

URGENT - Medical Device Correction Philips HeartStart MRx Monitor/Defibrillator with Q-CPR™ Meter May Provide Incorrect CPR Instructions

Dear Customer,

This is to inform you of a product correction initiated by Philips Healthcare due to an issue that may occur when the Philips HeartStart MRx Monitor/Defibrillator is used with the Philips Q-CPR Meter.

This Field Safety Notice is intended to inform you about:

- what the issue is and under what conditions it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the 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 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 Instructions for Use.

When the HeartStart MRx is used with the Q-CPR Meter in defibrillation mode, the Q-CPR Meter may incorrectly display the 'Do Not Touch the Patient' icon.

Please see the attached Field Safety Notice that provides 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.

Philips is initiating a software upgrade that will be provided to customers free of charge. A Philips Healthcare representative will contact you to arrange for installation of the software upgrade. We appreciate your patience as we work to schedule your upgrade as expeditiously as possible.

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

Philips sincerely apologizes for any inconvenience this may cause you. 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,



John Pardo
Director QA/RA, Emergency Care and Resuscitation

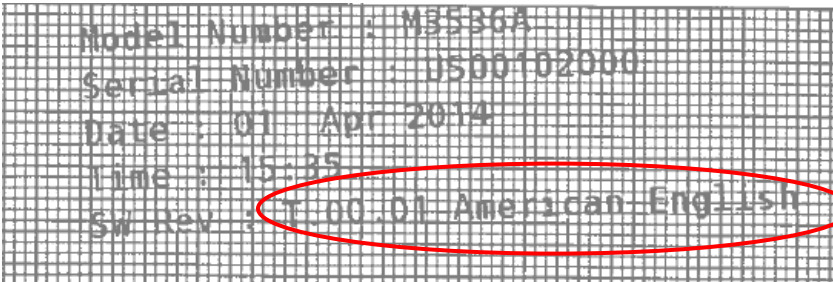
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<p><u>AFFECTED PRODUCTS</u></p>	<p>Product: Philips HeartStart MRx Monitor/Defibrillator, model numbers M3535A and M3536A with Q-CPR™ Meter Option B08</p> <p>Units Affected: MRx units with ALL (1+2+3) of the following:</p> <ol style="list-style-type: none"> 1. serial number in the range US00100153 to US00571587 2. the Q-CPR Meter Option B08 installed 3. Software revision F.xx, R.xx, T.00.00 or T.00.01 installed. <p><u>NOTE: This Medical Device Correction only affects HeartStart MRx units that meet ALL of the criteria above.</u></p>
<p>PROBLEM DESCRIPTION</p>	<p>When the HeartStart MRx is in AED mode, the Q-CPR meter is designed to display the 'Do Not Touch the Patient' icon during the shock advisory analysis period. If the user continues to deliver chest compressions when the shock advisory analysis begins, the 'Do Not Touch the Patient' icon may incorrectly remain on the screen after analysis or shock delivery is complete.</p> <p>When the HeartStart MRx is in Manual Mode, the Q-CPR meter is designed to display the 'Do Not Touch the Patient' icon when the device is charging to the selected energy. If the clinician continues to provide chest compressions while the device is charging, the Q-CPR meter 'Do Not Touch the Patient' icon may incorrectly remain on the screen after shock delivery is complete.</p> <p>NOTE:</p> <ul style="list-style-type: none"> •The MRx shock advisory decision and shock delivery continue to be executed correctly in all modes. •In AED Mode the MRx continues to re-analyze for the shock advisory decision every two minutes. •With the exception of CPR meter feedback, all other MRx voice prompt feedback including "Resume CPR" and "Pause, Analyzing" feedback operate as intended.
<p>HAZARD INVOLVED</p>	<p>Due to the incorrect CPR instructions, the clinician may follow the 'Do Not Touch the Patient' command on the Q-CPR Meter and may not resume chest compressions in a timely manner resulting in a delay in the delivery of CPR, and as a consequence potentially affect patient outcome.</p>

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<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Philips HeartStart MRx Monitors/Defibrillators with QCPR options with specific software revisions are affected by the issue.</p> <p>Devices with QCPR option have 'B08'text printed in the 'OPT:' field on the primary label on the back of the HeartStart MRx in battery bay B. Alternatively, part number '861444' is printed in the 'REF:' field on the upgrade primary label on back of the HeartStart MRx in battery bay A.</p> <p>The software revision can be observed by turning on the MRx, pressing the Menu Select Button, and selecting Other>Print Device Info in the menus. The software revision is shown on the printed strip.</p> 
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>You can continue to use your HeartStart MRx without the Q-CPR Meter attached.</p> <p>If you choose to use the HeartStart MRx with the Q-CPR Meter attached and you observe that the Q-CPR Meter is displaying the 'Do Not Touch the Patient' icon at an unexpected time, follow the MRx Instructions for Use and remove the meter from the patient and continue CPR according to your organization's protocol.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips is initiating a correction to affected devices. A software upgrade will be provided to customers with affected devices free of charge. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the software upgrade.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<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>