Urgent Medical Device Correction
HeartStart MRx Monitor / Defibrillator

HeartStart MRx Monitor/Defibrillator – Therapy Selector Switch

Dear Valued HeartStart MRx Customer,

Philips identified that the HeartStart MRx Monitor/Defibrillator Therapy Selector Switch may fail, resulting in abnormal device behaviors. If the user performs the Shift and Operational Checks that are recommended in the Instructions for Use and this letter, the user will be able to detect switch failures. A Therapy Selector Switch failure may exhibit the following behaviors:

- The device may not perform the selected function.
- The therapy knob may not change to the energy setting selected.
- The device may deliver a shock with an energy level different from the setting selected by the user.

If one of these behaviors occurs in clinical use, there may be a delay of therapy or a failure to deliver the intended therapy.

To date, Philips is not aware of any occurrences of patient harm related to the MRx Therapy Selector Switch.

This notice is intended to inform you about:

- What the problem is and under which circumstances it can occur.
- The actions that you as a customer can take to minimize the effect of the problem.
- The actions planned 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 with the equipment Instruction for Use.

If you need any further information or support concerning this issue, please contact your local Philips representative or call us at <Philips representative contact details to be completed by the KM / country>.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

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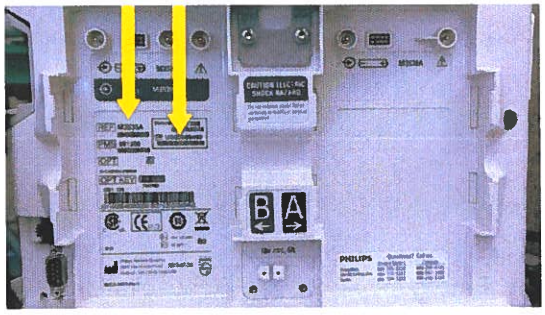
AFFECTED PRODUCTS	**Product:** HeartStart MRx Monitor/Defibrillators with model numbers: **Commercial (Sales) Product Numbers** 861288 M3535A / 861483 M3536M4 861289 M3536A / 861484 M3536M5 861464 M3536M / 861491 M3536M6 861465 M3536MC / 860396 M3536M7 861481 M3536M2 / 860397 M3536M8 861482 M3536M3 / 860398 M3536M9 **Units Affected:** Worldwide
PROBLEM DESCRIPTION	The Therapy Selector Switch, controlled by the therapy knob, is used to turn the HeartStart MRx on in the desired mode of operation and selects the energy setting. The therapy switch may fail, resulting in the device exhibiting the following behaviors: • The device may not perform the selected function. • The therapy knob may not change to the energy setting selected. • The device may deliver a shock with an energy level different from the setting selected by the user.
HAZARD INVOLVED	These device behaviors could result in a delay in therapy or a failure to deliver the intended therapy. There have been no reports of patient harm associated with the failure of the HeartStart MRx Monitor/Defibrillator MRx therapy switch.
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips HeartStart MRx Monitors/Defibrillators with the model numbers identified above are affected by this notification. The model and serial number of the HeartStart MRx Monitor/Defibrillator is printed on the primary label on the back of the device, in battery bay B. 

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ACTION TO BE TAKEN BY CUSTOMER / USER	The MRx is safe to use and can remain in service if the device does not exhibit any of the behaviors described in this Notice. If an MRx device does experience a switch failure as described in this notification, contact your local Philips representative, who can arrange for a replacement of the switch at no charge. For your MRx devices, continue to perform the Shift and Operational Checks described in the Instructions for Use, Maintenance Chapter ("IFU"). However, to detect possible switch failures as early as possible, the Weekly Shock Test, which is part of the Shift Check described in the IFU, should instead be performed ***daily.*** Because an Operational Check includes a Shock Test, it is not necessary to perform a Shock Test on days when an Operational Check is performed. Both the Shock Test and Operational Check involve the user delivering a test shock and then verifying that the energy level displayed on the screen matches the energy setting of the Therapy Selector Switch. For convenience, excerpts from the IFU related to Operational and Shift Checks are reprinted below. These checks are consistent with the guidance from the American Hospital Association for maintaining device readiness. A copy of this Field Safety Notification should be kept with each HeartStart MRx Instructions for Use. 20: Maintenance Operational Check **Operational Check** Operational Checks should be performed at regular intervals to supplement the hourly, daily, and weekly Automated Tests executed by the HeartStart MRx. Automated Tests provide adequate assurance that the device is in a functional state of readiness. Operational Checks supplement the Automated Tests by verifying therapy cables, the ECG cable, paddles, audio, the Charge and Shock buttons, Therapy Knob, and CPR meter, along with replicating the Weekly test. Operational Checks also notify you if the battery, NBP module, or CO_2 module need calibration. **WARNING:** Be sure the HeartStart MRx is not connected to the patient when performing an Operational Check. **NOTES:** It is important to establish a schedule for conducting Operational Checks, as well as for checking supplies and accessories associated with the HeartStart MRx. This will ensure that the device is ready to monitor and deliver therapy. The Operational Check is run with a battery installed to reflect optimal operating conditions for defibrillation. The device automatically disconnects AC/DC power.

