Urgent Product Defect Correction

17 MAY, 2024

To: Chief Executive Officer – CEO
Attention: Distributors and End Users of HeartSine® Defibrillators

TGA Reference #: RC-2024-RN-00356-1
ARTG #: 156690 – SAM 350P and SAM 500P
228210 – SAM 360P
Product Field Action #: RA 3540155

Catalogue	Product Model	Serial Numbers
350BASUK10 350BASUKGW	HeartSine SAM 350P	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
360BASSJ10 360BASUK10 360BASUKGW 360STRUK10	HeartSine SAM 360P	
500BASUK10 500BASUKGW	HeartSine SAM 500P	

Stryker has initiated a lot-specific Medical Device Product Defect Correction for the HeartSine Defibrillators listed in the table above, to remind customers to follow the User Manual and power the device upon receipt to ensure the audio prompts function as intended.

Product Description

The HeartSine samaritan® Public Access Defibrillators (PAD) are small, lightweight, portable, battery operated Automated External Defibrillators (AEDs) designed to treat victims of cardiac arrest.

Product Issue

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.

Additional maintenance instructions are being issued a Maintenance Supplement to the User Manual, to ensure audio prompts function as intended:

"Please store this supplement with your user manual/user handbook and AED.
As part of the monthly maintenance check, HeartSine Technologies recommends that the user performs the following check once every three months. This can be done quickly, without removing the AED from its case.

- *Press the On/Off button to turn on the AED.*
- *Listen for, but do not follow, the voice prompts to ensure you can hear the prompts.*
  - *If you do not hear a prompt, contact your authorized distributor or HeartSine Technologies directly.*
  - *If you hear the prompt "Adult patient" and/or "Call for medical assistance," no further action is needed.*
- *Press the On/Off button again to turn off the AED and verify that the status indicator is flashing green.*
  - *If you hear a warning message or see a red flashing status indicator, consult Troubleshooting in the user manual/user handbook."*

This Maintenance Supplement can also be found at: https://uk.heartsine.com/product-manuals-old/product-manuals-for-australia/

Potential Hazards & Harms

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 and functioning. There has been one reported adverse event to date in which the device failed to deliver audio prompts. **There have been no adverse events reported in Australia/New Zealand.**

Actions Required

1. Inspect your device inventory to identify if you have any of the devices with affected serial numbers listed on page 1.
2. For **Distributors:**
   a. For devices within your inventory: Please ensure the above Maintenance Supplement is included with all devices upon point of sale.
   b. For devices distributed: Please inform Stryker by emailing postmarketssp@stryker.com. Stryker will work with you to ensure recipients are notified appropriately.
3. **For End Users**: If devices with the specified serial number prefixes are found, please follow the instructions to power cycle your device listed in ***Appendix A***.
   a. Stryker recommends that the user carries out the check in ***Appendix A***, Step 6 to Step 8, **once every three months.** This can be carried out quickly without removing the AED from its case. Note that Steps 6-8 are the same as those in the Maintenance Supplement.
4. Please complete and return **one** of the Acknowledgement Forms to postmarketssp@stryker.com.
   a. **Distributors** – please complete and return the Distributor Acknowledgement Form (Page 6)
   b. **End Users** – please complete and return the End User Acknowledgement Form (Page 7)
5. Please keep a copy of the Maintenance Supplement provided above with your User Manual. This is provided above, or at the following link: https://uk.heartsine.com/product-manuals-old/product-manuals-for-australia/.

6. **If your organisation has distributed devices to other organisations**, please inform Stryker by emailing postmarketssp@stryker.com. Stryker will work with you to ensure recipients are notified appropriately.
7. Maintain awareness of this communication internally.
8. If your device does not deliver any voice prompts, please contact postmarketssp@stryker.com or your Authorised Distributor.
9. Stryker is also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Stryker informed of any adverse events associated with this product by emailing postmarketssp@stryker.com.

We are issuing this notice following consultation with the Therapeutic Goods Administration.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action by the target date and regret any inconvenience that may be caused. If you have any questions, please contact your Authorised distributor, your local Stryker representative or Stryker at postmarketssp@stryker.com or +61 2 9170 9162.

