URGENT - Medical Device Correction
Philips HeartStart MRx Monitor/Defibrillator

Dear Customer,

This is to inform you of a product correction initiated by Philips Healthcare due to an issue that occurs when the Philips HeartStart MRx Monitor/Defibrillator is used for synchronized cardioversion.

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.

The MRx could deliver a non-synchronized cardioversion shock when the user rotates the Therapy Knob while ***simultaneously*** pressing the Sync button, then charges the MRx and presses the shock button. Delivery of a non-synchronized cardioversion shock could result in the delivery of incorrect therapy, which may induce ventricular fibrillation.

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

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>.

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

Philips sincerely apologizes for any inconvenience this may cause you. If you have questions regarding this notification or need any further information or support, please contact your local Philips representative or call us at 1-800-722-9377.

Sincerely,

[redacted]

Director QA/RA, Patient Care and Clinical Informatics

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AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx Monitor/Defibrillator, model numbers M3535A, M3536A, M3536J, M3536M, M3536MC, M3536M2, M3536M4, M3536M5, M3536M6 **Units Affected:** Serial numbers within the range US00100100 to US00567299
PROBLEM DESCRIPTION	The Philips HeartStart MRx Monitor/Defibrillator can deliver a non- synchronized shock in the synchronized cardioversion mode as follows: This rare condition can occur if the specific steps for delivering a synchronized shock in the HeartStart MRx Instructions for Use **are not** followed. If the user rotates the Therapy Knob while ***simultaneously*** pressing the Sync button, then charges the MRx and presses the shock button, the MRx could deliver a non-synchronized shock. The MRx will still display R wave markers as if normally operating in synchronized cardioversion mode. The “Sync” Label will still be seen on the display. When the MRx is charged and the shock button pressed, the shock will be immediately delivered and may not be synchronized to the R wave. In addition, the label affixed to the top of the MRx device is not consistent with the MRx Instructions for Use on synchronized cardioversion.
HAZARD INVOLVED	The MRx may deliver a non-synchronized cardioversion shock resulting in the delivery of incorrect therapy, which may induce ventricular fibrillation.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators identified above are affected by the issue. 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.

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ACTION TO BE TAKEN BY CUSTOMER / USER	You can continue to use your MRx prior to receiving the software upgrade and device label revision, provided that you do the following: Perform synchronized cardioversion per the following MRx Instructions for Use, “Delivering a Synchronized Shock” section (NOTE: The MRx IFU workflow instructions align with AHA guidelines): 1. With the Therapy Knob in the Monitor position, press the Sync button located beside the Therapy Knob to activate the Sync function. A Sync message appears in the upper right corner of Wave Sector 1. 2. Confirm that the Sync marker appears only with each R-wave. R-wave markers do not always appear at the peak of the R-wave but always appear on the R-wave. Use the Lead Select button to change leads if the R-wave markers do not appear correctly. 3. Turn the Therapy Knob to the desired energy level setting. 4. Press the Charge button on the HeartStart MRx or, if using paddles, the yellow charge button located on the handle of the paddle. Wait until the charge has reached the energy level selected, and you hear a continuous charge done tone. To disarm the defibrillator, press [Disarm]. If Shock has not been pressed within the time period specified in the Time to Auto Disarm Configuration Choice, the defibrillator disarms automatically. If desired, you may increase or decrease the selected energy level after pressing the Charge button by moving the Therapy Knob to the desired setting. The defibrillator charges to the modified energy level automatically. Wait until the current charge reaches the selected energy level before proceeding. 5. Re-check your ECG, re-confirm the energy dose and waveform before making sure no one is touching the patient or anything connected to the patient. Call out clearly and loudly, “Stay Clear !” 6. Press and hold the Shock button on the HeartStart MRx or, if you are using external paddles, press and hold the orange buttons on both paddles. The shock will be delivered when the next R-wave is detected.
ACTIONS PLANNED BY PHILIPS	Philips is initiating a correction to affected devices. The correction will consist of a software upgrade and a device label revision. These will be provided free of charge for all units affected by this issue. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the software upgrade and label revision. The software upgrade will prevent a non-synchronized shock from being delivered in the event the MRx Instructions for Use on performing synchronized cardioversion are not followed. The MRx label revision will align the instructions on the device with the MRx IFU.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or call us at 1-800-722-9377.