



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

Frequently Asked Questions – as of January 29, 2024

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, May 16, 2023, and on July 24, 2023. Based on the comprehensive testing and analysis that has been conducted, Philips Respironics concluded that use of its sleep therapy devices is not expected to result in appreciable harm to health in patients.

In October 2023, following ongoing communications with the FDA, Philips Respironics confirmed that it has agreed with the FDA's recommendations to implement additional testing to supplement current test data. The FDA stated that the testing to date is extensive and conducted with independent parties and expressed no concerns with the validity or objectivity of the testing. Philips Respironics is in discussions with the FDA on the details of further testing.

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

The affected CPAP, BiPAP sleep therapy and ventilator devices can be found at www.philips.com/src-update. The CPAP and BiPAP sleep therapy devices represent the vast majority 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.

What material is used for sound abatement in the DreamStation 2 and other replacement devices?

The repaired and new replacement sleep therapy devices all contain silicone sound abatement foam. Silicone is a widely applied rubber-like material that is used in many applications of daily life, such as bakeware for cupcakes, and also in medical applications, including sleep therapy devices. This includes sleep therapy devices manufactured by other companies.

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.





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, complaints related to possible foam degradation were evaluated and addressed by Philips' subsidiary Philips Respironics on a case-by-case basis. 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 doing 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.

In the three months from October 2023 through December 2023, Philips Respironics filed approximately 10,270 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 (~93%) of the approximately 126,700 MDRs filed since April 2021 up to and including December 2023 are alleged malfunctions that do not involve reported serious injury or death.

Philips Respironics provided test result [updates](#) on December 23, 2021, June 28, 2022, December 21, 2022, May 16, 2023, and on July 24, 2023. Based on the comprehensive testing and analysis that has been conducted, Philips Respironics concluded that use of its sleep therapy devices is not expected to result in appreciable harm to health in patients.

In October 2023, following ongoing communications with the FDA, Philips Respironics confirmed that it has agreed with the FDA's recommendations to implement additional testing to supplement current test data. The FDA stated that the testing to date is extensive and conducted with





independent parties and expressed no concerns with the validity or objectivity of the testing. Philips Respironics is in discussions with the FDA on the details of further testing.

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.

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.

Based on the comprehensive testing and analysis that has been conducted, Philips Respironics concluded that use of its sleep therapy devices is not expected to result in appreciable harm to health in patients.

In October 2023, following ongoing communications with the FDA, Philips Respironics confirmed it has agreed with the FDA's recommendations to implement additional testing to supplement current test data. The FDA stated that the testing to date is extensive and conducted with independent parties and expressed no concerns with the validity or objectivity of the testing. Philips Respironics is in discussions with the FDA on the details of further testing.

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

Based on the comprehensive testing and analysis that has been conducted, Philips Respironics concluded that use of its sleep therapy devices is not expected to result in appreciable harm to health in patients.

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. Following ongoing communications with the FDA, Philips Respironics has agreed with the FDA's recommendations to implement additional testing to supplement current test data. The FDA stated that the testing to date is extensive and conducted with independent parties and expressed no concerns with the validity or objectivity of the testing. Philips Respironics is in discussions with the FDA on the details of further testing.

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](#).

Healthcare providers, patients, and other stakeholders should use the complete July 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.

Is Philips Respironics confident in its test results?

Philips Respironics has confidence in the test and research program that is based on thorough scientific methodologies using the appropriate ISO standards. Philips Respironics has worked together with five independent, certified testing laboratories in Europe and the US, as well as third-party experts with extensive scientific, toxicological, and medical expertise. The testing laboratories conduct the tests in accordance with their own professional standards, and they are making their own independent scientific assessment of the test results.

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.

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

The extensive data and results now available for the first-generation DreamStation, System One and DreamStation Go devices indicate that the use of these devices is unlikely to result in appreciable harm to health in patients.

Following ongoing communications with the FDA, Philips Respironics has agreed with the FDA's recommendations to implement additional testing to supplement current test data. The FDA stated that the testing is extensive and conducted with independent parties and expressed no concerns with the validity or objectivity of the testing. Philips Respironics is in discussions with the FDA on the details of further testing.

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.

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 these FAQs.

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

Philips Respironics 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. Additional testing up to 1300 cycles yielded similar results. Significant visible foam degradation and detected VOCs related to foam degradation (diethylene glycol) was observed from 200 cycles onwards.

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

Following ongoing communications with the FDA, Philips Respironics has agreed with the FDA's recommendations to implement additional testing on the sleep therapy devices to supplement





current test data. The FDA stated that the testing is extensive and conducted with independent parties and expressed no concerns with the validity or objectivity of the testing. Philips Respironics is in discussions with the FDA on the details of further testing.

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.

Can you help us reconcile the failed genotoxicity test with the 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).

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 these FAQs.

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

Further testing is ongoing and an update will be provided in due course. 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.

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.

There are media reports that the silicone sound abatement foam used by Philips Respironics in the replacement devices has been shown in some tests to emit chemicals, including formaldehyde. Can you explain this?

Philips Respironics' devices with silicone sound abatement foam have been subject to extensive testing in accordance with the applicable industry testing standards, and Philips Respironics has not identified any safety issues with the silicone foam.

