FAQs on Philips Respironics Ventilator, BiPAP Machine, and CPAP Machine Recalls

UPDATE – February 9, 2023: The FDA updated this safety communication to provide updated information about medical device reports (MDRs) (https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due#mdr) that the FDA received from November 1, 2022, to December 31, 2022, and are reportedly associated with the breakdown or suspected breakdown of the polyester-based polyurethane (PE-PUR) foam used in the Philips Respironics ventilators, BiPAP machines, and CPAP machines included in the recall announced in June 2021.

UPDATE - December 22, 2022: The FDA issued a safety communication to provide additional information to patients, caregivers, and health care providers about two recent issues in certain reworked Philips Respironics (Philips) Trilogy 100 and Trilogy 200 ventilators. Read more in the safety communication for Certain Reworked Philips Respironics Trilogy 100/200 Ventilators Recalled Due to Potential for Silicone Foam Adhesion Failure and Residual PE-PUR Foam Debris (/medical-devices/safety-communications/certain-reworked-philips-respironics-trilogy-100200-ventilators-recalled-due-potential-silicone-foam).

Philips Respironics (Philips) voluntarily recalled (/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks) certain ventilators, bi-level positive airway pressure (also known as Bilevel PAP, BiPAP, or BPAP) machines, and continuous positive airway pressure (CPAP) machines in June 2021 due to potential health risks. The polyester-based polyurethane (PE-PUR) foam used in these medical devices to lessen sound and vibration can break down. If the foam breaks down, black pieces of foam, or certain chemicals that are not visible, could be breathed in or swallowed by the person using the device.

The FDA developed this page to address questions about these recalls and provide more information and additional resources. The FDA recognizes that many patients have questions about what this information means for the status of their devices. The FDA has worked with patients and health care professional organizations, including the American Sleep Apnea Association, the COPD (chronic obstructive pulmonary disease) Foundation, the Muscular

Dystrophy Association, the Mended Hearts, Inc., American College of Chest Physicians, American Thoracic Society, and the American Academy of Sleep Medicine, and has included this feedback in these FAQs.

On this page:

Related FDA pages:

- FDA Safety Communication: Update: Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due) (November 2021)

How to Tell if Your Device Has Been Recalled and What to Do Next

1. Read the FDA's recommendations for using the following types of devices:
    - Ventilators (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due)
    - BiPAP or CPAP Machines (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due)
2. Talk to your health care provider to decide whether it is better to stop using your device, use other treatments, or continue using your recalled device while waiting for a replacement or repair.
3. Watch the short video (https://www.youtube.com/watch?app=desktop&v=_SR-vXWQEFw&feature=youtu.be) (http://www.fda.gov/about-fda/website-

policies/website-disclaimer) for an overview of how to tell if your device has been recalled, how to register with Philips, and what to expect after registration.

4. Find your device's serial number.
    - See How to Locate the Serial Number on your device (https://www.philipssrcupdate.expertinquiry.com/locate-serial-number?ulang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on the Philips website.
    - Entering your device's serial number during registration will tell you if it is one of the recalled models (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
5. Register your device.
    - Go to Urgent: Field Safety Notification (https://www.philipssrcupdate.expertinquiry.com/?ulang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on the Philips website and begin the registration at the bottom of the page (Iniciar proceso de registro para espanol (https://www.philipssrcupdate.expertinquiry.com/?ulang=es) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)). After you enter your device's serial number during registration, the site will tell you if it is one of the recalled models (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
    - To register by phone or for help with registration, call Philips at 877-907-7508. For Spanish translation, press 2; Para español, oprima 2.
6. Keep your registration confirmation number.
    - After you finish registering, **the Philips website will display your registration confirmation number. It's important to keep your registration confirmation number and serial number** where you can easily find them because Philips will ask for both in future communications. Registering your device will also give Philips your contact information for future communication.
7. If you want to be considered for **prioritized replacement** of your device, you may update your existing registration on the Philips patient portal (https://www.philipspatientportal.expertinquiry.com/?ulang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and provide additional information. You may visit the online patient portal and update your

information even if you did not receive an email notification from Philips. If you do not provide the additional requested information, you will receive a replacement device based on when you registered.

8. You may check the status (https://www.philipspatientportal.expertinquiry.com/?ulang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) of your replacement device on the Philips' patient portal.
9. If you have a health issue (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due) or have any problem with your device, talk to your health care provider and report the problem through the FDA's MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

If you do not find your device on the list of recalled models (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) **or during registration:** You may want to contact the medical equipment supplier (commonly known as a Durable Medical Equipment (DME) supplier) who gave you your device. The DME supplier can check to see if your device has been recalled.

