

URGENT FIELD SAFETY NOTICE: RA2021-2600240

ACTION REQUIRED

LIFEPAK® CR2 Defibrillator

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® CR2 Defibrillator.

February, 2021

Dear Valued Distribution Partner,

Stryker is conducting a voluntary action to notify customers with certain LIFEPAK CR2 devices manufactured with lids identified to have a manufacturing discrepancy that may cause the lid magnet to dislodge from the lid. In addition to these devices manufactured with affected lids, there is smaller risk that other LIFEPAK CR2 devices could also exhibit this issue. Please forward this notice to staff responsible for your AED business.

Description of issue

Stryker has received complaints that the LIFEPAK CR2 lid magnet has dislodged from the device, which may result in premature battery depletion. This issue has the potential to result in the inability for the device to turn on if the user does not use the on/off button or if the battery has fully depleted. There have been two adverse events associated with this issue where the patients ultimately expired.

The lid magnet is the primary means by which the device will turn on and off when the lid is opened or closed. If the lid magnet is missing, the device battery can deplete prematurely, even if the device is not powered on.

When the magnet is missing, the user can still use the power button to turn the device on and off. The device will automatically turn off within five minutes after being powered on if no patient is detected by the device. Overall, the occurrence of reported issues related to missing lid magnets is very low.

Stryker's planned actions

The company is notifying all LIFEPAK CR2 customers of this potential safety issue. We are requesting that all LIFEPAK CR2 devices be inspected according to the instructions provided in this letter to ensure the lid magnet is present. A replacement lid and battery will be provided at no charge for any device identified to have a missing magnet which may have begun prematurely depleting the battery. In addition, replacement lids will be provided at no charge for affected devices with lids identified to have a manufacturing discrepancy.

Required distributor actions

1. Review the Distributor Possession List attached to this notification letter of LIFEPAK CR2 devices that Stryker has record as being at your facility.
2. Inspect your inventory to confirm these devices are still in your possession.
3. **For devices confirmed to be at your facility**, please:
 - Contact your Stryker Representative for further instructions.

- Affix the LIFEPAK CR2 Supplemental Instructions (1-page attachment to this notification letter) to the device packaging or mail to your end customer at the time of device shipment
Or:
- Email an electronic copy of the LIFEPAK CR2 Supplemental Instructions to your end customer.

4. **For devices that are no longer at your facility**, please forward the associated Customer Notification Letters and attachments.
5. Return the completed LIFEPAK CR2 Notification Acknowledgment Form by Email **xxxx** to confirm your receipt of this safety notification.

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:

E-mail:

Phone:

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, 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 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,

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LIFEPAK® CR2 Automated External Defibrillator (AED) Device List

Place Label here with:

Account Number
 Account Name
 Address
 Cty State Zip

Completed by:

Sign and date:

Phone Number:

Email:

INSTRUCTIONS FOR IMPACTED DEVICES

1. Please review the list below indicating device(s) affected by this field action:

- Serial number(s) can be located on the back of your device.
- Verify the status of your affected device(s) using selections provided in the table below.
- If any device(s) with a serial number listed below is not in your possession, please provide the new address and contact information, if you have it.
- If any device(s) has a lid missing a magnet, please reference the customer letter for instructions to have replacement lid kit and battery sent at no cost.

Return completed form by Fax to Stryker at <insert fax number>, email to <enter email address>, or mail to Stryker <enter local address>.

Serial Number	Device in Possession		Lid has Magnet Intact		*Please provide the new address and new contact information
	Yes	No	Yes	No	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

We have further distributed subject devices to the following organizations:			
Facility Name			
Facility Address			
Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organization		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

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