The levels of formaldehyde detected in all devices that contain silicone sound abatement foam were well below the formaldehyde limit established by the World Health Organization, a global public health authority. Additionally, the levels detected were even further below the more recent formaldehyde limit established in 2023 by FDA, as well as other medical authorities.

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](#).

Remediation program

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

Globally, over 99% of the sleep therapy device registrations that are complete and actionable have been remediated, while the remediation of affected ventilators remains ongoing in coordination with the relevant competent authorities.

What is meant by a 'complete and actionable' registration?

Complete and actionable registrations are those that contain the necessary information needed to complete the remediation and are not awaiting further information. For example, the necessary information for patients who elect to receive a remediated device includes physician information, complete prescription, or election to receive an auto-adjusting PAP device.

When do you expect to complete the remediation of ventilator devices? Why is it taking so long?

The remediation of affected ventilators remains ongoing in coordination with the relevant competent authorities.

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?

Globally, over 99% of the sleep therapy device registrations that are complete and actionable have been remediated, while the remediation of the ventilator devices remains ongoing. 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?

Philips Respironics has existing inventory and manufacturing capacity to satisfy any current or forecasted new sleep therapy device registrations in a timely manner.

With awareness of the relevant Competent Authorities, Philips gradually started serving new patients with selected sleep therapy devices (with the new silicone sound abatement foam) in various countries. Philips believes that this measured approach will help to make these necessary devices more readily available in these countries, while still honoring our commitment to seeing remediation efforts through to completion. Philips Respironics is not currently serving new patients with sleep therapy devices in the US.





The FDA has issued a safety communication to carefully monitor DreamStation2 CPAP devices for signs of overheating. Given these machines were used as replacement devices for the remediation program, how does this affect the overall program? Are the machines safe to use?

Philips Respironics is in discussions with the FDA regarding the reports it filed with the FDA related to possible thermal issues in the humidifier of the DreamStation 2 sleep therapy device while in use.

Philips Respironics filed these approximately 270 reports between August 2023 and November 2023 which cover a three-year period following a retrospective review of possible thermal complaints related to DreamStation 2 since the launch of the product.

Philips Respironics conducted a review and analysis regarding reports of the possible thermal issues in accordance with its regulatory processes. The devices can safely be used when the [instructions for use for the DreamStation 2](#) device are followed.

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 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.

Is there an update on the status of the proposed consent decree related to the Respironics recall?

Philips agrees on the terms of a consent decree with the US Department of Justice (DOJ), representing the US Food and Drug Administration (FDA). The consent decree primarily focuses on Philips





Respironics' business operations in the US.

The consent decree is being finalized and will be submitted to the relevant US court for approval. The decree will provide Philips Respironics with a roadmap of defined actions, milestones, and deliverables to demonstrate compliance with regulatory requirements and to restore the business.

In the US, Philips Respironics will continue to service sleep and respiratory care devices already with healthcare providers and patients, and supply accessories (including patient interfaces), consumables (including patient circuits), and replacement parts (including repair kits). Until the relevant requirements of the consent decree are met, Philips Respironics will not sell new CPAP or BiPAP sleep therapy devices or other respiratory care devices in the US.

Outside the US, Philips Respironics will continue to provide new sleep and respiratory care devices, accessories (including patient interfaces), consumables (including patient circuits), replacement parts (including repair kits) and services, subject to certain requirements.

As a consequence of addressing this consent decree, which is a multi-year plan, Philips recorded a provision of EUR 363 million in Q4 2023 that relates to remediation activities, inventory write-downs and onerous contract provisions. In 2024, Philips expects around 100 basis points of costs that relate to remediation activities and disgorgement payments for Philips Respironics sales in the US.

Further details will become available once the consent decree has been finalized and submitted to the relevant US court for approval.

What is the financial impact of the consent decree?

As a consequence of addressing this consent decree, which is a multi-year plan, Philips recorded a provision of EUR 363 million in Q4 2023 that relates to remediation activities, inventory write-downs and onerous contract provisions. In 2024, Philips expects around 100 basis points of costs that relate to remediation activities and disgorgement payments for Philips Respironics sales in the US.

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 Phillips Respironics recall. The relevant subsidiaries are cooperating with the agency.

Litigation

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

As announced on September 7, 2023, Philips and certain of its US subsidiaries, including Philips Respironics, reached an agreement to resolve all economic loss claims in the US MDL. The agreement, which is subject to final Court approval, provides predefined cash awards to all eligible class members, among other benefits. The settlement, which received preliminary Court approval on October 10, 2023, does not include or constitute any admission of liability, wrongdoing, or fault by any of the Philips parties.

The agreement does not settle any personal injury or medical monitoring claims in the MDL, which the Philips parties have moved to dismiss. Formal discovery on these claims is ongoing and is expected to continue throughout 2023 and beyond.





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 updates from July 2023 for more information on that effort.

Why did the company agree to settle the economic loss claims in the US MDL?

Philips has sought to resolve these claims so that it may dedicate more time and energy to its central focus of transforming patient lives. This settlement, which is subject to final Court approval, is structured to quickly deliver value to eligible patients in the US and provide an additional measure of confidence in the safety and quality of Philips Respironics products. The settlement does not include or constitute any admission of liability, wrongdoing or fault by any of the Philips parties.

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 late 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 July 2023 for more information on that effort.

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

