PHILIPS

Sleep and Respiratory Care Bulletin #2

We know how important it is for you and your patients to be informed on all aspects of their sleep therapy and treatment. This bulletin was created to help address common questions and concerns as well as provide a status update on correction efforts as they become available. Please continue to visit our website, Information for Physicians and other medical care providers, for additional information on this product correction* as it becomes available.

*Urgent Product Defect Correction in Australia and Recall for Product Correction in New Zealand.

1. Safety of the replacement foam

Providing patients with safe and high-quality therapy devices is our primary focus. We want your patients to feel confident that their therapy device is safe to use. While affected DreamStation devices contained a polyester-based polyurethane (PE-PUR) sound abatement foam component, the sound abatement foam in all corrected DreamStation devices is a silicone foam.

Please remind your patients not to try to remove the foam from their device. This could affect the prescribed therapy.

2. Cleaning Guidance

Your patients need to be confident they are cleaning their device properly. For detailed information about caring for replacement devices, your patients are urged to refer to the device's User Manual and Accessory Cleaning and Inspection Instructions that come with the corrected device. It is important that they use only the cleaning methods approved for their device, as unapproved cleaning methods[1] such as ozone may contribute to foam degradation.

To effectively complete the product correction all affected devices must be corrected regardless of the cleaning method used. Please refer to the Philips.com/src-update page to determine if your patients' devices are affected by this product correction.

[1]Please note that both ozone and UV light cleaning products (including the Philips UV Light Sanitiser Box) are not currently approved cleaning methods for our devices or masks and do not remediate the current recall. Please refer to the FDA safety communication issued on February 27, 2020 and titled "Ozone and UV light: Potential Risks associated with the use of ozone and ultraviolet (UV) light for cleaning CPAP machines and accessories" for more information. The communication indicates that devices claiming to clean, disinfect or sanitise CPAP machines using ozone gas or UV light have not been FDA authorised.

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