

FIELD CHANGE ORDER

Service

Issued by : ECS, Sweta Patel

FCO Ref No. : FCO86100134A

Supersedes : N/A

Date : 11-Feb-2014

TITLE : FCO86100134A HeartStart MRx Rev J battery may shut down due to RF interference .

CLASSIFICATION:

- ☐ Mandatory Action
☒ Action for Performance – Proactive
☐ Action for Performance – Retrofit on Failure
☐ Service Recommendation

APPLIES TO:

Geography : Worldwide

Traceable Item Identification	PMS Number: N/A	Part Number: N/A
Range of Serial Numbers	M3538A MRx Lithium Ion batteries labeled Rev J See UAL86100134 for additional details.	
Commercial (Sales) Product Number	PMS Number: 989803129011	Part Number: M3538A

LIST OF PAGES & DRAWINGS:

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INTRODUCTION:

Note: This FCO does not require Field Service Engineer/Bench involvement. No Service Work Orders are required by the Business unit for this FCO – only the update of FCO Track.

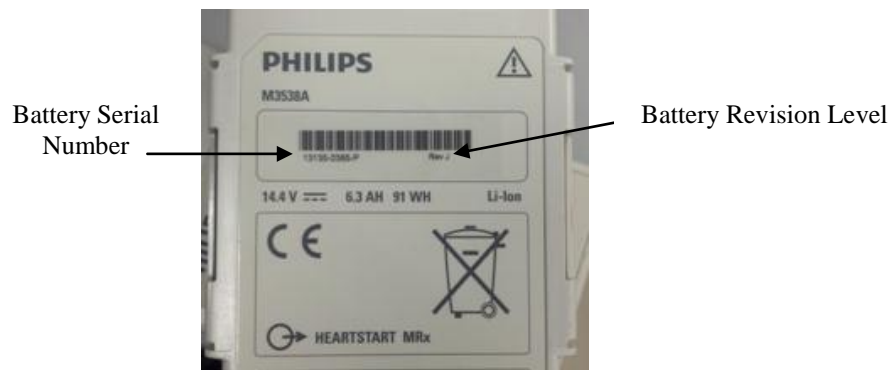
Symptom : A Philips HeartStart MRx Defibrillator/Monitor operating on battery power that is used in-hospital or in pre-hospital environments may experience an unexpected shutdown and fail

(Template Document Number: A-Q2920-00108-T1, Rev. M)

to restart.

Cause : External Li-Ion battery shuts down due to exposure to elevated levels of electromagnetic interference from RF energy sources. Examples of equipment that can cause interference are medical devices, cellular products, information technology equipment and radio/television transmissions.

Note: Affected batteries are identified by Revision level (Rev J) and Serial Number. This information can be found on the label on the back of the battery.



Remedy : Customers will be provided with a replacement battery(s) as soon as new production is available.

The condition can be avoided by operating the device on AC or external DC power or by following actions when operating a battery power.

- Before placing an MRx into use insert a fully charged MRx battery with illuminated LEDs on the battery fuel gauge.
- If an MRx device in use does not power on, press the fuel gauge button on battery and verify that the LEDs are illuminated. If there are not or dimly illuminated LEDs, insert a fully charge MRx battery.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See the HeartStart MRx Instructions for Use for the minimum recommended separation distance between RF communications equipment and the HeartStart MRx.

MANPOWER / TIME TO COMPLETE:

Implementation:
.25 Hours 00 Engineers
Implementer: Please check appropriate box or boxes: <input type="checkbox"/> Philips Engineer or Approved Service Provider <input checked="" type="checkbox"/> Customer <input checked="" type="checkbox"/> No Engineer Required

TOOLS & TEST EQUIPMENT:

N/A

MODIFICATION KIT / PARTS REQUIRED:

Modification kit: N/A

(Template Document Number: A-Q2920-00108-T1, Rev. M)

Ordering Info: N/A

For customers in the United States, the Business Unit (BU) will mail the Field Safety Notice, FSN86100134 to all customers on the Customer Affected List and track delivery to the customer. Outside the United States, the Key Markets will receive the FSN and the Customer Affected List. The Key Markets should translate the FSN, mail it to all customers based on the Customer Affected List and ensure that the package has been delivered to the customer. Once the Key Market has confirmed customer has received the package, they should update FCO Track.

[illegible]

N/A

453564042441 - Heartstart MRx M3535A/M3536A Service Manual Edition 3

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For Key Market use only; do not return to BU/BL.

