stryker

URGENT:
MEDICAL DEVICE RECALL

LIFEPAK® 15 AC Power Adapter

Recall Number: FA303 - PR 3359892

November 6, 2023

Product affected:

Catalog number	UDI	Product description	Serial number(s)	Date of Manufacturing
11140-000098	00883873940204	LIFEPAK 15 (LP15) AC Power Adapter (ACPA)	Please refer to this site for list of SNs: https://www.stryker.com/us/en/emergency-care/product-notices/lp15-acpa.html	11/03/2021 – 04/24/2023

*Please Note: In addition to the above, some of these units with the above parameters have been reworked and can be identified as **not within scope** of this recall if you see a black dot on the label as pictured below:*

Product description

The AC Power Adapter (ACPA) is intended for use with the LIFEPAK 15 (LP15) monitor/defibrillator. The power adapter consists of an AC power adapter, AC power cord, and power adapter output cable. An optional output extension cable is available.

Product issue

Stryker has identified an increase in number of complaints related to LP15 ACPA failures with the reported symptoms of "Battery Not Charging" and "Auxiliary Power Will Not Power Device or Charge Batteries". **This issue is only applicable to ACPAs used on 110V power grids.**

Potential risks

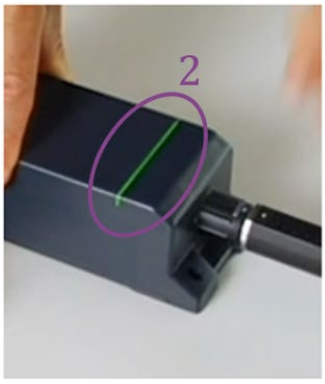
An ACPA exhibiting this failure mode may not charge the LP15 batteries and may not allow the LP15 to power on while plugged into the ACPA. If the ACPA is disconnected, the LP15 will power up and it will function normally on the batteries if they are charged to a functioning level. If the batteries are not charged, a delay in delivering treatment or inability to deliver treatment to patients in cardiac arrest could occur as the user will need to obtain a backup device or batteries.

Stryker has received a high volume of complaints, but there have been zero (0) Adverse Event Reports (AERs) submitted.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Actions needed

1. Immediately check your internal inventory to locate the affected product and complete the attached Business Reply Form (BRF).
2. Return the enclosed BRF by email to RSRecall@stryker.com to confirm receipt and understanding of this information.
    a. Upon receipt of the BRF, Stryker will arrange for the shipment of a replacement ACPA at no charge to you.
    b. Stryker will coordinate with you the return of the affected ACPA upon receipt of your new ACPA.
3. **Stryker recommends you continue to use your LP15 and current ACPA. Please follow the OI recommendations for daily inspection and testing according to the checklist provided in the Operating Instructions.**
    a. The checklist includes disconnecting the defibrillator from the power adapter, turning the device on, and confirming that two batteries are installed and charged. Then, the defibrillator should be reconnected to the power adapter and users should confirm that the battery charging LED on the defibrillator is illuminated or flashing.
    b. If an ACPA is experiencing this failure mode, this will present to the user as the Aux Power Indicator (1 on picture below) on the LP15 flashing instead of solidly illuminating and the green LED strip on the ACPA (2 on the picture below) flashing instead of solidly illuminating:



    c. If you have any questions or concerns or experience issues with your ACPAs while awaiting your recall replacements, please contact Stryker Customer Service at +1 800 787 9537, option 2, from 8:00 AM to 7:00 PM (Eastern Time), Monday – Friday or by email at medtechsup@stryker.com.
4. Maintain awareness of this communication internally until the required action has been completed within your facility.

5. If any of the subject ACPAs have been distributed to other organizations:
    a. Please check your stock and quarantine affected products.
    b. Customer Notifications:
        - Please notify impacted customers that were shipped or may have been shipped this affected product by sharing this recall notification letter; <or>
        - Email Stryker at RSRecall@stryker.com with a list of customers who received/may have received this product and we can work with you on notifications to impacted customers.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action by the target date September 30, 2025 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,

Saijal Naik
RAQA Manager

Once again, please email RSRecall@stryker.com the enclosed Business Reply Form to acknowledge receipt of this notification.

The US Food and Drug Administration has been notified of this action.

Attachments:

- Appendix A - Business Reply Form

Business Reply Form

Account number:
Account name:
Account Address:

LIFEPAK® 15 AC Power Adapter

Recall Number: FA303 - PR 3359892

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Response is required; Please complete and sign this form.
Email the completed form to RSRecall@stryker.com by **12/15/2023**.

Note: *Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.*

If you had affected units previously replaced, did you dispose of them? _____ YES _____ NO

- If no, how many do you have: _____

Product Identification:

Catalog number	Product	Serial/Lot number(s)
11140-000098	LIFEPAK 15 (LP15) AC Power Adapter (ACPA)	Please refer to this site for list of SNs: https://www.stryker.com/us/en/emergency-care/product-notices/lp15-acpa.html

Please Note: In addition to the above, some of these units with the above parameters have been reworked and can be identified as not within scope of this recall if you see a black dot on the label as pictured below:

1. Are you located in a 110V power grid? _____ YES _____ NO

2. If you answered yes to Question1, do your devices have a manufacturing date between 11/3/2021 – 04/24/2023? _____ YES _____ NO
    a. Quantity of Yes _____
    b. Quantity of No _____

3. Of the devices for which you answered yes to question 2, are your devices missing the black dot as noted in the picture above? _____ YES _____ NO
    a. Quantity of Yes _____
    b. Quantity of No _____

4. Of the devices for which you answered yes to question 3, are your devices listed on the attachment for Serial Numbers Affected? _____ YES _____ NO
    a. Quantity of Yes _____
    b. Quantity of No _____

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product:

☐ I have checked my stock and have inventory consisting of _____ units.

Please select one of the following options:

- ☐ I have identified and notified my customers that were shipped or may have been shipped this product and notified them of this issue by sharing this recall notification letter.
- ☐ Attached is a list of customers who received/may have received this product. Please notify my customers.