PHILIPS

**December 23, 2021**

## Updated clinical information for physicians and providers on DreamStation CPAP and Bi-Level PAP devices

On June 14, 2021, Philips Respironics, initiated a voluntary recall notification for certain sleep and respiratory care products to address potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in these devices.

Since then, together with certified testing laboratories and other qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE-PUR foam to better assess and scope potential patient health risks related to possible emission of particulates from degraded foam and certain volatile organic compounds (VOCs).

At the time the recall notification was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment.[1] Since then, using ISO 18562 guidance, additional VOC toxicological risk assessments were performed by certified testing laboratories and qualified third-party experts based on the initial and new VOC testing performed to date.

This communication to the clinical community summarizes the assessments to date derived from the additional testing. Specifically, in December 2021, Respironics assessed additional VOC emissions testing for the DreamStation BiPAP and CPAP devices.[2] A series of tests was performed to better characterize and assess the presence of VOCs within the DreamStation, including the detected phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl) and dimethyl diazene VOC emissions.

Testing was conducted using (a) new devices with 'pristine' foam, (b) devices with lab-degraded foam,[3] and (c) retrieved field devices. Based on these test results, a comprehensive toxicologic assessment was conducted to evaluate the risk associated with the identified VOCs to date.

**The results from additional DreamStation PE-PUR sound abatement foam testing and toxicologic assessment to date indicate that VOCs do not exceed safe exposure thresholds specified in the applicable safety standards (e.g. ISO 18562), and are not typically anticipated to result in long-term health consequences for patients. Using conservative health-protective exposure thresholds, the additional testing suggests no increased risk for adverse health effects in the general patient population nor the higher risk patient population as a result of VOC exposure.**

It is important to note that the tested DreamStation devices were not exposed to ozone cleaning. Additionally, this new assessment is limited to the evaluation of VOCs for first-generation DreamStation devices and does not evaluate the risks of potential foam particulates or cover other devices affected by the recall. Further health risk assessments are ongoing.

The update on these findings is intended to inform healthcare providers of the most recent data, but the overall guidance for physicians and patients in the recall notification remains unchanged at this time.

1. *The testing available at the time of the June 2021 recall suggested two compounds of concern were emitted from the device: dimethyl diazine and phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl). At that time, testing results suggested that the gases associated with the pristine foam taper off during the initial days of use of a new device. Possible gas emission of the degraded foam had not been fully characterized yet at that time.*
2. *The testing and analyses were conducted by certified third-party labs in conjunction with Philips. In addition, a third-party scientific consulting firm provided independent review of the testing and analysis reports.*
3. *Blower boxes containing PE-PUR sound abatement foam were degraded under high temperature and high humidity conditions for one week, two weeks, and three weeks; the aged blower boxes were installed then tested for VOCs; additional testing is ongoing for devices exposed to ozone cleaning.*