stryker

URGENT FIELD SAFETY NOTICE:
Medical device correction

Customer Name:
Attn: Safety Manager

Field action number:
RA2026-4444632 (FA336)
RA2026-4435298 (FA339)

November 2026

This device correction notification is being issued to alert customers with LIFEPAK 35 monitor/defibrillator (LP35) devices of **two** potential device malfunctions. Out of an abundance of caution, Stryker is completing a voluntary correction of these devices.

Product affected

Catalog Numbers	Product	Distribution Dates	UDI-DI
70335 – 000XXXX	LIFEPAK 35 Monitor/Defib	27th June 2024 to 08th May 2026	08858251006948UP

Product description

LP35 is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols.

Product issue

(Issue 1) Stryker has identified an issue with the LP35 where the device does not display the message "CHECK RHYTHM / ECG Analysis Inconclusive" as intended when all below conditions are present simultaneously. The issue does not affect the display of "Shock Advised" or "No Shock Advised" messages, and therapy delivery remains available. Additionally, this nonconformance is limited to the device on-screen prompts only and rhythm analysis is not impacted by this issue.
LP35 devices are manufactured to the default Setup Options configuration of **Manual Mode Voice Prompts ON** and **cprINSIGHT OFF.** If you have not changed this setting from its default configuration, your device will not exhibit the above issue. To verify your device configuration, please refer to action 4.a. under Interim Action needed for Issue 1 in the Customer actions needed section below.

The missing on-screen text prompt occurs when all the following conditions are simultaneously met for a device in Manual Mode:

- Device Setup Option is configured with **Manual Mode Voice Prompts OFF**, which silences voice prompts in Manual Mode

- Device Setup Option is configured with **cprINSIGHT Analysis Technology ON** in Manual Mode, which enables the option of cprINSIGHT usage in Manual Mode
- **cprINSIGHT is toggled ON** and the **CPR timer is started in the Manual Mode** display screen, which activates cprINSIGHT and rhythm analysis
- cprINSIGHT rhythm analysis result is determined to be **Inconclusive**

(Issue 2) During production of LP35, Stryker identified that certain printer and modem access port connectors may not have been fully seated within the rear housing assembly. As a result, the connectors may appear flush with or recessed relative to the retaining nut rather than extending beyond it as intended.

Product risks

(Issue 1) In the event that all conditions described above for Issue 1 occur simultaneously, users may not receive the expected visual notification that the rhythm analysis result was inconclusive. This could result in a delay in recognizing the need to reassess the patient's rhythm and could contribute to a delay in defibrillation energy.

(Issue 2) If a connector is not fully seated, the environmental seal may be compromised, potentially reducing the device's ability to prevent ingress of water or dust. In certain environments, this could increase the risk of moisture entering the device and impact product performance. If moisture enters the device through an improperly sealed access port, device performance could be compromised. Depending on the extent and location of the moisture ingress, the device could experience an inability to deliver therapy, a delay in therapy delivery, reduced pacing or synchronized cardioversion performance, loss of printing functionality, or interruption of data transmission capabilities. Stryker has received 18 complaints associated with loose or recessed printer/modem access ports .

To date, there have been no adverse event reports for either of these issues.

In accordance with Regulation EU MDR 2017/745, any serious incident occurring in relation to this device should be reported to the manufacturer and to the relevant Competent Authority, in accordance with the applicable reporting requirements.

Customer actions needed:

1. Immediately check your LP35 inventory to locate affected product(s) as listed in the above product grid.
2. To confirm receipt of this Medical Device Correction Notice and understanding of the provided information, please email the Business Reply Form (BRF), found on the following page, by **November XX, 2026** to xxxxx@stryker.com .
3. Upon return of the BRF, a Stryker Representative or Field Service Technician will coordinate a single site visit to correct both issues.
4. Interim actions needed for Issue 1 until the software is updated by a Field Service Technician:
    a. LP35 is confirmed to be configured to **Manual Mode Voice Prompt setting ON**
        i. Verify this by putting your device in **Setup Mode**. Navigate to the **Main Menu** button ☰ on the monitor, click **Options**, then **Setup Mode**. Enter set password or default (0000). Go to **Manual Mode** and see if the device has **Voice Prompts ON**.

