Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

The recall described in this notice is the same one that was announced in the FDA Safety Communication (/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks) on June 30, 2021.

Recalled Product

- **Continuous Ventilator, Minimum Ventilatory Support, Facility Use: Philips Respironics E30 with Humidifier**
- **Continuous Ventilator, Non-life Supporting devices: DreamStation ASV, DreamStation ST, AVAPS, SystemOne ASV4, C-Series ASV, C-Series S/T and AVAPS, OmniLab Advanced+, and**
- **Noncontinuous Ventilators: SystemOne (Q-Series), DreamStation, DreamStation Go, Dorma 400, Dorma 500, and REMstar SE Auto)**
- **Product codes: BZD and MNS**
- **Manufacturing Dates:** April 11, 2007 to April 22, 2021.
- **Distribution Dates:** July 21, 2009 to April 22, 2021
- **Date Initiated by Firm:** June 14, 2021

Device Use

The Continuous and Non-Continuous Ventilators are used to provide invasive and non-invasive support for people needing respiratory support or treatment for sleep disorders. The type of ventilators used depends on the therapeutic needs of a patient. Depending on the device, the CPAPs, BiPAPs, and ventilators may be used in the home, hospital and other institutional settings. For more information, please see the 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).

Reason for Recall

Philips Respironics, Inc., is recalling its Continuous and Non-Continuous Ventilators due to the polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, which 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. The exposure to debris or chemicals could cause serious adverse events in patients such as irritation (skin, eye, and respiratory tract), inflammation, headache, asthma, hypersensitivity, nausea/vomiting, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects.

There have been more than 1200 complaints and more than 100 injuries reported for this issue.

Who May Be Affected

- People using these devices
- Health care providers
- Durable Medical Equipment (DME) and sleep laboratories

What to Do

On June 14, 2021, Philips Respironics sent customers an "Urgent: Medical Device Recall" letter requesting them to take the following actions:

- Discontinue use of the device and work with a physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.
    - To continue use of the device due to lack of alternatives, consult with a physician to determine if the benefit of continuing therapy with the device outweighs the risks identified in the "Urgent: Medical Device Recall" letter.
- Philips will replace the PE-PUR foam sound abatement component with the new silicone foam sound abatement component in the affected devices to correct in the field.
- Customers and patients should cease the use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods. Customers and patients that do not use unapproved cleaning methods are also at risk of exposure of harmful particulates and chemicals as a result of PE-PUR degradation.
- **Register the device on the recall website www.philips.com/src-updates (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-**

fda/website-policies/website-disclaimer)

- The website provides current information on the status of the recall and how to receive permanent corrective action to address the issues
- The website also provides instructions on how to locate the device Serial Number and will guide people through the registration process.
- **Call 1-877-907-7508** if you cannot visit the website or do not have internet access.

BiPAP and CPAP customers and patients should review the age of their BiPAP and CPAP devices, as they are recommended to be replaced after five years of use.

Consumers and users of the recalled devices to follow the FDA Consumer Update, Always Tired? You May Have Sleep Apnea (/consumers/consumer-updates/always-tired-you-may-have-sleep-apnea), that may assist the conversation between patients and their healthcare providers and/or physicians for alternatives.

The FDA also recommends:

BiPap or CPAP

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).

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.

Contact Information

Customers with questions about this recall should contact Philips' recall support hotline at 1-877-907-7508 or visit the website at www.philips.com/src-update (https://www.usa.philips.com/healthcare/e/sleep/communications/src-update) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Additional Resources:

- Medical Device Recall Database Entry
    - Continuous Ventilator, Non-life Supporting: DreamStation ASV, DreamStation ST, AVAPS, SystemOne ASV4, C-Series ASV, C-Series S/T and AVAPS, OmniLab Advanced+ (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187799)
    - Noncontinuous Ventilators SystemOne (Q-Series), DreamStation, DreamStation Go, Dorma 400, Dorma 500, REMstar SE Auto (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187815)

How Do I Report a Problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.