

Field Safety Notice (FSN)

Philips Healthcare

Connected Care Solutions

-1/3-

FSN86201683B FSN86201684B
January 2016

**URGENT – Field Safety Notice
Philips IntelliVue Information Center (PIIC) iX**

Calculated ECG leads, also referred to as reconstructed leads when viewed or printed at the Information Center iX, may misrepresent the ECG waveform morphology in some reconstructed leads.

Dear Customer,

A problem has been detected in the Philips IntelliVue Information Center (PIIC) iX that, if it were to re-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.

Please retain a copy with the equipment Instruction for Use.

Calculated ECG leads, also referred to as reconstructed leads when viewed or printed at the Information Center iX, may misrepresent the ECG waveform morphology in some reconstructed leads.

The following pages provide additional instructions and actions that will be taken to address this problem.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem

Sincerely,




Thomas J. Fallon
Director, Quality & Regulatory

Field Safety Notice (FSN)

Connected Care Solutions

AFFECTED PRODUCTS	866023 IntelliVue Info Center iX, A.0 866117 PIIC Classic Upgrade 866389 IntelliVue Info Center iX, B.0
PROBLEM DESCRIPTION	Calculated ECG leads, also referred to as reconstructed leads when viewed or printed at the Information Center iX, may misrepresent the ECG waveform morphology in some reconstructed leads. (The full set of six limb leads is commonly calculated from 2 limb leads.) Following are the lead combinations that are affected. <ul style="list-style-type: none">• Lead I and Lead III-(aVL incorrectly reconstructed)• Lead I and Lead aVR-(aVL Lead incorrectly reconstructed)• Lead III and Lead aVF-(II incorrectly reconstructed)<ul style="list-style-type: none">○ With this combination and Hexad on, the 4 derived V leads morphology will also be misrepresented in review applications. TRx/MX40 only – III, V or aVR, V (aVL incorrectly reconstructed) review applications only.
HAZARD INVOLVED	There are two possible hazardous situations: <ul style="list-style-type: none">• If ECG waveform changes that are consistent with an evolving cardiac event are not detected immediately because the ECG wave morphology from one limb lead is misrepresented when viewed or printed at the iX, a delay in treatment could occur. (false negative). • If ECG waveform changes, that are consistent with an evolving cardiac event, are evident in the ECG waveform morphology data from one limb lead but do not represent a true clinical event for the patient (false positive); the wave morphology is visually misinterpreted by a clinician and incorrect treatment can occur.

Field Safety Notice (FSN)

<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>PIIC iX Revision A.0X or B.0X – Identify the affected product by clicking on the Philips watermark on the PIIC iX surveillance display. This will bring up the Product Support Page. Software Version has the release that the product is running.</p> 
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>Arrhythmia alarms are not affected. ST alarms, ST values and measurements are also not affected and could be used to assist with the decision to obtain a diagnostic ECG.</p> <p>The ECG waves at the bedside are not affected. Printing ECG waves from the bedside is an alternative to printing from the PIIC iX.</p> <p>Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.</p> <p>Contact your local Philips representative if you have a device impacted by this issue.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips has initiated a correction to address this issue. Contact your local Philips representative if you have a question about any device impacted by this issue. A software correction will be provided to customers with impacted devices at no charge.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>