PHILIPS

Philips Respironics announced a voluntary recall for Continuous and Non-Continuous Ventilators (certain CPAP, BiLevel PAP and Ventilator Devices) due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in these devices: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life. For information on the Recall Notice, a complete list of impacted products, and potential health risks, visit philips.com/src-update.

Upon discovery and further analysis of this issue, we proactively took corrective action. We placed shipment holds on all affected products on orders from our healthcare provider customers. We continued our rigorous testing and analysis to further understand the reports, and we began engaging regulatory agencies.

Philips is working tirelessly to remedy this issue by replacing the affected devices. A Recall Notice with immediate actions to be taken has been sent to distributors and institutions that are a direct customer of Philips for their own use as well as for engagement with patients. With this, clinicians and patients may reach out to professional associations for guidance and we are committed to providing information and tools to have an informed discussion.

For the past 40 years we have centered our business around our commitment to patient care, with solutions that are aimed at improving the lives of people with respiratory and sleep challenges. We recognize the importance of providing safe and effective therapy.

We are committed to holding ourselves to the highest standards of product quality and safety in an effort to do what is right for you and the patients who trust you with their care.

We are committed to resolving this issue and providing transparent, ongoing communication as we navigate the next steps.

We are committed to providing you information and resources for your own understanding, but also to help you communicate with your clinicians and patients effectively and efficiently. You can find FAQs and additional clinical information at philips.com/src-update.

Thank you for your continued trust.

Your Philips Sleep and Respiratory Care team

For more information, call 877-907-7508 or visit philips.com/SRC-update.