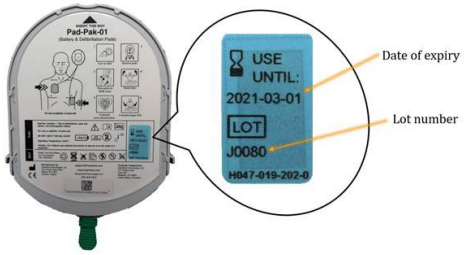
Urgent Field Safety Notice: RA2023-3293631

Recall Number: RA2023 -3293631

Affected Products: **HeartSine samaritan® PAD (Public Access Defibrillator) 350P/360P/450P/500P**

GTIN	Product Description		Lot Numbers							
N/A	360-BAS-UK-10	360-BAS-SJ-10	A3632	A3633	A3634	A3635	A3636	A3637	A3638	A3639
	350-BAS-UK-10	360-BAS-JA-08	A3640	A3641	A3642	A3643	A3644	A3652	A3653	A3654
	350-BAS-AS-10	450-BAS-JA-08	A3655	A3656	A3657	A3658	A3659	A3660	A3661	A3662
	350-BAS-CF-10	500-BAS-JA-08	A3663	A3664	A3665	A3666	A3667	A3668	A3669	A3672
	350-BAS-CN-10	500-BAS-AS-10	A3678	A3681	A3682	A3764	A3765	A3766	A3770	A3772
	350-BAS-JA-08	500-BAS-CF-10	A3773	A3774	A3775	A3776	A3777	A3778	A3779	A3780
	350-BAS-KO-10	500-BAS-CN-10	A3781	A3782	A3783	A3784	A3785	A3786	A3787	A3788
	350-BAS-MS-10	500-BAS-KO-10	A3799	A3800	A3801	A3802	A3803	A3804	A3805	A3807
	350-BAS-USROW-10	500-BAS-TH-10	A3821	A3829	A3832	A3833	A3834	A3840	A3842	A3843
	360-BAS-AS-10	500-BAS-UK-10	A3844	A3845	A3846	A3847	A3848	A3849	A3646	
	360-BAS-CN-10	PAD-PAK-01	J0748	J0749	J0750	J0751	J0752	J0753	J0754	J0755
	360-BAS-KO-10	PAD-PAK-03	J0756	J0758	J0759	J0760	J0761	J0786	J0787	J0788
		PAD-PAK-03j	J0789	J0790	J0791	J0792	J0793	J0794	J0795	J0796
			J0797	J0798	J0799	J0801	J0802			



Product description The Pad-Pak is a single use battery and electrode cartridge containing the battery to power the HeartSine samaritan PAD (LiMnO2 (18V – 1500mAh) non-rechargeable battery) and two electrode pads to provide the electrical connection for delivery of defibrillation to the patient's chest.

Product issue Stryker has determined that the affected Pad-Paks may be rendered inoperable due to depleted battery cells. As a result, the affected Pad-Paks could potentially fail to power on the device if needed for use.

Potential risks The issue could prevent device from analyzing patient condition or delivering therapy correctly. **There have been no reports of adverse events to date.**

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Planned Actions:

The company is notifying all customers that have received HeartSine devices that may have the affected Pad-Paks.

Customer actions needed:

1. Inspect your Pad-Pak inventory to identify if you have any of the affected lot numbers listed on page 1.
    a. If affected Pad-Paks are found, please request replacement by emailing XXXX.
2. Complete the attached acknowledgment form below (Attachment 1) and return it by email to XXXX confirming your receipt and understanding of this information.
    a. Upon receipt of the acknowledgment form, Stryker will arrange for the shipment of replacement Pad-Pak(s) at no charge to you.
3. In the interim, please continue monitoring the AED to ensure the status indicator is flashing green every 5 to 10 seconds. Please contact your Authorized Distributor or HeartSine Technologies immediately if you identify either of the following situations:
    a. If the status indicator is flashing red or you hear continuous beeping.
    b. If there is no status indicator operative.
4. Once you receive the replacement Pad -Paks, please destroy the affected Pad-Paks per local disposal guidelines.
5. Maintain awareness of this communication internally until the required action has been completed within your facility.
6. Inform Stryker if any of the subject Pad-Paks have been distributed to other organizations.
    a. If further distributed, please send an email to XXXX notifying Stryker of further distribution.
    b. Please use attached Customer Letter (Attachment 2) to notify your customers immediately and collect all responses and send it to XXXX. Stryker will work with you to ensure recipients are notified appropriately.

We request that you respond to this notice within XXX 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 within the target date 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, remain on the market.

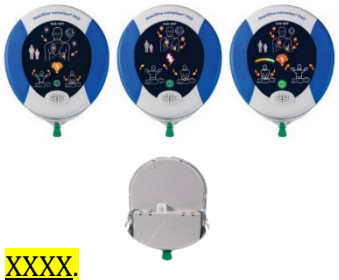
Sincerely,

XXXX

Attachment:
Attachment 1: Business Reply Form

Business Reply Form- response required

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



Account #

Recall Number: RA2023-3293631
May 2023

Response is required:
Please complete and sign this form by **XXXX.** Return the completed form by email to XXXX.

The quantities indicated below will be replaced upon receipt of this acknowledgment form. This form must be returned in order to receive replacement product.

Lot Number(s)	Quantity

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

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

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 destroyed all items identified.*