Ascent Respiratory Care

June 15, 2021

Dear Ascent Respiratory Care Customer,

On June 14, 2021, Ascent Respiratory Care was informed that Philips Respironics has issued a Medical Device Recall for Trilogy 100 ventilators and CPAP/BiPAP devices. The voluntary recall is due to degradation of sound abatement foam used in the devices. The recall notice states, "foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and off gassing may occur during operation." A copy of Philips' recall notice is attached for your information.

We have been informed that high heat and humidity environments, as well as use of unapproved cleaning methods, such as ozone, may contribute to the foam degradation. Per the Trilogy 100 Clinical Manual, appropriate operating temperatures are between 41- and 104-degrees Fahrenheit and relative humidity between 15 and 95 percent.

Philips is deploying permanent corrective action to address the issue, though at the time of this letter Philips has yet to notify Ascent of the action plan for immediate replacement of the sound abatement foam. Ascent will actively watch the Philips recall website and work closely with Philips to stay current on the issue and receive permanent corrective action on our Trilogy 100 ventilators as quickly as possible.

Immediate Actions to be taken by Trilogy 100 users:

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. As is normal protocol, Ascent will continue to provide inline bacterial filters to you.

As an Ascent customer, your Trilogy 100 unit is owned and maintained by Ascent. This means Ascent will manage all recall requirements. Ascent will notify you as we receive additional information from Philips.

If you have questions or concerns regarding this recall and your Trilogy 100, please call Ascent at 303-954-8953. Thank you for choosing us to be a part of your health care team.

Sincerely,

Roxanne Venard, RRT
President
Ascent Respiratory Care, LLC

6595 S. Dayton Street, Ste 1000 Greenwood Village, CO 80111
Phone: (303) 954-8953 Fax: (303) 954-8656

URGENT: Medical Device Recall

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 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 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. Register your device(s) on the recall website www.philips.com/src-update

    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.

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. 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 recall/issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

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