PHILIPS

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.

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

URGENT - Medical Device Correction
HeartStart MRx Monitor / Defibrillator

Operational Check recommended if HeartStart MRx has been dropped

AFFECTED PRODUCTS

Product: HeartStart MRx Monitor/Defibrillators with model numbers:

Commercial (Sales) Product Numbers			
M3535A	861288	M3536M4	861483
M3536A	861289	M3536M5	861484
M3536M	861464	M3536M6	861491
M3536MC	861465	M3536M7	860396
M3536M2	861481	M3536M8	860397
M3536M3	861482	M3536M9	860398

Units Affected: Worldwide

PROBLEM DESCRIPTION

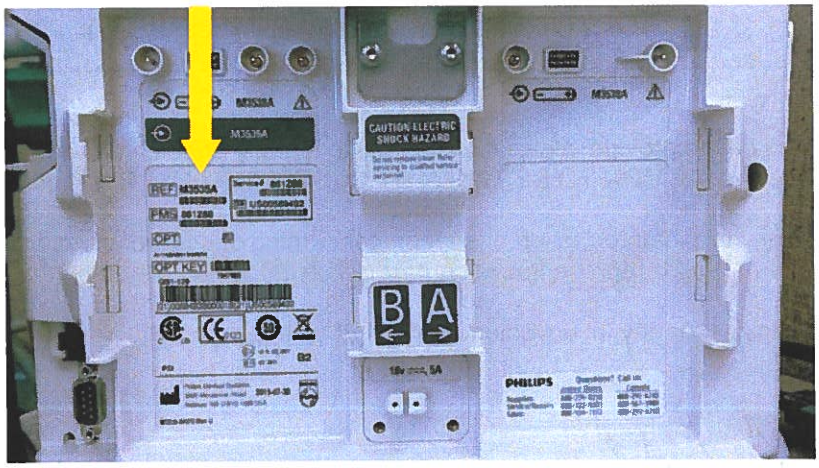
If the HeartStart MRx Monitor/Defibrillator MRx is dropped or subjected to a severe mechanical shock, the device may suffer internal damage even though the device did not have visible external damage or the Ready for Use ("RFU") indicator unit does not immediately indicate a problem. Unless the user 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.



URGENT - Medical Device Correction
HeartStart MRx Monitor / Defibrillator

Operational Check recommended if HeartStart MRx has been dropped

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. Insert a copy of this notice into each copy of the HeartStart MRx IFU. **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>.**
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 <Philips representative contact details to be completed by the KM / country>.

URGENT - Medical Device Correction
HeartStart MRx Monitor / Defibrillator

Operational Check recommended if HeartStart MRx has been dropped

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: _____

Please select one method below to return your completed form at your earliest convenience.

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>.
3. Return to your local Philips representative <Philips representative contact details to be completed by the KM / country>.