Urgent Product Defect Correction

April, 2021

TGA Reference #:	**RC-2021-RN-00732-1**
ARTG #:	**282772**
Product Field Action #:	**RA 2600240**
Description:	**LIFEPAK® CR2 Defibrillator**
Affected Item & Serial Numbers:	**Please see Response Form attached**

Stryker has initiated a Product Defect Correction for the operating instructions of all LIFEPAK® CR2 devices. A further subset of LIFEPAK® CR2 have been identified to have a manufacturing discrepancy that may cause the lid magnet to dislodge from the lid.

The intent of this letter is to list all known hazards potentially associated with the noted issue and the risk mitigation factors. Our records indicate that you have been supplied with a LIFEPAK® CR2 Defibrillator. We therefore request that you read this notice carefully and complete the actions requested.

Customer Information, that may include Personal Information, may be shared with Stryker Australia Pty Ltd for the limited purpose of conducting this Product Defect Correction, and is managed in line with Stryker's Australia's Privacy Statement. (See Stryker Australia's Privacy Statement at the end of this document).

Product Issue

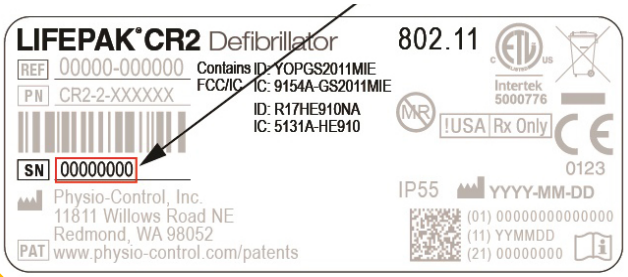
Stryker has received complaints that the LIFEPAK® CR2 lid magnet has dislodged from the device, which may result in premature battery depletion. This issue has the potential to result in the inability for the device to turn on if the user does not use the on/off button or if the battery has fully depleted. 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.

If you identify that your device has a missing lid magnet, you may continue to use your LIFEPAK® CR2 device according to the operating instructions and the supplemental labelling attached to this letter until you receive replacement parts.

To confirm the serial number of your device, remove the battery from the battery compartment, the SN is shown as below



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.

Actions Required by End Users

1. Please inform any users of your LIFEPAK® CR2 of this Product Defect Correction and forward this notice to them.

2. Please inspect your defibrillator to confirm whether your unit is a LIFEPAK® CR2 Defibrillator. Please refer to previous image on how to locate your device's Item and Serial Number.

    - If your device is not a LIFEPAK® CR2 Defibrillator, please proceed to step 6.

    - If you have a LIFEPAK® CR2 Defibrillator, please record the Item & Serial number in the table within the Product Defect Correction Notification Response Form on page 5 and proceed with all steps below.

3. Review the LIFEPAK® CR2 Supplemental Instructions attached to this notification letter. Please retain this document as supplemental labelling for your device(s).

4. Perform the below on all LIFEPAK® CR2 Defibrillators:

    i. Inspect for the presence of magnet as per the instructions in Attachment 1.

    ii. Conduct Device Readiness check in accordance with the LIFEPAK® CR2 Operating Instructions, maintaining a State of Readiness (pp. 77-78) and the Supplemental Instructions provided with this notification.

    Device Readiness is indicated by:

    - **All Devices:** Green Readiness Indicator on device flashes every 6 seconds. If device is not ready, the Readiness Indicator will not flash.

    - **Devices with Wireless Connectivity:** In addition to the green flashing Readiness Indicator on the device, the LIFELINKcentral AED Program Manager or LIFENET System will generate a monthly status report that the device is READY.

5. Please indicate the results of these inspections and checks for your LIFEPAK® CR2 Defibrillator(s) in the table within the Product Defect Correction Response Form on page 5.

6. Please return this completed form to your Distributor at *{Insert distributor email}* AND to Stryker either by fax on (02) 9467 1325 or via email to postmarketssp@stryker.com.

    This form can also be completed online at: https://form.jotform.com/strykerssp/ra2600240_enduser

    Please complete only one form for all your devices.

