



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

Frequently Asked Questions – as of April 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.





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 January through March 2024, Philips Respironics filed approximately 12,700 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 (~90%) of the approximately 139,400 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.

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.

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.

When do you expect to complete the remediation of ventilator devices?

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).



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.

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.

Why did the FDA and DOJ seek a consent decree from Philips Respironics?

Following Philips Respironics' voluntary recall of certain CPAP, BiPAP, and mechanical ventilator devices in June 2021, FDA's inspection of Philips Respironics' Murrysville facility in the second half of 2021, and the FDA's issuance of a Form FDA 483 with inspectional observations, the FDA and DOJ began discussions with Philips in July 2022 regarding the terms of a proposed consent decree.

Philips has agreed 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 decree provides Philips Respironics with a roadmap of defined actions, milestones, and deliverables to demonstrate compliance with regulatory requirements and to restore the business.

What are the main terms of the consent decree?

The main terms include:

- Philips Respironics' business operations must demonstrate continued compliance with the Current Good Manufacturing Practice requirements for medical devices, as incorporated in FDA's Quality System Regulation
- Philips Respironics will retain independent quality system experts to supervise the compliance improvement program
- Philips Respironics will retain independent design and quality system experts to review various aspects of the recall remediation.
- In the US, Philips Respironics will continue to service sleep and respiratory care devices already with healthcare providers and patients, and to provide accessories (including patient interfaces), consumables and replacement parts; will resume sales of new CPAP or BiPAP sleep therapy devices or other respiratory care devices only when the relevant requirements are met.
- Agreed to disgorgement payments from sales of Medically Necessary Devices. Sales of Patient Interfaces (masks) and other consumables and accessories in the US are allowed under a separate exemption, which does not have a disgorgement requirement.
- 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. It is



common for consent decrees (including this one) to include requirements (e.g. controls and documentation) for exports to prevent reimportation of medical devices into the US.

Can you summarize what are the key relevant requirements to lift the sales injunction and the profit disgorgement obligation?

Sales injunction and disgorgement payments to occur until Covered Respiroics Facilities are in compliance with the relevant requirements and the rework, replacement, and refund activities are completed in accordance with the Recall Remediation Plan.

The key relevant requirements are:

- Methods and controls to manufacture, hold and distribute sleep and respiratory care devices are compliant with the relevant requirements.
- Retain a quality system expert to inspect the Covered Respiroics Facilities: processes and methods, 483 observations, MDR governance, C&R reporting, design, CAPAs etc.
- Provide the FDA a certification from retained expert that Covered Respiroics Facilities are complying.

What is the financial impact of the consent decree?

As reported on January 29, 2024, 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 Respiroics sales in the US.

The previously stated 2023-2025 Group financial outlook of mid-single-digit comparable sales growth, low-teens Adjusted EBITA margin, and EUR 1.4-1.6 billion free cash flow now takes the consent decree into account and remains unchanged.

Are Patient Interfaces (Masks) subject to profit disgorgement obligation for sales in the US?

Sales of masks and other consumables and accessories in the US are allowed under a separate exemption specific to those items, which does not have a disgorgement requirement.



Resolution of economic loss, personal injury and medical monitoring litigation in the US

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

Philips and plaintiffs' leadership, through a Court-appointed mediator, have reached an agreement to resolve the personal injury litigation and the medical monitoring class action to end the uncertainty associated with litigation in the US. Philips and Philips Respironics do not admit any fault or liability, or that any injuries were caused by Respironics' devices.

The settlement addresses the claims filed in the US courts and potential claims submitted to the census registry. Under the settlement, Philips Respironics has agreed to pay a capped amount of USD 1.1 billion (EUR 982 million), for which a provision was recorded in Q1 2024. The related payments are expected in 2025 and to be funded from Philips' cash flow generation.

In addition, Philips Respironics also obtained the final court approval for the previously announced economic loss settlement in the US on April 25, 2024, for which a provision was recognized in Q1 2023. The settlement does not include or constitute any admission of liability, wrongdoing, or fault by any of the Philips parties.

How many patients and which injuries are eligible for the personal injury and medical monitoring settlement?

Philips and plaintiffs' leadership, through a Court-appointed mediator, have reached an agreement to resolve the personal injury litigation and the medical monitoring class action in the US addressing ~58,000 individuals who filed a claim or who entered the census registry.

Plaintiffs' leadership and the Settlement Administrator are responsible for allocation of the amount to claimants they deem eligible. Philips is not endorsing any particular injury or injury value.

Philips and Philips Respironics do not admit fault, liability, or that any injuries were caused by the devices.

Is the settlement amount for the personal injury litigation and medical monitoring class action of USD 1.1 billion subject to change depending on number of participants?

No, the total amount of USD 1.1 billion Philips Respironics has agreed to pay is capped regardless of number of participants.

Does the settlement conclude the MDL?

Plaintiffs' leadership will discontinue remaining claims in the Multidistrict Litigation (MDL), and Census registry will be terminated.

For any individuals who still wish to continue to pursue litigation, Plaintiffs' leadership and Philips Respironics will jointly seek a case management (so called Lone Pine Order), which requires claims to come forward with prima facie injury, exposure, and causation evidence, or else face dismissal.

What happens if claims surface after the six-month period?

Philips and Plaintiffs' leadership are confident that the vast majority of potential claimants have already submitted a claim or entered the census registry given Recall was initiated almost three years ago followed by extensive advertising, MDL was formed almost three years ago and Census registry has been active since September 2022, with volumes stable in recent months.



PHILIPS

New claims that surface after six months from the date of the settlement:

- Will also be subject to Lone Pine order
- Will have to prepare their own experts reports as those have not been filed and will not be exchanged, submitted to the Court, finalized or made public
- May be time barred as statute of limitation is which on average is 2-3 years after recall was initiated (in Jun-21) or from the date an injury allegedly connected to the devices manifests itself (while PE-PUR foam has been used since 2008)

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

