Philips Issues Recall of All First-Generation CPAP/BiPAP Machines

DreamStation 2 products are not impacted by the recall.

Philips is recalling millions of its CPAPs, bilevel PAPs, and ventilators to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.

"The PE-PUR foam may pose a threat if it enters the CPAP machine's air pathway, where it could then be ingested or inhaled by the patient. The foam may also off-gas certain chemicals. Philips advised that the foam degradation may be worsened by certain "unapproved" cleaning methods, such as ozone. High heat and high humidity environments may also contribute to foam degradation."

The recall notification advises patients and customers to take the following actions:

- For patients using affected bilevel and CPAP devices: Discontinue use of your device and work with your physician or durable medical equipment 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 the recall notification.

- For patients using affected life-sustaining mechanical ventilator devices: 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 identified in the recall notification.

FMCSA is aware of the situation and they expect to soon have some guidance on how to proceed with drivers with sleep apnea and the DOT medical certification process.

When performing a physical exam, all drivers being treated for sleep apnea should be informed of this recall.

Philips has developed a plan to work with consumers to replace the current sound abatement foam with a new material. Patients are being directed to fill out a form online, so the company can stay in touch with them regarding the next steps. The website also contains a list of impacted machines.

Patients who have devices that are less than five years old will not be able to get a new device covered by insurance under current policies. So if it is going to take months or up to a year to get a device through the Philips registration process, that is going to become a problem. A spokesperson of the company said, "They can't be without treatment for that long, so we are really petitioning the payors to add some flexibility."

For further questions, feel free to contact Greg McDermand with Interstate Sleep Solutions at 1-855-276-3227