

URGENT: FIELD SAFETY NOTICE

Philips Respironics CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is issuing a Field Safety Notification about the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may emit certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see [FDA safety communication](#) on use of Ozone cleaners). Emission of chemicals may occur during initial operation and may possibly continue throughout the device's useful life.

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 effects. The potential risks of chemical exposure due to emission of chemicals 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.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
Noncontinuous Ventilator	OmniLab Advanced+
	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Immediate Actions to be taken by You, the User:

1. Please contact your physician or care provider before making any changes to your prescribed therapy. While the risks identified in this letter have resulted in Philips recommending discontinued use, it is important that you consult with your physician to determine the most appropriate options for continued treatment. Together with your physician determine if the benefit of continuing therapy with your device outweighs the risks identified.
2. Register your device on the field action website:
<https://www.philips.ie/healthcare/e/sleep/communications/src-update>
 - a. The website provides you current information on the status of the field action 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 1800 851 241 if you cannot visit the website or do not have internet access.

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 Field Safety Notification. As part of the registration process above, 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 support hotline or visit the website:

1800 851 241

<https://www.philips.ie/healthcare/e/sleep/communications/src-update>

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care