Philips Healthcare

Patient Monitoring FSN86201863A March 22, 2019

URGENT - Medical Device Recall
IntelliVue MX40

<Date>Increased Battery Power Consumption and Absence of Low Battery Alerts

<Hospital/Clinic Name> cc: Chairman Medical Board and relevant Head of Departments

Dear Customer

Two problems have been detected in the Philips IntelliVue MX40 Patient Worn Monitor that could pose a risk to patients or otherwise affect patient care.

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 to patients
- 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.

Please retain a copy with the equipment Instruction for Use.

The first problem affects all MX40 Patient Worn Monitors with revision B software which may result in excessive battery power consumption. Specifically, the duration that the MX40 operates on a fully charged battery is approximately 25% shorter than is specified in the *MX40 Instructions for Use*.

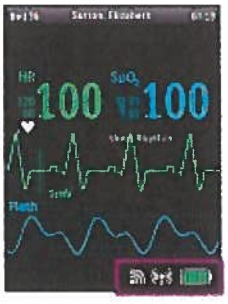
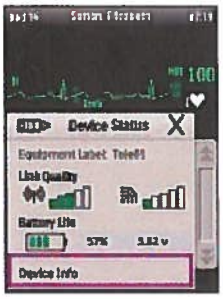
The second problem affects only a subset of MX40's with the pulse oximetry option and which use non-rechargeable AA batteries. In affected units, using SpO_2 automatic measurement mode may result in intermittent or missing low battery alerts. MX40 devices that use rechargeable batteries are not affected by this problem.

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>
Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)

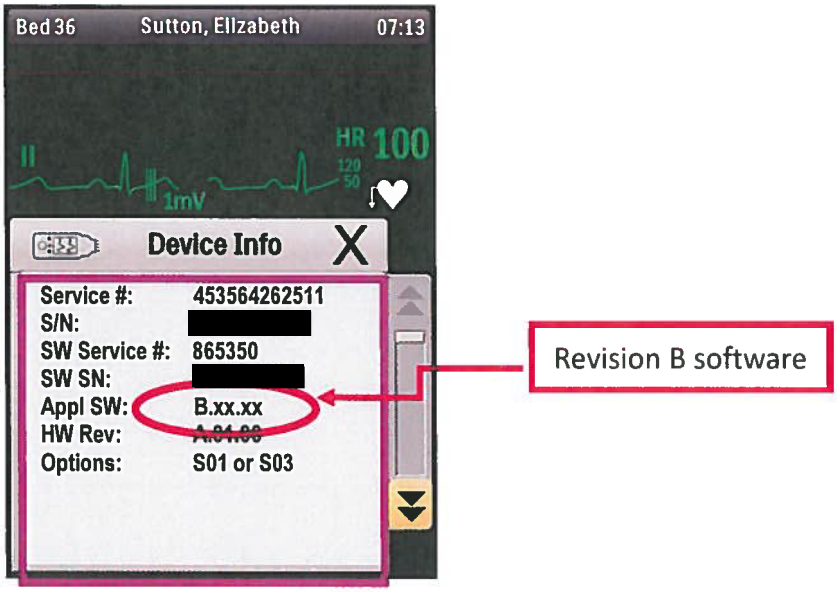
This recall will be reported to the appropriate regulatory agencies.

Philips apologizes for any inconvenience caused by this problem.

[redacted]
Head of Quality & Regulatory Affairs
Patient Monitoring, Andover

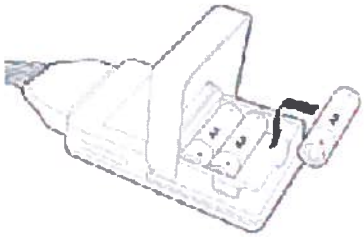
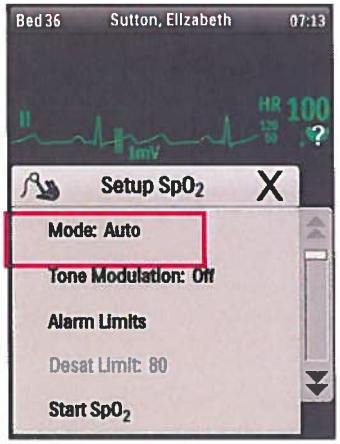
AFFECTED PRODUCTS	**Problem 1** **Excessive power consumption** All Philips IntelliVue MX40s with revision B software. **Problem 2** **Intermittent low battery alerts** All Philips IntelliVue MX40's that are configured to use AA disposable batteries and configured with SpO_2 (pulse oximetry) operating in automatic measurement mode.
PROBLEM DESCRIPTION	**Problem 1** Some MX40 Patient Worn Monitors may have excessive battery power consumption. For those MX40's with revision B software and fully charged batteries may last approximately 25% shorter than is specified in the *MX40 Instructions for Use*. This issue affects units operating on both rechargeable and disposable batteries. **Problem 2** Low battery technical alerts may not occur as specified in the *Instructions for Use* For those MX40's that: 1) operate with disposable AA batteries, and *2)* include optional SpO_2 used in automatic measurement mode. The technical alerts that may be absent include: • "Tele Battery Low", • "No SpO2T: Batt Low", • "Replace Tele Battery"
HAZARD INVOLVED	Although Problem 1 only involves more frequent replacement of discharged batteries by hospital staff than expected, Problem 2 could result in delay in therapy when the user does not have low battery alerts to warn them of loss of device function.
HOW TO IDENTIFY AFFECTED PRODUCTS (continued)	**Problem 1** Determine software revision installed. Plug in battery. After device boots up, touch the Device Status Area, then touch Device Info. Main Screen  Touch Device Status Area Device Status Screen  Touch Device Info

Device Info Screen



Confirm Revision B software

Problem 2 / Step 1
Confirm 865350 or 865351 part number ("REF")

	Problem 2 / Step 2 Confirm that AA batteries are used  **Problem 2 / Step 3** Confirm that MX40 includes SpO_2 operating in automatic mode 
ACTION TO BE TAKEN BY CUSTOMER / USER	MX40 monitors can continue to be used while awaiting a software upgrade. Customers should maintain an adequate supply of fully charged batteries given the approximately 25% increased power consumption. Switch to continuous or manual SpO_2 measurements if your unit is using automatic measurement mode.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare will release a software revision, which will correct both issues. Philips will contact you to arrange for software correction.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips Representative at <Philips representative contact details to be completed by KM/country> Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)