What the Health Risks Are

Breathing in chemicals or swallowing small pieces of foam that has broken apart could potentially result in serious injury, cause permanent impairment, and require medical intervention to prevent permanent injury.

The potential health risks from the foam (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health#risk) are described in the FDA's safety communication (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due).

How to Know if You Should Stop Using Your Device

To decide on the next steps, discuss the benefits and risks based on your individual health situation with your health care provider, such as your primary care physician or sleep doctor.

For some patients, stopping use of the recalled or repaired device may involve greater risk than continuing its use. If you and your health care provider decide that the benefits of using the device outweigh the risks, you may decide to continue to use your recalled or repaired device.

Philips has not yet provided the FDA with all information we requested to evaluate the risks from the chemicals released from the foam, though they have posted Clinical information for physicians (https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-corporate/philips-clinical-information-for-physicians-and-providers.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on their website.

What to Do with Your Device: Cleaners, Filters, Foam, Returns

Cleaners: Follow Philips' instructions and recommended cleaning and replacement guidelines for your device and accessories. Do **not** use ozone or ultraviolet (UV) light cleaners. Ozone cleaners may worsen the breakdown of the foam, even if you do not see pieces of the foam in the air tubes. There may be other risks with the use of ozone and ultraviolet (UV) light products for cleaning CPAP machines and accessories. See Potential Risks Associated With The Use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories (https://public4.pagefreezer.com/browse/FDA/08-02-2023T11:48/https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Filters:

- **Ventilators:** At this time, the information provided by Philips has not established that the filters can reduce the PE-PUR foam's risks. The FDA's evaluation of the information provided by Philips is ongoing, as noted in the FDA's safety communication (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due).
- **BiPAP and CPAP machines:** Do **not** add a filter to your CPAP or BiPAP machine. A filter may change how the device works and will not help to lessen contact with certain chemicals that may come off the foam.

Foam: Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.

Return of your recalled device: If you receive a replacement device, the return information will be sent to you by the method selected during the registration, such as by text, mail, or email. If you no longer use your recalled device, return it to Philips by contacting Philips (https://www.usa.philips.com/c-w/support-home/support-contact-page#n62Contact=PERSONALHEALTH_GR%2BHH_RESPIRATORY_CARE_CA)

(http://www.fda.gov/about-fda/website-policies/website-disclaimer), your local Philips representative, durable medical equipment (DME) supplier, or pharmacy for instructions and directions on how to return your recalled device.

What the FDA is Doing

The FDA is committed to assuring that Philips takes appropriate steps to correct the devices, working with other manufacturers and government partners to try to help make available more CPAP and BiPAP machines, and addressing concerns and questions raised by patients and health care providers about device replacement. We will keep the public informed as more information becomes available.

Medical Device Reports

On February 9, 2023, the FDA provided an update on the medical device reports (MDRs) received (https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due#mdr) by the FDA. The FDA continues to review and assess MDRs and will keep the public informed as new information becomes available. See the FDA Safety Communication (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due) for more information.

Proposal to Issue an Order for Device Repair, Replacement, or Refund

On May 2, 2022, the FDA's Center for Devices and Radiological Health (CDRH) sent notice (/media/158129/download) to Philips that CDRH is proposing that an order should be issued, under section 518(b) of the Federal Food, Drug, and Cosmetic Act [a 518(b) order], to require Philips to submit a plan for the repair, replacement, or refund of the purchase price of recalled devices manufactured after November 2015. Philips was provided an opportunity for an informal hearing before the FDA determines whether to issue an order requiring Philips to submit a plan for the repair, replacement, or refund of the purchase price (less a reasonable allowance for use if the device has been in possession of the user for one year or more). Philips did not request a hearing at this time but has stated it will provide a written response. CDRH will consider the response when it is received.

Prioritizing Replacement Devices

On March 14, 2022, the FDA updated these FAQs to include information about Philips' prioritization strategy (/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls#recall) for replacement devices. The FDA

recommended, and Philips has agreed, to implement a prioritization approach that ensures patients who are most vulnerable to poor health care outcomes with continued use or ceasing use of the Recalled Products receive replacement devices as quickly as possible.

