Accession Number:	A37110	**ECRI Priority:**	High	**Published:**	06/15/2021
Channel:	Devices	**FDA:**	Class I	**Last Updated:**	09/13/2021

Philips—CPAP and BiLevel PAP Devices and Mechanical Ventilators: Manufacturer Addresses Health Risks Caused by Sound Abatement Foam

Product Identifier(s)

[Capital Equipment]

Product	Philips Respironics Inc Model	Manufacture Date	Serial No.
Ventilators	A-Series BiPAP A30, A-Series BiPAP A40, A-Series BiPAP Hybrid A30, A-Series BiPAP V30 Auto, Aeris, C Series, Dorma 400, Dorma 500, DreamStation, DreamStation GO, E30, Garbin Plus, LifeVent, OmniLab Advanced Plus, REMStar SE Auto, SystemOne, Trilogy 100, Trilogy 200	< 2021 Apr 26	All

Manufacturer(s)

Philips Respironics Inc , 1001 Murry Ridge Ln, Murrysville, PA 15668, United States

Problem

In a June 14, 2021, Medical Device Recall Notification/Field Safety Notice letter, Philips states that on April 26, 2021, it advised on potential health risks related to sound abatement foam used in specific Philips continuous positive airway pressure (CPAP) devices, BiLevel positive airway pressure (PAP) devices, and mechanical ventilators. As a result of extensive ongoing review, on June 14, 2021, Philips issued a recall notification (U.S. only)/field safety notice (international markets) for specific affected devices. Possible health risks include exposure to degraded sound abatement foam (e.g., caused by unapproved cleaning methods, such as ozone) and exposure to chemical emissions from the foam material. Philips also states that high heat and high humidity environments may also contribute to foam degradation in certain regions. The environmental conditions that may be one of the causes of this problem refer to the climate and regional temperatures of the countries where the devices are used and stored. The potential risks of degraded foam 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. Philips further states that it 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 exposure because of chemical emissions from affected foam include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, and toxic and carcinogenic effects. Philips states that it has received no reports of serious harm because of this problem. The manufacturer has not confirmed the information provided in the source material.

Action Needed

Identify any affected devices in your inventory. If you have affected devices, verify that you have reviewed the Medical Device Recall Notification/Field Safety Notice letter from Philips. For patients using BiLevel PAP and CPAP devices, discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks. For patients using life-sustaining mechanical ventilator devices, do not discontinue or alter prescribed therapy without consulting physicians to determine appropriate next steps. 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. Philips recommends that customers and patients discontinue use of ozone-related cleaning products and adhere to the device instructions for use for approved cleaning methods. Review the age of your BiLevel PAP and CPAP devices because they are typically recommended to be replaced after five years of use. Philips will replace the current sound abatement foam with a new material that is not affected by this problem. The new material will also replace the current sound abatement foam in future products. Philips is currently unable to set up new patients on affected devices. Philips may work with new patients to provide potential alternative devices. Philips may repair/replace ventilator units that patients are reliant on in emergency situations, such as device failure

during required treatment, to ensure continuity of care. Register affected devices on the Philips website, which provides current information on the status of the problem and instructions on how to receive permanent corrective action to address the above problems. For more information on the recall notification, as well as instructions for customers, users, and physicians, contact your local Philips representative, visit www.philips.com/SRC-update, or call 44 (2080) 893822 or (877) 907-7508 if you do not have Internet access.

For Further Information:

Philips
Tel.: 44 (2080) 893822 or (877) 907-7508
Website: Click here

UMDNS Term(s)

Positive Airway Pressure Units [20742]
Positive Airway Pressure Units, Bi-Level [20743]
Positive Airway Pressure Units, Continuous [11001]
Ventilators, Noninvasive Positive Pressure [20746]

Geographic Region(s)

(Impact in specific regions has not been confirmed or ruled out at the time of this posting), Worldwide

Suggested Distribution

Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Pulmonology/Respiratory Therapy, Home Care, EMS/Transport

Comment

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:

- Philips. Sleep and respiratory care update. Medical device recall notification (U.S. only)/field safety notice (international markets) [online]. 2021 Jun 14 [cited 2021 Jun 14]. Available from Internet: Click here.