URGENT - Safety Notification

HeartStart HS1 Home, HS1 Onsite, FRx and FR2/FR2+

Devices may have been omitted from previous recalls

Dear Customer,

Philips has become aware that a HeartStart HS1 Home, HS1 OnSite, FRx or FR2/FR2+ AED in your possession may have been omitted from one or more previous recalls. Consequently, your device may have an issue that could significantly impact device operation or safety.

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 or users;
- 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.

Fewer than 300 AEDs worldwide were omitted from these previous recalls and are subject to this notice.

Regulatory Agencies have been informed of this action, as appropriate.

Philips apologizes for any inconveniences caused by this problem.

If you need any further information or support concerning this issue, please contact your local Philips representative:

0800 80 3000

Sincerely,

Tanya DeSchmidt
Director, Quality, Emergency Care and Resuscitation

AFFECTED PRODUCTS	Philips HeartStart HS1 Home, HS1 OnSite, FRx or FR2/FR2+ AED.
PROBLEM DESCRIPTION	Philips has become aware that a HeartStart HS1 Home, HS1 OnSite, FRx or FR2/FR2+ AED in your possession may be among fewer than 300 units that may have been omitted from one or more previous recalls: FR2+ Board Contamination (RES 36662) FR2+ Product Correction SRAM memory chip failure (RES 53383) FR2+ U34 Product Recall (RES 56816) FR2+ U8 Recall (RES 55682) FRx, HS1 Field Action for PCA Failed Supplier Testing Procedure (RES 84850) HS1 Button Recall (RES 47833) HS1 Contact Pin Contamination (RES 67612) HS1 Quick Reference Card Corrective Action (RES N/A) HS1/FRx Capacitor Recall (RES 53816) HS1/FRx Relay Recall (55579) HS1/FRx Reminder to Call Service upon a Triple Chirp Self-Test (R92) (RES 79343, 63030)
HAZARD INVOLVED	Most of the recalls involved issues that could lead to delay of therapy and/or failure of the device to operate. The precise hazard will depend on the model and date of manufacture of the AED and the reason for the previous recall.
HOW TO IDENTIFY AFFECTED PRODUCTS	Our records indicate that the affected AED was Philips Heartstart FRx Defibrillator, French, Exchange shipped in 2008. The quantity affected is 1. Our records do not, however, contain serial number information. Therefore, to confirm the identity of any AED affected by this issue, please contact your Philips representative. To do so, please complete the attached Customer Reply Form and a Philips representative will reach out to you to help you identify any affected AED.
ACTION TO BE TAKEN BY CUSTOMER / USER	1. To acknowledge receipt of this notification, **please complete and return the Customer Reply Form.** 2. A Philips representative will reach out to you to help you identify any affected AED 3. After it has been confirmed that you have an affected AED and a replacement Philips AED has been sent to you, please return the affected AED to Philips using the shipping label to be provided. 4. The affected AED may remain in service until you receive a replacement Philips AED.
ACTIONS PLANNED BY PHILIPS	Philips will exchange affected devices with a replacement Philips AED free of charge.

FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your Philips representative: **0800 80 3000**

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Customer Reply for FSN86100229A

Please complete, sign, and return this form as soon as possible

Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address	
City, State, Postal Code:	
Country:	

☐ Please check this box if you are no longer in possession of any AED of a model listed in this letter (for example, if your facility has changed to a different model AED.)

I received, read, and understood Field Safety Notification FSN86100229A.

Signature: _____ Date: _____

Please email completed and signed form to: **customercare.ch@philips.com**