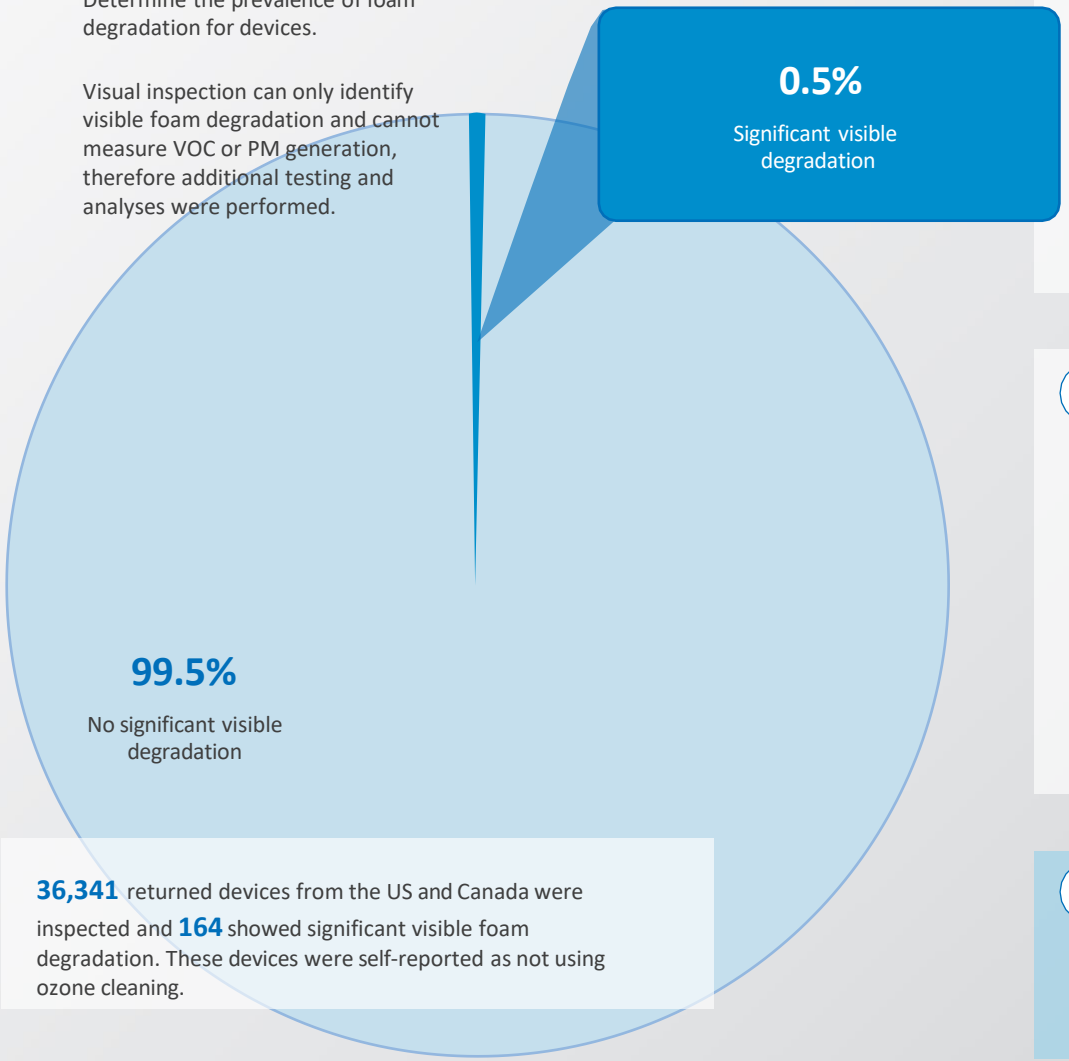
Test methods and results for first-generation DreamStation devices

Since June 2021, Philips Respironics has been working with five independent, certified testing laboratories and qualified third-party experts to assess the possible health risks related to emissions of particulate matter (PM) from degraded foam and volatile organic compounds (VOCs).

1: Visual inspection

Determine the prevalence of foam degradation for devices.

Visual inspection can only identify visible foam degradation and cannot measure VOC or PM generation, therefore additional testing and analyses were performed.



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 ozone cleaning.

2: Volatile organic compounds (VOCs) testing

Assess toxicological health risk for potential VOCs using industry standards.

Industry standards	Certified independent testing labs
ISO 18562-1, 3 ISO 10993-17	

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

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.