Philips Respironics CPAP, BiPAP, and Ventilator Recall: Frequently Asked Questions

Philips Respironics has voluntarily recalled certain ventilators, bi-level positive airway pressure (also known as Bilevel PAP, BiPAP, or BPAP), and continuous positive airway pressure (CPAP) machines due to potential health risks. The polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may break down and potentially enter the device's air pathway. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device. On June 30, 2021, the FDA issued a safety communication: Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks (/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks).

The FDA has heard from many of the people using these affected devices. We recognize the seriousness and scope of their concerns. The FDA is continuing to work with Philips Respironics to assure that the company provides sufficient evidence to show the safety and effectiveness of its proposed actions to correct the product defect.

This page provides answers to frequently asked questions related to this recall.

Q: When will the devices start to be repaired or replaced? (New 9/10/21)

A: Philips Respironics announced (https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210901-philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-in-relation-to-earlier-announced-recall-notification.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on September 1, 2021, "Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has already started replacing certain affected first-generation DreamStation CPAP devices in the U.S. with DreamStation 2 CPAP devices" and "intends to complete the repair and replacement programs within approximately 12 months."

Q: What is the status of Philips Respironics' plans for repairing or replacing the devices? (New 9/10/21)

Philips Respironics' implementation of a plan to fix the problems with the Philips Respironics products is a high priority for the FDA. The FDA reviewed and concurred with Philips' Respironics plan for recalled DreamStation CPAP and BiPAP machines, specifically DreamStation CPAP; Pro, Auto (All Configurations), Dream Station BiPAP; Pro, Auto (All Configurations) and DreamStation ST, ASV, AVAPS (All Configurations).

The FDA is committed to using every tool at our disposal to increase the availability of these medical products. The FDA is working with Philips Respironics to monitor the repair or replacement of impacted devices as expeditiously as possible and is continuing to gather information to inform our actions. We are collaborating with other manufacturers and government partners to support availability of CPAP and BiPAP machines.

Philips Respironics has not yet provided the FDA with all the information needed for the FDA to evaluate the plan to repair and replace products across all the Philips Respironics' recalled devices, including the Trilogy ventilators, A-series BiPAP machines, C-series BiPAP machines, OmniLab Advanced+, Garbin Plus, Aeris, LifeVen, E30 ventilator, REMstar SE Auto, and E30.

The FDA has also initiated on-site inspections of Philips Respironics' manufacturing facilities to assess compliance with regulatory requirements.

Q: Can Philips Respironics face any kind of fines or enforcement action by the FDA over its handling of this recall? (New 9/10/21)

A: If a firm's voluntary action is not rapid or complete, the FDA has the option to take enforcement action. The FDA has identified this as a Class I recall, the most serious type of recall, and the FDA will continue to work with the company to ensure that they provide sufficient evidence demonstrating the safety and effectiveness of its proposed actions to correct the product defect.

The FDA has also initiated on-site inspections of Philips Respironics' manufacturing facilities to assess compliance with regulatory requirements.

Q: Are the product codes for CPAP and BiPAP machines on the FDA's device shortage list? (New 9/10/21)

A: Yes, all the product codes under which CPAP and BiPaP machines are classified are on the device shortage list (/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency) due to device availability issues. These include product codes BZD, NOU, CBK, MNT, and MNS. The majority of these devices are classified under product code BZD.

In determining whether a medical device is in shortage, the FDA considers the entirety of relevant and reliable information and data available to the FDA at the time of a decision.

Q: What medical devices are recalled? (New 9/10/21)

A: Philips Respironics announced recalls of their medical devices due to risk of exposure to debris and chemicals and potential health risks from PE-PUR sound abatement. The recalled devices are identified in Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication (/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks).

In addition to these recalls, Philips Respironics also recalled other ventilators, which the FDA identified as a Class 1 recall but is not related to the sound abatement PE-PUR foam issue: Philips Respironics Recalls V60 and V60 Plus Ventilators Equipped with High Flow Therapy Software Versions 3.00 and 3.10 Due to Risk of Receiving Reduced Oxygen (/medical-devices/medical-device-recalls/philips-respironics-recalls-v60-and-v60-plus-ventilators-equipped-high-flow-therapy-software).

Q: I use one of the affected devices daily. I can't wait for a new device. What can I do now? (Updated 9/10/21)

A: First, confirm if your device is included in the recall. Philips Respironics has listed all affected models (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and provides instructions on how to identify if your device is included in the recall.
Philips Respironics has established a registration process that allows you to look up your device serial number and begin a claim if your unit is affected.

- Register online (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) with Philips Respironics
- Register with Philips Respironics by phone at 877-907-7508 (Spanish translation available)

If you do not find your device on the list, consult with your prescriber or the Durable Medical Equipment supplier where you purchased the device for verification.

