PHILIPS

URGENT Field Safety Notice

RE: Philips IntelliVue Patient Monitors Continuous Reboot with Active Display

August 25, 2026

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 Philips IntelliVue Patient Monitors rebooting causing loss of monitoring. The Philips IntelliVue MX750 and MX850 monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The monitors are only for use on one patient at a time and are not therapeutic devices.

The Philips AD75/AD85 is intended for use as an additional independent display for the connected Philips patient monitor. It is intended for viewing screens from the patient monitor, operating the patient monitor, and providing visual and audible alarms generated by the patient monitor. The AD75/AD85 provides all screen-operable functions of the connected patient monitor, including starting and stopping physiological measurements, changing measurement modes, changing alarm limits and acknowledging alarms.

This URGENT Field Safety Notice is intended to inform you about:

What the problem is and under what circumstances it can occur

It was found that under certain conditions the Philips IntelliVue Patient Monitors would reboot (error code H 18112 21016), causing loss of monitoring when the software was attempting to connect to the network. When the Online Certificate Status Protocol (OCSP) is configured, the IntelliVue Patient Monitors perform an OCSP query to verify that a digital certificate is still valid and has not been revoked in order to ensure communication with trusted systems. When performing an OCSP query, if prolonged due to a server/network shutdown, a connection timeout can occur causing an

unexpected internal state in the communication software, which then triggers a reboot of the monitor or active display. Additionally, if the OCSP query is not properly set (no DNS server), a reboot can occur. Following the initial reboot, the system may restart repeatedly until certificate verification is successful and a subsequent server or network connection is established.

This issue is specific to MX750 and MX850 monitors installed with AD, running software revisions R.00.01 or R.00.02. AD devices are only used with the MX750 and MX850 monitors.

Hazard/harm associated with the issue

When this issue occurs, patients may be exposed to the operational hazard of "Data / Data Availability" which may lead to incorrect/delayed treatment. Exposure to these hazards may cause patient harms up to death. The most at-risk population includes critically ill patients of all ages who are highly dependent on continuous physiological monitoring for clinical decision-making, such as those in intensive care units, operating rooms, or undergoing high-risk procedures. These patients are more vulnerable to adverse outcomes from delays in detection of clinical deterioration.

The device issue, characterized by unforeseen reboots and loss of monitoring, may not be immediately recognized by the user prior to a hazardous situation. While the device will restart with audible and visual indicators and monitoring will be interrupted (resulting in loss of the lifetick at the PIC and resulting 'No Data from Bed' INOP), there are no specific alarms or error messages indicating the root cause of the failure. Users may observe the device rebooting and loss of monitoring but may not be able to attribute this to a certificate verification failure or network connectivity issue. The absence of explicit notification may delay recognition and response while the user troubleshoots.

Affected products and how to identify them

The Philips Patient Monitors and Active Displays are identified below:

#	Product Name	Product/Model Number
1	IntelliVue Patient Monitor MX750	866471
2	IntelliVue Patient Monitor MX850	866470
3	IntelliVue Active Display AD75	867130
4	IntelliVue Active Display AD85	867133

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

- Ensure patients are monitored by multiple devices and are under continuous observation, to allow for timely detection of monitoring interruption and initiation of alternative monitoring or manual assessment.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this Urgent Notification with the documentation of the Philips IntelliVue Patient Monitors and associated devices in a place where it is most likely to be seen and viewed.

- Implement the Technical Solution established by Philips as soon as available within the defined timeframe.
- 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

- A Philips representative will contact customers to arrange a software update to R.00.03 or above to correct the issues listed.

If you need any further information or support concerning this issue, please contact your local Philips representative

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 Philips representative

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:

- Ensure patients are monitored by multiple devices and are under continuous observation, to allow for timely detection of monitoring interruption and initiation of alternative monitoring or manual assessment.
- Pass this notice to all those who need to be aware within your organization or to any organization where affected product(s) have been potentially transferred.
- Place this Urgent Notification with the documentation of the Philips IntelliVue Patient Monitors and associated devices in a place where it is most likely to be seen and viewed.
- Implement the Technical Solution established by Philips as soon as available within the defined timeframe.

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 representative.