    Note: Even if you do not have a LIFEPAK® CR2 Defibrillator, please return a signed form to acknowledge receipt of this notification and confirmation that you do not have a LIFEPAK® CR2 Defibrillator, then please proceed to step 9.

7. If your response indicates that you require a replacement lid and/or battery, a replacement will be provided at no charge. Users are able to replace the lids and batteries themselves, instructions will be provided with the replacement product.

8. Continue to check Device Readiness (indicated as per point 4 above), at least monthly in accordance with the LIFEPAK® CR2 Operating Instructions, maintaining a State of Readiness (pp. 77-78) and the Supplemental Instructions provided herein.

9. If you have disposed, transferred or sold any LIFEPAK® CR2 Defibrillators, please immediately let them know of this recall and notify Stryker through email to postmarketssp@stryker.com.

10. 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 request that you **respond to this notice within 7 calendar days** from the date of receipt. Thank you for your support on this important matter.

Additional Information: Please contact your local Stryker representative or Stryker's ProCare Service team on 1800 667 558 or at ssptechservices@stryker.com.

For any general enquiries, please contact Stryker's Post Market team on +61 427 540 168.

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

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact Stryker using the details below.

Sincerely,

Brigitte

Brigitte Rees
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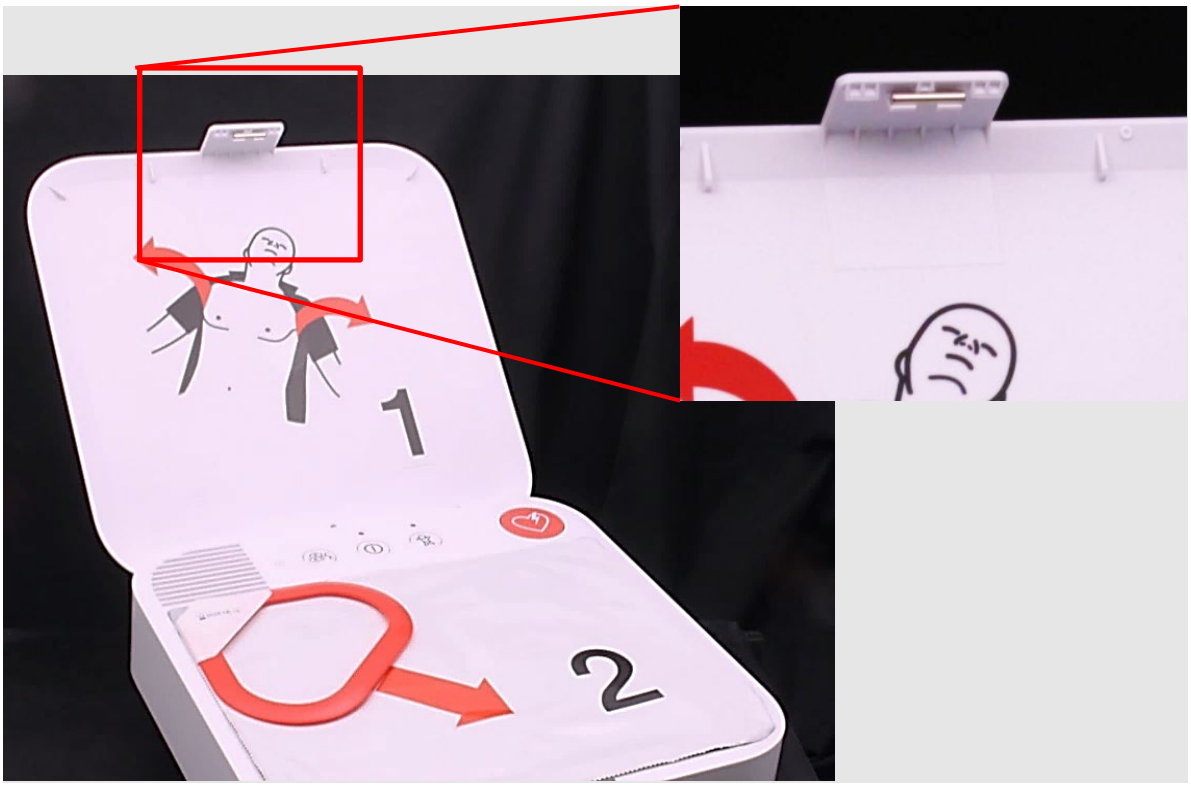
E: postmarketssp@stryker.com
www.stryker.com.au

