-UPDATE-
URGENT - Medical Device Recall
IntelliVue MX40

Increased Battery Power Consumption and Absence of Low Battery Alarms

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

Previously, you received an initial letter related to power consumption and battery alarms of the MX40. This letter provides a simplified "ACTIONS TO BE TAKEN BY THE CUSTOMER / USER". This Medical Device Recall letter 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.

Please retain a copy with the equipment Instruction for Use.

The MX40 may experience increased power consumption and may have a lack of visual and/or audible notifications while in a "Low Battery State".

If you need any further information or support concerning this issue, please contact your local Philips representative: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)
<Philips representative contact details to be completed by the KM / country>

This recall will be reported to the appropriate regulatory agencies.

Philips apologizes for any inconvenience caused by this problem.

Sincerely,

[redacted]

Kristen Phillips
Head of Quality & Regulatory Affairs
Patient Monitoring, Andover

AFFECTED PRODUCTS	All Philips IntelliVue MX40 Patient Worn Monitors.
PROBLEM DESCRIPTION	The MX40 may experience increased power consumption and may have a lack of visual and/or audible notifications while in a "Low Battery State".
HAZARD INVOLVED	The patient and nearby caregivers may not realize that monitoring has been lost and the battery should be replaced, which may result in a delay in recognition of the need for therapy and/or therapy delivery.
HOW TO IDENTIFY AFFECTED PRODUCTS	This action applies to all MX40's.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until you have upgraded the software on your MX40's, replace your batteries every 8 hours, unless you are using continuous monitoring mode and SpO2 monitoring with AA batteries, in which case replacement should be done every 2 hours.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare will release a software upgrade, which will correct this problem. 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: Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number) <Philips representative contact details to be completed by the KM / country>