Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 122 **dated** 13/6/23 **Regarding NCMDR Field Safety Corrective Action of Intellivue Mx40 Patient Monitor from (mfr: Philips Healthcare).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 122/2023

24 -11-1444 H

13 -06-2023

Field Safety Corrective Action of Intellivue Mx40 Patient Monitor from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19556
Product	Intellivue Mx40 Patient Monitor.
Description	Patient monitor.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co. LLC.
The affected products	- MX40 1.4 GHz Smart Hopping; Product number: 865350 - MX40 2.4 GHz Smart Hopping; Product number: 865351, 867146 - IntelliVue MX40 802.11a/b/g/n; Product number: 865352
Reason	When the MX40 is in Standby mode for an extended period without patient surveillance no monitoring or alarming is available because alarms, as designed, cannot be triggered when the MX40 is in standby mode.
Action	1. Please refer to the instructions in the IFU before using standby mode, see Sections: Standby Behavior, Unit Configurable Settings and Global Settings. 2. You can also find information about Standby mode from the PIC iX online Help. 3. In addition to the above, please refer to the instructions mentioned in "Actions that should be taken by the customer / user in order to prevent risks for patients or users" in the attachment. 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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PHILIPS

URGENT Field Safety Notice

INTELLIVUE MX40 PATIENT MONITOR

25 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,

This **Field Safety Notice** is to remind customers to review the information in the Intellivue MX40 Instructions for Use (IFU) on how to use Standby mode and to explain under what circumstances, use of or exposure to the device may pose a risk of harm. The notification alerts users of the associated risk of using Standby mode and steps to be taken to reduce or eliminate the risk.

Figure 1 – MX40 device

What's the problem

When the MX40 is in Standby mode for an extended period without patient surveillance no monitoring or alarming is available because alarms, as designed, cannot be triggered when the MX40 is in standby mode.

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When users place the MX40 device in Standby mode, there are 2 possible outcomes:
1) If a timed duration (i.e., 10 minutes to 4 hours) is used for Standby, the MX40 will automatically resume monitoring and end Standby mode at the end of the time period.

or

2) if Infinite duration is used for Standby mode, the device will not resume monitoring until Standby is manually ended by the user or a "Tele Battery Low" INOP condition occurs. While the MX40 device is in Standby, physiological monitoring and alarming is stopped.

Therefore, there may be a hazardous situation present if a user places an MX40 in Standby longer than intended for completion of a patient procedure or test if the device is not taken out of Standby.

Affected products and how to identify them

#	Product name	Product number
1	MX40 1.4 GHz Smart Hopping	865350
2	MX40 2.4 GHz Smart Hopping	865351, 867146
3	IntelliVue MX40 802.11a/b/g/n	865352

Hazard/harm associated with Standby mode

If a device in Standby mode is connected to a patient, it will not monitor or alarm, which may cause a delay in treatment if the patient's condition deteriorates.

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

Please refer to the instructions in the IFU before using standby mode, see Sections: *Standby Behavior*, *Unit Configurable Settings* and *Global Settings*.

You can also find information about Standby mode from the PIC iX online Help, Click on the ? in any sector.

Type Standby on the search field for more information.

In addition to the above, when the device is in Standby mode, a Standby mode screen is provided for a configured period at the MX40, including information describing how to resume monitoring from Standby mode. The duration of time the screen is displayed can be configured by the user, with options between 1 and 30 minutes. The default time configuration for display of this screen is 1 minute. This provides information to the clinician that monitoring is not active. The MX40 is designed to be used with the Patient Information Center iX central monitor, which also indicates that the device is in Standby. The sector displays a message: "Standby. Click to Resume".

- To resume monitoring from Standby mode, Press the blue Main Screen Button or disconnect/reconnect the MX40 patient cable.

- If the MX40 is placed in a timed Standby mode duration (i.e., not Infinite), a Standby mode timer is displayed on the MX40 screen. If in infinite Standby mode, the *Standby* message is always displayed until the device sleeps. **Remember, when the device has been placed in Standby mode without the user choosing a time for when monitoring will resume (i.e., after 10, 20, 30**

minutes or 1, 2, 3, or 4 hours), the device will remain in Standby mode until the user manually resumes monitoring thereby ending Standby mode.

- Note that the Standby mode time may differ between the MX40 and the default setting at the Patient Information Center iX central monitor. The duration is determined by the location of the Standby selection, i.e., placing the MX40 in Standby mode at the device or at the Information Center iX When the MX40 comes out of Standby mode at either location, the device is activated and monitoring resumes at both locations.

- This notice should be passed on all those who need to be aware within your organization or to any organization where the potentially the MX40 devices have been transferred.

Actions taken by Philips in order to prevent risks for patients or users

Philips is distributing this URGENT Field Safety Notice to the affected customers / users.

If you need any further information, please contact your local Philips representative:
met.quality@philips.com

Sincerely,

Hauke Schik
Head of Quality

PHILIPS

URGENT Field Safety Notice

Reference: CR # 2023-CC-HPM-014, Intellivue MX40 Patient Monitors

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the URGENT Field Safety Notice letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

Customer Actions:

- Please refer to the instructions in the IFU before using standby mode, see Sections: *Standby Behavior*, *Unit Configurable Settings* and *Global Settings*.
- Review the contents of this letter with your staff.
- Pass this notice to all those who need to be aware within your organization or to any organization where the potentially the MX40 devices have been transferred.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice letter and confirm that the information from this Letter has been properly distributed to all users that handle the Intellivue MX40 Patient Monitors

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips at: *met.quality@philips.com*