Cooper Clinic™
Preventive Medicine
A COOPER AEROBICS COMPANY

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Philips PAP Recall

Our patients who are using a Philips Respironics Bilevel Positive Airway Pressure (BiPAP) or Continuous Positive Airway Pressure (CPAP) device for treatment of sleep apnea already should have heard from Philips regarding the recall on many of these devices.

This is due to the possible degradation of sound abatement foam and exposure to chemical emissions from the degraded foam material. High heat and humidity as well as use of unapproved cleaning methods, such as ozone (for example, SoClean and PrimeClean), may contribute to this foam's degradation.

Philips has information on their web site regarding their efforts to rectify the issue as well as answers to questions. They offer a registration process, which allows patients to look up their device's serial number to begin a claim if the unit is affected. We encourage anyone using a Philips device to use the registration process.

The American Academy of Sleep Medicine and American Thoracic Society have issued recommendations about use of the affected devices. For patients using life-sustaining mechanical ventilator devices, **we recommend you do not stop or alter prescribed therapy until after talking to your physician.** Appropriate therapeutic decisions need to balance risks of continuing therapy versus temporarily discontinuing the device while awaiting a reasonable alternative.

For patients on Bi-level PAP and CPAP devices who have severe breathing difficulties and were very sleepy during the daytime before treatment, have chronic obstructive pulmonary disease (COPD), cardiovascular or neurologic comorbidities or who work in safety-critical positions (for example, professional drivers, pilots, heavy equipment operators), **we recommend you not stop your prescribed therapy until your PAP unit is replaced or repaired.** Philips advises patients to use an in-line bacterial filter with affected units in the meantime.

For other patients using Bi-level PAP and CPAP devices, contact your physician or durable medical equipment (DME) provider to determine the most appropriate option for continued treatment. Determination will be based on the severity of your sleep disorder, the availability of an alternate device (DME suppliers have very limited inventory), as well as other possible treatment methods, such as positional therapy or oral appliance therapy.

As noted above, if you need to continue use of an affected device, do not use unapproved cleaning methods and keep your device away from high heat and humidity.

See the Frequently Asked Questions on page 2 for additional information.

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Phillips PAP Recall – Frequently Asked Questions

Q. What is the risk to the patient associated with using a recalled device during one night for an in-lab titration?
A. Based on the information currently available from Philips, this risk is unknown.

Q. What is the risk to regular users of recalled PAP machines?
A. Philips has reported the complaint rate in 2021 was low (0.03%). However, it is unknown how many cases may have been unreported.

Q. Should filters be used with a recalled device?
A. According to Philips, if physicians determine a patient must continue using a life-sustaining mechanical ventilator device, patients are strongly urged to use an approved bacterial filter per instructions for use. The bacterial filter may reduce exposure to degraded sound abatement foam particles, though it will not reduce exposure to potential volatile organic compounds (VOCs). Contact your DME supplier to identify the appropriate filter for your device. Philips has made no public recommendation for or against the use of filters with recalled BiPAP and CPAP devices.

Q. I have an affected device so where can I get an in-line bacterial filter?
A. We do not have the in-line bacterial filters available, but they can be obtained from a few online suppliers (Amazon, CPAP.com, etc.)

Q. Do other PAP manufacturers use the same foam found in the recalled devices?
A. An online statement from ResMed indicates, "ResMed devices are not subject to this recall and are safe for patients to use. ResMed devices use a different material for sound reduction than the material used by Philips."

Q. How long will it take for Philips to repair and replace the recalled devices?
A. At this time, Philips has not disclosed a timeline. However, because the recall involves millions of PAP devices, it may take some time before this is completed. However, they have stated they will replace the current *sound abatement foam* with a new material after obtaining relevant regulatory clearances. Philips also has indicated they will address all affected devices in the scope of this correction as expeditiously as possible.

Please visit the Philips website:
https://www.usa.philips.com/healthcare/e/sleep/communications/src-update