PHILIPS

URGENT - Medical Device Recall
Philips HeartStart MRx Monitor/Defibrillator

Philips Healthcare
Therapeutic Care

FSN86100121B

May 2013

UPDATED - Device May Fail to Deliver Defibrillation Therapy

Dear Customer,

This Field Safety Notice **SUPERCEDES** Field Safety Notice, FSN86100121A, issued in April 2013. In particular, there is additional information in the sections **"PROBLEM DESCRIPTION"** and "**ACTION TO BE TAKEN BY CUSTOMER / USER**".

Note: If you have already had the software upgrade performed on your device as a result of FSN86100121A, you may disregard the remainder of this letter.

A problem has been detected in the Philips HeartStart MRx Monitor/Defibrillator that, if it were to occur, could pose a risk for patients. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients or users
- the actions planned by Philips to correct 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 with the equipment Instructions for Use.

The Philips HeartStart MRx Monitor/Defibrillator could fail to deliver defibrillation therapy in the Manual Defib, Sync Cardioversion, or AED modes. Although the likelihood of this problem occurring is extremely low, if it does occur, the MRx will simultaneously display the following:

- Flat line ECG
- "Device error. Service required." message
- "Shock Equip Malfunction" INOP, and
- Red X in the RFU indicator

This issue does not affect the Pacer mode.

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

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This issue has been reported to the appropriate regulatory agencies.

Philips is initiating a software upgrade that will be provided free of charge to our customers. A Philips Healthcare representative will contact you to arrange for installation of the software upgrade. Philips will make every effort to expedite this software upgrade for you, however we appreciate your patience as we work to schedule your upgrade within the overall upgrade schedule for our customers.

If you need any further information or support concerning this issue, please contact your local Philips representative at

☎ 0800 80 3000

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

David Lanfranchi,
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 US00565942.
PROBLEM DESCRIPTION	The Philips HeartStart MRx Monitor/Defibrillator could fail to deliver defibrillation therapy in Manual Defib, Sync Cardioversion, or AED mode. If this occurs, the MRx will simultaneously display the following: • Flat line ECG • "Device error. Service required." message • "Shock Equip Malfunction" INOP • Red X in the RFU indicator Note: This issue does not affect Pacer mode.
HAZARD INVOLVED	If the problem occurs, there may be a failure to deliver shock therapy to a patient in need of defibrillation or cardioversion therapy.
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	Although the likelihood of this problem occurring is extremely low, if it does occur you can continue to use your MRx for Manual Defib, Sync Cardioversion, or AED mode therapy prior to receiving the software upgrade, provided that you follow the instruction below: **IF** you have tried to shock your patient and simultaneously observe the following symptoms • Flat line ECG • "Device error. Service required." message • "Shock Equip Malfunction" INOP • Red X in the RFU indicator **THEN** 1. Turn off device 2. Wait at least 10 seconds 3. Turn on device 4. Acknowledge the "Device error. Service required" message 5. Observe the patient's physiological rhythm 6. Continue to administer shock therapy as needed. **IMPORTANT NOTES:** Upon Restart a "Device error. Service required" message will display which will clear after pressing the menu select button to acknowledge the message. Restarting the device will not clear the Red X and "Shock Equip Malfunction" INOP. Ignore these symptoms while continuing to administer shock therapy. Perform an Op-Check later to clear these symptoms.
ACTIONS PLANNED BY PHILIPS	Philips is initiating a correction to affected devices. The correction will consist of a software upgrade and will be provided free of charge to all units affected by this issue. A Philips Healthcare representative will contact customers with affected devices to arrange for installation of the software upgrade. **If you have already had software upgrade performed on your device as a result of FSN86100121A, you do NOT need to request a second software upgrade.**
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative at ☎ **0800 80 3000**