



To our Valued Patients:

On June 14, 2021, Philips issued a recall for almost all their CPAP machines in the US, approximately 2 million devices. For the rest of the world, they did not issue a recall, but rather a “safety advisory” for the millions of other CPAP machines. Their stated reason was the “difference in regulatory environments” between the US and the rest of the world, but what it really means is that they are concerned with the high risk of litigation in the US. This is much less of an issue in the rest of the world.

Because of this concern, the information from Philips to providers and patients is probably limited by their legal considerations.

What did they find?

Phillips has two concerns.

1. First, they found that, occasionally, in some unknown number of machines, the sound insulating foam that keeps the machine quiet can deteriorate. Tiny particles of foam could get into the airstream. Particles could, in some cases, irritate the airway and possibly cause coughing, wheezing and other allergic symptoms. This may be a more significant issue for patients with underlying lung disease, such as asthma or emphysema. As far as anyone knows, these foam breakdown particles are generally inert and similar to ordinary dust. Phillips has not released any data revealing long-term risks.

Is this common? They haven’t told us how often this occurs; whether it’s 1/100 machines, 1/1,000 machines or 1/100,000. We believe that Phillips’ perspective is that the recall is necessary to protect them from litigation, even if the risk is very small (or nonexistent).

2. The second concern is the foam may release trace amounts of several chemicals connected to the manufacture of the foam. These chemicals are in widespread use in industry, and in fact, appear in small quantities in many consumer products, cosmetics, personal care products, and medicines.

Based on studies done in the laboratory where bacteria are exposed to high concentrations of these chemicals, there is a concern that one or more may be carcinogenic at some dose. It is important to note that these screening tests do not correlate closely with human disease. At this time, there are no known human cancers associated with these substances. That does not mean they do not have the capability to contribute to cancers; we just don’t know. Even if does, we don’t know if it takes a month of exposure, a year, or a decade. Is it worse than smoking a pack of cigarettes for a year? Again, we just don’t know.



Even though the company just became an aware of this issue, it has always been there, even if you've had your device for 2,3, or 4 or more years.

In summary, we don't know how common foam breakdown occurs. If it does occur, we don't know how often it contributes to disease. We are not even sure that there is any meaningful risk at all.

What can you do?

In response to this information, patients have 3 choices, and we have had patients select each of these. We cannot give you advice, because there is not enough data to do that, but we can give you information to help you make a choice. The three choices are:

1. Keep using your CPAP until the recall is resolved, which could take up to a year, considering that the risk is unknown. Most of our patients with severe sleep apnea or who are very dependent on their machines have elected to do this. This includes most of our physician patients who are CPAP users.
2. Stop using your device until the recall has been resolved. Some patients, especially those with mild to moderate sleep apnea, who may feel minimally different without their CPAPs have elected to stop using CPAP until the recall is resolved. Remember that most people have had symptoms of sleep apnea for years before the diagnosis was made.
3. Purchase another brand of machine (such as Resmed) on your own with your own money. They are probably less expensive on the internet (about \$900) than from your current equipment provider. If you decide on this, SHMD can provide orders for you to use to purchase one.

If you decide to stop using CPAP, you should monitor your symptoms carefully and **DO NOT DRIVE IF YOU ARE SLEEPY.**

If you continue to use your device, keep the humidity and heat low or off. Do not use ozone cleaners, such as SoClean. Observe the tubing frequently to make sure there are no black particles or debris. If you decide to purchase a PAP device on your own on the internet, let us know and we can send an order to the company.

This has been a difficult time for all of us, and we are here to help you if we can.

The providers and staff of Sleep Health MD.