Field Safety Notice

Philips Healthcare

URGENT - Medical Device Correction

Missing ST elevation alarm using Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors

Dear Customer,

A problem has been detected with certain Philips IntelliVue Patient Monitors and Measurement Modules that, if it were to occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.

Philips has recently discovered that when the Hexad 12-Lead ECG Monitoring derivation is used in one specific configuration on affected monitors and modules, these devices do not alarm for ST Elevation (STE), which could lead to a delay in treatment.

Only the Hexad functionality is affected by this issue. All other ECG monitoring functionality works as specified.

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of the notice. This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Should you have any questions or concerns about this issue, please contact your local Philips representative <Philips representative contact details to be completed by the KM/country>.

This issue has been reported to the appropriate Regulatory Agencies.

Sincerely,

[redacted]

URGENT - Medical Device Correction

Missing ST elevation alarm using Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors

AFFECTED PRODUCTS	The following Philips IntelliVue Measurement Modules with software revisions listed below are affected: **Model** **Product** **SW Revision** X2 M3002A K.21.54 or L.00.96 X1 M3001A K.21.54 or L.00.96 The problem only occurs if either of the affected Philips IntelliVue Measurement Modules are used with Philips IntelliVue Patient Monitors with Hexad option #C54 (also bundled in options H11, H41, H42, CP2), or if an affected X2 Measurement Module is used in standalone mode (i.e., not connected to another monitor).
PROBLEM DESCRIPTION	The Hexad 12-Lead ECG Monitoring derivation uses a 6-lead set and derives remaining leads to provide a non-diagnostic 12-lead view, including ECG waves and ST measurements. The ST elevation alarm on the Patient Monitor or standalone X2 Measurement Module will not sound when indicated for all chest leads derived using Hexad 12-Lead ECG Monitoring in the Host Monitor configuration below: ST Analysis: "OFF" STE: "ON" STE Alarms: "ON"
HAZARD INVOLVED	If the STE alarm does not sound when indicated, a delay in treatment could occur.
HOW TO IDENTIFY AFFECTED PRODUCTS	The Software revisions and options of the device can be displayed by switching to the *"Stand by"* screen or *"Revisions => Appl SW or Config"* screen of the Philips IntelliVue host monitor or the Measurement Module X2, if operated in standalone mode. The software revision of the Monitor/Measurement Modules and the Monitor options can then be checked against those listed above.

URGENT - Medical Device Correction

Missing ST elevation alarm using Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors

ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a correction consisting of: • Distribution of this Field Safety Notice (FSN). • Software upgrade of the affected Philips IntelliVue Measurement Modules. A Philips Healthcare representative will contact customers with affected devices to arrange a software upgrade to correct the issues.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until your software is upgraded, please make sure that the ST Analysis is switched ON when using STE measurement in the Hexad 12-lead ECG Monitoring. This can be done by entering the ST Analysis Menu and select ST Analysis to “On”. For more detailed information, please refer to the Instructions for Use (IFU) of your host monitor or to the X2 Measurement Module IfU. Review this information with all staff members who may use this feature of the IntelliVue Patient Monitors.
FURTHER INFORMATION AND SUPPORT	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 KM/country>

URGENT - Medical Device Correction

Missing ST elevation alarm using Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors

Dear Customer,

A problem has been detected with certain Philips IntelliVue Patient Monitors and Measurement Modules that, if it were to occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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.

Philips has recently discovered that when the Hexad 12-Lead ECG Monitoring derivation is used in one specific configuration on affected monitors and modules, these devices do not alarm for ST Elevation (STE), which could lead to a delay in treatment.

Only the Hexad functionality is affected by this issue. All other ECG monitoring functionality works as specified.

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of the notice. This issue has been reported to the appropriate regulatory agencies.

It is imperative that all end-users with affected IntelliVue Patient Monitors as identified in the “AFFECTED PRODUCTS” section of the FSN, receive this Device Correction Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, send a copy of the attached Field Safety Notice to any customer to whom you have distributed one of the affected devices.

Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the “Ship To” field on the original invoice).

URGENT - Medical Device Correction

Missing ST elevation alarm using Hexad 12-Lead ECG Monitoring derivation with Philips IntelliVue Patient Monitors

I sincerely regret the inconvenience that this may cause you. Should you have any questions or concerns about this issue, please contact your local Philips representative <Philips representative contact details to be completed by the KM/country>.

Sincerely,