

**URGENT - Medical Device Removal**  
**Lithium-ion Rechargeable Battery for the Philips MX40 Wearable**  
**Monitor**

**Batteries May Have a Manufacturing Defect**

Baylor Medical Center at McKinney  
5252 W University Dr  
McKinney, TX 75071-7822

Dear Customer,

cc: Chairman Medical Board and relevant Head of Departments

Philips recently became aware that one lot of Lithium-ion Rechargeable Batteries for the Philips MX40 Wearable Monitor may have a manufacturing defect that may affect the operation of the monitor. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients
- the actions planned by Philips to correct 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.

Our records indicate that your facility was shipped affected batteries. The following page provides additional instructions and actions to be taken.

If you need any further information or support concerning this problem, please contact your local Philips representative: 1-800-225-0230, option 1, extension 4206.

This notice has been reported to the appropriate Regulatory Agencies. Philips apologizes for any inconveniences caused by this problem.




Sincerely,

  
Rusty Kelly  
Head of Quality & Regulatory  
Medical Consumables and Sensors

## URGENT - Medical Device Removal

### Lithium-ion Rechargeable Battery for the Philips MX40 Wearable Monitor

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<b>AFFECTED PRODUCTS</b>	<p>Lithium-ion Rechargeable Batteries for the Philips MX40 Wearable Monitor (REF 989803176201); lot 2018-28</p> <p>Listed below are the details about the sales order for the affected battery:</p> <p>Purchase Order Number: 4512824774  Date of Shipment: 11/19/2018  Quantity of Batteries Shipped: 2</p>
<b>PROBLEM DESCRIPTION</b>	<p>One lot of Lithium-ion Rechargeable Batteries for the Philips MX40 Wearable Monitor may have a manufacturing defect that may affect the operation of the monitor. These batteries were under investigation for poor workmanship by the supplier and did not meet Philips quality criteria for sale.</p>
<b>HAZARD INVOLVED</b>	<p>Use of the affected battery could possibly result in a delay of patient treatment due to the loss of monitoring if the battery fails while the MX40 is in use.</p>
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<div style="text-align: center;">    </div> <p style="text-align: center;"> <span>(battery front)</span> <span>(battery back showing REF number)</span> <span>(top of battery showing lot number location)</span> </p> <p>In order to identify an affected battery, the battery must first be removed from the MX40. The pictures above show the front, back and top of the battery. The model number (REF) is located on the back of the battery in the area outlined in red, and the lot number can be found on the top of the battery in the area outlined in green.</p>

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<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>Users should check all MX40s that may contain an affected battery, immediately remove any affected batteries found and replace them with unaffected batteries. Return the affected batteries using the address and RMA Number provided below. Also included with this communication is a return label for your use in returning affected batteries to Philips.</p> <p>Philips Healthcare Customer Returns 3000 Minuteman Road, Bldg. 2 Dock B Andover, MA 01810 Attn. RMA Number: 2019-1-30408</p> <p>It is important to follow any special requirements for shipping lithium-ion batteries specified by the carrier you select.</p>
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips is shipping replacement batteries free of charge to customers who received affected batteries. The quantity of replacement batteries being shipped to you is the number specified on the previous page under Affected Products.</p> <p>For your reference, your replacement order number is 5288476.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this problem, please contact your local Philips representative: 1-800-225-0230, option 1, extension 4206.</p>