The FDA provided recommendations for people who use an affected device in its safety communication, Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks (/medical-devices/safety-communications/certain-philips-

respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks)., including that you **may continue to use your affected device** if your health care provider determines that the benefits outweigh the risks identified in the recall notification.

Additional consumer information on obstructive sleep apnea treatment options is available at the FDA's consumer update: Always Tired? You May Have Sleep Apnea (/consumers/consumer-updates/always-tired-you-may-have-sleep-apnea).

Additionally, the FDA is engaging professional societies and patient advocacy groups to help connect sleep and dental professionals and patients with information regarding alternative treatment options for obstructive sleep apnea.

Q: When a medical device is recalled, what is the FDA's role? (Updated 9/10/21)

A: The mission of the FDA's Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. When a medical device is recalled, the FDA evaluates the health hazard presented by the product issue and determines if the device is in violation of the Federal Food, Drug, and Cosmetic Act or otherwise fails to comply with FDA requirements. The FDA assigns the recall a classification (I, II, or III) to indicate the relative degree of risk (class I is the most serious). After the recall is classified, the FDA monitors the recall to ensure the recall strategy is effective and has been implemented.

When the FDA learns of a company's decision to recall a device, the FDA reviews the adequacy of the firm's proposed recall strategy and recommends changes as appropriate. After the recall is implemented by the firm, the FDA monitors the recall to ensure that the recall strategy is effective and has been implemented.

Q: What is the FDA's role in the Philips Respironics recall? (New 9/10/21)

A: The FDA has classified the Philips Respironics recall (/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks) as a Class I recall, the most serious type of recall. Class I recalls present a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

The FDA reviewed and concurred with Philips' Respironics plan to rework the recalled DreamStation CPAP and BiPAP machines.

The FDA is committed to using every tool at our disposal to increase the availability of these medical products. The FDA is working with Philips Respironics to monitor the repair or replacement of impacted devices as expeditiously as possible and is continuing to gather information to inform our actions. We are collaborating with other manufacturers and government partners to support availability of CPAP and BiPAP machines.

In addition, the FDA has initiated on-site inspections of Philips Respironics' manufacturing facilities to assess compliance with regulatory requirements.

The FDA will continue to monitor the company's recall until Philips Respironics has met all requirements associated with a Class I recall and all recalled devices are repaired or replaced with safe and effective devices.

Q: Philips Respironics has stated they "will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances." Is the FDA reviewing Philips Respironics new submission? (Updated 9/10/21)

A: As the medical device manufacturer, Philips Respironics has a responsibility to ensure the manufacture of safe and effective devices and to establish an appropriate mitigation plan to reduce public harm in the event of device failure or defect.

The FDA reviewed and concurred with Philips' Respironics plan to rework the recalled DreamStation CPAP and BiPAP machines. The FDA is reviewing the information Philips Respironics has provided regarding replacement devices while continuing to work with Philips Respironics on their corrective actions for recalled devices. As the FDA reviews this information, the FDA will determine whether the devices pose any additional risk to people who use them.

Q: I understand the sound abatement foam may be causing the problems related to the recall. Should I try and remove the foam from my device? (Updated 9/10/21)

A: No. The FDA recommends you do not attempt to remove the sound abatement foam, as it may impact device performance and possibly introduce additional foam debris into the device air pathways. Philips Respironics is directly responsible for repair and replacement of all recall affected devices.

Q: Who is responsible for correcting the issue with the affected Philips Respironics devices? (Updated 9/10/21)

A: The recalling firm, Philips Respironics, is fully responsible for correcting the issue and developing a recall strategy that takes into account the following factors as they apply to this particular recall:

- Results of health hazard evaluation.
- Ease in identifying the product.
- Proactively identifying customers affected by the recall.
- Quantity of the available product that is not in use.
- Continued availability of essential products.

Q: What else can the FDA require Philips Respironics to do to correct the affected devices? (Updated 9/10/21)

A: The FDA can use advisory actions, administrative actions, and enforcement actions when a firm's voluntary action is not rapid or complete, or when the firm is uncooperative.

The FDA has initiated on-site inspections of Philips Respironics' manufacturing facilities to assess compliance with regulatory requirements.

Q: Do I need to register my device with Philips Respironics? (New 9/10/21)

A: Yes. Registering your device on Philips Respironics' recall website (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) will allow the firm to keep you informed of updates from Philips Respironics about any new instructions or other corrective actions.

Q: I have registered my recalled device on the Philips Respironics website. What should I expect now? (Updated 9/10/21)

A: Philips Respironics should keep you informed of their progress in addressing the issue and alert you to any actions that you may need to take. The FDA will continue to share updates with the public as new information becomes available.

Q: What should I do if I am unable to register my device on Philips Respironics' website?

A: For more information or help with the registration (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) process, call Philips Respironics at 877-907-7508, as indicated on their website. The website provides you the instructions on how to locate your device Serial Number for the registration.

