PHILIPS

July 08, 2019

Re: Philips FCO86201863

To whom it may concern:

The Field Safety Notice (FSN) for FCO86201863 was revised several times prior to this final version. The Revision C draft of the Field Safety Notice explains the relationship of Revision B and C to the initial notice. For Revision C, at the request of the FDA, Philips edited the opening statement to clarify that the more recent notices refer to additional issues related to battery use and makes changes to the "Actions to be taken by the customer" section. Revision C was created specifically to address the concern stated in our discussion with FDA on May 9, 2019 that users may be unclear as to which directions to follow as between the original notice and revision B.

The attached FSN for FCO86201863 reflects the final version, which now also includes a reply card.

Sincerely,

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

PHILIPS
3000 Minuteman Road
Andover, MA 01810
www.philips.com

-UPDATE-
URGENT - Medical Device Recall
IntelliVue MX40

Increased Battery Power Consumption and Absence of Low Battery Alarms

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments

Previously, you received notices related to power consumption and battery alarms of the MX40, including the original letter dated March 22, 2019. Subsequent to these communications, additional issues related to power consumption and low battery alarms have been found. This letter supersedes the prior notices with respect to the "Actions to be Taken by the Customer/User" to prevent risks to patients. As mentioned previously, Philips will be contacting you to arrange for a software upgrade and the installation of the software upgrade will correct these problems.

This Medical Device Recall letter is intended to update 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).

This recall will be reported to the appropriate regulatory agencies.

Philips apologizes for any inconvenience caused by this problem.

Sincerely,

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 units.
ACTION TO BE TAKEN BY CUSTOMER / USER	Until you have upgraded the software on your MX40, replace your batteries every 8 hours, unless you are using Monitor Mode and SpO2 measurement (Manual, Continuous or Auto modes) with AA batteries, in which case replacement should be done every 2 hours. Please complete the attached Reply Card and return to Philips as soon as possible.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare has released a software upgrade (MX40 rev B.06.59), which will correct these problems. 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).

-UPDATE-
URGENT - Medical Device Recall
IntelliVue MX40

Increased Battery Power Consumption and Absence of Low Battery Alarms

Customer Reply for FSN86201863C

Please complete and fax to Philips.

Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

Please fax or email this completed form to Philips.

CUSTOMER ACKNOWLEDGEMENT:

I acknowledge that I have reviewed this Medical Device Recall Customer Information Letter.

_____ _____

CUSTOMER NAME (please print) **TITLE**

_____ _____

CUSTOMER SIGNATURE **DATE**

Please email the completed reply Philips. If you experience difficulty carrying out the instructions contained in this communication, contact your local Philips representative-Healthcare Representative/Modality Engineer: 1800-744-5477.