This notice from Mid-South Pulmonary & Sleep Specialists, PC contains an important health and safety update. Please read this notice in its entirety.

Out of an abundance of caution and proactive efforts to address identified issues in a number of Sleep and Respiratory Care products, Philips has issued a **voluntary recall** for specific Philips Respironics CPAP, bilevel PAP, and mechanical ventilator devices. **The recalled machines include** the DreamStation devices that are used to treat obstructive sleep apnea. (The newer DreamStation 2 is not affected.) Philips has begun a process to repair and replace affected devices. This process may take upwards of a year.

The recall is related to the type of foam used to reduce the noise made by the devices. Over time, the foam inside the machine may fall apart into black particles. These particles potentially can enter the humidifier, tubing, and mask. As a result, you may inhale the particles when using the device. Testing by Philips also found that the foam can produce unsafe chemical levels which are released as gases. Testing results suggest these emissions taper off during the initial days of use of a new device.

Philips reports that the potential risks to you include:

- Headache
- Skin or eye irritation
- Asthma
- Irritation of the airway
- Nausea or vomiting

Philips reports that in 2020 the compliant rate for foam particles was low (0.03%). To date, there have been no reports of death. Philips has received no complaints related to chemical exposure.

What steps should you take if you have a Philips C-PAP device for sleep apnea:

1. Visit **the Philips recall webpage**, (Philips.com/SRC-update), for current information
2. Look up your device serial number and **use Philips registration process** to register and get your device in line for replacement or repair if it is a device under the voluntary recall.
3. If you are still confused on the process, call Philips at **877-907-7508**
4. **STOP using ozone products such as So Clean to clean your C-PAP device.** Philips reports that ozone- related cleaners may help wear down the foam in the device. Call your DME company or Philips to learn proper cleaning techniques for your device going forward.
5. **Patients should balance the risk of continuing therapy versus temporarily discontinuing use of the recalled device while waiting for a reasonable alternative.**

Risks from recalled devices:

- Philips list of potential risks of a particulate exposure are found above. Again, the foam-related complaint in 2020 was low or 0.03%. less than three one hundredths of one percent. Philips believes that most degraded foam particulates are too big to be inhaled.

Risks from Sleep Apnea:

- The severity of a patient's apnea along with co-morbidities will greatly affect a patient's health risk of discontinuing therapy.
- If left untreated, sleep apnea could cause: high blood pressure, stroke, heart failure, irregular heartbeats, heart attacks, diabetes, depression, worsening of ADHD, and headaches among others.

- **Based on information currently available, the likelihood and severity of adverse health impact from discontinuing apnea therapy appears to significantly outweigh the likelihood and adverse health impact from continued use of Philips devices.**

6. **The bottom line is patients diagnosed with sleep apnea still need to be treated. Do not discontinue using the device before consulting with your sleep physician. Patients should make an appointment with their sleep specialist as soon as practical to discuss treatment alternatives to avoid health consequences of untreated sleep apnea.**