

Philips Voluntary Recall Notice:

On June 14, 2021, Philips initiated a *voluntary* <u>recall notification</u> in the U.S. (and an international field safety notice) for <u>specific Philips Respironics models</u> of continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), and mechanical ventilator devices, stating that the recall is to "ensure patient safety in consultation with regulatory agencies." The recall is to address potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in certain devices. Philips <u>reports</u> that the foam-related complaint rate in 2020 was low (0.03%). Read the <u>AASM summary of the Philips announcement</u> for additional details and refer to the Philips website for ongoing updates and comprehensive information.

The AASM is providing the following information to help sleep centers and sleep medicine professionals understand their options. Additional information, including responses to frequently asked questions, will be made available by the AASM as soon as possible. Call Philips at **877-907-7508** for additional help and support.

Philips advises that patients using recalled BPAP and CPAP devices should stop using their devices and consult with their medical providers to determine the most appropriate options for continued treatment, based on the benefits of continuing therapy and potential identified risks. The AASM suggests that the medical provider prescribe for their patient a PAP device that is not affected by the recall. However, in the case that this is not an option, or another device is unavailable, then it is the AASM viewpoint that clinical factors such as comorbidities, severity of symptoms, risks associated with PAP discontinuation, and safety-sensitive roles should inform the decision to continue or discontinue therapy. This decision should be made in concert between the patient and their medical provider. The ultimate judgment regarding any specific care must be made by the treating clinician and the patient, taking into consideration the individual circumstances of the patient, available treatment options, and resources. The AASM advises that patients contact their medical provider as soon as possible to discuss whether to continue or discontinue treatment.

The above recall notice from Philips is being provided as a courtesy to all of our patients in case they have heard about this recall or use Philips Respironics equipment at home. A detailed review of the recall reveals that the sound abatement foam used in Respironics equipment degrades when cleaned using unapproved methods, particularly ozone-based cleaning. Please note that the Sleep Disorders Center only cleans its equipment using Philips-approved methods, therefore your care at the Sleep Disorders Center is not impacted by this recall. If you use Philips Respironics equipment at home, we recommend that you further explore the details of the recall and abide by its recommendations.