Dear Patient -

We have been notified by Philips Respironics ("Philips") of their recall of many CPAP/BIPAP machines/mechanical ventilator devices. You should be contacted by the manufacturer or your equipment supplier regarding this recall. However, we want to be sure GBMC also provides you with notice of this recall that may potentially affect you.

Philips' voluntary recall was issued on June 14, 2021, to address potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in certain devices. More information for patients can be found at:

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

What should you do?

- 1. Go to the Philips website to look up your device's serial number and begin a claim if your unit is affected. Please refer to the link on the Philips website for their registration process.
- 2. Call the toll-free number to learn more at 877-907-7508. A Spanish language option is available.
- 3. Inspect your CPAP humidifier and hose for any presence of black particles.
- 4. Philips has stated that unapproved CPAP cleaning methods such as ozone-based cleaning devices may worsen or exacerbate the foam degradation and should not be used to clean PAP equipment. We recommend that you discontinue using CPAP cleaning devices and follow the cleaning methods described in their device's "Instructions for Use."

Untreated sleep apnea, especially in moderate or severe degrees carries risks of chronic cardiac diseases and daytime drowsiness which may pose safety concerns. For some, the benefit of continuing CPAP therapy may outweigh the risks currently identified by the recall. Some specific examples include but are not limited to:

- Severe sleep apnea.
- DOT drivers, pilots, commercial drivers license holders, or if you have an occupation that requires operating heavy machinery.
- If you suffered from extreme sleepiness or drowsiness while driving prior to starting treatment for your sleep apnea.
- If you have lung disease, heart disease, or neuromuscular disease.
- The need for oxygen therapy

You should contact your physician if you have noticed relatively new symptoms of headache, upper airway irritation, cough, chest tightness, or sinus congestion. If you have any of these or other symptoms about which you are concerned, you may need to be evaluated by your provider.

Respectfully,

The Sleep Medicine Physicians at GBMC