URGENT - Medical Device Correction

Pneumograph, Chest, NM, 3160

Device Labeling Does Not Include Statement Regarding Natural Rubber Latex Content

Dear Customer,

A problem has been detected in the Philips chest pneumograph (also referred to as the pneumatic bellows, respiration bellows, or respiration sensor) that could pose a risk for patients and users. 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 you in order to prevent risks to patients and 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.

Please retain a copy with the equipment Instructions for Use.

The chest pneumograph contains 90-95% natural rubber latex in the tubing that extends from the bellows to the wireless oxygen saturation/pulse oximetry (SpO2) module or gating unit. The chest pneumograph is not labeled as containing natural rubber latex.

Our records indicate that you may have an affected chest pneumograph. The following page provides additional instructions and actions to be taken. If you need any further information or support concerning this problem, please contact your local Philips representative:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency. Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Suzanne Goodman
Head of Q&R, General and Specialty Care (AI)

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AFFECTED PRODUCTS

Part Number	Part Description
94023	Pneumograph, chest, NM, 3160

All chest pneumographs currently in distribution are affected.

PROBLEM DESCRIPTION

The chest pneumograph contains 90-95% natural rubber latex in the tubing that extends from the bellows to the wireless oxygen saturation/pulse oximetry (SpO2) module or gating unit (refer to red arrow in the picture to the right). The chest pneumograph is not labeled as containing natural rubber latex.

HAZARD INVOLVED

Natural rubber latex is a known allergen that may impact the patient or user due to contact with the device against bare skin. The chest pneumograph is expected to be used over a gown or clothing but there is the possibility of the natural rubber latex tubing contacting the patient's bare arm/leg, patient's bare torso (if no clothing is present), or the user's hands/arms during patient preparation. Allergen related issues could range from minor (irritation or rash) to major (anaphylactic shock).

HOW TO IDENTIFY AFFECTED PRODUCTS

The pictures to the right and below show the chest pneumograph part as packaged, as well as the label located on the outer packaging.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Please review this communication with all members of your staff who utilize this product. Please retain a copy with the equipment Instructions for Use. The chest pneumograph can continue to be used for monitoring as directed by a physician. 1. Identify all affected chest pneumographs in your facility using the guidelines provided in the **HOW TO IDENTIFY AFFECTED PRODUCTS** section above. • *Please do not return any product to Philips.* 2. Complete and sign the reply form provided on the last page of this letter. 3. Send the completed and signed reply form to Philips via the contact information located on the form. 4. Upon receipt of the reply form, Philips will send you one kit per chest pneumograph in your possession along with instructions for labeling each chest pneumograph. 5. Upon receipt of the kit, follow the included instructions to label each chest pneumograph in your possession. The label to be added identifies the product as containing latex.
ACTIONS PLANNED BY PHILIPS	Upon receipt of the completed and signed reply form, Philips will provide one kit per chest pneumograph in each customer's possession for the purposes of labeling each affected chest pneumograph. This kit will be provided free of charge.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this problem, please contact your local Philips representative: **0800 80 3000**

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Reply Form

Upon receipt of the completed and signed reply form, an order for a labeling kit will be entered and shipped to the address provided below.

Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Attention To: (Please indicate to whom the labeling kit should be sent; include department or other identifier, as necessary)	
Street Address City, State/Country Zip or Postal Code:	

Please check one option below:

☐ **Our facility does not have any inventory of these products.** *(Please sign below.)*

☐ **Our facility has inventory of these products.** *(Please complete the table and sign below.)*

	Total number in inventory
94023 (Pneumograph, chest, NM, 3160)	

I certify that our facility did not have any inventory of chest pneumographs.

–or–

I certify that this communication was reviewed with all members of the staff who utilize this product and that a copy of the communication has been retained with the equipment Instructions for Use. I certify that users have been notified of the need to ensure that the natural rubber latex tubing does not come into contact with a patient's skin (if no clothing is present) or the user's hands/arms during patient preparation, if the patient or user has an allergy to natural rubber latex. I certify that, upon receipt of the labeling kit, our facility will follow the included instructions to relabel each chest pneumograph in our possession.

Signature: _____ Date: _____

Please return the completed and signed reply form to: **customercare.ch@philips.com**