



## **Philips Respironics field safety notice announced on June 14, 2021**

### **Frequently Asked Questions – as of January 30, 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 are possible risks to users related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in specific CPAP, BiPAP and mechanical ventilator devices. Following the issuance of the field safety notice in June 2021, Philips Respironics initiated a global program to remediate the affected devices through a replacement or repair.

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, and on December 21, 2022. Based on the comprehensive testing and analysis that has been done over the past 18 months, Philips Respironics now has a complete set of results for the first-generation DreamStation devices. Further testing is still ongoing and results are expected in the coming months.

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

The affected 18 CPAP, BiPAP and mechanical 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 field safety notice?**

More information on the 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 prior years, 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 only more recently. When Philips became aware of the issue and its potential significance in early 2021, actions were taken leading to the field safety notice in June of 2021.





**Can you comment on the FDA's notification regarding the Philips Medical Device Reports update for this field safety notice?**

It is important to note that the submission of an [MDR](#) itself is not evidence that the device caused or contributed to the adverse outcome or event, and that the cause of an event cannot typically be determined from this reporting system alone. Philips Respironics investigates all allegations of technical malfunction, serious injury or death.

At the time the 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. Following Philips' public statements on the issue and possible risks to users in April 2021, and the announcement of the field safety notice in June 2021, Philips Respironics received a sharp increase in complaints allegedly associated with possible foam degradation.

This resulted in a steep increase by more than 20,000 Medical Device Reports (MDRs) filed by Philips Respironics to the FDA between April 2021 and April 2022. In the following 6 months through October 2022, Philips Respironics filed an additional approximately 70,000 MDRs. The vast majority (93%) of these approximately 90,000 MDRs are alleged technical malfunctions that do not involve serious injury.

**Medical Device Reports related to this field safety notice indicate reports of 260 deaths associated with reported or suspected foam breakdown in the devices. How does Philips explain this?**

There have been more than 90,000 MDRs filed by Philips Respironics to the FDA from April 2021 up to and including October 2022, 93 percent of which are related to technical malfunctions that do not involve serious injury. Among the remaining reports, it is important to note that the submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event, and that the cause of an event cannot typically be determined from this reporting system alone. Philips Respironics investigates all allegations of technical malfunction, serious injury or death. Based on the investigations to date, Philips Respironics has found no conclusive data linking these devices and the deaths reported in the MDRs.

The recently completed test results indicate exposure to particulate matter from degraded foam in the first-generation DreamStation devices is unlikely to result in appreciable harm to patients. Further, the test results indicate that exposure to volatile organic compound emissions (VOCs) is not anticipated to result in long-term health consequences for patients.

Independent of Philips Respironics' test and research program, clinical researchers in several countries have been examining the data of existing sleep therapy patient studies to assess the association of elevated cancer risk when using Positive Air Pressure (PAP) devices to treat obstructive sleep apnea. They have examined the data and found no statistical increase in cancer risk due to use of Positive Air Pressure devices, including those of Philips Respironics.

For example, an analysis was published in the American Journal of Respiratory and Critical Care Medicine that found no significant difference in the risk of incident cancer among obstructive sleep apnea patients who used a Philips Respironics PAP device as compared with OSA patients who used a PAP device from other manufacturers, or OSA patients without treatment. The analysis and conclusion were based on data from a large multi-center cohort study in Canada involving approximately 7,000 OSA patients on PAP devices between 2012 and 2020, including approximately 1,200 Philips Respironics PAP users, with a median follow-up time of 7.5 years.





More recently, an analysis was published in the European Respiratory Journal that concluded that sustained and adherent CPAP therapy of obstructive sleep apnea using Philips Respironics devices, compared with other manufacturers' devices, was not associated with an increased risk of cancer. This analysis and conclusion were based on data from a large multi-center cohort study in France involving approximately 4,500 obstructive sleep apnea patients on CPAP devices between 2007 and 2018, including approximately 1,700 Philips Respironics CPAP users, with a median follow-up time of 7.2 years.

