Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is alerting people who use Philips Respironics ventilators, BiPAP, and CPAP machines and their health care providers that Philips Respironics has recalled certain devices (see table below) 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.

If you use one of these affected devices (see table below), talk to your health care provider to decide on a suitable treatment for your condition and follow the recommendations listed below.

Philips Respironics is recalling the following affected devices manufactured between 2009 and April 26, 2021. For details, see Philips' Respironics recall notification (https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (PDF).

CPAP and BiPAP Devices

Device Type	Model Name and Number (All Serial Numbers)
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	• E30 (Emergency Use Authorization) (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas)
Continuous Ventilator, Non-life Supporting	• DreamStation ASV • DreamStation ST, AVAPS • SystemOne ASV4 • C-Series ASV • C-Series S/T and AVAPS • OmniLab Advanced+

Device Type	Model Name and Number (All Serial Numbers)
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	• E30 (Emergency Use Authorization) (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas)
Noncontinuous Ventilator	• SystemOne (Q-Series) • DreamStation • DreamStation Go • Dorma 400 • Dorma 500 • REMstar SE Auto

Ventilators

Device Type	Model Name and Number (All Serial Numbers)
Continuous Ventilator	• Trilogy 100 • Trilogy 200 • Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	• A-Series BiPAP Hybrid A30 (not marketed in US) • A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	• A-Series BiPAP A40 • A-Series BiPAP A30

BiPap or CPAP: Recommendations for People Who Use Affected BiPAP or CPAP Machines and Caregivers

- Talk to your health care provider to decide on a suitable treatment for your condition, which may include:
    - Stopping use of your device
    - Using another similar device that is not part of the recall
    - Using alternative treatments for sleep apnea, such as positional therapy or oral appliances, which fit like a sports mouth guard or an orthodontic retainer.

- Initiating long term therapies for sleep apnea, such as losing weight, avoiding alcohol, stopping smoking, or, for moderate to severe sleep apnea, considering surgical options.
- Continuing to use your affected device, if your health care provider determines that the benefits outweigh the risks identified in the recall notification.

- Follow the manufacturer's instructions and recommended cleaning and replacement guidelines for your CPAP machine and accessories. Ozone cleaners may worsen the breakdown of the foam, and there are other potential risks associated with the use of ozone and ultraviolet (UV) light products for cleaning CPAP machines and accessories (/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and).
- Register your device(s) 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 regarding any new instructions or other corrective fixes, which the FDA is requiring.
- Report any problems with a device (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) through the FDA's MedWatch Voluntary Reporting Form.

Ventilators: Recommendations for People Who Use Affected Ventilators At Home and Caregivers

- Do not stop or change ventilator use until you have talked to your health care provider.
  - Alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and in the judgment of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the potential risks identified in the recall notification.
- Talk to your health care provider about using an inline bacterial filter, which may help to filter out particles of foam, as indicated in the Philips recall notification. At this time, the FDA does not have evidence of the safety and effectiveness of a filter for mitigating the foam risks, and the FDA's evaluation is ongoing. It is important to note the following considerations:
  - Filters will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam.
  - Filters may affect ventilator performance because they may increase resistance of air flow through the device.

    - You should closely monitor for possible accumulation of foam debris on the filter or resistance-related problems in the breathing circuit after filter placement.

- Register your device(s) 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).
- Report any problems with a device (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) through the FDA's MedWatch Voluntary Reporting Form.

Recommendations for Health Care Providers and Facilities

- Follow the recommendations above for the affected devices used in health care settings.
- Review the recommendations above with patients who use the affected devices.
- Service affected devices and evaluate for any evidence of foam degradation.
    - If there is evidence of foam degradation, such as black debris in the device, stop use of the device, if possible, and report any problems with a device (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) through the FDA's MedWatch Voluntary Reporting Form.

Description of the Devices

These devices are used to provide breathing assistance. Specifically:

- A bilevel positive airway pressure (also known as **BiPAP**, **BiLevel PAP**, or **BPAP**) machine pumps air under pressure into the airway of the lungs. BiPAP machines have a higher pressure when you breathe in and lower pressure when you breathe out.
- A continuous positive airway pressure (**CPAP**) machine keeps your airway open by providing a continuous stream of air through a mask. CPAP machines are devices prescribed to people with obstructive sleep apnea to keep their airways open during sleep.
- A continuous **ventilator** device is intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas.

PE-PUR Foam May Be Inhaled or Swallowed, Presenting a Potential Health Risk

Polyester-based polyurethane (PE-PUR) is a sound abatement foam used to reduce sound and vibration in these devices and other medical equipment. The PE-PUR foam in the affected Philips Respironics CPAP, BiPAP, and ventilator devices may:

- Break down (degrade) into particles which may enter the device's air pathway and be inhaled or swallowed by the user
- Release certain chemicals into the device's air pathway, which may be inhaled

These issues can result in serious injury, which can be life-threatening, cause permanent impairment, and require medical intervention to prevent permanent damage.

To date, Philips Respironics has received several complaints about the presence of black debris/particles within the device's air pathway. Philips Respironics also has received reports of headache, upper airway irritation, cough, chest pressure, and sinus infection, which may be related to this issue, though the cause of the symptoms cannot be definitively linked.

The potential risks of particulate exposure include irritation to the skin, eye, and respiratory tract, inflammatory response, headache, asthma, and toxic or carcinogenic effects to organs, such as kidneys and liver.

The potential risks of exposure to chemicals released into the device's air pathway from the PE-PUR foam include headache; dizziness; irritation in the eyes, nose, respiratory tract, and skin; hypersensitivity; nausea/vomiting; and toxic and carcinogenic effects.

The foam degradation may be exacerbated by high heat and high humidity environments, and by use of unapproved cleaning methods, such as ozone.

To date, there have been no reports of death as a result of these issues.

FDA Actions

The FDA is working with Philips Respironics to evaluate the issue, the scope of the recall, and the most appropriate mitigation strategies, including corrective actions by the company.

The FDA is analyzing medical device reports (MDRs) related to the affected devices over the period of 2009-2021 for reports that could be related to this issue.

The FDA does not have evidence at this time that any other CPAP machines, BiPAP machines, or ventilators, from Philips or other manufacturers, are affected.

The FDA will continue to monitor supply and demand to assess availability of the affected devices and any potential shortages.

The FDA will continue to share updates with the public as we learn more.

Reporting Problems with Your Device

If you think you had a problem with a CPAP, BiPAP, or mechanical ventilator, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

For more information on the recall notification, contact your local Philips representative or visit Philips Respironics' recall notification web 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.