Stryker Australia's Privacy Statement

Stryker Australia Pty Ltd ("Stryker") is or has collected your personal information for the limited purpose of a Product Defect Correction for a product that we understand you have purchased. We may only disclose this personal information to our related companies, contractors providing services to us, and to other third-party service providers we use in conducting this action. We may also disclose your personal information where we are required or authorised to do so by Australian law. Further information about how we handle your personal information, including details about how you can access your information and how you can complain about a breach of the Australian Privacy Principles (as well as how we will deal with any complaint) can be found in our Privacy Policy available at https://www.stryker.com/au/en/legal/privacy.html. You can contact us by getting in touch with our Privacy Officer, by email to: privacyaustralia@stryker.com or by mail to: Privacy Officer. Stryker Australia Pty Ltd, 8 Herbert Street, St Leonards, NSW 2065.

Attachment 1 – Lid Magnet Inspection Instructions

1. Open the LIFEPAK® CR2 lid
2. Inspect lid magnet clip for presence of magnet as shown in figure below



Product Defect Correction End User Response Form

Please sign & return this form as soon as possible.

Please note this form is also available online:
https://form.jotform.com/strykerssp/ra2600240_enduser

For quick access, scan with your mobile phone or tablet camera over this QR code (compatible with iPhone & Android).

Please complete the table the below to confirm the status and completion of inspections/checks on your LIFEPAK® CR2 Defibrillators device(s).

Please refer to Product Defect Correction Letter, Attachment 1 & the Operating Instruction provided herewith to complete inspections & checks.

Item Number	Serial Number	Device in Possession?	Device readiness indicator is flashing?	Device lid magnet is present?	Distributor Name (if known/applicable)
		YES NO	YES NO	YES NO	
		YES NO	YES NO	YES NO	

OR ☐ I confirm that I do not possess a LIFEPAK® CR2 Defibrillator.

By signing below and returning to Stryker, you have acknowledged that you have received the notification for the Product Defect Correction involving the LIFEPAK® CR2 Defibrillator.

Name (Print): _____

Business/Facility Name (if applicable): _____

Email: _____

Phone: _____

Signature: _____ **Date:** _____

Please return a scanned copy to *{Distributor name}* AND Stryker using the contact details in table below.

If you have any questions in regard to completing this form, please contact your Distributor or Stryker using details below:

{Distributor Name}
Ph: XXXXX
Email: XXXXXX
Fax: XXXX

Stryker
Ph: 0427 540 168
Email: postmarketssp@stryker.com
Fax: (02) 9467 1325

LIFEPAK® CR2 Defibrillator

Supplemental Operating Instructions

Refer to the *LIFEPAK CR2 Defibrillator Operating Instructions* for complete directions for use.

Warning

Premature Battery Depletion. If the lid or lid magnet is missing, the LIFEPAK CR2 battery can become prematurely depleted.

Troubleshooting Tips

This table explains problem conditions that you may encounter while using the defibrillator.

OBSERVATION	POSSIBLE CAUSE	CORRECTIVE ACTION
Defibrillator does not provide voice prompts or beeping tones after you open the lid (turn it on).	Lid magnet is missing	• Use the ON/OFF button to turn the defibrillator on if required for emergency use. • Contact qualified service personnel.
	Depleted battery	• Replace the battery immediately. If a replacement is not available, order a new battery immediately.
	Speaker system failure	• Contact qualified service personnel.
Voice prompts continue after lid is closed.	Lid magnet is missing	• Use the ON/OFF button to turn the defibrillator off. • Contact qualified service personnel.

Stryker
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