Yours sincerely,

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Appendix A

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

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:

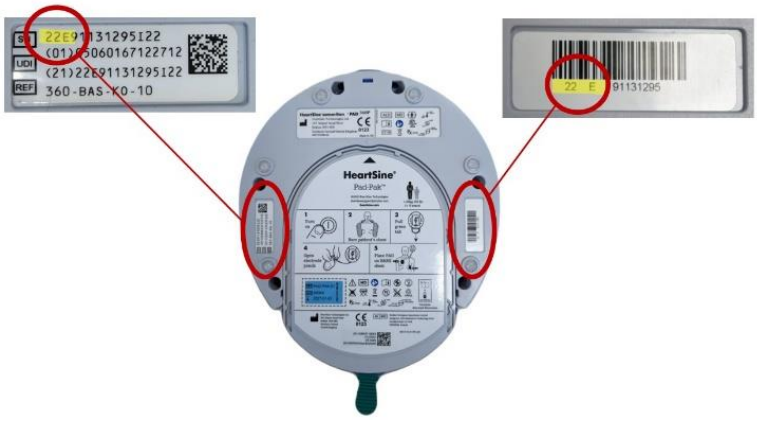

Figure 1 – Locating the device Serial Number & Prefix

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 (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.

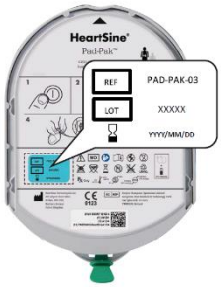

Figure 2 – Pad-Pak Expiry

Note: The following steps (3 – 8) are also found in the User Manual that accompany the device.

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 that no warning messages are played and that the device prompts are in the expected language.
   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, contact your Authorised Distributor or postmarketssp@strkyer.com

8) 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.

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).

Acknowledgement Form - Distributors

1. Please indicate how many affected devices are within your inventory _____(quantity)

2. For devices still within your inventory, you agree to include the Maintenance Supplement found on Page 2/at the following link: https://uk.heartsine.com/product-manuals-old/product-manuals-for-australia/
   ☐ YES ☐ NO

3. Have you provided a list to Stryker of devices that have been further distributed and End Customer contact information?

   ☐ YES ☐ NO

   If NO, please provide this to postmarketssp@stryker.com with the return of this Acknowledgement form.

4. Please tick ONE option for your preferred End Customer Contact Method:

☐ We (the distributor) will contact our End Customers regarding this Urgent Product Defect Correction. We understand that we are required to provide evidence to Stryker of at least three contact attempts to every customer, and all returned End Customer Acknowledgement Forms.

☐ We (the distributor) elect for Stryker to contact our End Customers regarding this Urgent Product Defect Correction. We have provided all available and requested customer contact information for all customers who have received affected devices.

Acknowledgement

By signing below and returning to Stryker, you acknowledge that you have received and understand the enclosed notification, and that all requested actions have been completed.

Any affected devices in your inventory will be provided to End Users with the Maintenance Supplement.

Form completed by:

Printed Name		**Title**	
Facility			
Signature		**Phone**	
Date		**Email**	

Please return a scanned copy via email at postmarketssp@stryker.com

Acknowledgement Form – End Users

This form is also available at the following link: https://form.jotform.com/strykerssp/ra-3540155

1. If known, please provide the name of your Pad-Pak/HeartSine samaritan PAD distributor:

_____

2. Please inspect your inventory of HeartSine samaritan PAD devices and complete the below table:

Serial Number	**Did you power cycle the device to check for audio prompts? (Y / N)**	**Did your device deliver audio prompts? (Y / N)**

OR (tick) ☐ I do not have any affected HeartSine samaritan PADs on hand.

3. If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed			
Facility Name		**Contact Person**	
Full Address			
Contact Number/Email			

Acknowledgement

By signing below and returning to Stryker, you acknowledge that you have received and understand the enclosed notification, and that all requested actions have been completed. I have performed the requested actions in Appendix 1 and understand that I should perform the recommended instructions on the Maintenance Supplement once every three months.

Printed Name		**Title**	
Facility			
Signature		**Phone**	
Date		**Email**	

Please return a scanned copy via email at postmarketssp@stryker.com