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Summary

Philips Respironics - PE-PUR testing results and conclusions available to date

Updated: July 24, 2023

Philips Respironics provides the latest results and conclusions on the comprehensive test and research program to assess potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in specific sleep therapy and ventilator devices under the voluntary June 2021 recall notification/field safety notice.*

- Philips Respironics completed the analyses for System One and DreamStation Go sleep therapy devices related to the impact of ozone cleaning on the foam in these devices. The analyses indicate that the volatile organic compounds (VOCs) and particulate matter (PM) emissions related to foam degradation in these devices are within the applicable safety limits and are unlikely to result in appreciable harm to health in patients.
- Additional visual assessments have been performed for used/returned first-generation DreamStation devices that confirmed the previously established low prevalence of significant visual foam degradation/volume reduction in these devices.

The risk assessments had already been completed for the first-generation DreamStation, System One and DreamStation Go sleep therapy devices (representing ~95% of the registered devices globally) that had not been exposed to ozone cleaning in line with the instructions for use. Additionally, tests and analyses had been completed for first-generation DreamStation devices that have been deliberately exposed to multiple cycles of ozone cleaning. The relevant updates can be accessed here: December 2021, June 2022, December 2022, and May 2023.

- **Philips Respironics has provided the summary of the PE-PUR test results and analyses available to date 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 July 24, 2023, update (including information on the limitations of the testing) for any informed decision making and should not solely rely on the overview in this summary.**
- **Completion of the test and research program, as well as the remediation program remain Philips Respironics' highest priorities. As described further below, Philips Respironics' guidance for healthcare providers and patients using devices that have not been remediated yet, remains unchanged.**
- **To date, a total of more than 4.5 million devices have been remediated globally, of which approximately 2.4 million devices in the US. Patients with any remaining sleep therapy device currently in use that has not been remediated yet and not registered yet, are requested to register their product to facilitate the remediation of their devices.**

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The impact of ozone cleaning on foam degradation in System One and DreamStation Go sleep therapy devices

Philips Respironics has completed testing and analyses on System One sleep therapy devices that have been exposed to ozone cleaning:

- **Exposure to VOC emissions from the assessed devices treated with ozone cleaning is unlikely to result in appreciable harm to health in patients.**
  ISO 18562-3 VOC testing was conducted after up to 500 ozone cleaning cycles with each cycle simulating one night of use and then ozone cleaning. The VOC toxicological risk of this ozone-induced degradation determined that exposure to VOC emissions from the assessed System One devices exposed to ozone cleaning suggests no appreciable risk to health for patients.

- **Exposure to PM emissions from the assessed devices treated with ozone cleaning is unlikely to result in appreciable harm to health in patients.**
  Regarding risks associated with respirable and non-respirable particulates, testing to date has been performed on devices with known ozone exposure. The third-party collective analysis concluded that exposure to particulate matter from ozone-induced degraded foam in System One devices is unlikely to result in appreciable harm to health in patients.

A third-party review concluded that the testing results on the first-generation DreamStation devices and System One devices are applicable to DreamStation Go devices to determine health risks for patients from ozone treatment and foam degradation, based on multiple lines of evidence including, but not limited to, the same intended use, the same operating parameters, the same type of foam, the same foam degradation products, less foam contained within DreamStation Go, and the conservative, protective nature of the testing and risk assessments performed.

Additional visual inspection of the foam in used first-generation DreamStation devices confirms the low prevalence of significant visual foam degradation/volume reduction

<u>US and Canada:</u>

- An additional analysis using an algorithm to assess collected images of foam within a representative random sample of 100,000 used devices from the US and Canada (devices were selected to represent different manufacture dates) showed that 2,011 devices (~2%) were identified as having significant visual degradation/volume reduction.
- A comparison of ozone use among these devices found that devices for which the user self-reported ozone use were approximately 17 times more likely to have significant visual foam degradation/volume reduction (1,368 out of 14,971 or 9.1%) than those where the user reported no ozone use (357 out of 68,702 or 0.5%).

<u>Europe and Japan:</u>

- An additional analysis of images from a representative random sample of 152,000 devices from Europe and 241,000 devices from Japan were analyzed by an algorithm to identify significant visual degradation/volume reduction.
- A subset of devices from Europe and Japan were identified by the algorithm as potentially having significant visual degradation/volume reduction, and this subset was manually

inspected. It was observed that 17 devices of the 152,000 devices (~0.01 %) from Europe and 3 devices of the 241,000 devices (0.001%) from Japan had significant visual degradation/volume reduction.

Summary of ongoing tests

Philips Respironics is in the process of completing various remaining tests and analyses. For the Trilogy 100/200 and OmniLab Advanced Plus ventilator devices, VOC and PM testing continues, as well as chemical evaluation and toxicological risk assessment. These devices contain a different type of PE-PUR foam than the first-generation DreamStation devices [1]. Philips Respironics expects to provide an update on this in Q3 2023.

