Urgent Field Safety Notice: RA2024-3530337

February 2024

Affected Products:

GTIN/HIBCC	Device Type	Catalog Number	Serial Number
+M727SAM350P0/$$+7	SAM 350P	350-UNIT-US-10	17D00023014
+M727SAM450P0/$$+7	SAM 450P	450-UNIT-US-08	17G00001893
+M727SAM350P0/$$+7	SAM 350P	350-UNIT-US-10	18D00020508
+M727SAM450P0/$$+7	SAM 450P	450-UNIT-US-08	18G00001553
5060167120671	SAM 350P	350-STR-US-10	19D00017655
5060167120671	SAM 350P	350-STR-US-10	20D00006524
5060167127670	SAM 350P	350-STR-UK-10	21D91081653
5060167122927	SAM 360P	360-STR-JA-10	21E91049810
5060167122453	SAM 500P	500-BAS-UK-10	22B91071233
5060167120671	SAM 350P	350-STR-US-10	22D91152391
5060167127311	SAM 360P	360-STR-DE-10	23E90001379
5060167127687	SAM 360P	360-STR-UK-10	23E90010409

Product description

The HeartSine® samaritan® PAD 350P, 360P, 450P and 500P are small, lightweight, portable, battery operated, prescription Automated External Defibrillators (AEDs) designed to treat victims of a cardiac arrest. The device incorporates a simple user interface of voice prompts and text/icon prompts to guide the user in the use of the device. The AEDs also incorporate an audible metronome (110 beeps per minute) to guide the user as to the correct rate at which chest compressions should be administered in accordance with current AHA resuscitation guidelines.

Product issue

Stryker has identified that there is a potential that the affected devices were shipped in their test configuration and there is a potential to have incorrect language and CPR duration. To date, Stryker has received 2 complaints regarding this issue.

Potential risks

The issue may be identified prior to use and install if the incorrect language is identified for the device, however the CPR duration as per test configuration would result in the device prompting the user to perform CPR for 5-seconds, rather than the intended 2-minutes. This would not be identified by the customer prior to use, potentially leading to a delay in therapy or suboptimal therapy delivered. **There have been no reports of serious incidents to date. Please keep Stryker informed of any serious incidents and quality problems experienced associated with this product by using Stryker's online reporting site: https://www.stryker.com/productexperience**

Stryker's planned actions:

The company is notifying all customers that have received potentially affected HeartSine devices that may have been shipped with test configurations.

Customer actions needed:

1. Review the Field Safety Notice. Please forward this information to all appropriate personnel within your organization. Maintain awareness of this communication internally until all required actions have been completed within your facility.
2. Check your internal inventory to locate the product listed on the attached Business Reply Form and confirm if you identify it.
3. Use the Business Reply Form to reconcile any affected product. **Complete the Business Reply Form even if there is no affected product identified. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter**.
4. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.
    a. On receipt of the form, a Stryker Representative will contact you to organize removal and return of the product to Stryker.
    b. Stryker Representative will organize a replacement for your device.
5. If you have further distributed this product to other organizations, please provide contact details on the Business Reply Form and please proceed to inform about the present Field Safety Notice.
6. Please keep Stryker informed of any serious incidents associated with this product by using Stryker's online reporting site: https://www.stryker.com/productexperience.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Please respond event 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.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: Email:

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,

Attachments:

- HeartSine Affected Device List and Business Reply Form

stryker

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[redacted]

HeartSine samaritan® PAD (Public Access Defibrillator) 350P/360P/450P/500P

Field Safety Notice reference: RA2024-3530337 (FA301)
February 2024

I have received the **Field Safety Notice** letter from Stryker dated February XX, 2024, stating that the company has initiated a voluntary recall on the above-referenced affected products.

Please complete the form even if you do not have inventory. This will preclude us from following up.

Customer information

Customer name: _____

Name of person completing this form: _____ Title: _____

Direct phone number: _____ Email _____

Address: _____ City: _____

Postal code: _____ Country: _____

If affected inventory, please provide the information below. Attach additional sheet if needed.

Device Type	Serial Number	Device at Facility?	
		Yes	No
SAM 350P	17D00023014		
SAM 450P	17G00001893		
SAM 350P	18D00020508		
SAM 450P	18G00001553		
SAM 350P	19D00017655		
SAM 350P	20D00006524		
SAM 350P	21D91081653		
SAM 360P	21E91049810		
SAM 500P	22B91071233		
SAM 350P	22D91152391		
SAM 360P	23E90001379		
SAM 360P	23E90010409		

We have not located any of these devices in our inventory *(please add check mark to box)*: ☐

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

Facility Name	Facility Address	Contact person	Product code	Lot number	Qty

I have read and understand the instructions provided and acknowledge receipt of the subject Field Safety Notice. 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.

Name (print): _____ Signature: _____Date: _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL _____ OR FAX _____