URGENT FIELD SAFETY NOTICE:
Medical device correction

Customer Name
Attn: Safety Manager

Field action number: RA2026-4435298 (FA339)

November 2026

This device correction notification is being issued to alert customers with LIFEPAK 35 monitor/defibrillator (LP35) devices of a potential device malfunction. 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 14th July 2026	08858251006948UP

Product description

The 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

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; rhythm analysis is not impacted by this issue.

The missing on-screen text prompt occurred when all the following conditions were 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

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.

Potential risks In the event all conditions described above 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.
To date, there have been no adverse event reports for this issue.

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. Each LP35 device will need to be connected to the computer and stepped through the LIFENET Device Setup Tool software application to complete the software update.
    a. Download and install the LIFENET Device Setup Tool from the LIFENET System website Downloads tab onto your computer.
        i. Note: If this application was previously installed, it may prompt you to update to the latest version. Newer versions of the tool can be installed over existing versions. Software applications can be installed on more than one computer if desired. If you do not have administrative rights on your computer, you may need to contact an IT representative from your organization to complete the installation.
        ii. The application should now be installed on your computer. You will be able to open the application from the start menu (under the Stryker folder) or by doing a search for the application name on your computer.
        iii. You will be required to register the application with your LIFENET System credentials at first launch. Once registered, you will need to login with LIFENET System credentials each time the application is launched.
4. Software Update
    a. Create a new Setup Options profile
        i. On the LIFENET System website, navigate to the **Device Software and Setup Options** page (under the **Assets** menu). Click "Create Setup Options" and select LIFEPAK 35 under "Device Model." If you are using the LIFENET Portal website, navigate to **Setup Options** on the left-hand side and then select "LIFEPAK 35."
        ii. Give your profile a name and select Software Version "LIFEPAK 35 – 80.1.33.21"
        iii. It is recommended that you import settings from an existing profile or existing device under "Import Setup Options From" so that your settings will not be changed.
        iv. Navigate to "23. Assign to Devices" and select all LIFEPAK 35s. If you prefer to assign different settings to a group of devices, repeat the previous steps to create another profile for "LIFEPAK 35 – 80.1.33.21" software version, and assign all remaining devices.
        v. Save changes
    b. Apply the new settings and software
        i. Put the LP35 into Setup Mode by navigating to the Main Menu button ☰, then Options
        ii. Connect the LP35 to your computer with the data access cable or printer cable paired with a USB-A to USB-B adapter. Make sure your device has two charged batteries or an AC power cable.
        iii. Open LIFENET Device Setup Tool on your computer and log in .
        iv. Click on the LP35 on the menu, then select the device you want to manage
        v. You will see "synchronization required" under **Software and setup options**

vi. Select "Synchronize with account" to update the device. The update will take up to 15 minutes.
vii. Repeat steps all steps for each device.
viii. If you need assistance with this, please contact your Local Stryker Customer Service team

5. With this software update, you can now configure Voice Prompt settings to ON or OFF without having this issue.
6. Maintain awareness of this communication internally until all required actions have been completed within your facility.
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: RA2026-4435298 (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.

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☐ 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) and
  - ☐ I have downloaded the new software according to the instructions provided.
- ☐ 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**	