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Philips Healthcare

URGENT Voluntary Medical Device Correction
HeartStart MRx (M3536A)
Unexpected MRx Power Cycling (re-boots)

Dear Customer,

This letter is to inform you that Philips has identified an issue with certain HeartStart MRx monitor/defibrillators (M3536A) with software versions, R.01.00, R.02.00 and R.03.01.

Under certain conditions M3536A HeartStart MRx Defibrillator Monitors with software versions, R.01.00, R.02.00 and R.03.01 can experience unexpected power cycling (system reboot) during device power on (startup).

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 from customer reports. Philips has not received any reports of patient harm.

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>.

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,

General Manager
Emergency Care Solutions

Attachments

Field Safety Notice

AFFECTED PRODUCTS	**Product:** Philips HeartStart MRx monitor/defibrillator, model M3536A with software version R.01.00, R.02.00 or R.03.01. **Units Affected:** All M3536A HeartStart MRx monitor/defibrillators, with software versions R.01.00, R.02.00 or R.03.01, distributed worldwide. **NOTE:** R.01.00, R.02.00 and R.03.01 software versions were only distributed in American and Commonwealth English languages. **Manufactured by:** Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
PROBLEM DESCRIPTION	M3536A HeartStart MRx Defibrillator Monitors with English software version, R.01.00, R.02.00 or R.03.01, intended for use on MRx monitor defibrillator model M3536A, may experience unexpected power cycling (system reboot) during device power on (startup). Some devices have been observed to experience rebooting cycles for up to five minutes before the MRx stabilizes.
HAZARD INVOLVED	If the problem were to occur there is a potential that therapy may be delayed.
HOW TO IDENTIFY AFFECTED PRODUCTS	M3536A HeartStart MRx Defibrillator Monitors with software versions R.01.00, R.02.00 or R.03.01are affected. The model number of your HeartStart MRx monitor/defibrillator can be located on the primary label on the back of the MRx in battery bay B. The software version can be identified by printing a device information report. Follow the instructions below to obtain this report. The first column of the report will contain the software revision. **To print the device information:** **1** Be sure a battery charged to at least 20% is in place, or that external power is connected. **2** Turn the Therapy Knob to **Monitor.** **3** Press the Menu Select button to access the Main menu. **4** From the Main menu, select **Other.** **5** From the Other menu, select **Print Device Info.** Detailed information about the device is printed.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Philips is preparing to release updated software with a version numbers greater than R.03.01. These software versions will be intended for M3536A HeartStart MRx monitor/defibrillators and will correct this problem. Updated software is planned to be released mid-April 2012. If you have affected product a Philips Representative or Service Engineer will contact you to install your updated software version at no cost to you. **Philips advises that you have a backup device available in the event the problem occurs before the updated software version is installed on your HeartStart MRx.**
ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a corrective action consisting of: • Distribution of this Field Safety Notice (FSN). • Installation of updated software on affected devices.
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>.