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URGENT - Medical Device Recall
HeartStart XL M4735A Defibrillator/Monitor

Device Does Not Turn On Due to Switch Failure

Dear Customer,

A problem has been detected in the Philips HeartStart XL model M4735A Defibrillator/Monitor 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 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.

The rotary energy select switch in affected devices may fail and prevent the user from turning the device on, rendering the device unusable for monitoring and defibrillation therapy. In addition, in some rare cases, the failure can be exhibited by the device spontaneously powering on.

There have been approximately 200 reports of this issue to date, representing less than 1% (.008) of affected devices installed worldwide. All of these occurrences have been reported from Asia Pacific or Latin America. There have been no reported occurrences in North America or Europe. Our investigation has determined that failures are more likely to occur in devices that have been exposed to high heat and humidity, which contributes to accelerated internal degradation of switch components over time. Devices used within environmentally controlled areas (i.e. normal room temperature and humidity) are less susceptible to premature failure. There have been no reports of a device failing to deliver therapy when used on a patient.

Please see the attached Field Safety Notice that provides information on how to identify affected devices and instructions on actions to be taken. Please follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

The source of the problem with the energy select switch has been identified and eliminated in new production. To reduce the possibility of this issue occurring, Philips will replace the energy select switches on affected units free of charge.

Should you have any questions or concerns about the Device Correction, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences caused by this problem. Ensuring that you have the highest quality defibrillators is our top priority. Your satisfaction with Philips products as well as with our response to this problem is very important to us.

Sincerely,

[redacted]

[redacted]
General Manager, Advanced Life Support
Cardiac Resuscitation

Attachments

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AFFECTED PRODUCTS	**Product:** Philips HeartStart XL, Model M4735A Defibrillator/Monitors. **Units Affected:** Units manufactured by Philips from March 2006 to December 2008, and shipped worldwide with a serial number within the range of US00442485 and US00469873. The following **additional units are also affected because their energy select switches were replaced within the relevant time period:**

US00100353	US00110688	US00121145	US00338153
US00100741	US00110914	US00121658	US00439208
US00100843	US00111399	US00123159	US00439504
US00101080	US00112143	US00124026	US00439652
US00101500	US00112685	US00125012	US00439661
US00102492	US00114680	US00125049	US00439688
US00102580	US00114900	US00125344	US00439930
US00102583	US00116677	US00126424	US00441252
US00102601	US00116965	US00127322	US00441758
US00102643	US00117003	US00127620	US00441855
US00103225	US00118060	US00213344	US00441862
US00103916	US00118260	US00213559	
US00104178	US00118602	US00230434	
US00105134	US00118915	US00230588	
US00106329	US00118985	US00231849	
US00106922	US00119444	US00232228	
US00108281	US00119624	US00232394	
US00108296	US00120241	US00233505	
US00109777	US00120466	US00234442	
US00110403	US00120589	US00234615	

Manufactured and Distributed by: Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.

PROBLEM DESCRIPTION	The rotary energy select switch may fail and prevent the user from turning affected devices on, rendering the devices unusable for monitoring and defibrillation therapy. In addition, in some rare cases, the failure can be exhibited by the device spontaneously powering on when in the off position.
HAZARD INVOLVED	The defibrillator may fail and prevent the user from turning the device on, rendering the device unusable for monitoring and defibrillation therapy.
HOW TO IDENTIFY AFFECTED PRODUCTS	Customers with a Serial Number identified above are affected by the issue. To identify an affected unit, locate the serial number on the bottom of the HeartStart XL.
ACTION TO BE TAKEN BY CUSTOMER / USER	• During the interim period as you await the repair of your device, if possible, remove the affected device from service. If it is not possible to remove the device from service, identify a readily available backup device to use in the event the defibrillator becomes unusable. • A Philips Healthcare representative will contact you in the near future regarding repair of your device.

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ACTIONS PLANNED BY PHILIPS	Philips is voluntarily initiating a correction to affected devices. Philips considers this correction to be required for all affected units and will perform the upgrade free of charge. A Philips Healthcare representative will contact customers with devices on the Units Affected List to arrange for replacement of the Energy Select Switch.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>