

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 January 19th, 2018 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
- Convenient power management reminders also found in the Instructions for Use

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,



Ralph Asencio
Head of QA/RA, Emergency Care and Resuscitation

URGENT – Medical Device Recall

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<p>AFFECTED PRODUCTS</p>	<p>Product: M3538A Lithium-Ion Batteries for the HeartStart MRx Monitor/Defibrillator.</p> <p>Units Affected subject to this Recall: A total of 1,880 Lithium-Ion Batteries manufactured between January 19th, 2018 and March 20th, 2018 with serial numbers 17362-0001-P through 18057-0266-P</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>The serial number of the rechargeable lithium-ion battery is printed on the primary label on the back of the battery.</p> 
<p>BEHAVIOR DESCRIPTION</p>	<p>Certain MRx M3538A lithium-ion batteries may contain a defective component. 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 a second charged battery is not installed or if the device is not connected to AC or DC power. Additionally, the LED status indicator on the battery will not illuminate, even if the battery has a charge. Should a second, unaffected battery be present in the HeartStart MRx, the battery failure may go unnoticed.</p>
<p>HAZARD INVOLVED</p>	<p>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.</p>

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ACTION TO BE TAKEN BY CUSTOMER / USER	<p>The user should follow the Instructions for Use to assure a fully functional and charged battery is in the device. Should a battery fail to charge, or if the LED status indicator stops functioning, the battery should be removed from service. If the battery exhibits none of these symptoms, it can be used until a replacement is obtained.</p> <p>Once the batteries are removed from service, either due to a failure or once a replacement is obtained, they will need to be disposed of in accordance with local regulations.</p> <p>Do not return affected batteries to Philips.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips will replace the affected HeartStart MRx M3538A Rechargeable Lithium-Ion Batteries at no charge to the customer. Philips will contact you when replacement batteries are available.</p>
FURTHER INFORMATION AND SUPPORT	<p>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>.</p>

