

URGENT – MEDICAL DEVICE RECALL
HeartStart Home and OnSite (HS1)

Contact Pin Contamination

Dear Customer,

A problem has been detected in the Philips HeartStart Home and OnSite (HS1) automated external defibrillators (AEDs) 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.

In a limited number of HeartStart Home and OnSite (HS1) AEDs, one or both contact pins may be contaminated by residue from the soldering process. This contamination could prevent an adequate connection between the pads cartridge and the AED. If poor contact between the pads cartridge and AED occurs, the device may be unable to deliver therapy in an emergency.

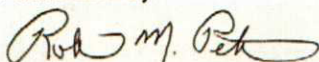
Please see the matrix on the following page, which provides instruction on how to identify affected devices and actions to be taken. Follow the "ACTION TO BE TAKEN BY CUSTOMER / USER" section of the notice.

If you need any further information or support concerning this issue, please visit www.philips.com/HeartStartHS1PinAction or contact your local Philips representative at 1-800-263-3342, and select option 5. Live technical support is available Monday through Friday, 7:00AM to 5:00PM PST. You can also leave a message 24 hours a day, seven days a week; a customer support representative will return your call promptly on the next business day.

This notice has been reported to the appropriate Regulatory Agency. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Philips apologizes for any inconveniences caused by this problem.


Sincerely,
Authorized by:



Bob Peterhans
General Manager
Philips Healthcare
Emergency Care & Resuscitation
Attachment



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HeartStart Home and OnSite (HS1)**Contact Pin Contamination**

AFFECTED PRODUCTS	A limited number of Philips HeartStart Home and OnSite (HS1) models M5066A and M5068A are affected by this action. Philips has identified the serial numbers of all affected devices.
PROBLEM DESCRIPTION	In a limited number of HeartStart Home and OnSite (HS1) AEDs, one or both contact pins may be contaminated by residue from the soldering process. This contamination could prevent an adequate connection between the pads cartridge and the AED.
HAZARD INVOLVED	If poor contact between the pads cartridge and AED occurs, the device may be unable to deliver therapy in an emergency.
HOW TO IDENTIFY AFFECTED PRODUCTS	<div>A limited number of Philips HeartStart Home and OnSite (HS1) models M5066A and M5068A are affected by this action. Affected units can be identified by locating the serial number on the back of your AED(s) and comparing it to the list of affected device serial number(s) provided with this notice. A sample of the device label is shown to the right.</div> <div>SN: A13G-##### </div>
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>If you have an affected device, please contact Philips for a replacement AED at 1-800-263-3342 and select option 5. Live technical support is available Monday through Friday, 7:00AM to 5:00PM PST. You can also leave a message 24 hours a day, seven days a week; a customer support representative will return your call promptly on the next business day.</p> <p>Please keep your AED in service until you receive a replacement if there are no alternative defibrillators readily available.</p>
ACTIONS PLANNED BY PHILIPS	Customers who have an affected device will be supplied with a replacement AED from Philips, free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please visit www.philips.com/HeartStartHS1PinAction or contact your local Philips representative at 1-800-263-3342, and select option 5.

