

## **URGENT - Medical Device Correction Philips HeartStart MRx Monitor/Defibrillator – Defective Component May Prevent Delivery of Shocks in AED Mode**

Dear Customer,

71 MRx units may have been built with a defective component that is intended to protect the internal circuitry from high voltages during shock delivery. These devices may fail over time, as repeated shocks continue to be delivered. Should the device fail, the device will no longer be able to deliver shocks in AED mode.

The purpose of this Field Safety Notice is to inform you about the:

- Issue and under what conditions it can occur
- Actions that you should take to mitigate risk to patients
- Corrective action planned by Philips to address the issue

### **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 should be aware of the contents of this communication.

Please retain a copy with the equipment Instructions for Use.

The following pages provide information on how to identify affected devices and instructions on actions to be taken. Follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice. To address this correction, Philips:

- 1) Is providing this document to describe:
  - a) The device behavior and potential hazards that may result from the defective component.
  - b) How Users can detect the issue, and actions to be taken by the Customer / User.
- 2) Is requesting that you contact us if your device fails to function as intended.
- 3) Will contact you to repair your device once parts are available.

This voluntary correction has been reported to the appropriate regulatory agencies.

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

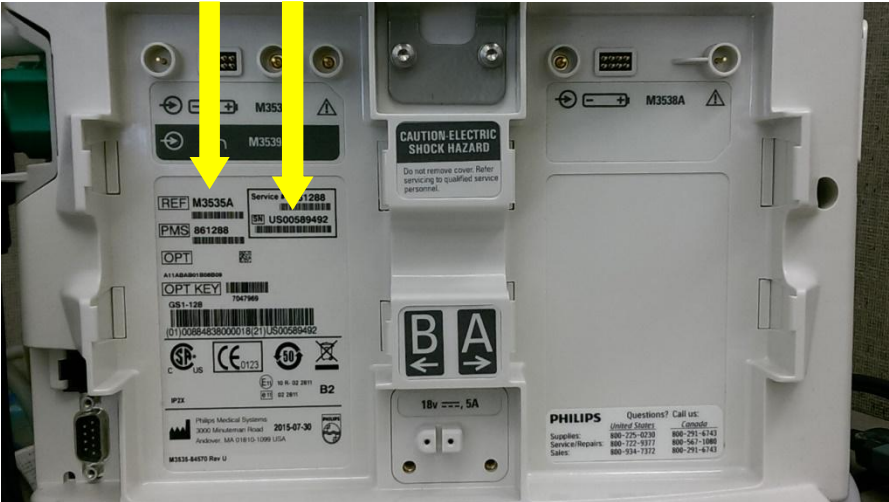
Sincerely,



Thomas Fallon  
Director QA/RA, Emergency Care and Resuscitation

## URGENT - Medical Device Correction

### Philips HeartStart MRx Monitor/Defibrillator – Defective Component May Prevent Delivery of Shocks in AED Mode

<p><b>AFFECTED PRODUCTS</b></p>	<p><b>Product:</b> 71 Philips HeartStart MRx Monitor/Defibrillators with model numbers M3535A and M3536A with the following serial numbers (SN):</p> <p><b>Units Affected:</b> US00601802, US00601968, US00601969, US00602114, US00602122, US00602124, US00602125, US00602126, US00602127, US00602128, US00602145, US00602180, US00602182, US00602184, US00602185, US00602186, US00602187, US00602189, US00602206, US00602236, US00602237, US00602238, US00602239, US00602240, US00602241, US00602242, US00602243, US00602244, US00602245, US00602246, US00602247, US00602248, US00602250, US00602251, US00602252, US00602253, US00602254, US00602344, US00602345, US00602346, US00602347, US00602348, US00602349, US00602350, US00602351, US00602352, US00602353, US00602354, US00602355, US00602356, US00602357, US00602358, US00602359, US00602360, US00602361, US00602362, US00602363, US00602364, US00602365, US00602366, US00602367, US00602368, US00602369, US00602370, US00602371, US00602372, US00602373, US00602374, US00602375, US00602376, US00602377</p>
<p><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p>	<p>Only Philips HeartStart MRx Monitors/Defibrillators with the serial numbers identified above are affected by this notification.</p> <p>The model and SN of the HeartStart MRx Monitor/Defibrillator is printed on the primary label on the back of the MRx in battery bay B.</p> 

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<p><b>BEHAVIOR DESCRIPTION</b></p>	<p>The affected MRx units contain a component defect that Philips became aware of during internal testing. The defective component is a gas discharge tube (“GDT”) used to protect other sensitive components within the MRx from the internal high voltages associated with defibrillator shocks. The defective GDT may cause other components to fail after repeated delivery of shocks. This failure may prevent the MRx from automatically detecting critical arrhythmias while in AED Mode, due to excessive artifact on the pads ECG. Shocks delivered in Manual Mode with pads and external paddles are not affected; however, the artifact on the pads ECG may interfere with the user’s ability to promptly and accurately identify a shockable rhythm.</p>
<p><b>HAZARD INVOLVED</b></p>	<p>If the MRx is being operated in AED Mode and experiences this inability to shock, there will be a delay in delivering any needed shock therapy until either:</p> <ul style="list-style-type: none"> <li>(1) a replacement defibrillator is found and delivers a shock or</li> <li>(2) an Advanced Life Support user changes the MRx to Manual Mode, places the ECG monitoring electrodes to make rhythm determination, if needed, and delivers a shock.</li> </ul>
<p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p>	<p>In some cases, the user may detect the issue if the MRx fails during a Shift Check, Weekly Shock Test or Operational Check (Op Check), which should be performed periodically, as directed in the Instructions for Use (IFU). However, users should not perform these checks more frequently than directed.</p> <p>If the device is:</p> <ul style="list-style-type: none"> <li>(a) operating in AED Mode and</li> <li>(b) indicating to the user poor pads placement, even though the pads are appropriately positioned and firmly attached to the patient,</li> </ul> <p>an Advanced Life Support trained user can change the device to Manual Mode and deliver shocks. Although there will be excessive artifact on the ECG from the multi-function pads, the user can use ECG waveforms from monitoring leads to identify a shockable rhythm and, if indicated, deliver shock therapy.</p>
<p><b>ACTIONS PLANNED BY PHILIPS</b></p>	<ul style="list-style-type: none"> <li>• Philips is requesting that you contact us if your device fails to function as intended.</li> <li>• Philips will contact you to repair your device once replacement parts are available.</li> </ul>
<p><b>FURTHER INFORMATION AND SUPPORT</b></p>	<p>If you need further information or support concerning this notification, please contact your local Philips representative Please contact your Philips Representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>