URGENT Voluntary Medical Device Correction

HeartStart MRx

Therapy Cable Connection Wear May Lead to a Malfunction in Detection of Defibrillation Pads/Paddles Therapy Cables

Dear Customer,

This letter is to inform you that Philips has identified an issue in the HeartStart MRx monitor/defibrillator. For those customers who had previously purchased HeartStart MRx monitor/defibrillators prior to July 2009 this letter may also serve as a re-notification that provides additional information regarding this issue.

Under certain conditions, use of the HeartStart MRx Defibrillator Monitor with the pads/paddles therapy cable could pose a risk for patients and/or caregivers.

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.

When used in external transport and Emergency Medical Service (EMS) environments the mechanical/electrical connection (connector pins and/or port pins) between the pads/paddles therapy cable (including pads CPR therapy cable and external paddles cable) and the MRx therapy connection port may experience high levels of stress causing accelerated wear.

Without routine periodic inspections and preventive action by users, accelerated wear of the connection could ultimately prevent the device from sensing that the pads/paddles therapy cable is connected. This wear also may cause the MRx to misidentify the pads therapy cable, external paddles, or internal paddles when they are connected to the therapy port which could result in a delay of therapy, incorrect energy delivered, spontaneous/unintended therapy energy discharge, shock to caregiver when delivering therapy, and/or interrupted pacing with lost capture and inability to regain cardiac recapture.

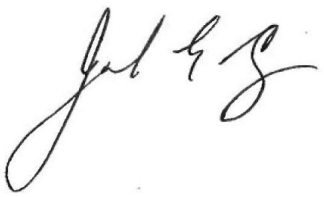
Please see the attached Field Safety Notice, which describes how to identify affected devices and provides instructions for actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER/USER" section of the notice.

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative <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/defibrillators, models M3535A and M3536A, M3536J, M3536M, M3536MC, M3536M1, M3536M2, M3536M3, M3536M4, M3536M5, M3536M6. **Units Affected:** All Philips HeartStart MRx monitor/defibrillators manufactured prior to June 2012 and used in external transport and Emergency Medical Service (EMS) environments, distributed worldwide. **Manufactured by:** Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
PROBLEM DESCRIPTION	When HeartStart MRx Defibrillator Monitors are used in external transport and EMS environments the mechanical/electrical connection between the pads/paddles therapy cable (including pads CPR therapy cable and external paddles cable) and the MRx therapy connection port may experience higher than expected levels of stress causing accelerated wear. Without routine periodic inspections and preventive action by users, wear of the connection could ultimately prevent the device from sensing that the pads/paddles therapy cable is connected. This wear also may cause the MRx to inappropriately identify the pads therapy cable, external paddles, or internal paddles. Pads/paddles therapy cable and therapy connection port wear could pose a risk for patients and/or caregivers.
HAZARD INVOLVED	If pads/paddles therapy cable and therapy connection port wear were to occur, there is a potential that one or more of the following can occur. A. Delay of therapy B. Incorrect energy delivered C. Spontaneous/unintended therapy energy discharge D. Shock to caregiver when delivering therapy E. Interrupted pacing with lost capture and inability to recapture
HOW TO IDENTIFY AFFECTED PRODUCTS	The model number and manufactured month/year of your HeartStart MRx monitor/defibrillator can be located on the primary label on the back of the MRx in battery bay B.

ACTION TO BE TAKEN BY CUSTOMER / USER	Carefully read the attached **HeartStart MRx Instructions for Use Addendum**. Immediately implement ongoing therapy connection inspection on all of your MRx devices to detect wear from higher than expected levels of stress. The **HeartStart MRx Instructions for Use Addendum** describes how a user can identify wear. If wear is detected, remove affected devices immediately from use and contact Philips to arrange for service. **WARNING:** The service life of your therapy cables/external paddles is up to three years. To maintain reliable performance and reduce the possibility of failure during patient use, replace them every three years from the time they were initially placed into service or if they fail the inspection criteria in the attached **Instructions for Use Addendum**.
ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a corrective action consisting of the following: • This urgent **Voluntary Medical Device Correction letter** • Distribution of revised Instructions for Use addendum with complete user information regarding ongoing inspections of pads/paddles therapy cable and therapy connector port. • Service support for Therapy Port and Cables requiring replacement. **Important Note:** Philips is sending each customer site one **Voluntary Medical Device Correction letter**. The number of **HeartStart MRx Instructions for Use Addendums** sent with each correction letter is based on the number of MRx units our records shows were delivered to each customer site. Please ensure a copy of the correction letter and the attached revised addendum is co-located with each MRx device.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative <key market add contact info here>.