

On June 14, 2021 Philips Respironics issued a recall notification for specific Philips Respironics bilevel positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), and mechanical ventilator devices. You are receiving this letter because our records show you may be using a device affected by this recall.

Philips Respironics has discovered that the sound abatement foam (foam within the machine used to make it quieter) can break down and be blown into patients' airways. Additionally, when this break down occurs, chemicals are released that are carcinogenic (meaning they may increase the risk for cancer with prolonged exposure).

We have no way of knowing which machines are being affected by this defect as it is only occurring in 300 out of every 1 million devices made by Philips Respironics in the last 14 years. Meaning only 0.03% of the device made are affected.

However, we do know you are at increased risk if your machine has been exposed to temperatures more than 90 degrees Fahrenheit, high humidity, or you have used an ozone cleaning device. Please notify your provider's office if you believe any of the above apply to your device.

Philips Respironics indicates that it will replace the current sound abatement foam with a new material and has already begun the preparations. Philips Respironics plans to address all affected devices as quickly as possible and is creating a registration process that will allow patients to look up their device serial number and begin a claim if the unit is affected. Please contact your durable medical equipment (DME) provider (CPAP company) to discuss the process for repair or replacement if you have a device affected by this recall. You may also contact Philips directly at (877) 907-7508.

Asante Physician Partners recommends that you immediately discontinue the use of ozone cleaning devices and use manual cleaning methods. Use of ozone cleaning devices (such as the SoClean) has been found to contribute to the breakdown of the sound abatement foam in these devices. All commercial cleaning devices should be avoided as they are not approved by the FDA.

Our providers have recommended to continue using your PAP device and contact the provider who ordered, or currently manages, your respiratory equipment (CPAP, BIPAP, Ventilator) with questions or if you are considering discontinuing use of your device.

Respectfully,

APP Pulmonary Consultants & Sleep Specialists Providers