PHILIPS

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to theLithium Ion Battery Module for the HeartStart MRx due to FSN 86100195 . Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Serial numbers>

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:
Customer Name/Signature:
Company Name/Stamp:
Date:

Philips Electronics Singapore Pte Ltd
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Singapore 319763
Tel: +65 6206 8000
www.philips.com.sg

Reg. No 199705989C

PHILIPS

URGENT – Medical Device Recall
Certain Philips HeartStart MRx M3538A Batteries May Fail to Function

Dear Customer,

Philips discovered that certain M3538A Lithium-Ion Batteries manufactured between December 28, 2017 and March 20th, 2018 for the HeartStart MRx monitor/defibrillator may fail to charge or to provide power due to an internal component failure.

Philips is providing this Field Safety Notice to inform you about the...

- Issue and under what conditions it can occur
- Actions that you should take to mitigate risk to patients

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 should be aware of the contents of this communication.

Please retain a copy with the equipment Instructions 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 have questions regarding this notification or need any further information or support, please contact your local Philips representative.
<Philips representative contact details to be completed by the KM / country>.

Sincerely,

[redacted]

Gregory M Ayers, MD, PhD
Associate Chief Medical Officer
Head of Post Market Surveillance
Monitoring & Analytics and Therapeutic Care

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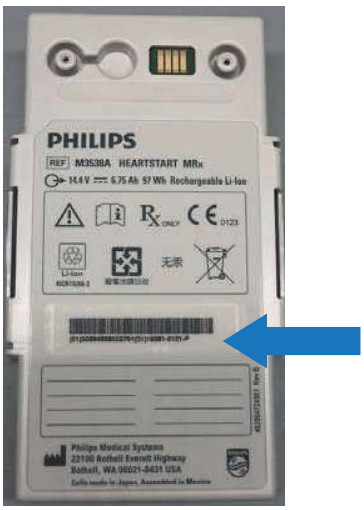
AFFECTED PRODUCTS	**Product:** M3538A Lithium-Ion Batteries for the HeartStart MRx Monitor/Defibrillator. **Units Affected subject to this Recall**: A total of 1,880 Lithium-Ion Batteries manufactured between December 28, 2017 and March 20, 2018 with serial numbers [redacted]
HOW TO IDENTIFY AFFECTED PRODUCTS	The serial number of the rechargeable lithium-ion battery is printed on the label on the back of the battery. 
BEHAVIOR DESCRIPTION	Affected MRx M3538A lithium-ion batteries may contain a defective component (Thermal Cut-off or TCO). Should the component fail, the battery will no longer charge or deliver power to the MRx Monitor/Defibrillator, which may prevent operation of the device if it is not connected to AC or DC power. Should a second, unaffected battery be present in the HeartStart MRx, the battery failure may go unnoticed.
HAZARD INVOLVED	If the MRx is being operated with a failed lithium-ion battery, the HeartStart MRx will no longer function, potentially delaying shock therapy or interrupting monitoring or pacing, which could result in reduced survival from a cardiac event.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Inspect the batteries installed in your MRx monitor/defibrillator to determine if they are affected by this recall. If any affected batteries are found, remove them from service immediately, along with any other affected batteries in your inventory. Your MRx monitor/defibrillator can only be returned to service once a charged battery, unaffected by this recall, is installed. Removed batteries should be disposed in accordance with local regulations. Do not return affected batteries to Philips. 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 will replace affected HeartStart MRx M3538A Rechargeable Lithium-Ion Batteries at no charge to the customer. Philips will contact you when replacement batteries are available.
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 Recall
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Customer Reply for FSN86100195B

Please complete and fax to: <Philips representative contact details to be completed by the KM / country>.

Contact Name:	
As-Shipped Customer Address	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address City, State Zip:	
Country:	
Battery Serial #s	

Please E-mail or Fax this completed form to the number or email address provided above.

☐ I certify that our facility has disposed of M3538A batteries with the Serial Numbers listed above.

Signature: _____ Date: _____

Please email the completed reply form to <Philips representative contact details to be completed by the KM / country>. or your local Philips representative.

If you are unable to carry out the instructions contained in this communication, please contact your local Philips representative.