PHILIPS

URGENT Field Safety Notice

Patient Information Center (PIC iX) and IntelliVue MX40
DHCP lease expiration re-connectivity issue between IntelliVue MX40 and PIC iX

22 -May-2023

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 this letter for your records.

Dear Customer,

Philips has become aware of a potential compliance issue with the Philips Patient Information Center (PIC iX) and IntelliVue MX40 that if it were to occur, could affect the performance of the equipment. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

   During extended operation of the MX40 with the PIC iX, the DHCP (Dynamic Host Configuration Protocol) lease can expire on the MX40. If the DHCP lease expires while the device is offline, upon reconnecting with the PIC iX, a new IP address will be assigned to the MX40. The PIC iX will not recognize the new IP address after reconnecting and therefore the expecting settings sync fails.

   This results in a the PIC iX displaying any changed setting but the device will not reflect the changed settings. Rather the will continue to operate under the previously synced settings from before the IP address change.

2. Hazard/harm associated with the issue

   In the event that this situation occurs patient harm is unlikely. This determination is based on a review of historical data associated with this issue, which did not result in any patient harm.

   The hazard identified is the potential for delayed treatment if the user does not identify that the patient settings have not been configured to the new IP address.

PHILIPS

3. Affected products and how to identify them

The defect is within the software of the PIC iX device, however the symptom only is observed when the PIC iX is connected to the MX40 devices. Therefore, product information and identification of both the PIC iX and products are listed below:

PIC iX

The intended use of the device is to receive, aggregate, process, display and distribute physiologic waves, parameters, alarms, and events for multiple patients.

Product Code	Product Description	Software Revision
866389	Patient Information Center iX	4.0.1
866390	Patient Information Center iX Expand	4.0.1

Use the following instructions to identify the software revision of your device:

Access the Product Support screen by clicking the Phillips icon in your application. The PIC iX Software Serial Number and Software Version appear on the Product Support screen in the Product Information Section under Serial Number and Software Version respectively. Refer to Image 1 below:

Image 1 — Software Version Identification
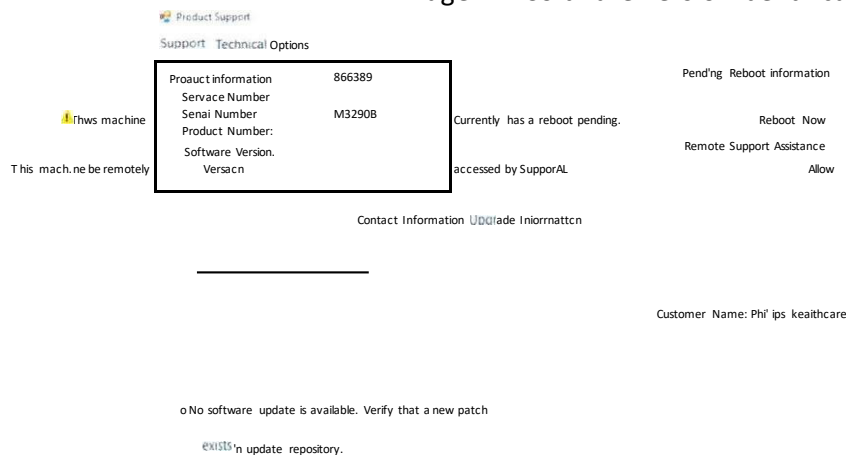
IntelliVue MX40:

The IntelliVue   patient monitor is a wearable patient monitor comprising of a 2.8in color touch sensitive display. The IntelliVue MX40 patient monitor is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The device is intended for monitoring and recording of, and to generate alarms for,

PHILIPS

multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals.

Product Code	Product Description
865350	MX40 1.4 GHz Smart Hopping
865351	MX40 2.4 GHz Smart Hopping
865352	IntelliVue MX40 802.11a/b/g/h
867146	2.4 GHz Smart Hopping

The ___ can be identified by finding the Product Code listed on the label on the back of the MX40. The Product Code is listed under REF.

Image 2 — MX40 device and rear label

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

This communication should be shared with all clinical staff to review and understand. Place this Important Product Notice with the documentation of the PIC iX Instructions for Use.

Additonal Actions Dependent on Normal Workflow:

1. <u>Workflow A: MX40 Routinely Cleared from Sector:</u>

    If the MX40 is routinely cleared from the sector upon discharge of a patient then no additional action is required.

2. <u>Workflow B: MX40 not Routinely Cleared from Sector:</u>

    <u>ODtion 1: Change Default Settings to Clear Sector Automatically.</u>

    The PIC iX can be setup to routinely clear the sector by executing the following:

    a. This can be set as the default as needed by selecting the "Clear Sector" selection and the "Clear unlocked Telemetry Devices from bed" in the "Configuration, Patient Management/Workflow", as highlighted in the image below:

    Image 3 — Default Clear Sector Settings

PHILIPS

CJClear sector by default on discharqe or transfer

- ZOtscharge

EZPtint Report

Twelve Lead Export Reminder

ÜClear all unlocked careqtver ass€qnments from the oed

in."ifiriiteStanetjv:

} unlocked.IelemeD• from tpedi,

DClear uniocked Monitors trom bed

C)Clear unlocked Bedside Monitors from bed

DCtear unlocked intelltetidge IAN Devices from bed

PHILIPS

<u>Option 2: Clear MX40 from Sector Manually</u>

The MX40 can be cleared from the sector manually by following the steps below:

  a. Identify the sector to be cleared from the PIC iX. These steps may be repeated for all sectors in use if they are not routinely cleared.
  b. Select the "Manage Patient" button and the "Manage Patient" window will display.
  c. Select the "Clear Sector" button and the discharge window will display.

Check the box next to the "Clear Sectod' option, as shown in the example Image 4 below

Image 4 — Clear Sector

Oa•.chatge

Warning:

This action will discharge the patient in BED9. Data will not be saved because the patient is not admitted.

Clear Sector (Stops central surveillance for BED9)

Please check tne settings. equ•pment and caregwer assignments for all admissions.

Discharge	Cancel

  d. Selecting the "Cancel" button does not change the sector assignment. Finalize the process by selecting the "Discharge" button.

3. <u>Workflow C: Clear Sector Option Not Available:</u>

In some configurations, the clear sector function will not be available. If this occurs, please contact the local response center for guidance on how to proceed.

5. Actions planned by Philips Hospital Patient Monitoring, to correct the problem

A Philips representative will reach out to you to arrange for a software upgrade to your device. This upgrade will be performed by a Field Service Engineer (FSE) or Authorized Service Provider (ASP) and will correct the software defect within the PIC iX device and resolve the issue.

If you need any further information or support concerning this issue, please contact your local Philips representative:

Philips regrets any inconvenience caused by this problem.

Sincerely,

…

PHILIPS