

Follow-up Communication to Important Product Notice (CIL-2021-CC-HPM-085) issued in September 2022
Replacement Product is Now Available!

February 2023

RE: Philips 12-Lead Chest Lead Set (AAMI/IEC)

Dear Customer,

This notice is related to the Philips 12-Lead Chest Lead Set (AAMI/IEC) Important Product Notification letter sent in September of 2022. Replacement product is now available for distribution. This letter informs customers of the process to obtain replacement product. As part of the process, any product(s) deemed affected can be discarded based on local policies and directives.

To review the Important Product Notice sent in September 2022 regarding the Philips 12-Lead Chest Lead Set (AAMI/IEC) visit URL: <https://www.philips.com/leadset-recall>

Customer should complete the Importance Product Notice Response Form at the end of this letter and [return to recall@cardiac-services.com](mailto:recall@cardiac-services.com) to submit both your acknowledgement of this recall and actions taken, as well as request for replacements (**optional**).

Important! To complete acknowledgement and request replacements, please provide the information listed below:

1. Quantity of the Philips 12-Lead Chest Lead Set (AAMI/IEC) for replacements
2. Complete the Importance Product Notice Response Form at the end of this letter and [return to recall@cardiac-services.com](mailto:recall@cardiac-services.com)

If you need any further information or support concerning this issue, please contact your local Cardiac Services representative.

Sincerely,

Jeffrey Hoebelheinrich
Head of Quality
Philips Healthcare

IMPORTANT PRODUCT NOTICE RESPONSE FORM
R-22-17 (2)

Reference: Philips 12-Lead Chest Lead Set (AAMI/IEC)

Customer Instructions: Please complete and return this form no later than 30 days from receipt. Completing this form confirms receipt of the Important Product Notice, understanding of the issue, required actions to be taken and as well as requesting replacement product.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Number of Affected Leads:

Product Number	Product Description	Affected Amount
989803151691	12-Lead Chest Lead Set (AAMI/IEC), Long	
989803151671	12-Lead Chest Lead Set (AAMI/IEC), Standard Length	

Customer Actions:

- This communication should be shared with all clinical staff to review and understand.
- Place this Important Product Notice with the documentation of the Philips 12-Lead Chest Lead-set (AAMI/IEC).
- Once a Lead-set is identified as being affected, we advise you to remove the affected Lead-sets from inventory.
- Affected leads should be discarded according to local disposal requirements

Please complete promptly and no later than 30 days from receipt of notice.

Complete and return this Response Form to your distributor at recall@cardiac-services.com.