## PAP Recall Advisory

Philips Respironics announced a voluntary recall of most of their CPAP and BiLevel PAP machines. This affects devices manufactured prior to April 26, 2021. The issue is related to deterioration of the sound abatement foam used in these devices that could result in particles and/or noxious volatile gases (carcinogens) to be released into the airway. The foam degradation may be exacerbated by use of unapproved cleaning methods such as ozone and environmental factors such as high heat and humidity (not from device use) in certain regions. Please stop using any ozone cleaning methods immediately.

While there is a potential risk from the deterioration of the sound abatement foam, those risks have to be weighed against each individual's own risk of untreated sleep apnea. Once you have identified that your machine is affected, please call us or send a secure message through MyChart to find out further recommendations.

Unfortunately the call volume is extremely high and we are doing our best to get back with you as soon as possible. Until your provider can get back with you regarding their specific recommendations we ask you use the following information to decide what is best for you:

- If you have severe sleep apnea and/or comorbidities such as history of stroke, arrhythmias, congestive heart failure, or ischemic heart disease, we will most likely recommend that you continue use as the benefit outweighs the potential risk.
- If you are able to function reasonably well without your machine, then stop using your
  device until we can discuss your case. Avoid sedating medications and alcohol. Avoid
  sleeping on your back and elevate your head while sleeping if possible. Avoid high risk
  situations such as driving while drowsy or other situations where excessive sleepiness
  may be dangerous.
- If you have a high risk occupation that requires an increased level of alertness then the risk of discontinuing use is most likely higher than the potential health risks of continuing PAP. This includes drivers, pilots, and heavy equipment operators.

Please note there have been no reported deaths related to this issue and the self-reported rate of side effects is small. less than 1%.

For complete information regarding the recall you can visit their website at https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

Frequently Asked Questions

Is my machine affected by this recall?

Philips Respironics has established a registration process that allows patients to look up their device serial number and begin a claim if the unit is affected.

To find out if your device has been affected by this recall, please go to this website <a href="https://www.philipssrcupdate.expertinguiry.com/">https://www.philipssrcupdate.expertinguiry.com/</a>.

If you don't have access to the internet please call 877-907-7508.

## What should I do next?

- If you use any Ozone cleaning products, stop use immediately.
- Register your device for replacement.
- Contact us to find out recommendations on the risk vs. benefit of continuing PAP therapy using the affected machine until the machine can be repaired or replaced.