**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?**

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, and on December 21, 2022. Based on the comprehensive testing and analysis that Philips has done over the past 18 months, the company now has a complete set of results for the first-generation DreamStation devices. Further testing is still ongoing and results are expected in the coming months.

**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 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 limits.

The new results indicate that exposure to particulate matter (PM) emissions from degraded foam in DreamStation 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.

**Based on the new test results for the first-generation DreamStation devices, is Philips Respironics now saying they are safe for patients to use?**

Philips Respironics has not completed all of the testing. The December 21, 2022, update primarily relates to the first-generation DreamStation devices, and testing is ongoing related to ozone cleaning, as well as for the System One and DreamStation Go sleep therapy devices.

The extensive data and results now available for the first-generation DreamStation 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.





The guidance for healthcare providers and patients remains unchanged. Philips Respironics is focused on making sure patients and their clinicians have all the information they need. As always, Philips Respironics advises patients to consult their physician or health care provider should they intend to make any changes to their therapy.

**Why is the Field Safety Notice unchanged if the testing results are favorable?**

The field safety notice relates to all affected CPAP and BiPAP devices. Philips Respironics is in the process of completing the tests for the DreamStation Go and SystemOne sleep therapy devices.

**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 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.

**Can you reconcile the failed genotoxicity test with the latest results published today?**

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 patient 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. 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).

**When can we expect the results for 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 results are expected in the coming months.





### **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 under laboratory conditions, 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.

### **When does Philips Respironics expect to provide the next update on testing results?**

Further testing is still ongoing and results are expected in the coming months.

### **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.

### **Which remaining test results will Philips announce and when are these results expected?**

Philips Respironics is in the process of completing various other tests. As mentioned above, the toxicological risk assessment of the VOC emissions resulting from ozone-induced foam degradation in first generation DreamStation devices is being finalized. Next to this, testing for the SystemOne sleep therapy devices (approximately 26% of the registered devices globally) and DreamStation Go (approximately 1% of the registered devices globally) that contain the same PE-PUR foam as the first-generation DreamStation devices is in progress.

Additionally, for the Trilogy 100/200 (approximately 3% of the registered devices globally) and OmniLab Advanced Plus ventilator devices (approximately 2% of the registered devices globally) 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.



# PHILIPS

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.

## **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?**

In December 2022, Philips Respironics completed around 90% of the production required for the delivery of replacement devices to patients.

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

Philips Respironics expects to repair or replace a total of around 5.5 million devices (specific CPAP, BiPAP and mechanical ventilator devices) globally, of which more than half are in the U.S. 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 expected 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 their 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 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 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 concerned 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 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 is in the best interest of affected patients. In 2022, Philips Respironics completed around 90% of the production for shipments of replacement devices to patients.

### **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, acting on behalf of the FDA, in July 2022 began discussions with Philips regarding the terms of a proposed consent decree to resolve the identified issues. 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 recently received a subpoena from the U.S. Department of Justice (DOJ) to provide information related to the events leading to the Respironics recall. The relevant subsidiaries are cooperating with the agency in the ongoing investigation.

## **Litigation**

### **What is the latest update on the multidistrict litigation (MDL) in the U.S.?**

The multidistrict litigation is still in its early stages. 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.

### **What is the company's view on the economic loss claims filed against the company?**

Philips and Philips Respironics have moved to dismiss the economic loss claims in their entirety. None of the plaintiffs alleges that the foam in his or her device degraded. Moreover, given third-party insurance, most of the plaintiffs do not allege that they spent any of their own money to acquire the devices. The non-Respironics defendants have also argued that they are not liable because they did not sell or warrant the devices.

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

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, and would refer you to our most recent [testing update](#) from December 2022 for more information on that effort.

### **Has Philips Respironics taken any provision related to potential litigation exposure?**

No. Litigation is in preliminary stages, and it is too early to speculate about any potential exposure.





**Does Philips Respironics have insurance for product liability?**

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

**Given the results, are you in a better position now to scope the impact of litigation?**

The latest test results are important for patient and their physicians. Litigation is in preliminary stages, and it is too early to speculate about any potential exposure.

