Important Information About the Philips Product Recall

On June 14, 2021, Philips issued a recall notification for many of its products within its Sleep & Respiratory Care portfolio, informing patients and customers of potential health risks related to the integrity of the sound abatement foam used in these products, specifically the Philips Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP) and mechanical ventilator devices. SoClean is committed to the health and safety of sleep equipment users, supports Philips in its recall efforts and wishes to ensure that consumers have as much information on this important action as possible.

IMPORTANT FACTS:

- Patients need to understand that whether you use a cleaner or not, you need to follow Philips' guidance regarding their specific medical device.
- During initial or subsequent operation of the device, a patient may be exposed to certain volatile organic compounds referenced by Philips.
- Toxicological risk assessment indicates that the levels of certain volatile organic compounds referenced by Philips exceed a safe exposure threshold.

Philips has not established in its written public communication a definitive cause of the foam degradation in its products, but it has indicated that there may be several possible factors that may have contributed to the degradation of the sound abatement foam. The risks, as identified by Philips, include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and that the foam may off-gas certain chemicals. While it was suggested that the foam degradation may be exacerbated by use of certain cleaning methods, such as use of ozone, almost 90% of the products that are within the scope of the recall have not been exposed to an ozone cleaning device. Rather, the risk assessment for certain volatile organic compounds referenced by Philips exceed safe exposure thresholds from initial use of the device regardless of whether the use of external cleaning methods occurs.

Almost all the machines affected by this recall have no connection to an ozone-related cleaning device.

Philips users should resume use once Philips has resolved their foam issue.

As Philips stated: *"As part of the [repair and replacement] program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue."*