# URGENT - Medical Device Correction

## Outdated waveform display on Philips IntelliVue Patient Monitors MX400, MX430, MX450, MX500, MX550

Dear Customer,

A problem has been detected with certain Philips IntelliVue Patient 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 risks for patients or users
- 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.

Philips has recently determined that when certain patient monitors (MX400, MX430, MX450, MX500, MX550) have been powered on continuously for at least three months, the waveforms displayed on the monitor may be outdated and therefore fail to reflect the patient's current condition. Should this occur, however, the monitor's alarms and numeric displays of vital signs will continue to function as specified and accurately reflect current patient data.

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice. This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Your satisfaction with Philips' products and with our response to this issue is very important to us. Please contact your local Philips representative <Philips representative contact details to be completed by the KM / country> with questions or concerns about this correction.

Sincerely,

[redacted]

Hauke Schik
Director of Quality & Regulatory Affairs

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| **AFFECTED PRODUCTS** | All units of the following models of Philips IntelliVue Patient Monitors are affected by this correction:<br><br>**Model** **Product**<br>MX400 866060<br>MX430 866061<br>MX450 866062<br>MX500 866064<br>MX550 866066 |
| **PROBLEM DESCRIPTION** | If an affected Patient Monitor has been powered on continuously for several months, any displayed waveforms will contain outdated data and therefore fail to reflect the patient's current condition.<br><br>Even if outdated waveforms are displayed as a result of this problem, the monitor's alarms and numeric displays of vital signs will continue to function as specified and accurately reflect current patient data.<br><br>The length of time that a monitor must be powered on before the problem occurs depends on the selected wave speed. It ranges from 102 days (@50 mm/s) to 820 days (@ 6,25 mm/s), and is approximately 205 days at the monitor's default wave speed of 25 mm/s.<br><br>The monitor must be powered off in order to avoid this problem. Simply placing it in stand-by mode is not sufficient. |
| **HAZARD INVOLVED** | Clinical decisions based on outdated waveform morphology may result in the administration of inappropriate therapy or a delay in the administration of appropriate therapy. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | The Product Number is contained on the devices product label, located on the back of the device. |

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| **ACTIONS PLANNED BY PHILIPS** | Philips is voluntarily initiating a correction consisting of:<br>• Distribution of this Field Safety Notice (FSN).<br>• A Software upgrade for affected Philips IntelliVue Patient Monitors.<br><br>A Philips Healthcare representative will contact customers with affected devices to arrange for the installation of the software upgrade. |
| **ACTION TO BE TAKEN BY CUSTOMER / USER** | Until your software is upgraded, users should cycle the power on affected devices on a monthly basis, especially if you usually do not completely switch off the device when no patients are monitored.<br><br>Please review this 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. |
| **FURTHER INFORMATION AND SUPPORT** | If you need any further information or support concerning this issue, please contact your local Philips representative <Philips representative contact details to be completed by the KM/country> |