



Philips Healthcare

Cardiac Care Emergency Care Solutions

-1/3-

FSN86100085 2009 NOVEMBER

**URGENT – Voluntary Medical Device Correction
HeartStart Vehicle Wall Mount (Model M5528A) and DC Power Module
(Model M5529A)**

Incorrect wiring during installation by user may result in a smoke or fire hazard

Dear Customer,

This letter is to inform you that a Philips investigation has found that a small number of users have modified the wiring of the HeartStart MRx Vehicle Wall Mount or the DC Power Module for the Philips HeartStart MRx defibrillator when connecting the Vehicle Wall Mount (Model M5528A) to the DC Power Module (Model M5529A). These user modifications involve cutting and splicing or soldering the DC output cable (that comes with the DC Power Module) and/or the electrical connector on the Vehicle Wall Mount.

Such improper connections can result in reversed electrical polarity from the DC Power Module to the Vehicle Wall Mount, and pose a smoke or fire hazard to patients or caregivers in proximity to the Vehicle Wall Mount. This Field Safety Notice is intended to inform you about:

- What the problem is and under what circumstances it can occur
- Actions that should be taken by the customer/user in order to mitigate risks for patients/caregivers
- Actions planned by Philips to address 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 Instructions for Use.

This issue can only arise when **both** the Vehicle Wall Mount and DC Power Module are installed together **and** modifications have been made to the DC Power Module power cable or Vehicle Wall Mount electrical connector. Vehicle Wall Mounts installed without a DC Power Module cannot be affected.

The HeartStart MRx monitor/defibrillator, which may be attached to the Vehicle Wall Mount, does not contribute to this issue under any circumstances and is not the subject of this correction.



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Cardiac Care Emergency Care Solutions -2/3- FSN86100085 2009 NOVEMBER
Philips is updating the Instructions for Use for both the DC Power Module and the Vehicle Wall Mount with warnings to not make any unauthorized modifications to the equipment (wall mount, cables, mounting brackets, or M5529A DC Power Module). The updated Instructions for Use are included with this letter, and should be implemented to ensure the Vehicle Wall Mount and DC Power Module are installed and operated properly.

Please see the attached Field Safety Notice which 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.

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>

Ensuring that you have the highest quality medical devices, accessories and supporting documentation is our top priority. Your satisfaction with Philips products as well as with our response to this problem is very important to us.

Sincerely,



Senior VP and GM
Emergency Care Solutions
Cardiac Resuscitation

Attachments

Field Safety Notice

AFFECTED PRODUCTS	<p>Product: Philips HeartStart Wall Mount, Model M5528A (if used with DC Power Module, Model M5529A).</p> <p>Units Affected: Units distributed by Philips and shipped between September 1, 2004 and October 1, 2009.</p> <p>Distributed by: Philips Healthcare, 3000 Minuteman Road, Andover, MA, 01810.</p>
PROBLEM DESCRIPTION	<p>A small number of users have modified the wiring of the HeartStart Vehicle Wall Mount for the Philips HeartStart MRx monitor/defibrillator when connecting the Vehicle Wall Mount to the DC Power Module (Model M5528A), as part of installation. These modifications involve cutting and splicing or soldering the DC output cable from the DC Power Module and/or the electrical connector on the Wall Mount. Such incorrect installation may result in reversing the electrical polarity of the connection, which can lead to excessive heating at the lower mounting bracket of the Vehicle Wall Mount, where it interfaces with the monitor/defibrillator.</p>
HAZARD INVOLVED	<p>Elevated temperatures at the lower mounting bracket on the Vehicle Wall Mount can melt the plastic mounting bracket and smoke. If not promptly detected, combustion of the assembly may result. These events could result in exposure of patients or caregivers to smoke or fire, particularly if they are in an enclosed space, such as an ambulance. Furthermore, resulting damage to the ambulance or to the monitor/defibrillator could disrupt patient care.</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	<p>See affected products above.</p>
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Immediately check all Vehicle Wall Mounts to verify that either (1) they are not connected to a DC Power Module or (2) that there is a proper connection between the two. The latter can be verified by checking whether the green external power indicator on a HeartStart MRx mounted on the Vehicle Wall Mount is lit when power is supplied to the DC Power Module.</p> <p>If you cannot verify either of the two conditions above, immediately disconnect the power to DC Power Module, and contact your local representative.</p> <p>Note: In any case, the associated HeartStart MRx is not affected and can remain in service.</p>
ACTIONS PLANNED BY PHILIPS	<p>Philips is voluntarily initiating a corrective action consisting of:</p> <ul style="list-style-type: none">• Issuance of a procedure for identification of incorrect installations as described in this Field Safety Notice• Issuance of revised Instructions for Use for Vehicle Wall Mount for HeartStart MRx and DC Power Module for the HeartStart MRx including a revised description of correct installation and verification of performance
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative at 1-800-722-9377.</p>