



## Press Information

May 16, 2023

### **Philips provides update on completed set of test results for CPAP/BiPAP sleep therapy devices**

**Amsterdam, the Netherlands** – [Royal Philips](#) (NYSE: PHG; AEX: PHIA), today provides an update on the comprehensive test and research program of its subsidiary Philips Respironics 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](#).\*

The risk assessments have now been completed for the CPAP/BiPAP sleep therapy devices under the recall notification/field safety notice\* i.e., the first-generation DreamStation, System One and DreamStation Go devices, representing approximately 95% of the registered devices globally. The assessments build on the previous updates in [December 2021](#), [June 2022](#), and [December 2022](#). Additionally, tests and analyses have been completed for first-generation DreamStation devices that have been exposed to ozone cleaning.

#### **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 [1,2] and ISO 10993 [3] industry standards. The design of the applied test methods was further scientifically underpinned based on a thorough consideration and mitigation of inherent testing limitations. For example, 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. Very conservative assumptions were included in the risk assessments. Further examples are provided at the bottom of this press release.

“Our first priority is the health and well-being of patients,” said Roy Jakobs, CEO of Royal Philips. “We have therefore focused on the comprehensive test and research program to gain more clarity about the safety of the affected devices, and on providing replacement devices to patients. The third-party risk assessments for the sleep therapy devices presented today are



positive and reassuring, and we are making good progress with the remediation of the affected devices. The relevant competent authorities globally, including the FDA, are still reviewing the test results and assessments. We share the same objective to ensure patient safety and quality in the delivery of healthcare, and we remain committed to working closely with these agencies. The completion of testing and remediation of the affected devices remain our highest priorities.”

- **Philips Respironics has provided the summary of the completed set of test results and analyses for the CPAP/BiPAP 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 16, 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 press release.**
- **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 approximately 4.3 million devices have been remediated globally, of which approximately 2.3 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.**

## Test results and analyses for sleep therapy devices not exposed to ozone cleaning

The completed set of test results and analyses for the first-generation DreamStation, System One and DreamStation Go sleep therapy devices indicate that potential patient exposure to foam particulate matter (PM) and volatile organic compounds (VOCs) from the PE-PUR foam within these devices is unlikely to result in an appreciable harm to health in patients. The conducted tests and conclusions have been summarized in the table below.

Devices grouped by device air path design	Device Level Testing		Foam Level Testing	Third-Party Risk Conclusions
	VOC Risk Analysis # of Devices/Foams	PM Risk Analysis # of Devices/Foams	PM Risk Analysis	
<b>DreamStation</b> (First-generation) DreamStation CPAP, BiPAP, Auto CPAP DreamStation ASV DreamStation ST, AVAPS E30	New – 20 devices Used – 21 devices Lab-Aged – 33 devices  Per ISO-18562-3 [2] or Indoor Air Quality Evaluation for VOC [4]	New – 63 devices Used – 96 devices Lab-Aged – 24 devices  Per ISO-18562-2 [1] or Indoor Air Quality Evaluation for PM [4]	Foam Level Testing and Risk Assessments are applicable to each of the three sleep therapy device platforms as they contain the same type of PE-PUR foam*	<b>Potential patient exposure to foam particulates and VOCs from the PE-PUR foam within the breathing gas pathway of first-generation DreamStation, DreamStation Go, and System One devices is unlikely to result in an appreciable harm to health in patients</b>
<b>DreamStation Go</b> (DS Go) DreamStation Go CPAP, APAP, Auto CPAP	New – 4 devices Lab-Aged – 3 devices  Per ISO-18562-3 [2] or Indoor Air Quality Evaluation for VOC [4]	New – 8 devices Lab-Aged – 6 devices  Per ISO-18562-2 [1] or Indoor Air Quality Evaluation for PM [4]	Chemical Characterization and Toxicological Risk Assessment per ISO 10993-18 and ISO 10993-17 [3] New, Used, ** Lab-Aged	
<b>System One</b> System One 60-Series System One 50-series System One ASV4 C-Series ASV C-series S/T, AVAPS System One (Q-series) REMstar SE Auto Dorma 400, 500 CPAP, Auto CPAP (not marketed in US)	New – 7 devices Used – 7 devices Lab-Aged – 20 devices  Per ISO-18562-3 [2] or Indoor Air Quality Evaluation for VOC [4]	New – 7 devices Used – 7 devices Lab-Aged – 20 devices  Per ISO-18562-2 [1] or Indoor Air Quality Evaluation for PM [4]	Genotoxicity, Cytotoxicity, Sensitization, and Irritation per ISO 10993-3, ISO 10993-5, and ISO 10993-10 [3] New, Lab-Aged	

VOC: Volatile Organic Compound

PM: Particulate Matter

\* The total amount of foam in the devices varies from approximately 1 g to 10 g, depending on the device airpath design and configuration. Devices within each platform share the same airpath design and configuration, including the amount of foam present.

