URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Cover Letter for Distributors and Institutions

Dear Device Customer,

Philips Respironics is voluntarily recalling Continuous and Non-Continuous Ventilators due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in the design of these devices. Detailed information associated with this recall and the impacted device populations can be found in the included Recall Notices.

You must take action, as a distributor or institution that is a direct customer of Philips, to isolate any impacted devices that are in your inventory. You must also facilitate the actions identified in the included Recall Notices for any impacted device users within your organization, among your past and present patient population, or among your customer base. You must take the following actions:

1. Read and understand the included Recall Notices. Distribute these notices to any member of your organization that must also be aware of the issues described.

2. Register for participation in this medical device recall and receive additional instructions to participate in corrective actions by visiting the website: www.philips.com/src-update

To respond to this recall, you will need your account number and passcode. This is included within the Response Instructions following the Recall Notices.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care