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URGENT Field Safety Notice

IntelliVue MX400-550 – Missing Software Option (CP2) in devices initially programmed to software version P.01.01

<Date of letter deployment,> *<date format: DD-MMM-YYYY, e.g. 02-JAN-2021>*

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code
<modify title block format as needed>

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 notify you that IntelliVue MX400/450/500/550 devices ordered with ***Option CP2*** and initially programmed to software version P.01.01 were configured incorrectly at the factory. Therefore, Enhanced ECG Capabilities provided by ***Option CP2*** were not enabled in these devices.

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

The commercial feature bundle CP2 (Extended ECG Capabilities) enables the following extended ECG capabilities (technical software options):

- **C01 (Full Arrhythmia)**
- C13 (ST/STE-Map)
- C51 (QT/QTc Analysis)
- C54 (HEXAD)

Impact of missing Option C01:
Without Option C01 Full Arrhythmia, the device will not provide the following yellow alarms for enhanced arrhythmia detection:

Non-Sustain VT	Vent Bigeminy	SVT
Vent Rhythm	Vent Trigeminy	AFIB
Run PVCs High	Multiform PVCs	End AFIB
Pair PVCs	Pause	Irregular HR
R-on-T PVCs	Missed Beat	End Irregular HR

If the device is deployed in a clinical environment where these alarms are required, the device may fail to alarm as expected by the clinical staff. The device will still provide red alarms, but will not be

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capable of monitoring the patient for early warning signs of developing arrhythmias. Therefore, this situation could potentially present a safety risk for the patients involved.
Important: ST analysis remains available, 12 lead ECG data can still be captured and measurements can be taken and alternate lead placement can be performed.

2. Hazard/harm associated with the issue

Although there have been no reports of harm associated with this issue, if patient is monitored using a device which does not have the required Enhanced ECG Alarm capabilities, delayed detection and notification of the arrhythmias may result in further deterioration of the patient's condition.

3. Affected products and how to identify them

#	**PRODUCT NAME (Only devices initially programmed to software version P.01.01 and ordered with Option CP2 are affected)**	**PRODUCT NUMBER**
1	IntelliVue MX400	866060
2	IntelliVue MX450	866062
3	IntelliVue MX500	866064
4	IntelliVue MX550	866066

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

- Please be aware that without Option C01 (Full Arrhythmia) the device will not provide the yellow alarms for enhanced arrhythmia detection.
- 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 affected devices might have been transferred.

5. Actions taken by Philips to correct the problem

Philips Representative will contact you to arrange reload of current device's software to enable missing software options (C01, C13, C51, C54).

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

Sincerely,

[redacted]

Head of Quality

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URGENT Field Safety Notice Response Form

Reference: CR # 2023-CC-HPM-019, IntelliVue MX400-550 – Missing Software Option (CP2) in devices initially programmed to software version P.01.01

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 be aware that without Option C01 (Full Arrhythmia) the device will not provide the yellow alarms for enhanced arrhythmia detection.
- 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 affected devices might 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 MX400-550, programmed to software version P.01.01.

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: recall.response@philips.com