Dear Patient:

You are receiving this communication as you *may* benefit from information related to a recall of CPAP, BI-PAP, ASV, Bi-Level or Trilogy devices.

THIS ONLY APPLIES TO DEVICES FROM PHILIPS. Positive airway devices from other manufacturers such as ResMed are not affected. If you have a device from another manufacturer, you can disregard the rest of this letter. ONLY some PHILIPS devices are recalled.

Affected devices include, but are not limited to, first-generation DreamStation (but not DreamStation 2). Other Philips Respironics devices are also included in this recall.

According to the manufacturer, insulation material in these devices may degrade over time causing inhalation of the particles or gases released by the material. It is not known what, if any, long-term health effects this may have. Some of the <u>potential</u> risks have been listed on the manufacturer's website.

The manufacturer believes this process may be accelerated by use of non-approved ozone cleaners and exposure to high heat or humidity and recommends you discontinue use of these non-approved cleaning devices immediately. Please follow your device's Instructions for Use for approved cleaning methods. The <u>American Society of Sleep Medicine</u> (AASM) can provide additional information.

For patients using life-sustaining mechanical ventilator devices such as a Trilogy, we recommend you continue until speaking with your treating physician.

For patients on CPAP or bilevel (BIPAP) who are using one of the affected devices, we recommend you suspend until you have had a chance to discuss treatment options with your physician and or homecare company **unless you fall into one of the following categories**:

- You have a commercial driver's license, pilot's license, operate heavy machinery or drive for a living
- You get sleepy without your CPAP or have severe sleep apnea
- You have underlying heart disease, lung disease or neurologic conditions
- You are using a life sustaining ventilator device such as a Trilogy
- You use oxygen with your CPAP

If you fall into one of the above categories, we recommend you continue with your CPAP device until you have had a chance to discuss treatment options and risk benefits with your physician.

The manufacturer recommends you <u>register your device</u> on the Philips website and they will give you direction regarding repair or replacement. If you do not have internet access, you can call **(877) 907-7508.** Replacement/repair timing was not provided. If your device is greater than 5 years old, we may be able to prescribe a new one for you that may be covered by your insurance. If your machine is less than 5 years old, but you do not want to wait for the recall information, we can provide you with a prescription to purchase a new machine.

Please contact your physician's office if you wish to discuss treatment alternatives. Due to the volume of phone calls received, responses may be delayed. We appreciate your patience.

Sincerely,

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