

**URGENT – Medical Device Recall
HeartStart XL Defibrillator/Monitor Battery (M3516A)**

Battery May Not Trigger a Low Battery Alarm on the HeartStart XL

Dear Customer,

A problem has been detected in certain Philips HeartStart XL Defibrillator/Monitor M3516A batteries that, if it were to occur, could pose a risk for patients. 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 risk to 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.

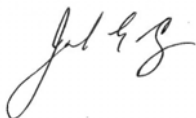
If the XL Defibrillator/Monitor (M4735A) is used on a patient when AC power is not in use, with a battery that may fail, the device may shut down unexpectedly without providing the user with a low battery warning message or audible tone.

If you need any further information or support concerning this issue, please contact your local Philips Representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



John Cadigan
General Manager, Emergency Care Solutions

Attachments



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AFFECTED PRODUCTS	<p>Product: Philips HeartStart XL Defibrillator/Monitor battery M3516A. Units Affected: HeartStart XL battery M3516A labeled with Made in Taiwan and an R-2011-12 Date of Manufacture.</p> <p>Manufactured and Distributed by: Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.</p>
PROBLEM DESCRIPTION	<p>If the XL Defibrillator/Monitor (M4735A) is used on a patient when AC power is not in use, with a battery that may fail, the device may shut down unexpectedly without providing the user with a low battery warning message or audible tone.</p> <p>Note: The XL can operate on AC power without a battery.</p>
HAZARD INVOLVED	<p>There is a potential for patient harm if the XL shuts down or becomes inoperable when in clinical use for providing therapy (i.e. defibrillation or non-invasive pacing).</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>Customers with a battery (M3516A) labeled with Made in Taiwan and a Date of Manufacture code of R-2011-12 are affected. To identify an affected battery, locate the Made in Taiwan and Date of Manufacture on the bottom of the battery label and confirm the date.</p> <div data-bbox="824 1121 1117 1310" style="text-align: center;"> <p>The image shows a close-up of a battery label. At the top left is a recycling symbol with 'Pb' below it. To the right of the recycling symbol, it says 'Philips Medical Systems' and 'Made in Taiwan'. Below that, it says 'Date of Manufacture'. A large grey box contains the date 'R-2011-12'. At the bottom, it says 'Nonspillable Battery'.</p> </div>
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Philips recommends the following actions::</p> <ul style="list-style-type: none"> • Operate the XL with AC power instead of battery power alone. • If you need to operate the XL on battery power alone, ensure the battery is from a different Date of Manufacture (it must not have the R-2011-12 Date of Manufacture code). • If unable to operate with AC power alone or locate a battery with a different Date of Manufacture than that identified above, use an alternative source for treatment or therapy (i.e., backup defibrillator/monitor).



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ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a corrective action consisting of: <ul style="list-style-type: none">• Distribution of this Field Safety Notice (FSN) advising affected customers of the potential issue and action to be taken• Providing affected customers no charge replacement battery (s) as soon as new production is available A Philips Healthcare representative will contact customers with affected battery(s) to arrange for replacement.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips Representative or the UK Philips Customer Care Service Centre on 0870 532 9741.



PHILIPS

Customer Reply: M3516A HeartStart XL Battery Order Form

Please complete and fax to: 978-659-3168, if busy, fax to 978-659-4878

This form is provided to allow your institution to order replacement M3516A batteries in conjunction with Field Safety Notice (FSN86100117) issued September 2012 by Philips Healthcare. Indicate below the number of affected batteries requiring replacement and fax the form to the number provided above. If you do not have any affected batteries, please indicate in the space provided below and return the form to the above fax number. We will send the replacement batteries to your attention at the address that you provide below as soon as new production of batteries is available.

***An affected battery will be labeled with Made in Taiwan and have a Date of Manufacture of R-2011-12.**



Note: Do not return affected batteries to Philips. Dispose of affected batteries in an environmentally safe manner according to your organization’s disposal procedures and local regulations.

Philips Part Number	Number of affected batteries needing replacement
M3516A (HeartStart XL Battery)	

_____ We have inspected our M3516A HeartStart XL batteries and have determined that we do not have any of the affected batteries and do not require replacement batteries.

Completed By:

Contact Name	Dept	Telephone Number	Email Address
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Shipping Information:

Institution/Account Name

Address

City	State	Zip	Country
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Attention To: _____

For Office Use Only:	
Receive Date: _____	by: _____
Ship Date: _____	Tracking #: _____