



Philips Healthcare

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Cardiac Care Emergency Care Solutions

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FSN86100090A

2010 FEBRUARY

**Urgent Medical Device Correction**  
**14.8-Volt Lithium Ion Battery (Product Number M3538A) for use with the**  
**Philips HeartStart MRx Monitor/Defibrillator**

**Philips Updates Instructions for Use on When to Replace Battery**

Dear Customer,

This letter is to inform you that Philips has updated the instructions for use for the Philips HeartStart MRx Monitor/Defibrillator describing when to replace the unit's 14.8-Volt Lithium Ion Battery (Product Number M3538A).

On-going monitoring of quality data has determined that batteries older than 2 years which are subject to continuous use have a higher potential for intermittent electrical contact, which may contribute to an interruption in monitoring or therapy if the monitor/defibrillator is operating on battery power.

Therefore, Philips is now recommending that the M3538A battery be replaced after two years of continuous service, or when it fails battery capacity calibration as described in the current instructions for use, which ever happens first.

**This document contains important information for the continued safe and proper use of your HeartStart MRx Monitor/Defibrillator**

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 of the attached Instructions for Use addendum with the MRx Instructions for Use.

After more than two years of continuous use, vibration or frequent connections and disconnections may cause mechanical wear which results in an intermittent electrical connection between the M3538A battery and the HeartStart MRx monitor/defibrillator. The resulting brief interruption of power to a monitor/defibrillator operating on battery power may cause it to reset itself, resulting in a short delay in monitoring or delivery of therapy.

To address this issue, Philips is adding to its Instructions for Use a recommendation that the M3538A battery be replaced after two years of continuous service. The updated M3538A Lithium Ion Battery Instructions for Use Addendum/Application Note is included with this letter.

Please see the attached Field Safety Notice which provides information on how to identify affected devices and instructions on actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

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-2/3-

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

This notice has been reported to the appropriate Regulatory Agencies.

Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products is very important to us.

Sincerely,

A large black rectangular redaction box covering the signature of the sender.

General Manager, Emergency Care Solutions  
Cardiac Care

Attachments



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-3/3-

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### Field Safety Notice

<b>AFFECTED PRODUCTS</b>	<b>Product:</b> Philips 14.8-Volt Lithium Ion Battery (Model M3538A) for use with the Philips HeartStart MRx model M3535A, M3536A and M3536J. <b>Distributed by:</b> Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
<b>PROBLEM DESCRIPTION</b>	After two years or more of continuous use, mechanical wear caused by vibration or frequent connections and disconnections may cause an intermittent electrical connection between the battery and the HeartStart MRx monitor/defibrillator.
<b>HAZARD INVOLVED</b>	A brief interruption of power to a monitor/defibrillator operating on battery power may cause it to reset itself, resulting in a short delay in monitoring or delivery of therapy. When the unit resets, it reverts back to the previous clinical mode and user default startup settings. The user then needs to re-establish patient specific parameters.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	All Philips M3538A batteries used in HeartStart MRx monitor/defibrillators. Refer to your organization's in-service records to determine length of overall use.
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	Upon receipt of this notification:  1) Philips recommends that all affected batteries be replaced after approximately two years of continuous service, or when they fail battery capacity calibration as described in the instructions for use, which ever happens first.  2) In addition, review and implement the revised Instructions For Use addendum and M3538A Lithium Ion Battery Application Note that is included with this letter.  Additional information is provided that: <ul style="list-style-type: none"><li>• Details ongoing instructions for battery care and diagnostics.</li><li>• Instructs the user to periodically conduct these activities in order to detect early signs of wear, and provides guidance on the useful life of the M3538A Lithium Ion battery</li><li>• Recommends replacement after two years of continuous service.</li></ul>
<b>ACTIONS PLANNED BY PHILIPS</b>	Philips is voluntarily initiating a corrective action consisting of: <ul style="list-style-type: none"><li>• Distribution of this Field Safety Notice.</li><li>• Distribution of the M3538A Lithium Ion Battery Instructions for Use Addendum/Application Note</li></ul>
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact your local Philips representative <Philips representative contact details to be completed by the KM / country>.