

## **URGENT – Medical Device Correction**

### **Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX**

Dear Customer,

A problem has been detected with certain Philips IntelliVue MX40 Patient Wearable Monitor, 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.

Please retain a copy with the equipment Instruction for Use.

Philips has recently discovered that when the local configuration setting 'Alarms On' is modified from its factory default, in certain software revisions the Philips IntelliVue MX40 Patient Wearable Monitor will disable generation and delivery of ECG alarms to the Philips IntelliVue Information Center iX (PIIC iX) without visual indication on the PIIC iX that the ECG alarms have been disabled. This could lead to a delay in treatment.

Please see the attached Field Safety Notice that provides information on how to identify affected devices and instructions on actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

This issue has been reported to the appropriate regulatory agencies.

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.

Sincerely,



Kristen Phillips  
Director of Quality Assurance and Regulatory Affairs

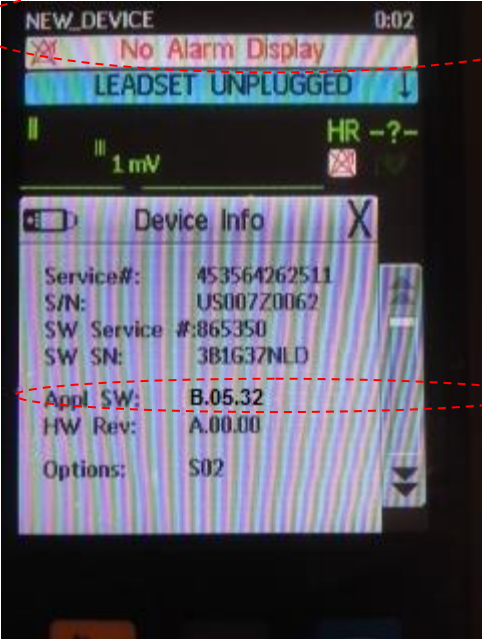
## URGENT – Medical Device Correction

### Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX

<p><b>AFFECTED PRODUCTS</b></p>	<p>The following product numbers and Exchange part numbers containing SW Revisions B.05.28, B.05.29, and B.05.32 of the Philips IntelliVue MX40 Patient Wearable Monitor are affected by this correction:</p> <p>Product:</p> <p style="padding-left: 40px;">865351 865352</p> <p>Exchange part:</p> <p style="padding-left: 40px;">453564262531 453564262551 453564262571 453564262591 453564615351 453564615371 453564467761 (Korea) 453564467781 (Korea) 453564451791 (Japan, Taiwan, Indonesia) 453564451811 (Japan, Taiwan, Indonesia) 453564467821 (Mexico) 453564467841 (China) 453564467861 (China)</p>
<p><b>PROBLEM DESCRIPTION</b></p>	<p>When the Patient Wearable Monitor local configuration setting ‘Alarms On’ is modified from its factory default, the Philips IntelliVue MX40 Patient Wearable Monitor will disable generation and delivery of ECG alarms to the Philips IntelliVue Information Center iX (PIIC iX) without a visual indication on the PIIC iX that the ECG alarms have been disabled.</p>
<p><b>HAZARD INVOLVED</b></p>	<p>If the generation and delivery of ECG alarms to the Information Center is disabled without a corresponding visual indication at the Information Center, a delay in treatment could occur.</p>

## URGENT – Medical Device Correction

### Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX

<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<p>The Product Number and Exchange part number is contained on the devices product label, located on the back of the device.</p> <p>The product number is indicated after the symbol <span style="border: 1px solid black; padding: 2px;">REF</span> and the exchange part number is indicated after the Service #.</p> <p>The MX40 software revision is identified by touching the battery icon in the lower right of the MX40 display which opens the Device Status window. In the Device Status window, touch the Device Info text, to display the application software (Appl SW) version:</p>  <p style="text-align: center;">Figure 1: Device Info screen indicating software revision</p>
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<p>Philips is voluntarily initiating a correction consisting of:</p> <ul style="list-style-type: none"> <li>• Distribution of this Field Safety Notice (FSN).</li> <li>• A Software upgrade for affected Philips IntelliVue MX40 Patient Wearable Monitors.</li> </ul> <p>A Philips Healthcare representative will contact customers with affected devices to arrange for the installation of the software upgrade.</p>

## URGENT – Medical Device Correction

### Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX

<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>Until your software is upgraded, please make sure that the MX40 Patient Wearable Monitor local configuration setting 'Alarms On' is configured to its factory default. This can be done by following these steps on each MX40 device to enable alarms:</p> <ol style="list-style-type: none"> <li>1. Unassign MX40 from the PIIC iX</li> <li>2. Remove and reinsert batteries</li> <li>3. Touch MX40 Smart Keys</li> <li>4. Scroll to select "Op Modes"</li> <li>5. Touch "Config"</li> <li>6. Enter password, press "Enter"</li> <li>7. Scroll to choose Alarms On and touch to toggle to Enabled</li> <li>8. X to close window</li> <li>9. Choose "Save" and "Confirm"</li> <li>10. MX40 reboots and enters Monitor mode</li> <li>11. Assign MX40 to PIIC iX and verify that "No Alarm Display" banner is no longer present</li> </ol> <div data-bbox="467 976 901 1764" style="text-align: center;"> </div>
<p><b>FURTHER INFORMATION AND SUPPORT</b></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>