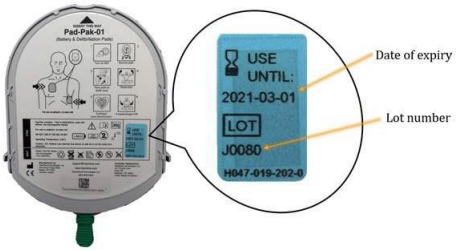
Urgent Field Safety Notice: RA2023-3293631

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 A3640
	350-BAS-UK-10	360-BAS-JA-08	A3641 A3642 A3643 A3644 A3652 A3653 A3654 A3655 A3656
	350-BAS-AS-10	450-BAS-JA-08	A3657 A3658 A3659 A3660 A3661 A3662 A3663 A3664 A3665
	350-BAS-CF-10	500-BAS-JA-08	A3666 A3667 A3668 A3669 A3672 A3678 A3681 A3682 A3764
	350-BAS-CN-10	500-BAS-AS-10	A3765 A3766 A3770 A3772 A3773 A3774 A3775 A3776 A3777
	350-BAS-JA-08	500-BAS-CF-10	A3778 A3779 A3780 A3781 A3782 A3783 A3784 A3785 A3786
	350-BAS-KO-10	500-BAS-CN-10	A3787 A3788 A3799 A3800 A3801 A3802 A3803 A3804 A3805
	350-BAS-MS-10	500-BAS-KO-10	A3807 A3821 A3829 A3832 A3833 A3834 A3840 A3842 A3843
	350-BAS-USROW-10	500-BAS-TH-10	A3844 A3845 A3846 A3847 A3848 A3849 A3646
	360-BAS-AS-10	500-BAS-UK-10	J0748 J0749 J0750 J0751 J0752 J0753 J0754 J0755 J0756
	360-BAS-CN-10	PAD-PAK-01	J0758 J0759 J0760 J0761 J0786 J0787 J0788 J0789 J0790
	360-BAS-KO-10	PAD-PAK-03	J0791 J0792 J0793 J0794 J0795 J0796
		PAD-PAK-03j	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 quality@medisolinternational.com.
2. Complete the attached acknowledgment form below (Attachment 1) and return it by email to quality@medisolinternational.com 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 quality@medisolinternational.com notifying Stryker of further distribution.

We request that you respond to this notice within 14 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.

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,

Department RAQA
Stryker

Attachment:
Attachment 1: Business Reply Form

Business Reply Form- response required

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

Recall Number: RA2023-3293631
May 2023

Response is required:
Please complete and sign this form by July 17th 2023. Return the completed form by email to quality@medisolinternational.com.

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.*