

Field Safety Notice

Philips Healthcare

PHILIPS

Patient Monitoring

-1/3-

FSN86201525A

2014 April 04

URGENT - Medical Device Correction

Lithium Ion Battery M4605A and M4607A for use with IntelliVue Patient Monitors

Dear Customer,

A problem has been detected with the Philips IntelliVue Patient Monitors that, if it were to occur, could pose a risk for patients or users. 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.

On-going monitoring of quality data determined that the risk of battery failure increases with age, when a battery remains in use longer than 3 years after the date of manufacture or 500 charge-discharge cycles. Such failure can result in overheating that, in rare cases, may cause the battery to ignite or explode.

Philips is issuing an addendum to the Instructions for Use of the affected IntelliVue Patient Monitors to describe battery management and safety practices for the batteries M4605A / M4607A. The Addendum to the IntelliVue Patient Monitor IFU is included with this letter.

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,



Hauke Schik
Director of Quality & Regulatory Affairs

