

## **URGENT - Medical Device Recall HeartStart MRx M3535A/M3536A Defibrillator/Monitor**

### **Potential Switch Failure May Cause Spontaneous Turn-On or Failure to Turn On**

Dear Customer,

A problem has been detected in the Philips HeartStart MRx model M3535A/M3536A Defibrillator/Monitor that, if it were to occur, could pose a risk for patients. 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
- 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.

Please retain a copy with the equipment Instruction for Use.

The therapy switch in affected devices has a small potential to fail. The most likely failure mode is a spontaneous turn-on which could deplete the battery, rendering the device unusable until power is restored. There is also the possibility of a failure mode in which the device fails to respond to user initiated turn-on, rendering it unusable for monitoring and therapy.

To date, there has been one report of a suspected failure worldwide. This failure could not be confirmed and no patient impact was reported. Philips is taking this corrective action to proactively limit the possibility of this failure occurring in the future.

Please see the attached Field Safety Notice that 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.

The source of the problem with the therapy switch has been identified and eliminated in new production. Philips will replace the switches on affected units free of charge. Our investigation has determined that failures are more likely to occur in devices that have been

exposed to high heat and humidity, which contributes to accelerated internal degradation of switch components over time.

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at 1-800-722-9377.

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem. Ensuring that you have the highest quality defibrillators is our top priority. Your satisfaction with Philips products as well as with our response to this problem is very important to us.

Sincerely,



Paul Lightfoot  
General Manager, Advanced Life Support  
Cardiac Resuscitation

Attachments

**FIELD SAFETY NOTICE**

<p><b>AFFECTED PRODUCTS</b></p>	<p><b>Product:</b> Philips HeartStart MRx, Model M3535A/M3536A Defibrillator/Monitors.  <b>Units Affected:</b> Units manufactured by Philips from March 2006 to March 2009, and shipped worldwide with a serial number within the range of US00210406 and US00333123. The following additional units are also affected because their therapy switches were replaced within the relevant time period:</p> <table border="1" data-bbox="573 579 1073 753"> <tr> <td>US00100313</td> <td>US00102303</td> <td>US00208545</td> </tr> <tr> <td>US00100482</td> <td>US00203090</td> <td>US00208780</td> </tr> <tr> <td>US00101138</td> <td>US00203793</td> <td>US00208856</td> </tr> <tr> <td>US00101180</td> <td>US00206364</td> <td>US00209017</td> </tr> <tr> <td>US00101331</td> <td>US00207141</td> <td>US00210351</td> </tr> </table> <p><b>Manufactured and Distributed by:</b> Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.</p>	US00100313	US00102303	US00208545	US00100482	US00203090	US00208780	US00101138	US00203793	US00208856	US00101180	US00206364	US00209017	US00101331	US00207141	US00210351
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<p><b>PROBLEM DESCRIPTION</b></p>	<p>The therapy switch may fail, causing the device to either spontaneously turn on or to fail to respond to user initiated turn-on. As a result, the device may be rendered unusable for monitoring and therapy.</p>															
<p><b>HAZARD INVOLVED</b></p>	<p>The device may become unusable, impacting the ability to assess patient condition and deliver therapy.</p>															
<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<p>Customers with a serial number listed above are affected by the issue. To identify an affected unit, locate the serial number on the back of the MRx, in battery bay B.</p>															
<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>During the interim period, as you await the upgrade for your device, you may continue to use the HeartStart MRx. However, to reduce the risk that a spontaneous turn-on could deplete the battery, it is advised that you keep:</p> <ul style="list-style-type: none"> <li>• a charged spare battery with the HeartStart MRx</li> <li>• AC power applied, if possible, when the device is not in use</li> </ul> <p>You should also consider identifying a readily available backup defibrillator to use in the unlikely event that the device fails to turn on.</p> <p>Devices that exhibit a spontaneous turn-on or failure to respond to user initiated turn on should be removed from service as soon as possible</p> <p>A Philips Healthcare representative will contact you in the near future regarding repair of your device.</p>															
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<p>Philips is voluntarily initiating a correction to affected devices. Philips considers this correction to be required for all affected units and will perform the upgrade free of charge. A Philips Healthcare representative will contact customers with devices listed in the Units Affected section above to arrange for replacement of the therapy switch.</p>															
<p><b>FURTHER INFORMATION AND SUPPORT</b></p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative at 1-800-722-9377.</p>															