PHILIPS

URGENT Field Safety Notice

RE: IntelliVue Philips Patient Monitor 6000 series Lasered Incorrectly

Date: March 6, 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 the Philips IntelliVue Patient Monitor 6000 series. It was discovered that the IntelliVue Philips Patient Monitor 6000 series was incorrectly lasered indicating a 12-Lead ECG symbol on the rear housing of the monitor when the monitor is only equipped to function with a 6-Lead ECG cable.

The devices are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The Philips Patient Monitors combine patient surveillance and data management; thus, they allow multi-measurement monitoring by linking separate modules.

What the problem is and under what circumstances it can occur

It was found that the Philips IntelliVue Patient Monitor 6000 series was incorrectly lasered with a 12-Lead ECG symbol on the rear housing of the monitor. However, the affected monitor was not ordered with the associated option to enable such functionality. As a result, it is possible for the clinical user to attempt to perform a 12-Lead ECG, based on the symbol indicating that the monitor is capable, when it does not contain the software to perform a 12-Lead ECG.

The missing option is only detectable by the user after a patient has been admitted and set up for monitoring. The back housing of the IntelliVue Philips Patient Monitor 6000 series displays the 12-Lead compatible symbol and therefore the clinical user has no reason to suspect the device is not 12-Lead compatible.

Hazard/harm associated with the issue

This issue could cause an incorrect treatment or a delay in treatment due to unexpected functioning of the device leading to late detection of a change in patient condition or development/worsening of cardiac arrythmia. There is a remote probability of serious adverse health consequences for

populations at greatest risk, seriously ill, or unstable patients who may not be able to tolerate delays in treatment.

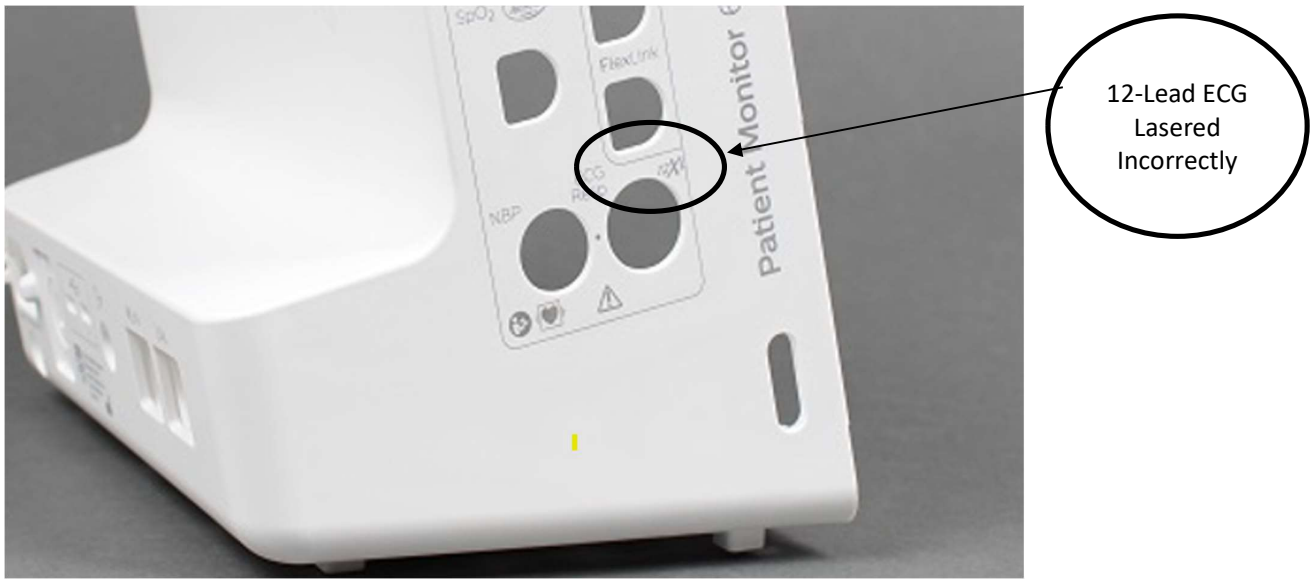
To date, Philips has not received any reports of this issue resulting in patient harm.

Affected products and how to identify them

The Philips IntelliVue Patient Monitor 6000 series are identified below:

#	Product name	Product number	UDI or UPC Number
1	IntelliVue Philips Patient Monitor 6000 series	867311, 867313, 867315	00884838107786, 00884838107793, 00884838107809

Incorrectly lasered with a 12-Lead ECG



NOT lasered with a 12-Lead ECG

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

- This communication should be shared with all clinical staff to review and understand.
- Place this Field Safety Notice with the documentation of the Philips IntelliVue Patient Monitor 6000 series and associated devices.
- 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.
- Implement the Technical Solution established by Philips as soon as available within the timeframe communicated by Philips and confirm with Philips the implementation of the correction of all affected devices. In case any devices cannot be corrected, inform Philips of the reason why the Technical Solution could not be implemented.
- Customers should complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both their acknowledgement of this recall and confirm understanding of actions to be taken.

Actions planned by Philips to correct the problem

A Philips representative will contact customers to arrange an upgrade to the affected devices' software to enable the missing C12 option to match rear housing lasering with product features.

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 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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URGENT Field Safety Notice Response Form

Reference: IntelliVue Philips Patient Monitor 6000 series Lasered Incorrectly (FCO86202041)

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this 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:

- This communication should be shared with all clinical staff to review and understand.
- Place this Field Safety Notice with the documentation of the Philips IntelliVue Patient Monitor 6000 series and associated devices.
- 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.
- Implement the Technical Solution established by Philips as soon as available within the timeframe communicated by Philips and confirm with Philips the implementation of the correction of all affected devices. In case any devices cannot be corrected, inform Philips of the reason why the Technical Solution could not be implemented.
- Customers should complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both their acknowledgement of this recall and confirm understanding of actions to be taken.

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 IntelliVue Philips Patient Monitor 6000 series.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

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Email Address: _____

Date (DD / MMM / YYYY): _____

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

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URGENT Field Safety Notice

RE: IntelliVue Patient Monitor 6000 series Lasered Incorrectly

March 6, 2025

Dear Distributor,

Philips has become aware of a potential safety issue with the Philips IntelliVue Patient Monitor 6000 series being lasered Incorrectly with a 12-Lead ECG symbol on the rear housing of the monitor.

It is imperative that all customers with affected devicess receive the attached URGENT Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- Affected devicess and how to identify them
- The actions that the customer/user should take to prevent risk to patients
- The actions planned by Philips to correct the problem

Philips is requesting that the information from this letter be properly distributed to all users that handle the affected devices.

Together with this letter we are providing a list of affected devicess that Philips has sold to your organization. As distributor of the affected devices, we kindly request that you:

- Send the attached URGENT Field Safety Notice to each customer to whom you have distributed any affected devices as soon as possible and no later than 5 days.
- Perform a good faith effort to reach each customer a minimum of three (3) times, and if possible, using multiple contact methods.
- Implement the Technical Solution established by Philips as soon as available within the timeframe communicated by Philips, and confirm with Philips the implementation of the correction of all affected devices. In case any devices cannot be corrected, inform Philips of the reason why the Technical Solution could not be implemented.
- Customers should complete the URGENT Field Safety Notice Response Form at the end of the notification to submit both their acknowledgement of this recall and confirm understanding of actions to be taken.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the Market/Business>.

Sincerely,

Deborah Currlin
Head of Quality, Hospital Patient Monitoring
Philips Healthcare