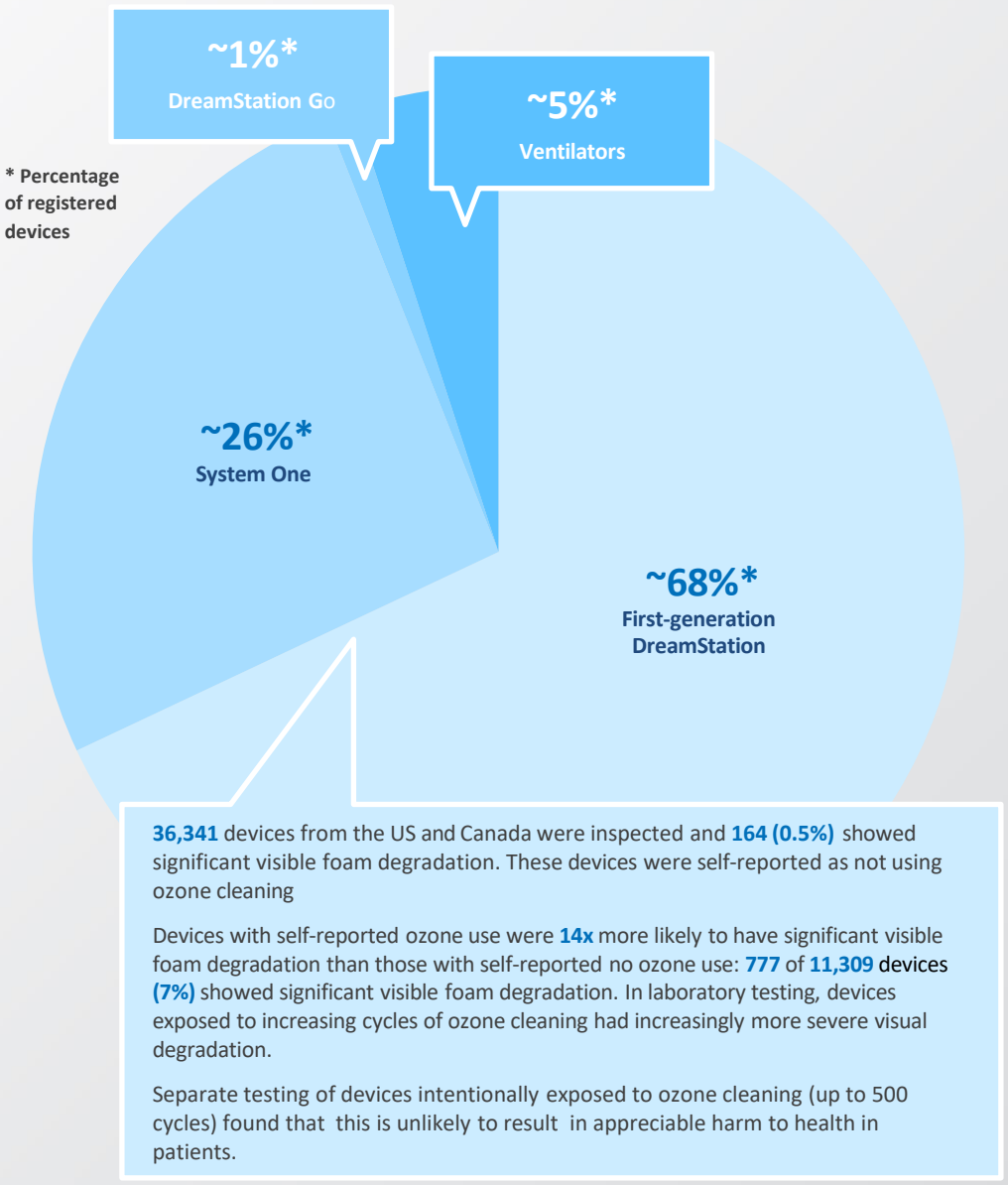
Test methods and results for CPAP/BiPAP sleep therapy devices

Since June 2021, Philips Respironics has been working with five independent, certified testing laboratories, qualified third-party experts and an external medical panel to assess the possible health risks related to emissions of particulate matter (PM) from degraded foam and volatile organic compounds (VOCs) for first-generation DreamStation (DS1), DreamStation Go (DS Go) and System One sleep therapy devices.



36,341 devices from the US and Canada were inspected and **164 (0.5%)** showed significant visible foam degradation. These devices were self-reported as not using ozone cleaning

Devices with self-reported ozone use were **14x** more likely to have significant visible foam degradation than those with self-reported no ozone use: **777** of **11,309** devices **(7%)** showed significant visible foam degradation. In laboratory testing, devices exposed to increasing cycles of ozone cleaning had increasingly more severe visual degradation.

Separate testing of devices intentionally exposed to ozone cleaning (up to 500 cycles) found that this is unlikely to result in appreciable harm to health in patients.

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 potential exposure to VOCs from DS1, System One, and DS Go are unlikely to result in an appreciable harm to health in patients.

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.

Overall conclusion

Potential patient exposure to foam particulates and VOCs from the PE-PUR foam within the first-generation DreamStation, DreamStation Go, and System One devices is unlikely to result in an appreciable harm to health in patients.

Philips Respironics has provided the completed set of test results and analyses for the sleep therapy devices to the FDA and other competent authorities. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach a different conclusion. Healthcare providers, patients, and other stakeholders should use the complete May 2023 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 using devices that have not been remediated yet remains unchanged.