



## **Philips Respironics recall notification/field safety notice\* announced on June 14, 2021**

Frequently Asked Questions – as of May 16, 2023

### **General**

#### **What is the component quality issue in certain of Philips Respironics sleep and respiratory care products?**

In 2021, Philips Respironics determined from user reports and initial testing that there were possible risks to users related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in specific CPAP, BiPAP and ventilator devices. Following the issuance of the recall notification/field safety notice\* in June 2021, Philips Respironics initiated a global program to remediate the affected devices.

Additionally, together with five independent, certified testing laboratories and qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE- PUR foam to better assess and scope potential patient health risks related to possible emission of particulates from degraded foam and volatile organic compounds.

Philips Respironics provided test result [updates](#) on December 23, 2021, June 28, 2022, December 21, 2022 and on May 16, 2023. Based on the comprehensive testing and analysis that has been conducted, Philips Respironics has a complete set of results for the CPAP/BiPAP sleep therapy devices under the recall, i.e., first-generation DreamStation, System One and DreamStation Go devices, representing approximately 95% of the registered devices globally. Additionally, tests and analyses have been completed for the first-generation DreamStation devices that have been exposed to ozone cleaning. Further testing is still ongoing, and Philips Respironics expects to provide a further update in Q3 2023.

#### **Which sleep and respiratory care products are affected by the recall notification/field safety notice\*?**

The affected ~20 CPAP, BiPAP and ventilator products can be found at [www.philips.com/src-update](http://www.philips.com/src-update). The products can be grouped in five device categories by their air path design. The first-generation DreamStation devices are the largest device category, representing approximately 68% of the registered affected devices globally.

#### **Did the first-generation DreamStation devices follow industry standards?**

The first-generation DreamStation devices were designed to meet all relevant standards at the time of development and launch and have been marketed pursuant to the relevant regulations. The devices were commercially launched in 2016.

#### **Where can I find more information on the recall notification/field safety notice\*?**

More information on the recall notification/field safety notice\* can be found at [www.philips.com/src-update](http://www.philips.com/src-update).

#### **Was Philips Respironics aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions prior to 2021?**

In the years prior to 2021, there were limited complaints related to foam degradation, which Philips' subsidiary Philips Respironics evaluated and addressed on a case-by-case basis. Potential concerns relating to the emission of volatile organic compounds began to surface more recently. When Philips became aware of the issue and its potential significance in early 2021, actions were taken leading to





the recall notification/field safety notice\* in June of 2021

**Can you comment on the Medical Device Reports that Philips Respironics has filed for this recall notification/field safety notice\*?**

As part of its post market surveillance activities, Philips Respironics received and continues to receive device associated complaints that have subsequently been filed by Philips Respironics as [Medical Device Reports](#) (MDRs) with the US Food and Drug Administration (FDA).

Philips Respironics investigates all received complaints and allegations of malfunction, serious injury or death. While done so in line with FDA reporting requirements, the submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event. In addition, in many cases the cause of an event cannot be determined from this reporting system alone.

Furthermore, it is important to note that the complaint volume pattern observed for the recall notification/field safety notice\* is not typical but rather directly correlated to the increased awareness resulting from the recall notification/field safety notice\* and is predominantly observed in the US.

Following Philips' public statements on the issue and possible risks to users in April 2021, and the announcement of the recall notification/field safety notice\* in June 2021, Philips Respironics received a steep increase in complaints allegedly associated with possible foam degradation. At the time the recall notification/field safety notice\* was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment, and assumed a reasonable worst-case scenario for the possible health risks.

This led to a steep increase by approximately 20,500 MDRs filed by Philips Respironics to the FDA between April 2021 and April 2022. In the following eight months through December 2022, Philips Respironics filed approximately 78,800 MDRs. In January and February 2023, Philips Respironics filed a total of approximately 4,800 MDRs. In March 2023, Philips Respironics filed approximately 1,200 MDRs.

**Medical Device Reports related to this recall notification/field safety notice\* indicate reports of deaths associated with reported or suspected foam breakdown in the devices. How does Philips explain this?**

Based on the investigations to date, Philips Respironics has found no conclusive data linking these devices and the deaths reported in these MDRs. The vast majority (~94%) of the approximately 105,200 MDRs filed since April 2021 up to and including March 2023 are alleged malfunctions that do not involve reported serious injury or death.

