

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. If you need any further information or support concerning this, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

Sincerely,



Hauke Schik
Director of Quality & Regulatory Affairs

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ACTIONS PLANNED BY PHILIPS	<p>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.</p> <p>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.</p>
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>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.</p> <p>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.</p> <p>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.</p>
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>

Addendum

Addendum to the Instructions for Use

This addendum provides additional information for the IntelliVue Patient Monitor Instructions for Use for MP2, X2, MP5/MP5T, and MP20-50 for software releases up to and including G.0.

Please store it with your monitor documentation.

Lithium Ion Battery Management and Safety Practices

Introduction

The following information is valid for the M4605A and M4607A lithium ion batteries used in the Philips IntelliVue monitoring product family.

Lithium ion technology is the state-of-the-art in DC energy storage and has been widely adopted to meet the demand for more power and longer operating times. Lithium ion batteries store a large amount of energy in a small, lightweight package, so you can carry less and do more for a longer period of time.

Our lithium ion batteries are designed to provide the following characteristics:

- **Built-in fuel gauge** - intelligence enables the battery to estimate its current state of charge. Convenient battery power indicators illuminate to show you the state of charge as a percentage of a fully-charged battery.
- **Safe and reliable** - redundant safety features in the batteries protect the batteries and their users.
- **Quick charging** - lithium ion batteries can quickly charge to their full capacity because they do not require an overnight trickle charge.
- **Tolerant of partial charging** - because lithium ion batteries are tolerant of partial charging, there is no effect on battery life when patient care requires you to suspend charging and use the battery before it is fully charged.

Batteries are a consumable item, and their age and condition will impact the operation of the products they power. Lithium ion technology is a relatively new battery chemistry. While our batteries have been designed and manufactured using the best safety techniques available, it is important to understand and follow proper and safe practices for **use, storage, battery lifetime management and disposal** of lithium ion batteries in order to reduce any residual risk.

We strongly recommend that you implement the following battery management practices. Failure to follow safe practices may result in bodily injury and/or property damage.

Use and Handling

Use only Philips batteries of the type indicated in your patient monitor's Instructions for Use. These specially designed, high performance batteries are the only ones that have been verified for safe and effective use with the monitors.

Always use the batteries in accordance with the instructions in your patient monitor's Instructions for Use.



Do not store batteries in direct sunlight.

Stored batteries should be partially charged to 20% to 40% of their capacity every 6 months. They should be charged to full capacity prior to use.

Note: Storing batteries at temperatures above 38°C (100°F) for extended periods of time could significantly reduce the batteries' life expectancy.

Battery Lifetime Management

The lifetime of a Lithium Ion battery depends on the frequency and duration of use. When properly cared for, the useful life is approximately 3 years or 500 charge-discharge cycles, whichever comes first. In addition, experience indicates that the incidence of failure increases with battery service life due to the accumulated stresses of daily use. We therefore strongly recommend that lithium ion batteries be replaced after 3 years or 500 charge-discharge cycles.

The age of a lithium ion battery begins at the date of manufacture. To see the date of manufacture and the number of charge-discharge cycles:

- 1 Select the battery symbol on the patient monitor screen.
- 2 Select the appropriate battery pop-up key.
- 3 If necessary, select the battery pop-up key again to view the battery details.

The date of manufacture and the number of charge-discharge cycles are listed with other battery data on the screen.

WARNING The risk of battery failure increases with age, when a battery remains in use longer than 3 years or 500 charge-discharge cycles. Such failures can result in overheating that in rare cases can cause the battery to ignite or explode.

Disposal

Discharge the batteries and insulate the terminals with tape before disposal. Dispose of used batteries promptly and in accordance local recycling regulations.

Please return to:

Mr Andrew Jackson, Regulatory Affairs Officer
Philips Healthcare
1st Floor Q&R, The Philips Centre
Guildford Business Park
Guildford
Surrey. GU2 8XH

FAX: 01483 298831
Email: andrew.jackson@philips.com

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***To the EBME Manager,**

As per MHRA Device Bulletin DB2010(01) February 2010 it is important that the actions advised in this FSN are taken and that receipt of the FSN is acknowledged by your organisation.

This receipt provides Philips Healthcare and subsequently the MHRA, with the means to monitor the progress of Field Safety Corrective Actions.

It is important this acknowledgement form is returned for our records and enable us to meet our obligations to notify the MHRA of non-responders.

This can be done via post, fax, email or telephone using the details above.

Acknowledgement Form – Customer Safety Notification for Philips:

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

Our Ref: FCO 86201525

Hospital Facility _____

Post Code _____

I acknowledge receipt of the Customer Safety Notification for the issue referenced above.
The information has been brought to the attention of all users.

Name _____

Signed _____

Date _____

***This is not a disclaimer**