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Philips Healthcare

URGENT Voluntary Medical Device Correction
HeartStart MRx (M3535A, M3536A, M3536J, and M3536MC)

Additional detail in instructions for primary lead selection

Dear Customer,

This letter is to inform you that Philips has updated the HeartStart MRx monitor/defibrillator Instructions for Use. The update provides more detailed information on:

- Default ECG Lead Behavior
- Synchronized Cardioversion using External Paddles

Philips has received feedback from some users related to primary ECG configuration settings and the automatic lead selection behavior of the HeartStart MRx. It is important for users to fully understand these advanced features in order to avoid the potential for inappropriate therapy or a delay in diagnosis and/or therapy.

The 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.

Please retain a copy of the enclosed Addendum with the equipment Instructions for Use.

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 <Philips representative contact details to be completed by the KM/country>.

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Cardiac Care Emergency Care Solutions -2/4- **FSN 86100096A** 2010 July

This notice has been reported to the appropriate Regulatory Agencies.

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,

[redacted]
General Manager
Emergency Care Solutions

Attachments

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Cardiac Care Emergency Care Solutions -3/4- **FSN 86100096A** 2010 July

Field Safety Notice

AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx monitor/defibrillator, models M3535A, M3536A, M3536J, and M3536MC. **Units Affected:** All HeartStart MRx units with serial numbers less than US00542779 **Manufactured by:** Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
PROBLEM DESCRIPTION	**Synchronized cardioversion using external paddles** Synchronized cardioversion is attempted on a device that is configured with Paddles as the default primary ECG lead. In such a case, the user may observe a valid ECG waveform from a lead other than paddles in Wave sector 1. Once the paddles are applied to the patient, the Primary ECG lead will switch to the paddles waveform, but the user may not notice the change even though the display properly indicates the correct ECG source. **Dropped ECG lead behavior** Users do not press the Lead Select Button to select an available lead if the original lead they were monitoring is lost. This results in a dashed line on the HeartStart MRx display.
HAZARD INVOLVED	**Synchronized cardioversion using external paddles** • Inappropriate therapy could be administered if paddles are used for ECG monitoring during synchronized cardioversion. Artifact introduced by paddle movement may resemble an R-wave and trigger an asynchronous defibrillation shock. **Dropped ECG lead behavior** • If the displayed lead is lost, e.g., an electrode detaches from the patient, the HeartStart MRx does not automatically switch to another available ECG lead. Diagnosis or therapy can be delayed if the user does not select another lead using the Lead Select Button or re-establish the original ECG signal.
HOW TO IDENTIFY AFFECTED PRODUCTS	• All M3535A, M3536A, M3536J, and M3536MC HeartStart MRx units with serial numbers less than US00542779.
ACTION TO BE TAKEN BY CUSTOMER / USER	Review the enclosed HeartStart MRx Instructions for Use addendum. Insure that all users are fully trained on the MRx and, in particular, have reviewed and understand the additional detail provided.

ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a corrective action consisting of: • Distribution of this Field Safety Notice (FSN). • Distribution of the enclosed revised HeartStart MRx Instructions for Use addendum.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative at <Philips representative contact details to be completed by the KM/country>.

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HeartStart MRx Instructions for Use Clarification

NOTE This document is an addendum to and should be kept with your HeartStart MRx *Instructions for Use.*

Default Lead Behavior

The HeartStart MRx allows you to configure the lead displayed as the Primary ECG lead in Wave Sector 1 when the device is turned on. The factory default is Lead II. Refer to Chapter 17 of the HeartStart MRx *Instructions for Use* for more information on Configuration.

When you first turn your HeartStart MRx on, it searches for the default Primary ECG lead which was selected in configuration setup. If the default lead is not available, the device automatically searches for the next available lead. Once it finds an available lead, it is displayed in Wave Sector 1. If the default Primary ECG lead becomes available, the HeartStart MRx automatically switches the monitored wave in Wave Sector 1 to that default lead.

If the lead in Wave Sector 1 is lost, a dashed line is displayed. The device does not revert back to another lead, even if one is available. Press the Lead Select Button multiple times until another available lead is displayed (see Figure 1).

Synchronized Cardioversion using External Paddles

WARNING When performing Synchronized Cardioversion using external paddles, you should not use paddles as your monitoring lead in Wave Sector 1. Artifact introduced by paddle movement may resemble an R-wave and trigger a defibrillation shock.

Carefully review the waveform prior to administering Synchronized Cardioversion and confirm that you have a non-paddles Wave Label (see Figure 1).

Steps for performing Synchronized Cardioversion using External Paddles:

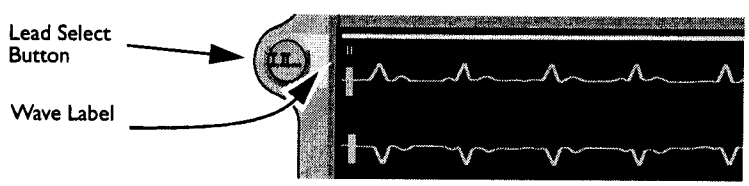
1 Prepare your patient for Synchronized Cardioversion according to the HeartStart MRx *Instructions for Use* and your institution's protocol

2 Place paddles on the patient's chest prior to charging the defibrillator

3 Look at the Wave Label appearing in Wave Sector 1

- **If the Wave Label is Paddles:**
  - change the monitored lead in Wave Sector 1 by pressing the Lead Select Button (see Figure 1) multiple times to cycle through the available leads. Select the waveform you wish to use
  - confirm a non-paddles monitoring lead appears in Wave Sector 1. Then proceed with your institution's protocol for Synchronized Cardioversion
- **If the Wave Label is not Paddles:**
  - proceed with your institution's protocol for Synchronized Cardioversion

Figure 1 Locating the Waveform Label



NOTE Use External Paddles as the monitoring lead for Synchronized Cardioversion only if no other lead source is available.