PHILIPS

Philips Healthcare

URGENT Medical Device Correction
HeartStart FR3 Carry Case

Dear Philips HeartStart AED Dealer,

This letter is to inform you that Philips Healthcare is voluntarily conducting a field action to remove the small soft carry cases used with the HeartStart FR3 automated external defibrillator (AED). The HeartStart FR3 AED itself is not part of this action. Only the small soft carry cases [model numbers 989803173711 (Philips) and 989803173721 (Laerdal)] manufactured by Philips and shipped between May 2011 and August 2011 are part of this action. This action does not affect carry cases distributed in North America.

The carry cases subject to this action incorporate a magnet in the lid that enables the auto-on feature of the case; the FR3 AED automatically turns on when the case is opened. The function of the magnet is dependent on correct alignment when the case is closed. It has come to the attention of Philips that the case may be closed in such a way that the magnet is not aligned properly over the FR3 AED, which may be interpreted by the AED as a case opening. Thus, the AED may turn on repeatedly while stored in the case, inadvertently depleting the battery. This issue does not prevent the FR3 from providing alarm chirps and text instructions if battery power becomes low.

There have been no reported incidents of failure of the FR3 AED during emergency use due to a low-battery condition, and no reported injuries to users or patients. However, because the carry case can be closed in such a way that the auto-on feature may activate unintentionally, Philips has decided to replace all model 989803173711 and 989803173721 carry cases. Our records indicate that you have distributed one or more of these affected carry cases. No other carry case models are affected by this field action.

Philips has determined that the resolution of these aspects represents a mandatory field action. Philips will be replacing affected carry cases with small soft carry cases without a magnet (which will not enable the auto-on feature of the FR3 AED), and providing a replacement battery at no charge. When available, Philips will provide replacement FR3 small soft carry cases with a magnet, which will enable to auto-on feature of the FR3 AED. Refer to the attached Field Safety Notice for instructions. The Field Safety Notice will also inform you about:

- What the aspect is and under what circumstances it may occur
- Actions that the customer should take in order to mitigate risks for patients or users
- Actions to be taken by dealers to ensure all affected carry cases are destroyed
- Actions planned by Philips to correct this

Please follow the “ACTION TO BE TAKEN BY DEALER” section of this notice.

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

Please review the following information with all members of your staff who need to be aware of the contents of this communication. **The destruction of affected FR3 small soft carry cases is mandatory for all identified units.**

This field action is being conducted with the knowledge of the appropriate Regulatory Agencies.

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

Sincerely,

[redacted]

Director of Quality & Regulatory
Philips Healthcare

FIELD SAFETY NOTICE

AFFECTED PRODUCTS	Small soft carry cases (model numbers 989803173711 and 989803173721) manufactured by Philips and shipped between May 2011 and August 2011. (These carry cases are used with the HeartStart FR3 automated external defibrillator.) Philips records indicate that you have received affected carry cases. This action does not affect carry cases distributed in North America.
PROBLEM DESCRIPTION	The affected small soft carry cases incorporate a magnet in the lid that automatically turns the FR3 AED on when the case is opened. If the case is not aligned properly when closed, the FR3 may interpret the resulting intermittent misalignment of the magnet as a case opening. Thus, the AED may turn on repeatedly while stored in the case, inadvertently depleting the battery.
HAZARD INVOLVED	A drained battery may not allow the FR3 to deliver therapy in case of an emergency.
HOW TO IDENTIFY AFFECTED PRODUCTS	All small soft cases, models 989803173711 and 989803173721, are affected. The model number can be found on the carry case label, located directly under the FR3 when it is stored in the case. 
ACTION TO BE TAKEN BY DEALER	**The destruction of affected FR3 small soft carry cases is mandatory.** You will receive enough replacement batteries and FR3 small soft carry cases without a magnet (which will not enable the auto-on feature of the FR3 AED) to replace each affected case that was shipped to you, as well as batteries to replace those that may have been depleted by a misalignment of the magnetic case. There will be no charge to you for this shipment. When available, Philips will provide replacement FR3 small soft carry cases with a magnet, which will enable to auto-on feature of the FR3 AED. **As a Dealer, it is your responsibility to confirm that each affected carry case has been destroyed**. To simplify this process, follow the steps below. 1. Destroy all affected magnetic FR3 small soft carry cases in your possession. Using scissors or another tool, cut the affected carry cases into two or three pieces in a way that ensures that they can no longer be used with the FR3 AED. Use the *Destruction Confirmation Form* included with this notification to record the action. 2. Identify the owners of any affected carry cases that have been sold or transferred.

	3. Provide each owner with the following: • Notification on your letterhead about the mandatory destruction of affected magnetic FR3 small soft carry cases. A sample notification is enclosed for your reference. • One replacement non-magnetic FR3 small soft carry case (which will not enable the auto-on feature of the FR3 AED) to replace each of the owner's affected cases. • One replacement battery. • A copy of the *Destruction Confirmation Form*. • Field action information and a request (such as the *Sample Notification to Owners of Affected FR3 Carry Cases*) that the owner take prompt action to (a) destroy the affected carry cases by using scissors or another tool to cut them into two or three pieces, ensuring that the affected carry cases can no longer be used with the FR3 AED; and (b) complete, sign, and date the *Destruction Confirmation Form* and return it to you as soon as possible. 4. After you have received signed forms from all affected customers, summarize the responses using the *FR3 carry case Destruction Summary Form*,* also enclosed with this letter. 5. Sign and date the completed FR3 carry case *Destruction Summary Form.* 6. **No later than 90 days from receipt of this notice**, submit scanned copies of all *Destruction Confirmation Forms* received from the carry case owners, and the *Destruction Summary Form,* to FR3FieldAction@philips.com, or fax it to +49 7031 463 1003, attention marked to Emergency Care and Resuscitation (SMC). * If an owner does not respond in a timely fashion, record the date of each attempt to contact the owner and an explanation for the failure to respond. Submit the resulting document to Philips along with the *Destruction Summary Form*.
ACTIONS PLANNED BY PHILIPS	Philips will replace all carry cases involved in the field action free of charge with a FR3 small soft carry case without a magnet, which will not enable the auto-on feature of FR3. When available, Philips will provide replacement FR3 small soft carry cases with a magnet, which will enable to auto-on feature of the FR3 AED.
FURTHER INFORMATION AND SUPPORT	For further information or support concerning this issue, please contact your regional Philips or Laerdal representative.