URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

To the patients who use Philips Sleep & Respiratory Care devices:

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 initial operation and may possibly continue throughout the device's useful life.[1]

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. Philips Respironics has received complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). 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.

[1] https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

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. Talk to your health care provider to decide on a suitable treatment for your condition, which may include:
    a. Stopping use of your device
    b. **Continuing to use your affected device**, if your health care provider determines that the benefits outweigh the risks identified in the recall notification.
    c. Using another similar device that is not part of the recall or using alternative treatments for sleep apnea[2].
2. Follow the manufacturer's instructions and recommended cleaning and replacement guidelines for your CPAP machine and accessories. Ozone cleaners may exacerbate the breakdown of the foam, and there are other potential risks associated with the use of ozone and ultraviolet (UV) light products for cleaning CPAP machines and accessories.[3]
3. Report any problems with a device through the FDA's MedWatch Voluntary Reporting Form[4].
4. Register your device 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 register with Philips to address the two (2) issues.
    b. The website 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.

Devices should be serviced only by qualified technicians. They do not include user serviceable parts. Attempts to remove the sound abatement foam may render the device permanently inoperative.

[2] https://www.fda.gov/consumers/consumer-updates/always-tired-you-may-have-sleep-apnea

[3] https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

[4] https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Devices damaged due to attempts by the user to remove the sound abatement foam will not be able to be remediated.

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

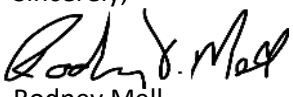
1-877-907-7508
www.philips.com/src-update

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, or 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
Philips Respironics - Sleep & Respiratory Care

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

To the patients who use Philips Sleep & Respiratory Care devices:

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.[1]

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. Philips Respironics has received complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). 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.

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

[1] https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and

Immediate Actions to be taken by You, the User:

1. Do not stop or change ventilator use until you have talked to your health care provider.

    - 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 in the judgment of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the potential risks identified in the recall notification.

2. Talk to your health care provider about using an inline bacterial filter, which may help to filter out particles of foam. At this time, the FDA does not have evidence of the safety and effectiveness of a filter for mitigating the foam risks, and the FDA's evaluation is ongoing.[2] It is important to note the following considerations:

    - Filters will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam.
    - Filters may affect ventilator performance because they may increase resistance of air flow through the device.
    - You should closely monitor for possible accumulation of foam debris on the filter or resistance-related problems in the breathing circuit after filter placement.
    - Consult your Instructions for Use for guidance on installation.

3. Report any problems with a device through the FDA's MedWatch Voluntary Reporting Form.[3]
4. Register your device(s) on the recall website www.philips.com/src-update
    - 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.
    - The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
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Devices should be serviced only by qualified technicians. They do not include user serviceable parts. Attempts to remove the sound abatement foam may render the device permanently inoperative. Devices damaged due to attempts by the user to remove the sound abatement foam will not be able to be remediated.

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[2] https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks

[3] https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

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:

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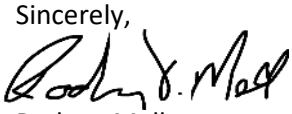

Rodney Mell
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