Guidance for healthcare providers and patients

Patients currently using an affected sleep therapy device that has not been remediated and not registered yet, are requested to register their devices to facilitate the remediation.

Philips Respironics continues to advise patients using affected sleep therapy devices that have not been remediated yet to contact their physician or care provider to decide on a suitable treatment for their condition, which may include stopping use of their device, continuing to use their affected device, using another similar device that is not part of the recall, or using alternative treatments for sleep apnea. Moreover, patients are advised to follow Philips Respironics' instructions and recommended cleaning and replacement guidelines for their sleep therapy device and accessories. Ozone and UV light cleaning products are not currently approved cleaning methods for sleep therapy devices or masks and should not be used.

Philips Respironics also continues to advise users of ventilator devices to contact their healthcare providers before making any changes to their therapy.

Scientific underpinning of the test methods

The test and research program has been conducted together with five independent, certified testing laboratories, and the results have been reviewed and assessed by third-party qualified experts and Philips Respironics., as well as an external medical panel. The applied test methods – comprising test planning, test execution, and interpretation of the results for the completed risk assessments – are in accordance with the applicable ISO 18562 [2,3] and ISO 10993 [4] industry standards.

The design of the applied test methods was scientifically underpinned based on a thorough consideration and mitigation of testing limitations that are inherent to any test standard and/or scientific research. To illustrate this, examples of such considerations and mitigations have been listed below.

The scientific underpinning of the applied test methods included a thorough consideration and mitigation of testing limitations, for example:

- Testing of a device per ISO 18562 only captures a "snapshot" of device performance during degradation, and it may not be known whether there will be maxima in concentration of hazards (i.e., VOCs or particulates). **To address this, testing was performed on multiple used devices with differing amounts of patient usage and observed visual foam degradation, and on Lab-Aged foam that had been intentionally degraded to different degrees.** Therefore, multiple "snapshots" of potential patient exposure can be captured as a function of device degradation to determine if a patient health risk may exist during the degradation process.
- Lab-Aging of foam is being used to induce various levels of foam degradation in controlled conditions without contamination from the environment, for comparison to levels of degradation in Used devices. Lab-Aging conditions are not intended to be predictive of foam degradation progression observed in Used devices. **Differences may exist in how the Lab-Aged PE-PUR foam degrades compared to the Used foam over the lifetime use of the device, and these differences were considered in the completed risk assessments.**
- ISO 18562-2 testing of devices quantifies the concentration of respirable particulates based only on their size range (i.e., up to 10 µm in diameter), but does not measure non-respirable particles (i.e., greater than 10 µm), nor does the standard characterize the chemicals present in particles detected. **To address this, additional testing in accordance with ISO 10993 and very conservative assumptions were included** such as a risk assessment calculation assuming that all of the foam in the device could become degraded and contact the patient, and chemical characterization and toxicological risk characterization of chemicals present in PE-PUR foam in accordance with ISO 10993-18 and -17 [4].
- Visual inspections are qualitative in nature and do not quantify VOCs or particulates within or emitted from a device. **The visual inspection results did not contribute to the risk assessment calculation.** While visual inspections have identified visual foam degradation in a limited number of first-generation DreamStation devices (e.g., 0.5% of used devices from the US and Canada, self-reported without ozone use), the associated risk assessment very conservatively assumed that all first-generation DreamStation, System One and DreamStation Go users could be exposed to all of the PE-PUR foam within the device, and that all of that PE-PUR foam was degraded. Even with the conservative assumption of exposure to all degraded PE-PUR foam within the device, the third-party risk assessment concluded that exposure to particulates from degraded foam in first-generation DreamStation devices is unlikely to result in appreciable harm to health in patients.

Notes

* *Voluntary recall notification in the US/field safety notice for the rest of the world.*

[1] *First-generation DreamStation, System One and DreamStation Go devices contain Type A PE-PUR foam, while Trilogy 100/200 devices contain Type B PE-PUR foam, and OmniLab Advanced Plus devices contain Type A and Type B PE-PUR foams. The known differences between the Type A and Type B foams are that Type B foam can be used with an acrylic pressure sensitive adhesive, has a lower density, has a different thickness, and also contains an additive to reduce potential flammability.*

[2] *ISO 18562-2: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter.*

[3] *ISO 18562-3: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds.*

[4] *ISO 10993: Biological evaluation of medical devices; Part 1: Evaluation and testing within a risk management process; Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity; Part 5: Tests for in vitro cytotoxicity; Part 10: Tests for irritation and skin sensitization; Part 17: Establishment of allowable limits for leachable substances; Part 18: Chemical characterization of medical device materials within a risk management process.*