PHILIPS

Sleep and Respiratory Care Bulletin #11

September 2023

Field Safety Notice: 2021-05-A & 2021-06-A.

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 field safety notice 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.

1. PE-PUR Foam voluntary 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 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 Europe and Japan confirms the low prevalence of significant visual foam degradation:

- An additional analysis of images from a representative random sample of 152,000 devices from Europe and 241,000 devices from Japan were analysed by an algorithm to identify significant visual degradation/ volume reduction.
- A subset of devices from Europe and Japan were identified by the algorithm as potentially having significant visual degradation/volume reduction, and this subset was manually inspected. It was observed that 17 devices of the 152,000 devices (~0.01 %) from Europe and 3 devices of the 241,000 devices (0.001%) from Japan had significant degradation/volume reduction.

Learn more here.

(continued on next page)

For the most current information, visit our clinician information page
philips.com/src-clinician-update

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 field safety notice, or using alternative treatments for sleep apnoea. 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.

2. Useful links

PE-PUR Foam voluntary 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

For the latest ventilation news and updates, please visit **this page**.

Note: the data and information in this document are valid as of the date indicated on the document. If you read this document at a later date, the details and information may no longer be up-to-date due to new developments.

For the most current information, visit our clinician information page
philips.com/src-clinician-update