

Dear Colleagues:

Philips Respironics announced a recall notification (U.S. only) / field safety notice (Outside of U.S.) 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 more information, 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 notification (U.S. only) / field safety notice (Outside of U.S.) 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, your patients are likely to contact you for guidance. We understand that every patient's care is unique and requires individual consideration. Therefore, we respect the alignment that needs to happen between patient and physician for a personalized recommendation on the best course of action. We are committed to providing clinical information on the recall notification (U.S. only) / field safety notice (Outside of U.S.) to support patient care. Please visit philips.com/src-clinician-update for up to date information and resources.

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 patients effectively and efficiently. You can find FAQs and additional clinical information at philips.com/src-update.

As the Medical Leader of Sleep and Respiratory Care, I am confident in our ability to make lasting change and live up to our commitment to you, and your patients. Thank you for your continued trust.



Dr. John Cronin

Medical Leader, Philips Sleep and Respiratory Care

For more information, visit philips.com/SRC-update.