\*\* The foam from 7 different Used first-generation DreamStation devices was chemically characterized per ISO 10993-18 and -17 [3] and included foam representative of a range of visual degradation states.

### A. The results indicate that the exposure to VOC emissions is unlikely to result in an appreciable harm to health in patients.

Expanded testing and toxicological risk assessments on multiple devices with New, Used, and Lab-Aged foam have shown no appreciable harm to health for the VOCs detected based on ISO 18562-3 [2] testing, and a third-party risk assessment concluded that exposure to VOCs for these devices is unlikely to result in an appreciable harm to health in patients.

**B. The results indicate that exposure to PM emissions from degraded foam in these devices, including potential respirable and non-respirable particulates, is unlikely to result in an appreciable harm to health in patients.**

New, Lab-Aged and Used devices were tested and all were compliant with ISO 18562-2 [1] allowable limits for PM emissions. Testing was performed on Used devices (i.e., devices previously used by patients) with varying degrees of degradation (i.e., from no visible degradation to severe visible degradation), New devices, and devices with Lab-Aged foam that intentionally had been exposed to significantly elevated temperatures ( $\geq 80^{\circ}\text{C}$ ) and humidity ( $\geq 75\% \text{ RH}$ ) to accelerate degradation.

Further, tested PM emissions of Used devices with visible degradation were not statistically different than PM emissions of Used devices without degradation, suggesting that degradation did not contribute to appreciable elevated levels of respirable particles in the devices tested.

Even with the very conservative and theoretical assumption that all of the foam could degrade and that a patient is then exposed to all of the degraded PE-PUR foam within the devices, the third-party risk assessment concluded that exposure to particulates from degraded foam in these devices, including potential respirable and non-respirable particulates, is unlikely to result in an appreciable harm to health in patients.

**C. Prevalence of visible foam degradation in inspected Used first-generation DreamStation devices was found to be low.**

Based on the visual inspection of the foam in returned first-generation DreamStation devices, the prevalence of visible foam degradation was found to be low. Visual inspection can only identify visible foam degradation and cannot measure volatile organic compounds generation or quantify particulate loss, therefore additional testing and analyses were performed as described above and in the complete update.

**The impact of ozone cleaning on foam degradation in first-generation DreamStation devices**  
Philips Respironics has completed testing on first-generation DreamStation devices that have been exposed to ozone cleaning:

**A. Exposure to VOC emissions from the assessed devices treated with ozone cleaning is unlikely to result in an appreciable harm to health in patients.**

ISO 18562-3 VOC testing showed that after 200 ozone cleaning cycles - each cycle simulating one night of use and then ozone cleaning - diethylene glycol (DEG) became detectable as a VOC. The testing was conducted up to 500 ozone cleaning cycles, and a VOC toxicological risk of this ozone-induced degradation determined that exposure to VOC emissions from the assessed first-generation DreamStation devices exposed to ozone cleaning suggests no appreciable risk to health for patients.

**B. Exposure to PM emissions from the assessed devices treated with ozone cleaning is unlikely to result in an 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. For example, two Used

first-generation DreamStation devices with user-reported ozone exposure were included in extractables and leachables testing, which formed the foundation for a toxicological risk assessment of the sleep therapy device PE-PUR foam particulate. That third-party collective analysis concluded that exposure to particulate matter from degraded foam in the first-generation DreamStation devices is unlikely to result in an appreciable harm to health in patients.

**C. Ozone cleaning exacerbates foam degradation, but ozone-induced degradation is unlikely to result in an appreciable harm to health in patients.**

As previously [published](#), data for first-generation DreamStation indicates that devices with user-reported ozone cleaning are 14 times more likely to have significant visible foam degradation/volume reduction compared to devices with no user-reported ozone exposure. This observation is consistent with laboratory testing, where first-generation DreamStation devices exposed to increasing cycles of ozone cleaning had increasingly more severe visual degradation. However, as concluded above, this is unlikely to result in an appreciable harm to health in patients.

**Summary of ongoing tests**

Philips Respironics is in the process of completing various remaining tests and analyses. The risk assessments for System One and DreamStation Go devices (that contain the same foam as the first-generation DreamStation devices) treated with ozone cleaning are being completed. 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 [5]. 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 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 [3].
- 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 (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 an appreciable harm to health in patients.

## Notes

- \* *Voluntary recall notification in the US/field safety notice for the rest of the world.*
- [1] *ISO 18562-2: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter.*
- [2] *ISO 18562-3: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds.*
- [3] *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.*
- [4] *The standard that was used for tests prior to ISO 18562.*
- [5] *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.*

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## About Royal Philips

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## Forward-looking statements

This statement contains certain forward-looking statements with respect to the financial condition, results of operations and business of Philips and certain of the plans and objectives of Philips with respect to these items. Examples of forward-looking statements include statements made about the strategy, estimates of sales growth, future EBITA, future

developments in Philips' organic business and the completion of acquisitions and divestments. By their nature, these statements involve risk and uncertainty because they relate to future events and circumstances and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these statements.