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## **IMPORTANT NOTICE**

#### VOLUNTARY RECALL BY PHILIPS FOR CERTAIN PAP DEVICES

This notice contains an important health and safety update. Please read this notice in its entirety.

Philips has issued a <u>voluntary recall</u> for specific Philips Respironics CPAP, Bilevel PAP, and mechanical ventilator devices. The <u>recalled machines</u> include the DreamStation devices that are used to treat obstructive sleep apnea (*Note: the newer DreamStation 2 is not affected*). Philips has begun a process to repair and replace affected devices. How long this process will take, is unclear.

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 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. These "volatile organic compounds" are released as gases.

### 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 complaint 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 should you do if you use a Philips PAP device?

- ✓ Visit the <u>Philips recall webpage</u> for current information.
- ✓ Use the <u>Philips registration process</u> to look up your device serial number.
- ✓ Begin a claim with Philips if your unit is affected.
- ✓ Call Philips at 877-907-7508 if you have questions about your device.
- ✓ Philips also advises you to avoid using ozone products to clean your PAP device. Philips reports that ozone-related cleaners may help wear down the foam in the device.
- ✓ If your recalled device is a **CPAP** or **BiPAP** device for sleep apnea, Dr. Barthlen and GSC Clinicians recommend:
  - Discontinue use of your ozone-related CPAP cleaning devices.
  - Check with your primary care provider to discuss possible discontinuation of your PAP machine. *Essentially, it's your health and your decision.*
  - Note that the side effects were generally mild and not life threatening and occurred in only 0.03% of patients (as abovementioned). The more serious side effects like possible carcinogenicity are, in my opinion, listed based on lawyer's precautionary verbiage. If you read the possible side effects of most prescription medicines, the listed side effects are usually much more serious.
  - Discontinue use of affected PAP machines older than 3 years or PAP machines that show "black debris", and obtain a replacement.
    - We can write a prescription for replacement for our patients; check with our office staff. You may also ask your primary care provider to write the prescription.
  - Replace accessories, such as mask, tubing, and water chamber.
- ✓ The American Academy of Sleep Medicine <u>advises you</u> to contact your medical provider as soon as possible. Your medical provider can help you determine if you should continue or discontinue treatment. Your provider may prescribe a new PAP device for you. Your provider also may discuss other treatment options with you.

Please contact **Guam Sleep Center** at *sleep@secure.guamsleepcenter.com* or **671-647-6669** for more information about this notice or to discuss your treatment options.