

New York State Office Of General Services  
Procurement Services Group  
Corning Tower Building  
Empire State Plaza  
Albany, New York 12242  
<http://www.ogs.state.ny.us>

## PURCHASING MEMORANDUM

### GENERAL INFORMATION BULLETIN

**NUMBER:** CL-718

**DATE:** July 9, 2009

**GROUP:** Automated External Defibrillators (AED's)  
Accessories And Related Products (Statewide)

**PLEASE ADDRESS INQUIRIES TO:**

**STATE AGENCIES**

Mary P. Schneider  
Purchasing Officer I  
(518) 474-0912  
[mary.schneider@ogs.state.ny.us](mailto:mary.schneider@ogs.state.ny.us)

**OTHER AUTHORIZED USERS**

Customer Services  
(518) 474-6717  
[customer.services@ogs.state.ny.us](mailto:customer.services@ogs.state.ny.us)

**SUBJECT:** WORLDWIDE VOLUNTARY RECALL

**TO ALL STATE AGENCIES AND OTHERS AUTHORIZED TO USE STATE CONTRACTS:**

The contractor for PC64282 PHILIPS MEDICAL SYSTEMS, has issued the following information regarding a voluntary recalls for HeartStart MRx M3535A/M3536A Defibrillator Monitor and HeartStart XL M4735A Defibrillator/Monitor.

**Cardiac Care Advanced Life Support - [FSN86100077](#) 2009 MAR**

### **URGENT - Medical Device Recall HeartStart MRx M3535A/M3536A Defibrillator/Monitor**

#### **Potential Switch Failure May Cause Spontaneous Turn-On or Failure to Turn On**

Dear Customer,

A problem has been detected in the Philips HeartStart MRx model M3535A/M3536A 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

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(continued)

- the actions planned by Philips to correct the problem.

<b>This document contains important information for the continued safe and proper use of your equipment</b>
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 therapy switch in affected devices has a small potential to fail. The most likely failure mode is a spontaneous turn-on which could deplete the battery, rendering the device unusable until power is restored. There is also the possibility of a failure mode in which the device fails to respond to user initiated turn-on, rendering it unusable for monitoring and therapy.

To date, there has been one report of a suspected failure worldwide. This failure could not be confirmed and no patient impact was reported. Philips is taking this corrective action to proactively limit the possibility of this failure occurring in the future.

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 therapy switch has been identified and eliminated in new production. Philips will replace the switches on affected units free of charge. 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.

Should you have any questions or concerns about this Device Correction, please contact your local Philips representative at 1-800-722-9377.

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,  
Paul Lightfoot  
General Manager, Advanced Life Support  
Cardiac Resuscitation  
Attachments

(continued)

**FIELD SAFETY NOTICE**

<b>AFFECTED PRODUCTS Product:</b> Philips HeartStart MRx, Model M3535A/M3536A Defibrillator/Monitors.
<b>Units Affected:</b> Units manufactured by Philips from March 2006 to March 2009, and shipped worldwide with a serial number within the range of US00210406 and US00333123. The following additional units are also affected because their therapy switches were replaced within the relevant time period:
US00100313 US00102303 US00208545
US00100482 US00203090 US00208780
US00101138 US00203793 US00208856
US00101180 US00206364 US00209017
US00101331 US00207141 US00210351
<b>Manufactured and Distributed by:</b> Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
<b>PROBLEM</b>
<b>DESCRIPTION</b>
The therapy switch may fail, causing the device to either spontaneously turn on or to fail to respond to user initiated turn-on. As a result, the device may be rendered unusable for monitoring and therapy.
<b>HAZARD INVOLVED</b> The device may become unusable, impacting the ability to assess patient condition and deliver therapy.
<b>HOW TO IDENTIFY</b>
<b>AFFECTED PRODUCTS</b>
Customers with a serial number listed above are affected by the issue. To identify an affected unit, locate the serial number on the back of the MRx, in battery bay B.
<b>ACTION TO BE TAKEN</b>
<b>BY CUSTOMER / USER</b>
During the interim period, as you await the upgrade for your device, you may continue to use the HeartStart MRx. However, to reduce the risk that a spontaneous turn-on could deplete the battery, it is advised that you keep:
<ul style="list-style-type: none"><li>• a charged spare battery with the HeartStart MRx</li><li>• AC power applied, if possible, when the device is not in use</li></ul>
You should also consider identifying a readily available backup defibrillator to use in the unlikely event that the device fails to turn on.
Devices that exhibit a spontaneous turn-on or failure to respond to user initiated turn on should be removed from service as soon as possible
A Philips Healthcare representative will contact you in the near future regarding repair of your device.
<b>ACTIONS PLANNED BY</b>
<b>PHILIPS</b>
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 listed in the Units Affected section above to arrange for replacement of the therapy switch.
<b>FURTHER</b>
<b>INFORMATION AND</b>
<b>SUPPORT</b>
If you need any further information or support concerning this issue, please contact your local Philips representative at 1-800-722-9377.

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**Cardiac Care Advanced Life Support - FSN86100076 2009 MAR**

**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.

<b>This document contains important information for the continued safe and proper use of your equipment</b>
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 this Device Correction, please contact your local Philips representative at 1-800-722-9377.

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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,

Paul Lightfoot  
General Manager, Advanced Life Support  
Cardiac Resuscitation  
Attachments

<b>AFFECTED PRODUCTS Product:</b> Philips HeartStart XL, Model M4735A Defibrillator/Monitors.
<b>Units Affected:</b> Units manufactured by Philips from March 2006 to December 2008, and shipped worldwide with a serial number within the range of US00442485 and US00469873. <b>The following additional units are also affected because their energy select switches were replaced within the relevant time period:</b>
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
<b>Manufactured and Distributed by:</b> Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.
<b>PROBLEM</b>
<b>DESCRIPTION</b>
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.
<b>HAZARD INVOLVED</b> The defibrillator may fail and prevent the user from turning the device on, rendering the device unusable for monitoring and defibrillation therapy.

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<b>HOW TO IDENTIFY</b>
<b>AFFECTED PRODUCTS</b>
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.
<i>Affected Products Table (cont'd)</i>
<b>ACTION TO BE TAKEN</b>
<b>BY CUSTOMER / USER</b> • 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.
<b>ACTIONS PLANNED BY</b>
<b>PHILIPS</b>
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.
<b>FURTHER INFORMATION AND</b>
<b>SUPPORT</b>
If you need any further information or support concerning this issue, please contact your local Philips representative at 1-800-722-9377.

We will to keep you informed of any further developments.

All other terms and conditions remain the same.

Please contact the Purchasing Officer above if you should have any questions.