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URGENT:
MEDICAL DEVICE SAFETY NOTICE

Attn: Customer Name

Attn: Customer Contact Person
Safety Notice Number: PR3540155-FA305
February 20, 2024

Affected Products:

HeartSine® samaritan® PAD (Public Access Defibrillator) 350P/360P/500P

Product Description	Serial Numbers
SAM 350P SAM 360P SAM 500P	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, D, E, G, or H**). See example below: **16B00001234** Devices affected by this notification begin with the following prefixes and device codes: 16B, 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 PADs are small, lightweight, portable, battery operated Automated External Defibrillators (AEDs) designed to treat victims of cardiac arrest.

Product issue

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

Potential risks

The issue could prevent the device from delivering instructional voice prompts to the user during use of the device; however, the visual instructional icons will still be present. There has been one reported adverse event to date in which the device failed to deliver audio prompts.

Stryker's planned actions:

The company is notifying all customers that have HeartSine samaritan PAD devices within the identified range of potentially affected devices.

Customer actions needed:

1. Inspect your device 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.
2. Maintain awareness of this communication internally until the required action has been completed within your facility.
3. Inform your Authorised Distributor if any of the subject devices have been distributed to other organizations. If further distributed, please notify your Authorised Distributor of further distribution. The Authorised Distributor will work with you to ensure recipients are notified appropriately.
4. If your device does not deliver any voice prompts, please contact your Authorised Distributor to raise a complaint. Authorised Distributor will work with Stryker to support a replacement unit.

If you have any questions or concerns, please contact Distributor at **Distributor Email**.

Sincerely,

Distributor contact name
Contact position
Email: Distributor email

Attachments:
(*as extracted from the User Manual*)

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

Instructions to Identify and Power Cycle Device

(*as extracted from the User Manual*)

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. Check the expiration date (YYYY-MM-DD) on the rear of the Pad-Pak (see Figure 3). If the expiration date has passed, do not use and immediately replace the expired Pad-Pak. If it is within expiration date, please skip step 3 and 4.

Figure 2 – Pad-Pak Expiry

Note: The following steps (3 – 9) are also found in the User Manual that accompany the device.

3) 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

4) 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.
5) Press the On/Off button to turn on the HeartSine samaritan PAD.
6) Listen for, but do not follow, the voice prompts to ensure that no warning messages are played and that the device prompts are in the expected language.
7) Press the On/Off button to turn off the HeartSine samaritan 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.
8) If any warning messages are played, or you see a red flashing status indicator, please refer to Appendix B – Troubleshooting
9) If you have completed the troubleshooting steps and find the device is still not working correctly, contact your Authorised Distributor or HeartSine Technologies Technical Support at: **heartsinesupport@stryker.com**

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Appendix B

HeartSine® samaritan® PAD PAD (Public Access Defibrillator) 350P/360P/500P

Troubleshooting

(as extracted from the User Manual)

Indication	Solution
Flashing red status indicator/continual beeping, or no status indicator light is lit	Check the expiration date on your Pad-Pak (see Set-up on page 15). If the expiration date has passed, immediately replace the Pad-Pak. If the expiration date has not passed, press the On/Off button on the face to turn on the HeartSine samaritan PAD and listen for the voice prompt "Call for medical assistance". Then press the On/Off button again to turn off the device. If either of these actions do not correct the problem, contact your Authorised Distributor or HeartSine Technologies immediately.
"Low battery" warning	While this message does not indicate a fault, you should replace the battery as soon as possible. The first time you hear the message "Warning low battery," the device will continue to function properly. However, it may have fewer than 10 shocks left so prepare the spare Pad-Pak for use and be prepared to swap it quickly. Order a new Pad-Pak as soon as possible.
"Memory full" prompt	This message does not indicate a fault. The memory is full and can no longer record ECG data or events. However, the device can still analyse and deliver a shock if required. Contact HeartSine Technologies Technical Support for guidance on how to clear the memory.
Three rapid beeps when device is turned off or after weekly self-test has been performed	Your device has sensed that the ambient temperature is outside the specified operating range. Return your device to the specified operating conditions of 32°F to 122°F (0°C to 50°C), in which your device, with its battery and electrodes is designed to operate, and verify that the beeping has stopped.
Red status indicator and beeping while device is on	WARNING There is insufficient battery capacity to deliver a shock. Immediately replace the Pad-Pak or seek an alternative defibrillator. If a spare Pad-Pak or alternative defibrillator is not available, the device will continue to analyse the patient's heart rhythm and advise when CPR is needed, but it will not be able to deliver a shock.
"Device service required" warning	WARNING If you hear this message during use, seek an alternative defibrillator immediately. Do not attempt to service the device as no modification of this equipment is possible. Contact HeartSine Technologies or your Authorised Distributor immediately.
"Warning off button pressed" prompt	You have pressed the On/Off button while the AED is being used to treat a patient. If you are sure you want to turn off the AED, quickly press On/Off again.
"Disarming" prompt	This message does not indicate a fault; rather it means that the AED has converted to a decision to not shock after it has initially decided to shock. This occurs when your AED has initially determined that the patient's rhythm is shockable (such as VF) and upon confirming the decision (before proceeding with a shock), the rhythm changed or interference (due to CPR) prevents the confirmation. Continue to follow the device prompts.
"Check pads" prompt	If you hear the voice prompt "Check pads", confirm that the pads have fully adhered to the patient as directed on the electrode placement diagram and

	that the skin is free from hair, moisture and debris. Adjust pads if needed. If message continues, remove the Pad-Pak and reinsert.

Obtaining support

If you have completed the troubleshooting steps and find the device is still not working correctly, contact your Authorised Distributor or HeartSine Technologies Technical Support at: **heartsinesupport@stryker.com**