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

Philips Respironics has voluntarily recalled certain ventilators, BiPAP, and 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 understands the concerns from people using these affected devices. 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: I use one of the affected devices daily. I can't wait for a new device. What can I do now?

A: The FDA has 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.

You may also read the FDA's consumer update, Always Tired? You May Have Sleep Apnea (/consumers/consumer-updates/always-tired-you-may-have-sleep-apnea), which includes updates on obstructive sleep apnea treatments.

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?

A: When the FDA learns of a company's correction or removal action, it reviews the strategy the company proposes to address the problem, assesses the health hazard presented by the product, determines if the problem is in violation of the Federal Food, Drug, and Cosmetic Act or otherwise fails to comply with FDA requirements, and, if appropriate, assigns the recall a classification (I, II, or III) to indicate the relative degree of risk. After the recall is classified, the FDA monitors the recall to ensure that the recall strategy has been effective.

For the Philips Respironics recall, the FDA has identified this as a Class I recall (/medical-devices/medical-device-recalls/2021-medical-device-recalls), the most serious type of recall, and is continuing to work with the company to assure it has sufficient evidence to support the Philips Respironics recall strategy, including its corrective actions. The FDA will continue to monitor the company's recall.

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 submission for clearance of the new foam?

A: As the medical device manufacturer, Philips Respironics has a responsibility not only to ensure the manufacture of safe and effective devices, but also to establish an appropriate mitigation strategy to reduce public harm in the event of device failure or defect.

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 existing devices. As the FDA reviews this information, the FDA will determine whether the proposed replacement devices pose any additional risk to people who use these devices.

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?

A: No. The FDA recommends that you do not remove the sound abatement foam, as it may impact device performance and possibly introduce foam debris into the device.

Q: Who is responsible for correcting the issue with the affected Philips Respironics devices?

A: The recalling firm, Philips Respironics, is 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.
- Degree to which the product's deficiency is obvious to the consumer or user.

- Degree to which the product remains unused in the marketplace.
- Continued availability of essential products.

The FDA is reviewing the adequacy of Philips Respironics' proposed recall strategy as it becomes available from Philips and is recommending changes as appropriate.

Q: What else can the FDA require Philips Respironics to do to correct the affected devices?

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.

Q: Should I expect any notification from Philips Respironics?

A: The FDA recommends you register 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) to stay informed of updates from Philips Respironics about any new instructions or other corrective actions required by the FDA.

Q: I have registered my recalled device on Philips' website. What should I expect now?

A: The FDA is working with Philips Respironics to assure the company sufficiently evaluates the device problems, the scope of the recall, and the most appropriate mitigation strategies, including adequate corrective actions by the company. 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 Philip's 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, please 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?

A: Please contact Philips Respironics (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) as indicated on their website.

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.