BRANCH	SERVICE UNIT /
REGION /	SERVICE AREA NO.:
DEALER:	
SIGNATURE CUSTOMER SERVICES ENGINEER	DATE
SIGNATURE CUSTOMER SERVICES MANAGER	MAIL TO: Country Customer Services manager

ADDENDUM B



Philips Healthcare
Therapeutic Care

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FSN86100134
February 2014

URGENT - Medical Device Correction Philips HeartStart MRx M3538A Lithium Ion Batteries

Dear Customer,

This is to inform you of a product correction initiated by Philips Healthcare due to an issue with certain HeartStart MRx M3538A Lithium Ion batteries.

This Field Safety Notice is intended to inform you about:

- what the issue is and under what conditions it can occur
- the actions that should be taken by the customer/user in order to prevent risks for patients
- the corrective action planned by Philips to address the issue

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 Instructions for Use.

The Philips HeartStart MRx Monitor/Defibrillator, when operating on battery power only, may experience an unexpected shutdown if exposed to elevated levels of electromagnetic interference from RF energy sources.

Please see the attached Field Safety Notice that provides information on how to identify affected batteries and instructions on actions to be taken. Follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice. To correct this issue, Philips will replace affected HeartStart MRx M3538A Lithium Ion batteries free of charge.

This voluntary correction has been reported to the appropriate regulatory agencies.

Philips sincerely apologizes for any inconvenience this may cause you. If you have questions regarding this notification or need any further information or support, please contact your local Philips representative or call us at 1-800-722-9377.

Sincerely,

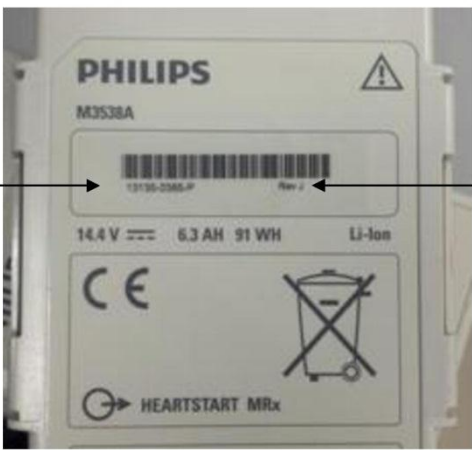
John Pardo
Director QA/RA, Emergency Care and Resuscitation



URGENT - Medical Device Correction
Philips HeartStart MRx M3538A Lithium Ion Batteries

AFFECTED PRODUCTS	Product: Philips HeartStart MRx Lithium Ion batteries (M3538A Revision J) with the following serial numbers :			
	11327-0019-P 11315-0023-P 11315-0027-P 11315-0031-P	11315-0032-P 11315-0033-P 11315-0036-P 11315-0109-P	11315-0214-P 11315-0219-P 11315-0391-P 11322-0084-P	11322-0088-P 11327-0043-P 11327-0044-P
	Or within the following range: 11335-xxxx-P to 13214-xxxx-P			
PROBLEM DESCRIPTION	The Philips HeartStart MRx Monitor/Defibrillator, when operating on battery power only, may experience an unexpected shutdown if exposed to elevated levels of electromagnetic interference from RF energy sources. Examples of equipment that can cause electromagnetic interference are medical devices, cellular products, information technology equipment and radio/television transmissions.			
HAZARD INVOLVED	If the problem occurs there may be an interruption of or failure to deliver defibrillation or pacing therapy when such therapy is needed.			

URGENT - Medical Device Correction Philips HeartStart MRx M3538A Lithium Ion Batteries

<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>Refer to the Affected Products section above for the serial numbers affected.</p> <p>The serial number and revision level of the Philips HeartStart MRx lithium ion battery (M3538A) are located on the label affixed to each battery. They are printed just below the bar code on the label. Affected batteries will have 'Rev. J' printed on the label and are within the affected serial number range.</p> <div data-bbox="486 698 1278 1146">  </div>
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>The condition can be avoided by operating the device on AC or external DC power or by the following actions when operating on battery power: The condition can be avoided by operating the device on AC or external DC power or by the following actions when operating on battery power:</p> <ol style="list-style-type: none"> Before placing a HeartStart MRx into use, insert a fully-charged battery with five solid green lights on the battery fuel gauge when the fuel gauge button is pressed. If your device does not power on, press the fuel gauge button and verify that at least one solid green light is illuminated. If there are no lights, insert a fully-charged MRx battery. <p>Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See the HeartStart MRx Instructions for Use for the minimum recommended separation distance between RF communications equipment and the HeartStart MRx.</p>



Philips Healthcare
Therapeutic Care

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URGENT - Medical Device Correction
Philips HeartStart MRx M3538A Lithium Ion Batteries

ACTIONS PLANNED BY PHILIPS	Philips will replace affected battery (s) free of charge. Each affected customer is receiving a form to be faxed or emailed back to Philips with instructions on how to obtain replacement batteries.
FURTHER INFORMATION AND SUPPORT	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.