In May 2023, Philips provided an [update](#) on the completed set of test results for the CPAP/BiPAP sleep therapy devices under the recall, i.e., first-generation DreamStation, System One and DreamStation Go devices, that was positive and reassuring. In addition, based on 13 epidemiological studies identified from a [systematic literature review](#), no association has been established between use of PAP devices, including Philips Respironics PAP devices, and risk of cancer in patients with obstructive sleep apnea.

**What does the previously announced field action provision relate to?**

The provision is related to the cost to repair or replace affected devices and includes the cost of intensified communication with physicians and patients, labor cost and logistics. The provision does not include any product liability costs.





## **Test and research program**

### **Why has Philips Respironics been conducting a test and research program?**

At the time the recall notification/field safety notice\* was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment, and assumed a worst-case scenario for the possible health risks out of an abundance of caution. Together with five independent certified testing laboratories and qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE- PUR foam to better assess and scope potential patient health risks related to the possible emission of particulates from degraded foam and volatile organic compounds.

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.

### **Following the latest testing results, is Philips Respironics now excluding the health risk of possible carcinogenic effects?**

The extensive data and results now available for the first-generation DreamStation, System One and DreamStation Go devices indicate that the occurrence of visible foam degradation is low and volatile organic compounds and particulate emissions related to foam degradation are within the applicable safety limit.

The results indicate that exposure to particulate matter (PM) emissions from degraded foam in DreamStation, System One and DreamStation Go devices, including potential respirable and non-respirable particulates, is unlikely to result in an appreciable harm to health in patients, and that the exposure to volatile organic compound emissions (VOCs) is not anticipated to result in long-term health consequences for patients.

In July 2022, Philips Respironics [published](#) a summary of a systematic literature review of Positive Airway Pressure (PAP) device use and cancer risk: Based on 13 epidemiological studies identified from a systematic literature review, no association has been established between use of PAP devices, including Philips Respironics PAP devices, and risk of cancer in patients with obstructive sleep apnea (OSA). Two rigorous independent studies showed no statistical difference in cancer risk between OSA patients who used Philips Respironics PAP devices versus other brands of PAP devices. Eleven other epidemiological studies provided little additional insight into this question, but their results generally suggested no excess risk of cancer associated with PAP use for OSA. The complete summary of the systematic literature review can be found [here](#).

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 these FAQs.

### **Based on the new test results for the CPAP/BiPAP sleep therapy devices, is Philips Respironics saying they are safe for patients to use?**

Philips Respironics has not completed all of the testing. The May 16, 2023, update primarily relates to the System One and DreamStation Go sleep therapy devices and for first-generation





DreamStation devices that have been exposed to ozone cleaning.

The extensive data and results now available for the first-generation DreamStation, System One and DreamStation Go devices indicate 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.

Testing also found that for first-generation DreamStation devices the use of ozone cleaning exacerbates foam degradation. After conducting testing of up to 500 ozone cleaning cycles, potential patient exposure to foam particulate matter (PM) and volatile organic compounds (VOCs) from the PE-PUR foam is unlikely to result in an appreciable harm to health in patients.

The guidance for healthcare providers and patients using devices that have not been remediated yet, remains unchanged. As always, Philips Respironics advises patients to consult their physician or health care provider should they intend to make any changes to their therapy. Philips Respironics is focused on making sure patients and their clinicians have all the information they need.

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 these FAQs.

**Why did you conduct the ozone testing up to 500 cycles specifically? How was this threshold selected?**

We have conducted testing up to 500 cycles as that resulted in foam degradation that was in line with the degree of degradation that we have observed in the inspected used devices, with self-reported ozone use. We saw significant visible foam degradation and detected VOCs related to foam degradation (diethylene glycol) from 200 cycles onwards.

**Why is the recall notification/field safety notice\* unchanged if the testing results are favorable?**

Any change to the field safety notice would need to be aligned with the relevant competent authorities, who are still reviewing the extensive data and insights gathered over the last 24 months. The FDA is still considering the data and analyses that Philips Respironics has provided and may reach a different conclusion. We have incorporated their initial feedback and will of course address any feedback and questions that these competent authorities may have.