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ACTION TO BE TAKEN BY CUSTOMER / USER (continued)

Shift Checklist

In order to ensure defibrillators are ready when needed, the American Heart Association (AHA) recommends that users complete a checklist, often referred to as a shift check, at the beginning of each change in personnel. The activities on this check list include verifying that the appropriate supplies and accessories are present, the device is plugged in and has sufficient battery power, and the device is ready for use. Philips Healthcare supports the AHA checklist recommendations and has provided a Shift Checklist document with the device and published a copy in this book. See the "Appendix I - HeartStart MRx Shift Checklist" on page 363.

Weekly Shock Test

In addition to the shift check, you must verify the ability to deliver defibrillation therapy once a week by performing one of the following:

- Operational Check
- Weekly Shock Test (See following instructions.)

NOTE: Test reusable sterilizable paddles (internal or external) prior to each use. See the *Sterilizable Defibrillator Paddles Instructions for Use* for more information.

To perform the Weekly Shock test:

1 If you are using paddles, make sure the paddles and the paddle tray are thoroughly clean and there is no debris or residue (including all conductive material) on the electrode surfaces of the paddles and tray. Secure the paddles in the paddle tray and confirm the Patient Contact Indicator (PCI) LEDs located on the sternum paddle are not lit. If the LEDs light, adjust the paddles in their pockets. If the LEDs continue to light, clean both the adult and pediatric paddle electrode surfaces.
or
If you are using multifunction electrode pads, attach a test load to the end of the patient Therapy cable.

2 Turn the Therapy knob to 150J.

3 Press the Charge button.

NOTE: If it becomes necessary to disarm the defibrillator, press **[Disarm]**.

4 The strip prints if configured to do so. If the strip does not print immediately, press the Print button.

5 If using:
- Pads, press the Shock button on the MRx to deliver a shock into the test load.
- External paddles, simultaneously press the shock buttons located on the paddles to deliver a shock into the pockets.

6 Confirm on the printed strip that the energy delivered to the test load is 150J ± 23J (127J to 173J). If not, take the device out of use and begin troubleshooting.

NOTE: Detach the test load from the patient Therapy cable after performing the Shift Check. So your device is ready for use when needed, do not leave the test load attached after performing an Operational Check.

To acknowledge receipt of this notification, please complete and fax the Customer Reply Form to: <Philips representative contact details to be completed by the KM / country>.

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ACTIONS PLANNED BY PHILIPS	Philips is voluntarily providing this Field Safety Notification to remind customers to perform the Shift and Operational Checks as described in the ACTION TO BE TAKEN BY CUSTOMER / USER section of this notification. If the MRx Therapy Switch fails, Philips will arrange for the replacement of the switch at no charge to the customer.
FURTHER INFORMATION AND SUPPORT	If you need further information or support concerning this notification, please contact your local Philips representative or call us at <Philips representative contact details to be completed by the KM / country>.

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Customer Reply for FSN86100212A

Please complete, sign, and return this form at your earliest convenience.

Customer ID:	
Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address	
City, State, Postal Code:	
Country:	

CUSTOMER ACKNOWLEDGEMENT

I certify the Field Safety Notification FSN86100212A was received, read, and understood by staff who may use the HeartStart MRx and that a copy has been placed with the HeartStart MRx Instructions for Use.

Signature: _____ Date: _____

Please return your completed form at your earliest convenience by either method below.

1. Email completed and signed form to <Philips representative contact details to be completed by the KM / country>.

2. Fax completed and signed form to <Philips representative contact details to be completed by the KM / country>.