b. If your device is configured with the **Voice Prompt setting OFF**, please do the following until a Stryker Field Service Technician can update the software on your device:
    i. Find **Setup Options** through one of the following steps, depending on your system preference.
        1. If using the **LIFENET System website**, navigate to the **Device Software and Setup Options** page (under the **Assets** menu). Find the **device setup options profile** assigned to impacted device(s) and select the crossed-hammers icon for the desired setup option in the list.
        2. If using **LIFENET Portal website**, navigate to **Setup Options** on the left-hand side. Click on the **device setup options profile** assigned to the impacted device(s). Click **Edit Profile**.
    ii. Update Setup Options
        1. In the **Navigation Steps** (left-hand side), click on **3. Manual Mode** and change the **Voice Prompt setting from OFF to ON**.
        2. Navigate to **23. Assign to Devices** and ensure all impacted devices are selected or will be selected under a different profile.
        3. Click **Save Changes**.
        4. You will see the status of your **Setup Option** change from **Applied** to **Pending**.
    iii. To apply the changes, complete the following steps for each impacted device.
        1. Put the LP35 into **Setup Mode**.
        2. If you have Wi-Fi or cellular connectivity set up on the monitor:
            - Allow the device for up to two minutes to establish a Wi-Fi or cellular connection, then click **Check for Updates** in the top right-hand corner once available.
            - The device will ask if you want to apply the update, click **YES** to accept the change.
        3. If you do not have connectivity on your device:
            - You will need to use **LIFENET Device Setup Tool** to apply changes over Bluetooth or cable. If you need assistance with this, please contact your local Stryker Customer Service team.

5. Interim action for Issue 2:
    a. Follow the Operating Instructions (OI) for use and avoid immersing any porting of the monitor/defibrillator in water or other fluids until the corrective action has been completed.
    b. Avoid spilling any fluids on monitor/defibrillator or accessories, as spilled liquids may cause the monitor/defibrillator and accessories to perform inaccurately or fail.

6. Maintain awareness of this communication internally until all required actions have been completed within your facility.
    a. **Please ensure this letter is kept with the affected device until the device software is updated and corrections are complete**.
7. If you have further distributed any affected product, please provide this notification to the relevant recipients. **Recipients who are not direct Stryker customers should respond to the facility or organization from which they receive this notification and **not directly to Stryker**.*
8. Email your Stryker representative at xxxxx@stryker.com when you have collected all the responses from your end-users.

If you have any questions or concerns, please contact Customer Service/local RAQA team by email xxxxx@stryker.com

On behalf of Stryker, we thank you sincerely for your help and support in completing this action by the target date **November xx, 2026** 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.

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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

Attachments:
Attachment A: Business Reply Form

Business Reply Form

Account Name:
Customer Number:
Account Address:

Field action number:
RA2026-4444632 (FA336)
RA2026-4435298 (FA339)

November 2026

Response is required. Please complete and sign this form.
Email the completed form to xxxxx@stryker.com by **November XX, 2026.**

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

Catalog numbers	Product	Distribution Dates	UDI-DI
70335 – 000XXXX	LIFEPAK 35 Monitor/Defib	27th June 2024 to 08th May 2026	08858251006948UP

- ☐ I confirm receipt of the Medical Device Correction Notice and understand the information provided.
- ☐ I have checked my inventory and:
  - ☐ Yes, we have affected device(s)
    - ☐ The devices are with Voice Prompt setting ON, **or,**
    - ☐ I have configured the Voice Prompt setting OFF, but have now switched it to ON.
  - ☐ No, we don't have affected device(s) – see below:
    If you have further distributed any affected product, please provide this notification to the relevant recipients. **Recipients who are not direct Stryker customers should respond to the facility or organization from which they receive this notification and **not directly to Stryker**.*
    Email your Stryker representative at xxxxx@stryker.com when you have collected all the responses from your end-users.

Form completed by:

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