Issuance of a Notification Order

On March 10, 2022, the FDA issued a notification order (/news-events/press-announcements/fda-orders-philips-respironics-notify-patients-regarding-recall-certain-breathing-assistance) under section 518(a) (/medical-devices/regulatory-controls/general-controls-medical-devices#notification_and_other_remedies) of the Federal Food, Drug, and Cosmetic Act [a 518(a) order] to Philips requiring the company to notify patients and others of the company's June 14, 2021, recall and the unreasonable risk of substantial harm to the public health posed by the degradation of the PE-PUR sound abatement foam used in the recalled products because the company's notification efforts to date have been inadequate.

Update to the Recall of Certain Ventilators

In December 2021, Philips initiated the recall of certain Trilogy EVO Ventilators for potential health risks from PE-PUR foam (/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-trilogy-evo-ventilators-potential-health-risks-pe-pur-foam). The FDA classified the recall of certain Trilogy Evo ventilators as a Class I recall, the most serious type of recall.

As noted in the FDA inspectional observations in November 2021, an incorrect and non-specified polyester polyurethane, raw foam product, not intended for use in Trilogy Evo ventilators, was used to manufacture certain Trilogy Evo ventilators. The foam was determined to be PE-PUR foam, the same type of foam used in Philips' devices previously recalled in June 2021.

Manufacturing Facility Inspection

- The FDA conducted an inspection (/news-events/press-announcements/fda-provides-update-recall-certain-philips-respironics-breathing-assistance-machines) of a Philips' manufacturing facility in Murrysville, PA, from August-November 2021. The FDA provided the inspectional observations (/news-events/press-announcements/fda-provides-update-recall-certain-philips-respironics-breathing-assistance-machines) to Philips and posted to the public FDA.gov website.
- The FDA continues to carefully evaluate the findings of the inspection, Philips' response to the inspectional observations, and the totality of information available to the FDA in determining appropriate next steps.

Silicone-Based Foam Independent Testing

- During the manufacturing facility inspection, the FDA obtained information, not previously available to the agency, regarding the silicone-based foam used in a similar device marketed outside the U.S., which failed one safety test for the release of certain chemicals of concern, called volatile organic compounds (VOCs). Similar testing provided by Philips to the FDA on devices authorized for marketing in the U.S. had demonstrated acceptable results. The FDA is aware that patients have already received devices with silicone-based foam as part of the repair and replace program.
- The FDA requested that Philips retain an independent laboratory to perform additional testing of the silicone-based foam (/news-events/press-announcements/fda-provides-update-recall-certain-philips-respironics-breathing-assistance-machines) to determine what, if any, potential safety risks are posed to patients by the silicone-based foam.

  While this independent testing is performed, the FDA recommends patients who use a repaired or replaced device continue use of their product. The FDA has reached this determination based on an overall benefit-risk assessment. At this time, the agency has determined that discontinuing use of one of these devices may be more harmful to a patient's health and quality of life. The results from the independent testing are needed to determine if the silicone-based foam used in the repaired devices does in fact present any risks to patients, and the FDA will communicate those results to the public as soon as they are available.

Class I Recall

The FDA classified the June 2021 Philips recall (/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks) of certain ventilators, BIPAP machines, and CPAP machines as a Class I recall, the most serious type of recall. Class I recalls (/medical-devices/medical-device-recalls/what-medical-device-recall) involve a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. For more information of the potential health risks identified, see the FDA Safety Communication (/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due).

The FDA continues to:

- Monitor Philips' actions related to the repair or replacement of impacted devices until Philips has met all requirements related to the conduct of their Class I recall and the Medical Device Quality System regulation.

- Work with consumers, patient organizations, and health care professional societies to understand and address common questions and concerns related to this recall.
- Work with other manufacturers and government partners to try to help make available more BiPAP and CPAP machines.
- Carefully evaluate the totality of information available to the FDA in determining appropriate next steps.

In general, when the FDA finds out about a company's voluntary recall, the FDA will follow the process outlined in the What Is a Medical Device Recall (/medical-devices/medical-device-recalls/what-medical-device-recall) web page.