Q: Can I be reimbursed for the cost of a replacement device? (Updated 9/10/21)

A: Philips Respironics announced (https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210901-philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-in-relation-to-earlier-announced-recall-notification.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on September 1, 2021, "Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has already started replacing certain affected first-generation DreamStation CPAP devices in the U.S. with DreamStation 2 CPAP devices" and "intends to complete the repair and replacement programs within approximately 12 months."

Contact Philips Respironics (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) at 877-907-7508 for more information.

Q: If I obtain a new CPAP machine, what should I do with my recalled device?

A: Contact Philips Respironics (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) or your health care provider for information on your local Philips Respironics representative to receive instructions and directions on how to return your recalled device(s). Do not discard or recycle the recalled device.

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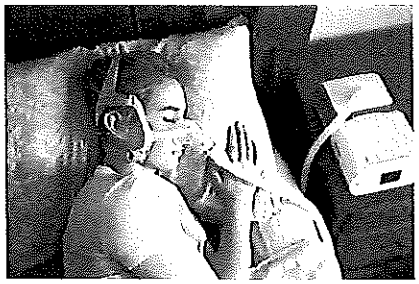
New Orleans Philips DreamStation CPAP Lawyer

Philips has manufactured, marketed, and sold the DreamStation and similar CPAP, BiPap, and ·tor units using a defective sound abatement foam since 2009. Recent studies have

First Name *

shown that foam degradation has led to a variety of negative health side effects in users of Philips devices.



What is a Philips CPAP Machine?

CPAP is an acronym that stands for Continuous Positive Airway Pressure. First designed in 1980, CPAP devices are primarily designed to assist sufferers of sleep apnea. By sending a steady flow of oxygen to the mouth and nose of a sleeping user, the device can keep airways open thereby keeping the user breathing normally. These are slightly different than Bi-Pap machine, which have two pressure settings, and ventilators, which are a wider range of assisted breathing devices.

Has there been a recall on Philips CPAP devices?

Yes. In June of 2021, Philips recalled certain Respironics ventilators, BiPAP, and CPAP machines. The FDA has also issued a safety communication (https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks) with more information regarding the specific devices recalled.

While more recalls may occur, below is a list of recalled CPAP, BiPAP, and ventilator r nes.

Last Name *

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Description *

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What issues does the Philip CPAP cause?

While the individual cases can vary, patients with Philips CPAP devices have a wide variety of potential risks due to foam degradation. Beyond potential inhalation or swallowing of PE-PUR foam present in the devices, foam degradation can also lead to "outgassing." This means the foam breakdown can result in the release of toxic gasses, which can cause many other issues if inhaled. Examples include:

- Various cancers
- Respiratory distress or failure
- Heart attack
- Chemical burns
- Brain damage
- Cellular damage to DNA

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What kind of cancers is breathing Polyurethane foam associated with?

Unfortunately, there are a variety of cancers that are tied to the breathing of vapors released through polyurethane foam degradation, including:

- Stomach Cancer
- Testicular Cancer
- Thyroid Cancer
- Acute Respiratory Distress System (ARDS)
- Bladder Cancer
- Brain Cancer
- Breast Cancer
- Hematopoietic Cancer
- Kidney Cancer
- Leukemia
- Liver Cancer
- Liver Damage
- Lung Cancer
- Rectal Cancer
- Lymphatic Cancer
- Multiple Myeloma
- Nasal Cancer
- Non-Hodgkin Lymphoma
- Papillary Carcinoma
- Prostate Cancer

How many Philips CPAP devices have been recalled?

It is now estimated that 2 million to 3 million different Philips CPAP, Bi-PAP, and other ventilation devices have now been recalled. It is estimated that nearly two-thirds of these devices have been sold within the United States.

Have you been using a Philips CPAP or BiPAP device?

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Patients who have been using a CPAP or BiPAP device from Philips have been advised by the company to discontinue use immediately and talk to their doctors regarding a safer alternative. However, those using life-sustaining devices should first consult with their physician regarding the risks and to determine what steps they should take next.

If you or a loved one has experienced complications after Philips CPAP, BiPap, or other ventilator use, you may be eligible to file a claim for medical costs, emotional distress (https://www.morrisbart.com/blog/emotional-distress/) and further damages. As more and more negative health side effects of these devices are emerging, we recommend speaking to an experienced Philips CPAP attorney. To learn more, fill out our free case evaluation form or call us at (800) 537-8185 (tel:8005378185) for your free consultation. The experienced mass tort attorneys at Morris Bart can assist you in the evaluation process. Click here (https://www.morrisbart.com/locations/new-orleans-la/dangerous-drugs-lawyer/) to see more about our office locations throughout Louisiana, Mississippi, Alabama, and Arkansas. Contact us (https://www.morrisbart.com/contact/) today!

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