stryker

URGENT:
MEDICAL DEVICE FIELD CORRECTION

Attn: Safety Manager
Recall Number: PR3224192-FA305
April 2024

Affected Products: HeartSine® samaritan® PAD 350P/360P/450P

Product Model	Serial Numbers
SAM 350P SAM 360P SAM 450P	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 (**D, E, or G**). See example below: **16D00001234** Devices affected by this notification begin with the following prefixes and device codes: 16D, 16E, 16G 17D, 17E, 17G 18D, 18E, 18G 19D, 19E, 19G 20D, 20E, 20G 21D, 21E, 21G 22D, 22E, 22G 23D, 23E, 23G 24D, 24E, 24G

Product description

The HeartSine samaritan PADs 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 adverse event to date in which the device failed to deliver audio prompts.** Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Stryker's planned actions:

The company is notifying all customers that have HeartSine samaritan PAD 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* – Acknowledgement Form and return to RSRecall@stryker.com.
3. Maintain awareness of this communication internally within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organizations. If further distributed, please send an email to RSRecall@stryker.com notifying Stryker of further distribution. Stryker will work with you to ensure recipients are notified appropriately.
5. If your device does not deliver any voice prompts, please contact your Authorized Distributor or HeartSine Technologies Technical Support at: *heartsinesupport@stryker.com.*

If you have any questions or concerns, please contact HeartSine Customer Support at +44 28 9093 9400, 9:00 A.M. to 5:00 P.M. (GMT), Monday – Friday or by email at RSRecall@stryker.com.

Sincerely,

Saijal Naik
RAQA Manager
Email: Saijal.Naik@stryker.com
Phone: 469 289 8909

Attachment:

- Appendix A – Instructions to Identify and Power Cycle Device
- Appendix B – Acknowledgement Form

Instructions to Identify and Power Cycle Device

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

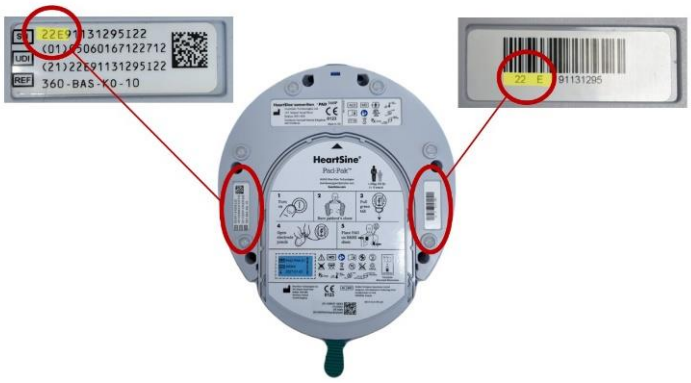

Figure 1 – Locating the device Serial Number & Prefix

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.

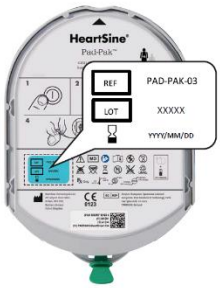

Figure 2 – Pad-Pak Expiry

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.
   a) If you do not hear a prompt, contact your Authorized Distributor or HeartSine Technologies Technical Support at: heartsinesupport@stryker.com.
   b) If you hear the prompt "Adult patient" and/or "Call for medical assistance", no further action is needed.

8) Press the On/Off button to turn off the AED. 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

HeartSine samaritan® PAD (Public Access Defibrillator) 350P/360P/450P

Recall Number: PR3224192-FA305
April 2024

Account Name:

Account Address:

Affected Products:

Product Description	Serial Numbers
SAM 350P SAM 360P SAM 450P	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 (**D, E, or G**). See example below: **16D00001234** Devices affected by this notification begin with the following prefixes and device codes: 16D, 16E, 16G 17D, 17E, 17G 18D, 18E, 18G 19D, 19E, 19G 20D, 20E, 20G 21D, 21E, 21G 22D, 22E, 22G 23D, 23E, 23G 24D, 24E, 24G

Response is required: Please complete and sign this form. Return the completed form by email to RSRecall@stryker.com by **May 15, 2024**

Please indicate how many affected devices you have: _____

Did you power cycle your device(s) and check for the presence of audio prompts: _____ YES _____ NO

Did your device(s) deliver audio prompts: _____ YES _____ NO

Will you carry out the check in *Appendix A,* Step 6 – Step 8, once every three months? _____ YES _____ NO

Have you further distributed any affected product: _____ YES _____ NO
Please send an email to RSRecall@stryker.com notifying Stryker of further distribution. Stryker will work with you to ensure recipients are notified appropriately.

Form completed by:

Printed 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.