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 voluntarily recalling 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 off-gas 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), and off-gassing 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 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.

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
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

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 notification (U.S. only) / field safety notice (International Markets) website www.philips.com/src-update
    a. The website provides you current information on the status of the recall notification (U.S. only) / field safety notice (International Markets) 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 number listed below 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 recall notification (U.S. only) / field safety notice (International Markets). 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 recall notification (U.S. only) / field safety notice (International Markets) support hotline or visit the website:

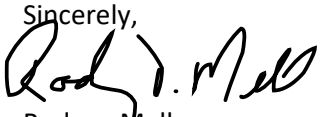
Country	*Toll Free Number*
Philippines PLDT/Smart	1800-1888-6182
Philippines NCR/Globe	028-667-9001
Singapore	1800-28-63-020
Thailand	1800-999-119
Malaysia	1800-220-778
Others ASEAN	+44 20 8089 3822 (Toll Line Number)

www.philips.com/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