URGENT - Medical Device Recall

Philips IntelliVue Neuromuscular Transmission Patient Cable 989803174581

Dear Customer,

A problem has been detected with certain Philips IntelliVue Neuromuscular Transmission (NMT) Patient Cables that if it were to occur, could pose a risk for patients. This product is used with Philips IntelliVue Patient Monitors that are configured to make NMT measurements.
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.

Please retain a copy with the equipment Instruction for Use.

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.

Should you have any questions or concerns about this recall, please contact your local <Philips representative contact details to be completed by the KM/country>.

This recall has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Attachment

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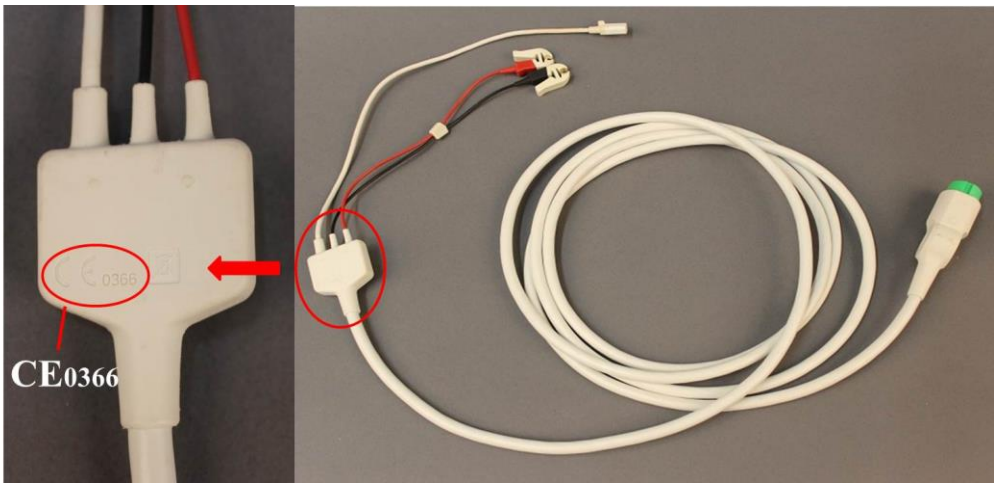
AFFECTED PRODUCTS	All Philips IntelliVue Neuromuscular Transmission (NMT) Patient Cables 989803174581 which have been manufactured between July 2012 and December 2015 are affected by this correction. This cable is used with Philips IntelliVue NMT Module 865383 and Philips IntelliVue Patient Monitors for the measurement of NMT. The 989803174581 NMT Patient Cable is also distributed as part of the 865383 IntelliVue NMT Module, Product Option #K01. **Model:** **Name:** 989803174581 Philips IntelliVue NMT Patient Cables 865383 #K01 Philips IntelliVue NMT Module, Product Option #K01
PROBLEM DESCRIPTION	A small number of IntelliVue NMT Patient Cables may contain a localized isolation defect in the shielding of the acceleration sensor housing. This manufacturing defect may cause localized heating due to an unintended current flow between the acceleration sensor housing attached to the patient thumb and the NMT stimulation electrode connection attached to the wrist of the same hand.
HAZARD INVOLVED	Using a defective NMT Patient Cable on a patient under anesthesia who receives repeated NMT stimulations during a procedure may result in a localized skin burn of up to several millimeters in diameter.

HOW TO IDENTIFY AFFECTED PRODUCTS	Check the Notified Body number which amends the CE mark on the NMT Patient Cable (see picture below).  All affected NMT Patient Cables bear the CE Mark with the suffix **0366:** CE 0366 Currently shipped NMT Patient Cables with CE mark and suffix **0123** are not affected. These have already been modified and do not need to be replaced.
ACTIONS PLANNED BY PHILIPS	Philips is voluntary initiating a correction consisting of: • Distribution of this Field Safety Notice (FSN). • Replacement of affected NMT Patient cables. A Philips Healthcare representative or authorized service provider will contact customers to arrange for a visit to exchange all affected cables at the customer site.
ACTION TO BE TAKEN BY CUSTOMER / USER	Immediately identify all affected cables, remove them from inventory and hold them for exchange by a Philips Healthcare representative or authorized service provider. 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 content of this communication.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local <Philips representative contact details to be completed by the KM/country>.