Name		**Contact person**	
Address		**Title**	
Email		**Phone**	
Date		**Signature**	