Urgent Medical Device Correction
HeartStart MRx Monitor / Defibrillator

HeartStart MRx Monitor/Defibrillator – Therapy Selector Switch

Dear Valued HeartStart MRx Distributor,

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.

It is imperative that all end-users with affected devices as identified in the “AFFECTED PRODUCTS” section of the Customer Information Letter, receive this Device Correction Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, send a copy of the attached package to any customer to whom you have distributed an HeartStart MRx. Be sure to include the Customer Information Letter. Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the “Ship To” field on the original invoice).

The Customer Information Letter 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. If you have questions regarding this notification or need any further information or support, please contact your local Philips representative: **0800 80 3000**.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

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Distributor 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:	

DISTRIBUTOR ACKNOWLEDGEMENT

☐ I acknowledge that I have reviewed and understand this Field Safety Notice.
I confirm that all customers are notified with the HeartStart MRx Monitor/Defibrillators with model numbers listed above. I certify that the information in the Field Safety Notice is sent to all customers.

Signature: _____ Date: _____

Please return your completed form at your earliest convenience to **customercare.ch@philips.com**