

Clinical Bulletin #16

We are committed to supporting clinicians through the complete remediation process and will provide a range of resources to help you better inform, instruct, and support your patients.

The clinical bulletin will continue to offer news and updates on the PE-PUR foam voluntary recall/FSN and will also be expanded to help address common topics and concerns on additional topics.

Please find below some recent information that we wanted to bring to your attention.

PE-PUR Foam voluntary recall/FSN News and Updates

Philips Respironics provides the latest results and conclusions on the comprehensive test and research program to assess potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in specific sleep therapy and ventilator devices under the voluntary June 2021 recall/field safety notice.

The impact of ozone cleaning on foam degradation in System One and DreamStation Go sleep therapy devices:

- **Exposure to VOC emissions from the assessed devices treated with ozone cleaning is unlikely to result in an appreciable harm to health in patients.**
- **Exposure to PM emissions from the assessed devices treated with ozone cleaning is unlikely to result in an appreciable harm to health in patients.**

Additional visual inspection of the foam in used first-generation DreamStation devices from the US and Canada confirms the low prevalence of significant visual foam degradation:

- An additional analysis using an algorithm to assess collected images of foam within a representative random sample of 100,000 used devices from the US and Canada (devices were selected to represent different manufacture dates) showed that 2,011 devices (~2%) were identified as having significant visual degradation/volume reduction.
- A comparison of ozone use among these devices found that devices for which the user self-reported ozone use were approximately 17 times more likely to have significant visual foam degradation/volume reduction (1,368 out of 14,971 or 9.1%) than those where the user reported no ozone use (357 out of 68,702 or 0.5%).

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Guidance for healthcare providers and patients

Philips Respironics continues to advise patients using affected sleep therapy devices that have not been remediated yet to contact their physician or care provider to decide on a suitable treatment for their condition, which may include stopping use of their device, continuing to use their affected device, using another similar device that is not part of the recall, or using alternative treatments for sleep apnea. Moreover, patients are advised to follow Philips Respironics' instructions and recommended cleaning and replacement guidelines for their sleep therapy device and accessories. **Ozone and UV light cleaning products are not currently approved cleaning methods for sleep therapy devices or masks and should not be used.**

Useful Links

PE-PUR Foam voluntary recall/FSN - Information for Clinicians

Be sure to visit [our clinicians information page](#) regularly for the most current information for you and your patients

Masks and Magnets

Have additional questions about Philips Respironics masks and magnets? Learn more [here](#)

Ventilation

www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/ventilation-news-and-updates



For more information, visit Philips.com/src-update