At the same time, Philips Respironics is nearing the completion of the remediation of the sleep therapy devices. 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.

**What can you say about the flow rates that you used for the VOC and PM measurements?**

The Volatile Organic Compound (VOC, ISO 18562-3) and Particulate Matter (PM, ISO 18562-2) tests were performed under different flow rate conditions. The VOC emission has the highest concentration at the lowest clinically relevant flow rate. Particulates are stirred up via high flow rates, thus the maximum clinically relevant was used for those tests. A 17 L/minute flow rate was used for





the VOC emission tests and of 90 L/minute for the PM emission tests. Philips Respironics checked that testing at other flow rates did not yield higher VOC or PM concentrations. All test results to date are consistent with the overall test conclusions.

**How did the mischaracterization and misidentification of the VOC compounds occur in the first place?**

There were initially very limited test results. The additional test results delivered new insights, and data to date, including tests conducted prior to June 2021, were carefully reviewed and re-assessed.

At the time the recall notification/field safety notice\* was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment. Out of an abundance of caution, a reasonable worst-case scenario was considered. At the time, Philips Respironics could not exclude possible carcinogenic effects with the limited dataset that was available. Philips Respironics did not have conclusive data indicating that exposure to the particulates or emitted chemicals would lead to cancer.

Since then, together with five independent, certified testing laboratories in the US and Europe and other qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE-PUR foam to better assess and scope the potential patient health risks related to possible emission of particulates from degraded foam and volatile organic compounds. This also includes an in-depth review and re-assessment of data and toxicological risk-assessments prior to June 2021.

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.

**Can you help us reconcile the failed genotoxicity test with the latest results published on May 16, 2023?**

Lab-aged first-generation DreamStation foam failed ISO 10993 genotoxicity testing under laboratory conditions, and therefore a follow-up weight of evidence assessment was conducted, per the ISO 10993 standard, to provide a confirmed conclusion on potential risks for patients under the expected usage.

To support the full toxicological risk assessment, additional chemical characterization (extractables and leachables testing) as recommended by the ISO 10993 standard was conducted to determine the identity and amount of chemicals in lab-aged and used foam samples. To support the full toxicological risk assessment, additional chemical characterization (extractables and leachables testing) as recommended by the ISO 10993 standard was conducted to determine the identity and amount of chemicals in lab-aged and used foam samples. A third-party risk assessment of the extractables and leachables testing results concluded that there was no appreciable harm to health in patients even with conservative assumptions for exposure (e.g., patient contacted 100% of the foam in the device).

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 these FAQs.

## **When can we expect the next update on testing results, including Trilogy 100/200 and other ventilator devices?**

Philips Respironics continues with the remaining VOC and PM testing, as well as chemical evaluation and toxicological risk assessment for the Trilogy 100/200 (representing approximately 3% of the registered affected devices) and OmniLab Advanced Plus ventilator devices (representing approximately 2% of the registered affected devices), that contain a different type of PE-PUR foam than the first-generation DreamStation devices. Further testing is still ongoing and Philips Respironics expects to provide an update for Trilogy 100/200 and OmniLab Advanced Plus ventilator devices in Q3 2023.

## **Can you comment on the failed test for the Trilogy devices?**

New Trilogy 100/200 devices passed VOC and PM testing to date. New Trilogy 100/200 foam passed ISO 10993 cytotoxicity, irritation, and sensitization testing. New and Lab-aged Trilogy 100/200 foam failed ISO 10993 genotoxicity testing, and therefore a weight of evidence assessment is ongoing to provide a confirmed conclusion on potential risks for patients under the expected usage.

Similar to the analyses performed for the first-generation DreamStation foam, additional chemical characterization as well as experiments to assess the probability and amount of degraded PE-PUR foam that can potentially reach the patient are being conducted to support the full toxicological risk assessment. The Trilogy 100/200 devices contain a different type of PE-PUR sound abatement foam. The known differences between the DreamStation foam and the foam for the Trilogy 100/200, are that the latter 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.

## **Why is testing taking so much time?**

The test and research program involves hundreds of very time-consuming tests. Philips Respironics is doing multiple tests to assure confidence in the results. Philips Respironics is running comprehensive testing by product category, and for each product category, it is investigating three types of situations: new devices, devices with lab-aged foam, and used devices. The time taken to test and analyze the data per product category and situation is substantial and impacts throughput time for each test. The complexity of the test results also adds to the throughput time.

