

## **URGENT Voluntary Medical Device Correction HeartStart MRx (M3535A, M3536A, M3536J, and M3536MC)**

### **Additional detail in instructions for primary lead selection**

Dear Customer,

This letter is to inform you that Philips has updated the HeartStart MRx monitor/defibrillator Instructions for Use. The update provides more detailed information on:

- Default ECG Lead Behavior
- Synchronized Cardioversion using External Paddles

Philips has received feedback from some users related to primary ECG configuration settings and the automatic lead selection behavior of the HeartStart MRx. It is important for users to fully understand these advanced features in order to avoid the potential for inappropriate therapy or a delay in diagnosis and/or therapy.

The Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur
- Actions you must take
- Actions taken by Philips to address 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 of the enclosed Addendum with the equipment Instructions for Use.

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

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at:

 **German: 0800 80 3000, French: 0800 80 3001**

This notice has been reported to the appropriate Regulatory Agencies.

## Philips Healthcare

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**Cardiac Care Emergency Care Solutions**    -2/4-    **FSN 86100096A**    2010 July  
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,



John Cadigan  
General Manager  
Emergency Care Solutions

Attachments

## Field Safety Notice

<p><b>AFFECTED PRODUCTS</b></p>	<p><b>Product:</b> Philips HeartStart MRx monitor/defibrillator, models M3535A, M3536A, M3536J, and M3536MC.  <b>Units Affected:</b>          All HeartStart MRx units with serial numbers less than US00542779  <b>Manufactured by:</b> Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.</p>
<p><b>PROBLEM DESCRIPTION</b></p>	<p><b>Synchronized cardioversion using external paddles</b>          Synchronized cardioversion is attempted on a device that is configured with Paddles as the default primary ECG lead. In such a case, the user may observe a valid ECG waveform from a lead other than paddles in Wave sector 1. Once the paddles are applied to the patient, the Primary ECG lead will switch to the paddles waveform, but the user may not notice the change even though the display properly indicates the correct ECG source.</p> <p><b>Dropped ECG lead behavior</b>          Users do not press the Lead Select Button to select an available lead if the original lead they were monitoring is lost. This results in a dashed line on the HeartStart MRx display.</p>
<p><b>HAZARD INVOLVED</b></p>	<p><b>Synchronized cardioversion using external paddles</b></p> <ul style="list-style-type: none"> <li>Inappropriate therapy could be administered if paddles are used for ECG monitoring during synchronized cardioversion. Artifact introduced by paddle movement may resemble an R-wave and trigger an asynchronous defibrillation shock.</li> </ul> <p><b>Dropped ECG lead behavior</b></p> <ul style="list-style-type: none"> <li>If the displayed lead is lost, e.g., an electrode detaches from the patient, the HeartStart MRx does not automatically switch to another available ECG lead. Diagnosis or therapy can be delayed if the user does not select another lead using the Lead Select Button or re-establish the original ECG signal.</li> </ul>
<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<ul style="list-style-type: none"> <li>All M3535A, M3536A, M3536J, and M3536MC HeartStart MRx units with serial numbers less than US00542779.</li> </ul>
<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>Review the enclosed HeartStart MRx Instructions for Use addendum. Insure that all users are fully trained on the MRx and, in particular, have reviewed and understand the additional detail provided.</p>
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<p>Philips is voluntarily initiating a corrective action consisting of:</p> <ul style="list-style-type: none"> <li>Distribution of this Field Safety Notice (FSN).</li> <li>Distribution of the enclosed revised HeartStart MRx Instructions for Use addendum.</li> </ul>

**FURTHER  
INFORMATION AND  
SUPPORT**

If you need any further information or support concerning this issue,  
please contact your local Philips representative at:  
☎ **German: 0800 80 3000, French: 0800 80 3001**