PHILIPS

URGENT Field Safety Notice

RE: Patient Monitor 6500 Potential Loss of Touchscreen Function May Require Monitor Restart

DD MMM, 2025

To: Customer Name
Customer Street Address
City, State, Zip Code

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with Patient Monitor 6500, specifically regarding instances where the touchscreen may not respond to user input. This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

PM 6500 monitors are experiencing an issue with the touchscreen display being unresponsive and the only way to recover monitoring controls (touch functionality) is if the user performs a hard restart. It was determined that the issue is not related to user interaction, e.g. locking the display. No touch lock icon and no technical alarm (inoperative or INOP) is displayed on the screen when the touchscreen becomes unresponsive, therefore a user would only become aware of the issue when they attempt to interact with the touchscreen.

Hazard/harm associated with the issue

The restart, if performed by the clinician when deemed safe and appropriate, is completed in order to restore touch functionality and will result in a temporary loss of monitoring. This temporary loss of monitoring may cause a delay of diagnosis or a delay in treatment as a result of a change in patient condition that may go unnoticed until continuous monitoring is restored. To date, Philips has not received any reports of harm as a result of this issue.

Affected products and how to identify them

#	Product name	Product number	UDI or UPC Number
1	Patient Monitor 6500	867315	(01)00884838107809(21)

Actions that should be taken by the customer / user in order to prevent risks for patients or users

- Review this notice carefully.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.
- Complete the URGENT Field Safety Notice Response Form at the end of this notification to submit both acknowledgment of this URGENT Field Safety Notice and confirm understanding of actions to be taken.

Actions planned by Philips to correct the problem

Implement the Technical Solution as soon as available within the timeframe communicated. Philips representative will contact you to arrange a new touchscreen configuration file upload to the Display touch controller.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product(s) may be reported to *< Markets to insert to whom the customer should report>*.
Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare

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Instructions: Please complete and return this Response Form to Philips promptly and no later than 30 days from receipt. Completing this Response Form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

Review this notice carefully.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all users that handle the affected product(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: <Response Form return details to be completed by the KM/country>