ADDENDUM C

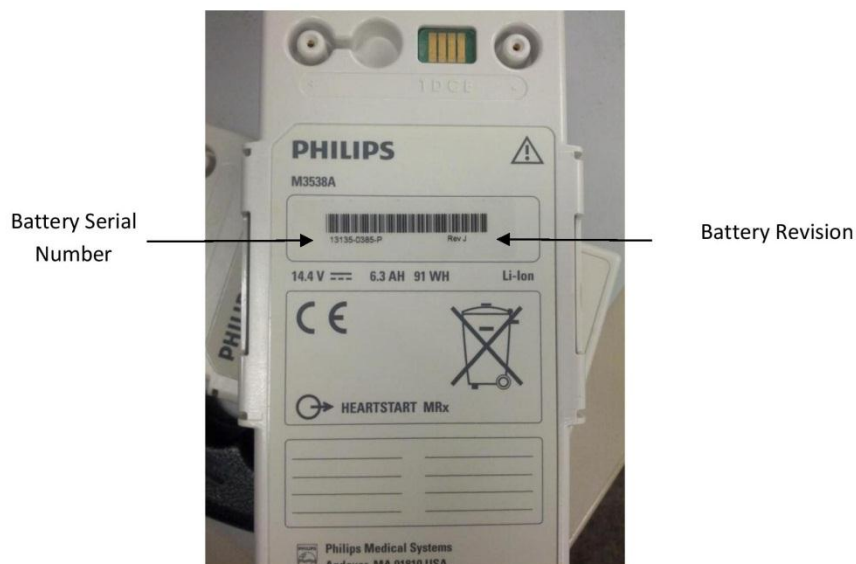
PHILIPS

Customer Reply: HeartStart MRx M3538A Lithium Ion Battery Order Form

Please complete and fax to: 978-659-7711 or email to MRx_Battery_Replacement@philips.com

This form is provided to allow your institution to order HeartStart MRx M3538A Lithium Ion batteries to replace those affected by the Medical Device Correction (FSN86100134) issued by Philips. If you have affected batteries, please provide the Serial Numbers on the attached sheet and fax or email per the instructions on the following page. If you no longer have affected batteries, please indicate this on the following page and fax or email the completed form to us.

The Battery Serial Number is located directly below the bar code on the M3538A battery label as shown below.



Note: Only batteries that are Rev. J and have the following serial numbers are affected:

11233-0673-P	11315-0032-P	11315-0107-P	11322-0084-P
11276-0169-P	11315-0033-P	11315-0109-P	11322-0086-P
11315-0023-P	11315-0036-P	11315-0214-P	11322-0088-P
11315-0027-P	11315-0102-P	11315-0219-P	11327-0043-P
11315-0031-P	11315-0103-P	11315-0391-P	11327-0044-P

11335-xxxx-P to 13214-xxxx-P



Customer Reply: HeartStart MRx M3538A Lithium Ion Battery Order Form

Please complete and fax to: 978-659-7711 or email to MRx_Battery_Replacement@philips.com

Please check one of the following boxes:

- ☐ I have inspected our HeartStart MRx M3538A Lithium Ion batteries and have determined that we have affected batteries with the Serial Numbers listed on the back of this document. I agree to take responsibility to dispose of all affected batteries in accordance with my local regulations (*Please do not return affected batteries to Philips*).
- ☐ I have inspected our HeartStart MRx M3538A Lithium Ion batteries and have determined that we DO NOT have affected batteries and DO NOT require replacements.

Completed By:

Contact Name

Institution/Facility

Telephone Number

Email Address

Please complete if you have affected HeartStart MRx M3538A Lithium Ion batteries and require replacements. You must provide us with the serial numbers of ALL affected batteries. Please fax or email this completed form to the numbers or email address provided above.

M3538A Lithium Ion Battery Serial Numbers (attach additional sheets if needed):

Please provide us with your Shipping Address where Philips should send Replacement HeartStart MRx M3538A Lithium Ion Batteries:

Institution/Facility Name

Address

City

State

Zip

Country

Attention To: _____