



URGENT: Field Safety Notice

Philips Respironics

Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent,
BiPAP V30, and BiPAP A30/A40 Series Device Models

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is issuing voluntarily Field Safety Corrective Action on 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 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 operation.

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	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



Immediate Actions to be taken by You, the User:

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that 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 at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.
2. If your physician determines that you must continue using this device, **use an inline bacterial filter**. Consult your Instructions for Use for guidance on installation.
3. Contact your device distributor to arrange repair or replacement of your device. Philips is working to provide corrected devices and repair kits to your distributor to correct this issue as soon as possible.

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 Notice. 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 Field Safety Corrective Action support hotline or visit the website:

Country	Toll Free Number
Philippines	1800-1888-6182 For PLDT/ Smart Subscribers
Philippines	028-667-9001 NCR/ Globe Subscribers
Singapore	1800-28-63-020
Thailand	1800-999-119
Malaysia	1800 220 778
Vietnam	+84 2838 688 588; +84 868 800 240

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



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 voluntarily Field Safety Corrective Action of 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 effects. 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
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. Discontinue use of your device and work with your physician or care provider 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. Contact your device distributor to arrange repair or replacement of your device. Philips is working to provide corrected devices and repair kits to your distributor to correct this issue as soon as possible.

Permanent Corrective Action to be Taken by the Company:

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