



# PULMONARY ASSOCIATES

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We were notified about the Phillips Respironics CPAP recall on June 14, 2021. It appears that some of the soundproofing foam built into the machine has the potential to break apart and release particles and unwanted gases into the airflow system.

We have not received any scientific data or other information about the actual incidence of side effects except that: 1> there have been no reported deaths and 2> the self-reported rate of side effects is small, well less than 1%. Most concerning is that the gas released is reported to be a carcinogen, which means that there is a potential cancer risk particularly with long term exposure.

The potential short term side effects could include nasal irritation, chest congestion, and headaches (please refer to recall letter for more potential symptoms). Long term side effects including the potential of cancer are uncertain at this point. However, based on currently available information, we believe the risk of long term side effects including cancer is very small.

The company has reported that a fix will be released this week (link to be added when available) for which you will have to register and manage through your equipment company. In the meantime we recommend the following for patients using devices involved with the recall (this will be all CPAP, Aflex, BiPAP devices manufactured by Phillips Respironics **other than** the new Dream Station 2):

- 1> If you are able to function reasonably well without CPAP, BiPAP, etc., then stop using the device until it can be fixed. Avoid sedating medicine, alcohol, and sleep aids if possible. Avoiding sleeping on your back and elevating your head of bed may be helpful to mitigate symptoms.
- 2> If you stop using your PAP device, then avoid high risk situations. This includes avoiding driving while sleepy and avoiding other situations where excessive sleepiness might be dangerous.
- 3> If you are in a high risk occupation (e.g. drivers, pilots, heavy equipment operators) that requires a high level of alertness, then the risk of not using the PAP device may outweigh the small health risk associated with using the PAP device. It may be appropriate in this situation to continue PAP therapy, but you will have to make the decision based on your personal circumstances.
- 4> If you are on a Trilogy ventilator, have chronic respiratory failure requiring BiPAP, or are otherwise dependent on the PAP machine you should continue regular use at this point.
- 5> If you continue to use PAP, avoid using 3<sup>rd</sup> party cleaning systems such as the SoClean device. These ozone based cleaning systems may accelerate the foam breakdown.

Generally speaking, untreated sleep apnea poses serious health risks. We continue to recommend therapy for all sleep apnea patients and consider CPAP effective treatment that has been utilized for over 50 years. The seriousness of the reported manufacturing defect with these specific machines will only be known with time, but we believe the vast majority of patients will not be harmed by these machines.