What Philips is Required to Do

Because the FDA issued a notification order (/news-events/press-announcements/fda-orders-philips-respironics-notify-patients-regarding-recall-certain-breathing-assistance) under section 518(a) of the Federal Food, Drug, and Cosmetic Act on March 10, 2022, Philips is required to take certain actions related to the June 2021 recall of certain ventilators, BiPAP machines, and CPAP machines (Recalled Products), as follows:

- Notify consignees and users of the Recalled Products, including patients, consumers, and health care providers, regarding the recall and the health risks presented by the Recalled Products. This will allow all end users to make informed decisions regarding the risks of continued use of the Recalled Products while awaiting a replacement device. Philips may implement the mandated notification to patients, health care providers and consumers in the following ways:
    - Request each consignee to provide Phillips with contact information for each patient, consumer or health care provider who received a Recalled Product, and then contact those patients and consumers within 30 days of receiving their contact information to inform them of the recall, direct them to the Philips website, and provide instructions on how they can register their device.
    - In the alternative, obtain from each consignee documentation confirming that the consignee has provided, within 30 days of receiving Philips' notification, each patient, consumer or health care provider who received a Recalled Product with the Philips notification that informs them of the recall, directs them to Philips' website, and provides instruction on how they can register their device.
- Maintain prominently displayed information on the risk of using ozone cleaners on the Recalled Products on the Philips Recall main landing page.
- Provide a link for health care providers and registrants to access all available testing results and third party confirmed conclusions on results and findings from testing PE-

PUR foam used in devices manufactured by Philips for VOCs and particulates, regardless of the Philips device that the foam may have been tested in. The information currently available on Philips' website is vague, and does not provide health care providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients.

- Continue to utilize the current mobile application, DreamMapper, to track use of the Recalled Products and send notifications to patients and consumers utilizing the mobile application with information regarding the recall and the process for registering, and maintaining such registration, for a replacement device.

In addition, Philips, as a medical device manufacturer, must comply with all applicable laws and regulations, including quality system regulations (21 CFR Part 820).

As part of the voluntary recall, Philips is responsible for addressing the problems with the recalled devices and creating a recall strategy that includes:

- Considering the results of the health hazard evaluation (/about-fda/cdrh-transparency/health-hazard-evaluations-hhes-and-health-risk-assessments-hras) to reduce the health risks to people using the recalled devices.
- Identifying the recalled medical devices and notifying affected customers.
- Determining the number of devices in use and in distribution.
- Creating a plan to repair or replace recalled devices.
- Repairing and replacing the recalled devices.*

* Philips has not yet provided the FDA with all the information needed for the FDA to evaluate the plan to repair and replace all recalled Philips devices, including the:

- A-series BiPAP machines
- DreamStation Go
- OmniLab Advanced+
- REMstar SE Auto

Philips' Recalls Not Associated with the Foam Issue

Philips has voluntarily recalled certain devices for issues **not associated with** the PE-PUR foam, including:

- September 2022: Philips Respironics Recalls Certain Masks for BiPAP, CPAP Machines Due to Safety Issue with Magnets That May Affect Certain Medical Devices (/medical-

devices/medical-device-recalls/philips-respironics-recalls-certain-masks-bipap-cpap-machines-due-safety-issue-magnets-may-affect)

- September 2022: Philips Respironics Recalls Certain BiPAP Machines for Plastic Issue that May Expose Patients to Certain Chemicals of Concern (/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-bipap-machines-plastic-issue-may-expose-patients-certain)
- March 2022: Philips Respironics Recalls All V60 and V60 Plus Ventilators for Power Issue that May Cause Ventilator to Stop with or without Alarms (/medical-devices/medical-device-recalls/philips-respironics-recalls-all-v60-and-v60-plus-ventilators-power-issue-may-cause-ventilator-stop)
- January 2022: Philips Respironics Recalls V60 and V60 Plus Ventilators for Expired Adhesive that May Cause Ventilator to Stop Working With or Without an Alarm (/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-v60-and-v60-plus-ventilators-expired-adhesive-may-cause)
- June 2021: 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)

The FDA has classified these recalls as Class I, the most serious type of recall. We recognize that patients rely on these devices, and we are closely monitoring the company's actions to ensure that the issues are resolved in a timely manner given the impact on patients. We continue to work with Philips to ensure that the company takes appropriate steps to correct the products.

How to Report a Health Issue or Problem to the FDA

If you have a health issue and are using or have used a recalled or replaced device or have any problem with your device, talk to your health care provider and report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Questions?

For more information on the company's recall notification, contact your local Philips representative or visit Philips' medical device recall information page (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

More information on medical device recalls, including What is a Medical Device Recall (/medical-devices/medical-device-recalls/what-medical-device-recall), is available on FDA.gov.