URGENT - Medical Device Correction

Philips IntelliVue Patient Monitors:

MP20 (M8001A), MP30 (M8002A), MP40 (M8003A), MP50 (M8004A), MP60 (M8005A), MP70 (M8007A), MP80 (M8008A), MP90 (M8010A), D80 (M8016A), MX600 (865242), MX700 (865241) MX800 (865240)

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 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 of this Notice.

Philips has recently received reports that, under certain circumstances, alarms announced at the patient monitor are not announced (either visual or audible) at the central station. This issue affects the following IntelliVue patient monitor models with SW rev. H.xx.xx

MP20 (M8001A), MP30 (M8002A), MP40 (M8003A), MP50 (M8004A), MP60 (M8005A), MP70 (M8007A), MP80 (M8008A), MP90 (M8010A), Intelligent Display D80 (M8016A), MX600 (865242), MX700 (865241) and MX800 (865240)

If this issue occurs, the primary alarm function at the bedside monitor is not affected.

Philips is conducting this voluntary correction to upgrade software on affected devices. Please refer to the following pages, which provide instructions for actions to be taken. Follow the “Action to be taken by Customer/User” section of the instructions. This issue has been reported to the appropriate regulatory agencies.

Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products is very important to us.

Please contact your local Philips Healthcare Customer Service representative <Philips representative contact details to be completed by the KM/country>with questions or concerns about this correction.

Sincerely,

Director of Quality & Regulatory Affairs

Attachment

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AFFECTED PRODUCTS	The following Philips IntelliVue Patient Monitors shipped or upgraded to SW Revision H.xx.xx between October 6, 2010 and January 23, 2012: **Model** **Product** MX800 865240 MX700 865241 MX600 865242 MP20 M8001A MP30 M8002A MP40 M8003A MP50 M8004A MP60 M8005A MP70 M8007A MP80 M8008A MP90 M8010A D80* M8016A Only the above referenced models with SW Revision H (up to and including H.15.36) are affected. * Although the D80 Intelligent Display (M8016A) is not affected by the issue; a software upgrade is required to ensure product compatibility.
PROBLEM DESCRIPTION	Under certain circumstances, alarms announced at the affected patient monitors are not announced (either visual or audible) at the central station. If this issue occurs, the primary alarm function at the bedside monitor is not affected. All physiological information transferred from the bedside monitor is correctly displayed at the central station.
HAZARD INVOLVED	If a patient develops a condition leading to an alarm and is being monitored with a monitor which has entered the state where alarm information is not communicated to the central station, clinical personnel monitoring the central station may not be advised of an alarm condition. This could cause a delayed response to the alarm condition of the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	The Product Number and Serial Number is contained on the devices product label, located on the front of the device. The SW revision can be accessed via the Revision Screen at the bedside monitor.
ACTIONS PLANNED BY PHILIPS	Philips will provide a software upgrade for all affected devices at no charge.A Philips Healthcare representative will contact customers with affected devices to arrange an upgrade of the Intellivue software.

ACTION TO BE TAKEN BY CUSTOMER / USER	The alarm function of the bedside IntelliVue Patient Monitor is not affected. Until the software upgrade is installed, do not rely on the alarm function of the central station. Review this information with all staff members who interface with the central station and need to be aware of the contents of this communication.
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>