URGENT: Medical Device Recall

Philips Respironics CPAP and Bi-Level PAP Devices

Valued Customer,

CPAP CENTRAL has very recently learned that Philips Respironics is voluntarily recalling specific Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.

The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.

Immediate Actions to be taken by You, the User:

1. Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.
2. Register your device on the recall website https://www.philipssrcupdate.expertinquiry.com/.

Or you can call CPAP CENTRAL to register the device for you.

a. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects.

The potential risks of chemical exposure due to off-gassing include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

Which devices are affected by the recall?

CPAP and Bi-level PAP Devices
All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers:

Continuous Ventilator, Minimum Ventilatory Support, Facility Use:	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting:	DreamStation ASV DreamStation ST, AVAPS System One ASV4 C-Series ASV C-Series S/T and AVAPS OmniLab Advanced+
Noncontinuous Ventilator:	System One (Q-Series) DreamStation DreamStation Go Dorma 400 Dorma 500 REMstar SE Auto

Products not affected by this recall notification include:

- Trilogy Evo
- Trilogy Evo OBM
- Trilogy EV300
- Trilogy 202
- BiPAP A40 EFL
- BiPAP A40 Pro
- M-Series
- DreamStation 2
- Omnilab (original based on Harmony 2)
- Dorma 100, Dorma 200, & REMStar SE
- All oxygen concentrators, respiratory drug delivery products, airway clearance products

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. You will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:
1-877-907-7508
www.philips.com/src-update

Frequently Ask Questions can be accessed here FAQ

This notice has been reported to the appropriate Regulatory Agencies. Philips regrets any inconveniences caused by this problem.

CPAP Central is still awaiting further information from Philips as they are currently deploying a permanent corrective action to address the issues described in the Recall Notice. We will be providing you further information as it becomes available to us.

If you require any further clarification or assistance CPAP CENTRAL is here to assist.

Sincerely,

CPAP CENTRAL
1-289-389-1730