# URGENT - Medical Device Correction
## HeartStart MRx Monitor / Defibrillator

### Operational Check recommended if HeartStart MRx has been dropped

Dear Valued HeartStart MRx Customer,

Philips has received a number of reports of HeartStart MRx Monitor/Defibrillators that have suffered internal damage and were not able to deliver therapy after having been dropped or subjected to a severe mechanical shock, even though the device did not have visible external damage or the Ready for Use ("RFU") indicator on the unit did not immediately indicate a problem. One report involved the death of a patient following the failure of an MRx that may have been damaged in this way, although the user concluded that the failure of the device did not contribute to the inability to resuscitate the patient.

The automatic, periodic self-tests that the MRx performs and the regularly scheduled manual operational checks recommended in the Instructions for Use will, in many cases, detect such damage and alert the user via the RFU indicator and an audible chirp. However, if the device may be needed for therapeutic use before the next automatic self-test or manual operational check occurs, Philips is now recommending that the user perform an operational check after an MRx is dropped, subjected to a severe mechanical shock or otherwise mishandled.

This notice is intended to inform you about:

- what the problem is and under what 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.

The following pages provide 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. It is imperative that all end-users with affected devices as identified in the "AFFECTED PRODUCTS" section of the Field Safety Notice, 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 Monitor/Defibrillator. Be sure to include the Field Safety Notice. 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).
If you need any further information or support concerning this issue, 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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| **AFFECTED PRODUCTS** | **Product:** HeartStart MRx Monitor/Defibrillators with model numbers:<br><br>Commercial (Sales) Product Numbers<br>M3535A 861288 M3536M4 861483<br>M3536A 861289 M3536M5 861484<br>M3536M 861464 M3536M6 861491<br>M3536MC 861465 M3536M7 860396<br>M3536M2 861481 M3536M8 860397<br>M3536M3 861482 M3536M9 860398<br><br>**Units Affected:** Worldwide |
| **PROBLEM DESCRIPTION** | If the HeartStart MRx Monitor/Defibrillator MRx is dropped or subjected to a severe mechanical shock, the device may suffer internal damage even though the device did not have visible external damage or the Ready for Use (“RFU”) indicator unit does not immediately indicate a problem. Unless the user initiates a manual operational check as described in the Instructions for Use (“IFU”) immediately after the unit is dropped or mishandled, the device may not identify a fault and alert the user until the next scheduled automated self-test or operational check. |
| **HAZARD INVOLVED** | A damaged unit may not be able to deliver therapy. |
| **HOW TO IDENTIFY AFFECTED PRODUCTS** | The model of the HeartStart MRx Monitor/Defibrillator is printed on the primary label on the back of the device, in battery bay B.<br><br>  |

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| **ACTION TO BE TAKEN BY CUSTOMER / USER** | Inform all users that if a HeartStart MRx Monitor/Defibrillator is dropped or subjected to severe mechanical shock and the exterior case is still intact, they should immediately perform an operational check as described in the IFU section *Performing the Operational Check* in the Maintenance Chapter. The unit should be taken out of service and Philips Customer Service contacted if the unit is visibly damaged or if the device fails the operational check, i.e., if the RFU indicator changes to a “red-X” or the device emits a periodic audible “chirp”, as described in the IFU.<br><br>Insert a copy of this notice into each copy of the HeartStart MRx IFU.<br><br>**To acknowledge receipt of this notification, please complete and mail the Customer Reply Form to: customercare.ch@philips.com** |
| **ACTIONS PLANNED BY PHILIPS** | Philips is directing users to insert a copy of this notice with each copy of the HeartStart MRx IFU. |
| **FURTHER INFORMATION AND SUPPORT** | If you need further information or support concerning this notification, please contact your local Philips representative<br>**0800 80 3000** |

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**Customer Reply for FSN86100198A**

**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: | |

I certify that our facility received, read and understand the Field Safety Notification FSN86100198A.

Signature: _____ Date: _____

Email completed and signed form to **customercare.ch@philips.com**