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URGENT Field Safety Notice

Philips IntelliVue Patient Monitors MX400/450/500/550 Shipped or Upgraded with Incorrect Software Options

25-JUN-2024

To: Name / Title / Customer Name
Attention To:
Street Address
City, State, Zip Code

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 safety issue related to IntelliVue Patient Monitors MX400/450/500/550 that were shipped or upgraded with incorrect software options.

This notification is intended to inform you about:

1. The problem and under what circumstances it can occur

The IntelliVue MX400/MX450 and MX500/MX550 monitor is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The monitor is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained health care professionals in a hospital environment.
Software options M05, M06, and M20 for MX400/MX450/MX500/MX550 monitors provide expanded measurement capabilities for: 1 extra IBP line, 2 extra IBP lines, or 1 extra SpO2 line respectively. Refer to Table 1 below detailing default measurement capabilities for each device model and option.

Table 1. Measurement Capabilities

Device	Default Measurements		Additional Measurements by Option(s)		
	IBP	SpO2	M05 (Support 1 adtl. IBP)	M06 (Support 2 adtl. IBPs)	M20 (Support 1 adtl. SpO2)
MX400	2	1	+1	-	-
MX450	2	1	+1	-	-
MX500	2	1	-	+2	+1
MX550	2	1	-	+2	+1

Philips recently modified the software configuration for the IntelliVue MX400/450/500/550 patient monitors. These changes were made to reflect some options becoming standard capabilities for software

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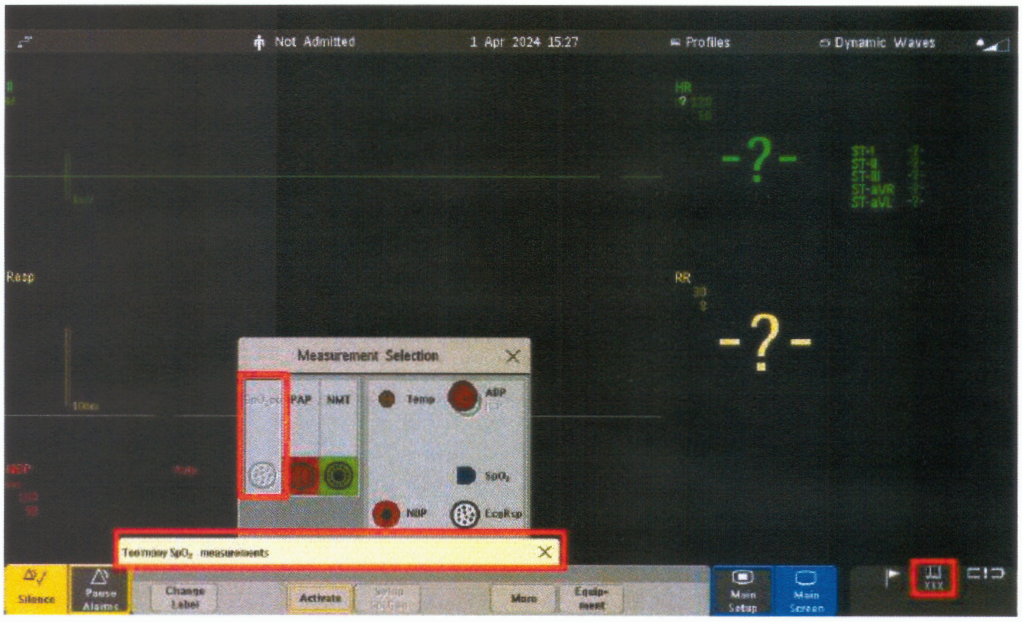
version N.x. In the process, the entitlements of software options M05, M06, and M20 were removed for software versions L.x and M.x. As a result of these changes Patient Monitors manufactured with or updated to the latest versions of software L.x or M.x will not offer the capabilities offered by software options M05, M06, and M20 when ordered/required by the customer.
NOTE: MX400/MX450/MX500/MX550 monitors with software version K.x may experience this issue too, due to software version K being out of support and the devices being provided with L.x entitlements.

The example below provides a representative image of the patient monitor screen when the device is missing the M20 option (needed for two SpO2 measurements).
In this example the monitor does not have the M20 option and has a measurement module with one SpO2 port connected as well as a standalone SpO2 port connected by the measurement rack. As highlighted in Red, the monitor provides multiple indications that the second SpO2 port cannot be activated by the user.



2. Hazard/harm associated with the issue

If a clinical user attempts setting up the patient for monitoring with additional lines, but the monitor is unable to turn on these additional measurements, there is the potential for incorrect or delayed treatment for the patient, caused by the device being incorrectly configured for the monitoring required. Although unlikely, this could potentially result in patient harm.

3. Affected products and how to identify them

#	Product Name(s)	Model Number(s)	Software Version(s)	UDI
1	IntelliVue Patient Monitor MX400	866060	L.x and M.x; K.x provided with L.x entitlements	00884838038752
2	IntelliVue Patient Monitor MX450	866062		00884838038769
3	IntelliVue Patient Monitor MX500	866064		00884838038776
4	IntelliVue Patient Monitor MX550	866066		00884838038783

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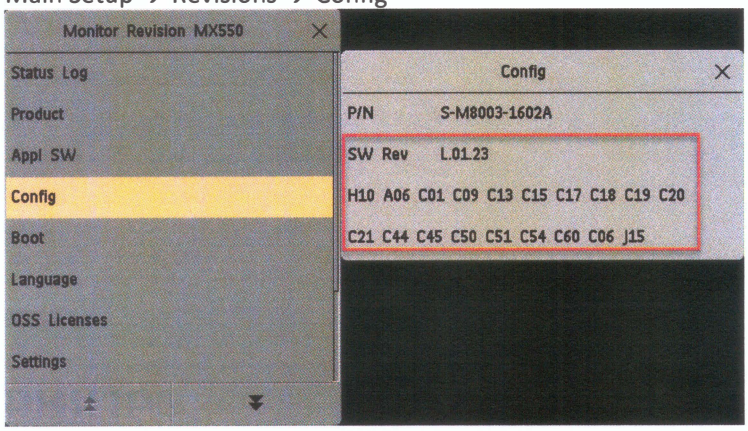
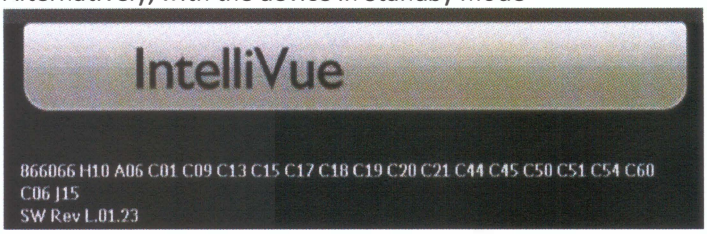
The currently installed software version and software options can be retrieved at the device via Main Setup → Revisions → Config



Alternatively, with the device in Standby mode



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

Use only default measurement capabilities, as indicated in Table 1 above, for monitoring purposes. Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a visit from a Philips Field Service Engineer who will reload the current device software to enable missing options (M05, M06, M20).

If you need any further information, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin,
Head of Quality

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URGENT Field Safety Notice Response Form

Reference: CR # 2024-CC-HPM-020, Philips IntelliVue Patient Monitors MX400/450/500/550 Shipped or Upgraded with Incorrect Software Options

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt by email: **<Philips representative contact details to be completed by the Market/Business>** . Completing this form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

_____

_____

Customer Actions:

Use only default measurement capabilities, as indicated in Table 1 above, for monitoring purposes.
Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.
We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle affected devices.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____