URGENT – Medical Device Correction

Philips IntelliVue MX40 WLAN Patient Wearable Monitor may not automatically switch to Monitor Mode with audible alarms when association with central monitoring system is unsuccessful [incomplete]

Dear Customer,

A problem has been detected with certain Philips IntelliVue MX40 Patient Wearable 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 risk to 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 under specific 802.11 network conditions, a partial re-association of the MX40 WLAN monitor to a compatible central monitoring system ("Information Center") is possible. In this state, although the Information Center provides a visible and audible "No Data Tele" INOP alert, the MX40 WLAN itself enters telemetry mode, i.e., its screen turns off in one minute and local alarming is disabled.

To date, the necessary network conditions have only been found during system testing by a customer and Philips. It is unlikely that these conditions occur in clinical use, and Philips has received no complaints involving clinical use that we have been able to associate with this problem Nonetheless, if the problem were to occur while monitoring a patient, it could result to a delay in treatment.

This issue only involves MX40 WLAN monitors, i.e., those operating on a customer-provided 802.11 wireless LAN. MX40 monitors with 1.4 GHz and 2.4 GHz Smart-Hopping radios are not affected.

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

Sincerely,

[redacted]

Kristen Phillips
Head of Quality and Regulatory
Patient Monitoring Andover

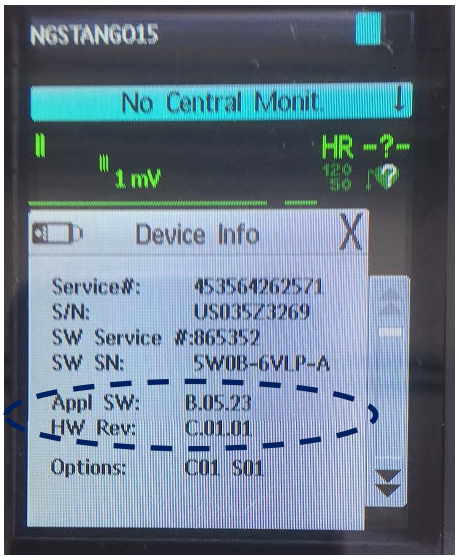
URGENT – Medical Device Correction

Philips IntelliVue MX40 WLAN Patient Wearable Monitor may not automatically switch to Monitor Mode with audible alarms when association with central monitoring system is unsuccessful [incomplete]

AFFECTED PRODUCTS	Philips IntelliVue MX40 WLAN Patient Wearable Monitor The following product number and Exchange part numbers containing the combination of HW Revision C.01.01 with SW Revisions B.05 or B.06 of the Philips IntelliVue MX40 Patient Wearable Monitor are affected by this correction: Product: 865352 Exchange part (service numbers): 453564615311 TELE PWM,802.11a/b/g,ECG only, US only 453564615331 TELE PWM,802.11a/b/g,ECG&Sp02, US only Note that MX40 monitors with 1.4 GHz and 2.4 GHz Smart-Hopping radios are not affected.
PROBLEM DESCRIPTION	Philips has recently discovered that under specific 802.11 network conditions, a partial re-association of the MX40 WLAN monitor to a compatible central monitoring system (“Information Center”) is possible. In this state, although the Information Center provides a visible and audible “No Data Tele” INOP alert, the MX40 WLAN itself enters telemetry mode, i.e., its screen turns off in one minute and local alarming is disabled.
HAZARD INVOLVED	If an alarm is not annunciated either at the MX40 monitor or at the Information Center, a delay in treatment could result.

URGENT – Medical Device Correction

Philips IntelliVue MX40 WLAN Patient Wearable Monitor may not automatically switch to Monitor Mode with audible alarms when association with central monitoring system is unsuccessful [incomplete]

HOW TO IDENTIFY AFFECTED PRODUCTS	The Product Number and exchange part number are contained on the device's product label, located on the back of the device. The product number is indicated after the symbol REF and and may be either 6-numbers or 12-numbers long. The exchange part number is indicated after the Service #. 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. The Service # and serial number (S/N) are also displayed in this window.  Figure 1: Product number and Exchange part numbers on the product label. Please note, the REF product number may be either 6-numbers or 12-numbers.  Figure 2: Device Info screen indicating software revision.
ACTIONS PLANNED BY PHILIPS	• Philips is releasing a software upgrade B.06.18 for affected Philips IntelliVue MX40 Patient Wearable Monitors. A Philips Healthcare representative will contact customers with affected devices to arrange for the installation of the software upgrade.

URGENT – Medical Device Correction

Philips IntelliVue MX40 WLAN Patient Wearable Monitor may not automatically switch to Monitor Mode with audible alarms when association with central monitoring system is unsuccessful [incomplete]

ACTION TO BE TAKEN BY CUSTOMER / USER	When a "No Data Tele" INOP alert is displayed on an Philips IntelliVue Information Center iX ("PIIC iX"), check the MX40 as directed in the PIIC iX B.01 IFU, page 87. If the MX40 is in the Coverage Area, remove the battery, and reinsert the battery. If the MX40 is not in the Coverage Area, place the sector in the PIIC iX in "standby" as directed in the MX40 B.06 IFU, page 53, or return the patient and MX40 to the Coverage Area.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact <Philips representative contact details to be completed by the KM / country>.