Field Change Order (FCO)

PHILIPS

Revision: U
Tier: 2
Number: A-Q2920-00108-T1
Element: : Installation and Servicing

Quality System Document

Issued by	:	ECR – Michelle Thompson	**FCO Ref No.**	:	FCO86100198A
Supersedes	:	N/A	**Date**	:	21-FEB-2020

TITLE	:	FCO86100198A Operational Check recommended if HeartStart MRx has been dropped

CLASSIFICATION:

_X__ Mandatory Action

____ Action for Performance – Proactive

____ Action for Performance – Retrofit on Failure

____ Service Recommendation

APPLIES TO:

Geography	:	Worldwide

Traceable Item Identification	**PMS Number:** 861288 861289 861464 861465 861481 861482 861483 861484 861491 860396 860397 860398	**Part Number:** M3535A M3536A M3536M M3536MC M3536M2 M3536M3 M3536M4 M3536M5 M3536M6 M3536M7 M3536M8 M3536M9
Range of Serial Numbers	See current supported version of UAL86100198	
Commercial (Sales) Product Number	**PMS Number:** 861288 861289 861464 861465 861481 861482 861483 861484 861491 860396 860397 860398	**Part Number:** M3535A M3536A M3536M M3536MC M3536M2 M3536M3 M3536M4 M3536M5 M3536M6 M3536M7 M3536M8 M3536M9

LIST OF PAGES & DRAWINGS:

INTRODUCTION:

Symptom : A damaged unit may not be able to deliver therapy.

Cause : 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.

Remedy : Philips is informing 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. Philips is also instructing users to insert a copy of FSN86100198A into each copy of the HeartStart MRx IFU.

MANPOWER / TIME TO COMPLETE: This FCO does not require Field Service Engineer/Bench involvement. No Service Work Orders (SWOs) are required by the Business Unit for this FCO. The FCO closure will be tracked by receipt of signed Customer Reply Form confirmation to BG Q&R.

Implementation: .25 Hours* 01 Engineers*
Implementer: Please check appropriate box or boxes: ☐ Philips Engineer or Approved Service Provider ☒ Customer ☒ No Engineer Required

* Minimum requirement for ServiceMax

TOOLS & TEST EQUIPMENT: N/A

MODIFICATION KIT / PARTS REQUIRED: N/A

PROCEDURE:

There is no modification kit for this FCO. Instead, the customer affected list will be distributed with instructions to send the following documents to the customers on the list.

- Medical Device Correction – FSN86100198A
- Customer Reply Form

Customers in the U.S. will receive their documents from the Recall Program Manager. The Recall Program Manager will mail documents to all customers based on the Customer Affected List and update FCO Monitor upon confirmation receipt of the Customer Reply Form. The Recall Program Manager is responsible for receiving Customer Reply Forms in the U.S. and completing the Verification Procedure below. Three documented attempts, made via two methods, to obtain the customer reply. Response and communication may be completed via reply card, phone call, email, or on-site visit in accordance with local regulations. For U.S., fax the completed Customer Reply Form to: +1.877.499.7223 or email to recall.response@philips.com .

All Customers outside the U.S. will receive their documents from the Key Markets. The Key Markets are responsible for translation of the Field Safety Notice – FSN86100198A. The Key Markets will mail documents to all customers based on the Customer Affected List and update FCO Monitor upon confirmation receipt of the Customer Reply Form in their geography. Key Markets are responsible for receiving Customer Reply Forms in their geography and completing the Verification Procedure below. Three documented attempts made via two methods to obtain the customer reply. Response and communication may be completed via reply card, phone call, email, or on site visit in accordance with local regulations. For Outside U.S., send the completed Customer Reply Form to <Philips representative contact details to be completed by the KM / country>.

Location Category: _____On-site _____Philips RSC
__X__Customer Installable _____Remote

Verification Procedure(s):.

This action will be considered closed when the following is reported to BG Q&R:

A. Customer confirmation that they took the applicable actions outlined in the customer letter.

OR

B. Three documented attempts via two methods to obtain the customer response.

Response and communication may be completed via reply card, phone call, email, on site visit, etc; in accordance with local regulations. The included reply card is a sample and may be used.

PARTS DISPOSAL: N/A

DOCUMENTATION:
2945-2019-05-05999

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.

If you need any further information or support concerning this issue, please contact your local Philips representative or call us at 1-800-722-9377.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

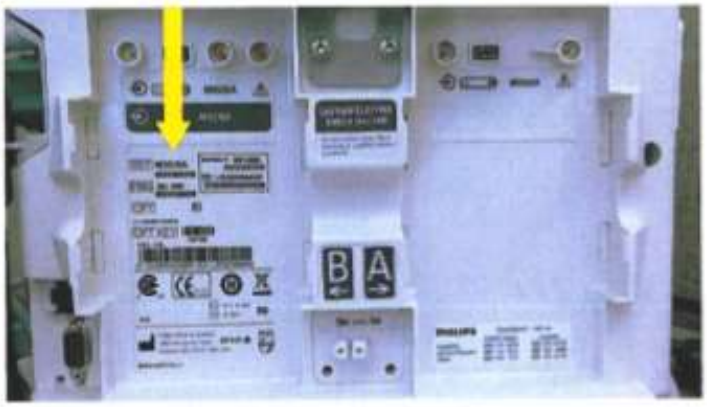
URGENT - Medical Device Correction
HeartStart MRx Monitor / Defibrillator

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: +1.877.499.7223 or email to recall.response@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 or call us at 1-800-722-9377. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax.

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 Recall.Response@Philips.com
2. Fax completed and signed form to **1-877-499-7223**
3. Return to your local Philips representative