URGENT Medical Device Recall

HeartStart FR3 Automated External Defibrillators

Potential Water Ingress

Dear Philips HeartStart FR3 AED Customer,

This letter is to inform you that Philips Healthcare is conducting a voluntary recall of 432 HeartStart FR3 automated external defibrillators (AEDs; model 861388 and 861389), that may not fully meet their IPx5 water ingress specification. IPx5 is defined as withstanding a strong water jet from all directions for three minutes.

As of the date of this letter, Philips has received no reports of water ingress affecting the performance of these devices. As a precaution, however, we are notifying FR3 owners that these AEDs may not meet their IPx5 specification.

If precautions are taken to avoid exposing The FR3 AED to pressurized water streams, the FR3 AED remains safe to use and able to deliver therapy to a victim of cardiac arrest until a replacement FR3 AED is provided from Philips.

This document contains important information about this recall. Please see attached Field Safety Notice for details.

Please review the following information with any AED owner or program manager who needs to be aware of the contents of this communication.

This voluntary recall is being conducted with the knowledge of the appropriate Regulatory Agencies.

Philips apologizes for any inconveniences this may cause. Your satisfaction with Philips products and with our response to this situation is very important to us.

Sincerely,

Ralph Asencio
Head of QA/RA, Emergency Care and Resuscitation

Attachment

FIELD SAFETY NOTICE

AFFECTED PRODUCTS	HeartStart FR3 (model 861388 and 861389) automated external defibrillators (AEDs) manufactured from October 2016 through February 2017 and distributed from January 2017 to March 2017.
ISSUE DESCRIPTION	The recalled AEDs may not meet their IPx5 water ingress specification. An affected device subjected to strong water streams for an excessive amount of time may suffer from water intrusion into the device, potentially resulting in a failure of the AED.
HAZARD INVOLVED	The potential hazard is that the device may fail to perform analysis and/or deliver therapy to a patient should water intrusion occur. Additionally, a risk assessment determined that there was no risk of harm to the user. Philips has received no reports of safety hazards or performance issues related to this problem.
HOW TO IDENTIFY AFFECTED PRODUCTS	Our records indicate that you have received at least one of the affected devices. The serial numbers of your affected devices will start with the letters “C16J”, “C16K”, “C17A”, or “C17B”. The serial number is printed on a label on the back of your AED, as shown in the sample drawing below. 
ACTION TO BE TAKEN BY CUSTOMER	• Identify the HeartStart FR3 AEDs affected by this Field Safety Notice by checking the serial numbers. Affected AEDs begin with C16J, C16K, C17A, or C17B. • You may continue to use your present device until a replacement FR3 AED is provided by Philips. As a precaution users should prevent the use of a pressurized water stream on the device for purposes such as cleaning. Please ensure that any owner or program manager of an affected device is promptly made aware of this notification. If you have transferred the device to another owner, please forward a copy of this notice to that owner and notify Philips of this transfer as soon as possible.

ACTIONS PLANNED BY PHILIPS	A Philips representative will contact you to replace your affected FR3 AEDs. Philips will replace affected devices with service exchange units free of charge. Please refer to the previous section, "Action to be taken by customer," concerning the continued use of your present device.
FOR FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact