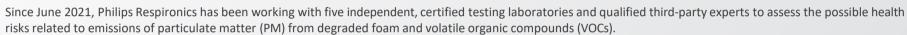
Test methods and results for first-generation DreamStation devices







99.5%

No significant visible

degradation

ozone cleaning.

36,341 returned devices from the US and Canada were inspected and **164** showed significant visible foam

degradation. These devices were self-reported as not using

Significant visible degradation

2: Volatile organic compounds (VOCs) testing

Assess toxicological health risk for potential VOCs using industry standards.

Industry standards ISO 18562-1.3 ISO 10993-17

Certified independent testing labs

Testing and toxicological risk assessment was performed on devices with new, used and lab-aged foam. Third-party analyses indicate that the exposure to VOCs emissions is not anticipated to result in long-term health consequences for patients.



3: Particulate matter (PM) testing

(respirable and non-respirable particulates)

Assess toxicological health risk using industry standards based on a conservative 100% exposure to degraded foam.

Industry standards ISO 18562-1. 2 ISO 10993-1, 3, 5, 10, 17, 18 Certified independent testing labs

PM emission testing, bioassay evaluation, chemical evaluation and toxicological risk assessment on devices with new, used and lab-aged foam were performed in accordance with ISO 10993 and ISO 18562. Third-party analyses conclude that exposure to respirable and non-respirable particulates from degraded foam is unlikely to result in an appreciable harm to patients' health.



4: Overall conclusion

The extensive data and results now available for the first-generation DreamStation devices show that the occurrence of visible foam degradation is low and test results for volatile organic compounds and particulate emissions related to foam degradation are within the applicable safety limits.

Philips Respironics has provided the data and analyses to the FDA and other competent authorities. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach different conclusions. Healthcare providers, patients, and other stakeholders should use the complete December 21, 2022, update (including information on the limitations of the testing) for any informed decision making and should not solely rely on the overview presented here. Philips Respironics' guidance for healthcare providers and patients remains unchanged.