Field Safety Notice

Philips Healthcare

URGENT - Medical Device Correction

Distorted ST-Segment when using 12-Lead ECG Monitoring with Philips IntelliVue Patient Monitors

Dear Customer,

A problem has been detected with the Philips IntelliVue Patient Monitors that, if it were to occur, could pose a risk for patients. 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
- 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 performing 12-lead ECG monitoring, if an affected monitor detects and alerts the user that the ECG lead set is damaged or otherwise not performing appropriately, it will apply corrective filtering that can distort the ST-segment, which could contribute to a misdiagnosis or a misinterpretation causing a delayed or even an incorrect treatment if relied on by the user.

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 this notice. This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Your satisfaction with Philips’ products and with our response to this issue is very important to us. Please contact your Philips Representative or the UK Philips Customer Care Service Centre on 0870 532 9741 with questions or concerns about this correction.

Sincerely,

Hauke Schik
Director of Quality & Regulatory Affairs

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AFFECTED PRODUCTS	The Philips IntelliVue Patient Monitors with the ECG 12-lead option #C12 for following products with the combination of SW version (J.0, J.1, K.2, L.0) and ECG Firmware revision E.01.22: **Model** — **Product Number** IntelliVue Multi Measurement Server — M3001A IntelliVue Multi Measurement Server SLCP — M3001AL IntelliVue Multi Measurement Server X2 — M3002A IntelliVue MP2 — M8102A IntelliVue MP5 — M8105A
PROBLEM DESCRIPTION	ST-segments in a 12-lead ECG may become distorted and the ST-value may be inaccurate when an affected monitor automatically activates ECG filtering in the event that a “ECG Check Cable” or “ECG Noisy Elec xx” INOP condition is triggered and displayed. These INOPs are triggered when the monitor detects a low impedance between ECG lead wires and the cable shield in the lead set, which can be caused by mechanical damage or fluid ingress.
HAZARD INVOLVED	Distortions on the ST-segment and associated numerics can contribute to a misdiagnosis or misinterpretation, which can cause a delayed or an incorrect treatment.
HOW TO IDENTIFY AFFECTED PRODUCTS	The Software/Firmware revisions and options of the device can be displayed by switching to the “Revisions → Appl SW“ or Revisions → ECGRsp” screen of the Philips IntelliVue monitor. The software revision of the Monitor/Measurement Modules and the Monitor options can then be checked against those listed above.
ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a correction consisting of: • Distribution of this Field Safety Notice (FSN). • Software update of the affected devices. A Philips Healthcare representative will contact customers with affected devices to arrange a software update to correct the issues.

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<table>
<tr>
<td>ACTION TO BE TAKEN BY CUSTOMER / USER</td>
<td>Until your software is updated, please make sure that the “ECG Check Cable” or “ECG Noisy Elec xx” INOP is taken care of by following the instructions in the corresponding IfU:
<table>
<tr><th>INOP message, Indication</th><th>What to do</th></tr>
<tr><td>ECG Noisy Elec <ECG Lead></td><td>The ECG signal from the named ECG electrodes [RA, LA, LL, RL, V (or C)] is noisy. Check the ECG connections and make sure that the electrode indicated is attached.
Depending on the software version in the measurement device, this INOP can also indicate a defective ECG cable (see INOP ECG Check Cable).</td></tr>
<tr><td>ECG Check Cable
INOP tone</td><td>Defective ECG cable was detected, which can result in inaccurate ECG signals and measurements, e.g. ST numeric, displayed on the monitor. Check trunk cable and lead set for damage and replace if INOP persists.</td></tr>
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Review this information with all staff members who are using the conventional 12-lead ECG of the IntelliVue Patient Monitors and need to be aware of the contents of this communication.</td>
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<td>FURTHER INFORMATION AND SUPPORT</td>
<td>If you need any further information or support concerning this issue, please contact your local Philips representative Please contact your Philips Representative or the UK Philips Customer Care Service Centre on 0870 532 9741</td>
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