

**URGENT – Field Safety Notice
IntelliVue MX40 B.00 and B.01**

Paused Alarms Do Not Automatically Restart the Alarming

Dear Customer,

A problem has been detected in the Philips IntelliVue MX40 (part numbers 865351, 865352) with software revisions B.00 and B.01, that, if it were to occur, could pose a risk for patients. This IntelliVue MX40 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.

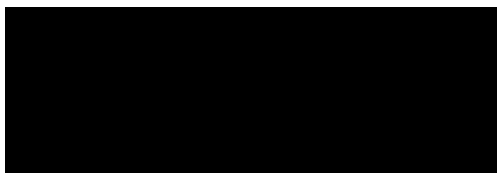
IntelliVue MX40 (part numbers 865350, 865352) with software revisions B.00 or B.01 may not resume alarming when the alarms are paused and the pause timer ends. This issue will only occur when the MX40 is in monitor mode connected to a Philips IntelliVue Information Center iX (PIIC iX) that is not in a specific default configuration.

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 call us at <Philips representative contact details to be completed by the KM / country>.

Sincerely,





Director of Quality Assurance and Regulatory Affairs

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AFFECTED PRODUCTS	The following products with software versions B.00.x or B.01.x are affected: 865350 IntelliVue MX40 Smart-hopping 1.4 GHz, 865351 IntelliVue MX40 Smart-hopping 2.4 GHz, 865352 IntelliVue MX40 WLAN
PROBLEM DESCRIPTION	<p>IntelliVue MX40 (part numbers 865350, 865352) with software revisions B.00 and B.01 is set in monitor mode with the Philips IntelliVue Information Center iX (PIIC iX); when using the Pause Alarms feature in the non-default configuration. The Alarms Paused condition remains indefinitely unless alarming is manually restarted by deselecting the Pause Alarm button at the MX40 or at the PIIC iX.</p> <p>The Alarm Pause time is user selectable from 1 to 3 minutes, with a default of 2 minutes, when operating the MX40 with the PIIC iX.</p> <p>When the following specific conditions are met, the Alarm Pause time does not automatically restart when it reaches its selected time limit:</p> <ul style="list-style-type: none"> the Pause Alarms configuration is enabled in the non-default setting of both Red and Yellow level alarms, and the MX40 is selected for the non-default setting of monitor mode, and the Pause Alarms is initiated to pause an active alarm or to maintain a short 'non-alarm' state while in the patient's vicinity, and an alarm condition occurs during the Pause Alarms time. <p>The MX40 will continue to display “Alarms Paused: 0:00” (Figure 1), and the PIIC iX display “Alarms Paused” (Figure 2) until the Pause Alarms feature is disabled manually.</p>  <p>Figure 1: IntelliVue MX40 displays the Alarms Paused banner with countdown timer.</p>  <p>Figure 2: PIIC iX displays the Alarms Paused banner.</p> <p>For more information regarding alarm settings and controls, refer to IntelliVue Information Center iX Instructions for Use and the IntelliVue MX40 Instructions for Use.</p>

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HAZARD INVOLVED	There is potential for the Alarms Paused banner to go unnoticed at the IntelliVue Information Center iX and the IntelliVue MX40. The user may expect the Alarms Paused to automatically restart according to the selected Pause Alarm time, rather than deselecting the Alarms Paused button manually, whereby the Pause Alarm state will persist and an alarm condition will not be audibly heard potentially resulting in a delay of treatment.
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>A device label is located on the back of the device referencing “IntelliVue MX40” and part number (865351 or 865352).</p> <p>The software revision can be identified by touching the MX40 screen in the lower right located where the battery icon resides, which opens the Device Status window. From this window, touch the Device Info text, which displays Appl SW to determine software version:</p> 
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>The following two items must be configured when using MX40 with the IntelliVue Information Center iX:</p> <ol style="list-style-type: none"> 1. Utilize the default state of Pause Alarms at Yellow only, which disables the ability to Pause/Suspend all Red level alarms 2. Utilize the default state of Remote Suspend Alarms as Off, which disables the use of the Pause Alarms feature at the MX40 device
ACTIONS PLANNED BY PHILIPS	Philips is initiating a correction to affected devices. The correction will consist of a software upgrade and will be provided free of charge to all devices affected by this issue. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the upgrade.
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> .