URGENT Voluntary Medical Device Correction
HeartStart MRx (M3535A, M3536A, M3536M4, M3536M5 and M3536M6)
Unexpected Pads/Paddles ECG Failure

Dear Customer,

This letter is to inform you that Philips has identified a problem with certain HeartStart MRx monitor/defibrillators (M3535A, M3536A, M3536M4, M3536M5, and M3536M6) manufactured between the dates of July 12, 2011 through September 2, 2011 and January 19, 2012 through May 22, 2012. Some HeartStart MRx monitor/defibrillators manufactured or repaired within these time periods may contain compromised electronic components and present the following behaviors.

- In automatic external defibrillator (AED) mode, the MRx may have difficulty interpreting the pads ECG waveform. The MRx may incorrectly analyze the rhythm or may fail to analyze the rhythm.
- In manual defibrillation mode, if the pads/paddles ECG signal is viewed, the user may have trouble interpreting the pads/paddles ECG waveform and determining whether or not to deliver therapy.
- When using Q-CPR Measurement and Feedback, the feedback on ventilation rate may be inaccurate.

You are receiving this letter because we believe that one or more of your HeartStart MRx monitor/defibrillators may be affected.

This 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.

Philips became aware of this issue through standard manufacturing tests within the Philips manufacturing facility. Philips has not received any reports of patient harm as a result of this problem.

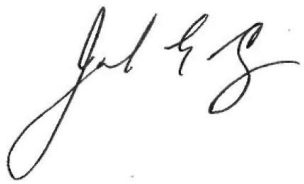
Please see the attached Field Safety Notice, which describes how to identify affected devices and provides instructions for actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER/USER" section of the notice.

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at <key market add contact info here>.

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 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

AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx monitor/defibrillator, model numbers M3535A, M3536A, M3536M4, M3536M5, and M3536M6. **Units Affected:** Certain M3535A, M3536A, M3536M4, M3536M5, and M3536M6 HeartStart MRx monitor/defibrillators were manufactured with compromised components within the time frames of July 12, 2011 through September 2, 2011 and January 19, 2012 through May 22, 2012 with serial numbers within the ranges of: US00550047 to US00551654 and US00556357 to US00559493 respectively. There are also some additional MRx units that were repaired and may contain compromised components. These MRx unit serial numbers are identified below: US00210180, US00210183, US00210738, US00211000, US00213281 US00214706, US00316827, US00318163, US00319241, US00328491 US00329811, US00333101, US00536832, US00538140, US00543161 US00543825, US00544081, US00544214, US00546107, US00548046. **Manufactured by:** Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
PROBLEM DESCRIPTION	Affected MRx devices may exhibit the following behaviors (A, B and/or C): A. In AED mode the MRx experiences difficulty interpreting pads ECG waveforms and may incorrectly analyze the waveform (potential for inappropriate therapy) or fail to analyze the waveform. B. In Manual mode the user may have trouble interpreting the pads ECG waveform and determining whether or not to deliver therapy In addition the MRx may provide erroneous alarms (e.g. PVC/min High, VTACH, Asystole) or indicate an asystolic rhythm when paddles are not in patient contact. C. If CPR meter is in use, users may not get an accurate impedance derived ventilation feedback. Note: This problem impacts the ability to acquire an ECG signal from pads and paddles to determine need for therapy, and does not impact the ability to acquire an ECG signal from leads and associated manual delivery of defibrillation or pacing therapy.

HAZARD INVOLVED	A. If the problem were to occur during a resuscitation attempt in AED mode the MRx experiences difficulty interpreting ECG waveforms and may incorrectly analyze the waveform (with a potential for inappropriate therapy) or fail to analyze the waveform to determine the need to apply defibrillation therapy. This behavior may lead to delivery of inappropriate therapy or a failure to deliver therapy. B. In Manual mode the user experiences difficulty interpreting pads and paddles ECG waveforms for determining the need to apply defibrillation therapy. In addition the MRx may provide erroneous alarms. This behavior may lead to a failure to deliver therapy. C. If CPR meter is in use, users may not get an accurate impedance derived ventilation feedback. This behavior may affect the quality of delivered ventilations.
HOW TO IDENTIFY AFFECTED PRODUCTS	HeartStart MRx defibrillator/monitors, model numbers M3535A, M3536A, M3536M4, M3536M5, and M3536M6, with specific serial numbers are affected. The model and serial numbers of your HeartStart MRx monitor/defibrillator are printed on the primary label on the back of the MRx in battery bay B.
ACTION TO BE TAKEN BY CUSTOMER / USER	Perform an Op Check at the start of each shift or change in personnel. If the problem has occurred, the device will fail the Op Check and display a solid Red X with an audible chirp to alert the user. If the device fails Op Check, remove it from service and contact your Philips service representative. Affected units may remain in service provided that the following instructions are followed: • Op Checks are performed at the beginning of each shift or change in personnel. • AED mode is not used. • When manual defibrillation is performed, use the Lead Select Button to select a leads ECG signal (Lead I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6) and view the leads ECG signal while making a shock/no-shock decision and while delivering the shock. • All users are informed of these constraints. If possible, Philips recommends that a backup defibrillator be made available.

ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a corrective action consisting of: • Distribution of this Field Safety Notice (FSN). • No charge installation of updated printed circuit assembly (PCA) boards in affected devices to correct the problem. A Philips representative will be contacting you to schedule the installation of updated PCAs in all affected devices.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative at <key market add contact info here>.