## **Did Philips Respironics run additional testing on the silicone foam as requested by the FDA?**

In November 2021, the FDA [requested](#) that Philips retain an independent laboratory to perform additional testing to determine what, if any, potential safety risks may be posed to patients by silicone-based foam. Philips Respironics engaged independent testing laboratories to perform additional VOC testing. Based on the final reports subject to FDA review, Philips Respironics has not identified any safety issues.

## **Where has Philips Respironics published the testing results and conclusions to date?**

The update on the PE-PUR testing results and conclusions available to date can be found [here](#).





### **Have there been third-party clinical studies in connection with the possible health risks?**

In July 2022, Philips Respironics [published](#) a summary of a systematic literature review of Positive Airway Pressure (PAP) device use and cancer risk: Based on 13 epidemiological studies identified from a systematic literature review, no association has been established between use of PAP devices, including Philips Respironics PAP devices, and risk of cancer in patients with obstructive sleep apnea (OSA). Two rigorous independent studies showed no statistical difference in cancer risk between OSA patients who used Philips Respironics PAP devices versus other brands of PAP devices. Eleven other epidemiological studies provided little additional insight into this question, but their results generally suggested no excess risk of cancer associated with PAP use for OSA.

The complete summary of the systematic literature review can be found [here](#).

### **Remediation program**

#### **What is the progress of Philips Respironics' repair and replacement actions?**

To date, a total of approximately 4.3 million devices have been remediated globally, of which approximately 2.3 million devices in the US.

#### **How many devices are affected by this recall notification/field safety notice\*?**

Philips Respironics expects to remediate up to 5.6 million devices (specific CPAP, BiPAP and ventilator devices) globally, of which more than half are in the US. Approximately 95% of the registered affected devices globally are CPAP and BiPAP sleep therapy devices (i.e., first-generation DreamStation, DreamStation Go and SystemOne devices).

#### **Why is remediating the devices taking so long?**

The repair and replacement of the affected devices is a complex undertaking, because of the volume of devices to be remediated, and the outreach to every individual patient. In an average year, Philips Respironics produces and distributes around one million sleep therapy devices. The increase of the production rate is impacted by supply chain shortages. In the meantime, Philips Respironics has increased production by more than a factor of three.

#### **Is Philips Respironics selling devices to new patients?**

Because of the prioritization of the remediation program, Philips Respironics is currently not taking new orders for sleep therapy systems, while masks and other consumables continue to be sold.

### **FDA/DoJ**

#### **What is the Form 483 published by the FDA on November 12, 2021, about?**

In connection with the recall notification/field safety notice\*, the FDA conducted an inspection of a Philips Respironics manufacturing facility in the US. Following the inspection, the FDA provided a list of its observations to Philips Respironics. On November 12, 2021, the FDA published these observations on its website and distributed a press release on the matter.

Philips Respironics evaluated the inspectional observations and has submitted a comprehensive response, as well as a detailed action plan to the FDA. Philips Respironics continues to provide routine updates to the FDA on its progress on the action plan and will continue to work closely with the agency.





**As stated in FDA’s November 2021 Form 483, the FDA search identified 222,000 complaints related to the affected devices. Can you explain the discrepancy between Philips’ disclosure and that of the FDA?**

The 222,000 complaints identified by the FDA were the result of broad word searches over multiple years retrieved from the Philips Respironics’ database, and thus do not all relate specifically to the issues that led to the recall notification/field safety notice\* or the foam issue. Using a validated protocol and a statistical methodology based on an established industry standard, Philips Respironics reviewed the complaints cited by the FDA, and found that approximately 3% of these complaints concern alleged foam degradation.

**What does the FDA 518(a) order published on March 10, 2022, direct Philips Respironics to do?**

The order directs Philips Respironics to take certain actions to ensure that users, DMEs/distributors and health professionals receive notice of the recall notification/field safety notice\* and the potential health risks presented by the recalled devices within 45 days from the date of the order.

