

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.

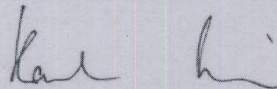
On-going monitoring of quality data determined that the risk of battery failure increases with age, when a battery remains in use longer than 3 years after the date of manufacture or 500 charge-discharge cycles. Such failure can result in overheating that, in rare cases, may cause the battery to ignite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

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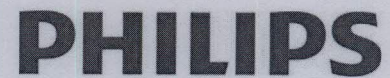
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AFFECTED PRODUCTS	<p>The following IntelliVue Patient Monitors with software releases up to and including G.0(SW B.0/B.1/C.0/D.0/E.0/F.0/G.0) containing battery operation.</p> <table border="0"><thead><tr><th>Model Number:</th><th>Product Numbers</th></tr></thead><tbody><tr><td>MP2</td><td>M3002A</td></tr><tr><td>X2</td><td>M8102A</td></tr><tr><td>MP5</td><td>M8105A</td></tr><tr><td>MP5</td><td>M8105AT</td></tr><tr><td>MP20</td><td>M8001A</td></tr><tr><td>MP30</td><td>M8002A</td></tr><tr><td>MP40</td><td>M8003A</td></tr><tr><td>MP50</td><td>M8004A</td></tr></tbody></table>	Model Number:	Product Numbers	MP2	M3002A	X2	M8102A	MP5	M8105A	MP5	M8105AT	MP20	M8001A	MP30	M8002A	MP40	M8003A	MP50	M8004A
Model Number:	Product Numbers																		
MP2	M3002A																		
X2	M8102A																		
MP5	M8105A																		
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MP20	M8001A																		
MP30	M8002A																		
MP40	M8003A																		
MP50	M8004A																		
PROBLEM DESCRIPTION	<p>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 may result in overheating.</p> <p>Battery management and safety practices information for the batteries M4605A / M4607A are not clearly documented in the Instructions for Use for IntelliVue Patient Monitors with software releases up to and including G.0.</p>																		
HAZARD INVOLVED	<p>Overheating of the battery may cause the battery to ignite or explode, which may result in injury to a patient or user.</p>																		
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>To identify the software revision of your IntelliVue Patient Monitor</p> <ol style="list-style-type: none">verify in the revision screen in the monitor software (Main Setup /Revision) orverify in the Instructions for Use for your IntelliVue Patient Monitor (cover page). <p>To identify if battery operation is available, verify in the bottom right corner of the monitor's display if a battery symbol is exhibited.</p> <p>Monitors that do not have available battery operation are not affected by this action.</p>																		

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ACTIONS PLANNED BY PHILIPS	Philips is initiating this correction to provide an <i>Addendum to the Instructions for Use for IntelliVue Patient Monitors</i> with software releases up to and including G.0. The addendum describes that batteries M4605A / M4607A should be replaced after 3 years of continuous use after date of manufacture or 500 battery charge-discharge cycles. The addendum to the IntelliVue Patient Monitor IFU is included with this letter.
ACTION TO BE TAKEN BY CUSTOMER / USER	Upon receipt of this notification, ensure that the IntelliVue Patient Monitor Addendum to the Instructions for Use on battery management and safety practices for the batteries M4605A / M4607A is being reviewed and implemented. This includes that the batteries M4605A / M4607A should be replaced after 3 years of continuous use after date of manufacture or 500 charge-discharge cycles by using standard Philips replacement processes. Review this information with all staff members who are involved in the operation and battery management of the IntelliVue patient Monitors and need to be aware of the contents of this communication. The addendum should be stored with the Monitor Instructions for Use.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning, please contact your local Philips representative: <to be completed by the KM /country>.