The order also directs Philips Respironics to (1) highlight language regarding the risk of using unapproved ozone cleaners on the recalled devices on its main webpage for the recall notification/field safety notice\*; (2) provide access to information regarding available test data; and (3) continue to utilize Philips Respironics’ mobile application to provide notice for device users regarding recall updates and information. Philips Respironics continues to comply with the order.

**Did Philips Respironics respond to the proposed May 2, 2022, 518(b) order? Will patients receive a refund for their device as per the proposed 518(b) order?**

Philips Respironics has submitted a written response to the FDA’s proposal to issue a 518(b) order. Philips Respironics is working hard to repair or replace the affected devices as quickly as possible, as it believes that it is in the best interest of affected patients. To date, approximately 2.3 million devices have been remediated in the US and a total of approximately 4.3 million devices globally.

**What does the proposed consent decree require Philips Respironics to do?**

Following the FDA’s inspection of certain of Philips Respironics’ facilities in the US in 2021 and the subsequent inspectional observations, the US Department of Justice (DOJ), acting on behalf of the FDA, began discussions with Philips Respironics regarding the terms of a proposed consent decree to address many of the identified issues on a forward-going basis. Philips cannot speculate on the outcome and cannot provide further information at this time.

**What is the April 2022 subpoena from the US Department of Justice about?**

Philips Respironics and certain of Philips’ subsidiaries in the US received a subpoena from the DOJ to provide information related to events leading to the Philips Respironics recall. The relevant subsidiaries are cooperating with the agency.

## Litigation

**What is the latest update on the multidistrict litigation (MDL) in the US?**

In September 2022, the Court requested that plaintiffs resubmit consolidated or master complaints for their economic loss, medical monitoring and personal injury claims, and a new motion to dismiss briefing process is under way. Philips, Philips Respironics and the other Philips defendants have filed motions to dismiss each of these claims. The Court has yet to rule on these motions. Formal discovery has started and is expected to continue throughout 2023 and beyond.







And, as announced on April 24, 2023, Philips has recorded a provision in anticipation of a resolution of the economic loss class action pending in this MDL. Philips Respironics believes that the anticipated resolution is an important step in addressing the litigation related to the Philips Respironics recall.

**What is the company's view on the personal injury and medical monitoring claims filed against Philips and Philips Respironics?**

Philips and Philips Respironics have moved to dismiss the personal injury and medical monitoring claims in their entirety. Importantly for patients, a systematic review of 13 independent epidemiological studies shows no association between use of Continuous or Bilevel Positive Airway Pressure (PAP) devices, including Philips Respironics PAP devices, and risk of cancer in people with obstructive sleep apnea.

Philips Respironics continues to conduct a comprehensive test and research program to understand and scope the possible patient risk and make a full assessment on the merits of the claims. Please refer to the most recent [testing update](#) from May 2023 for more information on that effort.

**Philips recorded a provision in connection with the anticipated resolution of economic loss claims in the MDL. Why is the company considering settling the economic loss claims?**

The provision was booked as Philips Respironics expects to submit a negotiated settlement agreement to the court for preliminary approval in the second quarter of 2023. It is important to note that the economic loss resolution is being negotiated, with the assistance of a court-appointed mediator, as a potential class action settlement. That will resolve the economic claim loss claims of all device users, hospitals, and private insurers in the US, whether they have filed a lawsuit or not. Subject to final court approval, payments to class members under the settlement are not expected to begin until the first quarter of 2024 at the earliest.

**Does Philips Respironics have insurance for product liability? Would it cover the anticipated economic loss settlement?**

Philips Respironics does have product liability insurance in place but does not share policy details such as limits and terms externally.

**Does the company also anticipate a resolution of the personal injury and medical monitoring claims?**

Philips and Philips Respironics do not anticipate visibility on potential outcomes of any remaining medical monitoring and personal injury claims before 2024, due to a number of variables, including uncertainty regarding the ultimate number of claimants and their allegations. Philips Respironics has also not yet completed its test and research program for all the categories of the recalled devices.

Importantly for patients, a systematic review of 13 independent epidemiological studies shows no association between use of Continuous or Bilevel Positive Airway Pressure (PAP) devices, including Philips Respironics PAP devices, and risk of cancer in people with obstructive sleep apnea. Please refer to the most recent [testing update](#) from May 2023 for more information on that effort.

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

