Philips Respironics CPAP Mask Recall

On September 6, 2022, Philips Respironics announced a voluntary recall of over 17 million CPAP/BIPAP masks that are used by people living with sleep apnea or other respiratory health issues. The recall pertains to people using these masks who have implanted metallic medical devices or other metallic objects in their body. The recall is due to risks related to the magnets on the masks that may affect some implanted medical devices or implanted metal objects.

Five mask types are affected by this recall: the DreamWisp, DreamWear Full Face Mask (not nasal mask), Amara View, Wisp and Wisp Youth masks.

If you believe this recall may pertain to you, please call and schedule an appointment to discuss and formulate a plan moving forward.

Full FDA News Release of Philips Respironics Mask Recall

ResMed masks are not impacted by this recall. Please find Safety Guidance for use of ResMed CPAP masks with magnetic clips here.

Hello,
As you may have recently heard, Philips Respironics announced a recall notification for several of their CPAP and BIPAP devices on Monday, June 14, 2021.

Philips Announcement:

- “For patients using affected BiLevel PAP (BiPAP) and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.

- For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.

- Philips is recommending that customers and patients halt use of ozone-related cleaning products and adhere to their device instructions for Use for approved cleaning methods.”

Here is what we know so far:

There is a foam that surrounds the motor of the CPAP/BiPAP devices to help reduce noise that may get degraded or damaged. It seems that this damage/degradation is at a higher occurrence in devices exposed to CPAP/BiPAP cleaning devices that utilize ozone, such as SoClean. This is not proven, although seems to be the likely cause from the information we have. The risk of experiencing negative symptoms is small. Since 2020, there have been 0.03% of users reporting symptoms, or 3 people for every 10,000 devices.

From the FDA:
"To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions."
From the information we have, it seems the benefit of continued use of your CPAP/BiPAP device does outweigh the risk for certain at-risk patients who should continue using their current Respironics devices until this situation can be resolved.

These patients include:
- Patients with ischemic heart disease
- Patient with congestive heart failure (CHF)
- Patients with cardiac arrhythmias, such as atrial fibrillation.
- Patients with a recent stroke or heart attack (myocardial infarction).
- Patients with moderate to severe COPD or asthma
- Patients with underlying neuromuscular disease
- Patients with complex sleep apnea that use an ASV or BiPAP S/T device
- Patients with marked daytime sleepiness or chronic fatigue that significantly benefit from CPAP/BiPAP use.

We do recommend discontinuing use of any type of CPAP cleaner or sanitizer, and to use soap and water as per manufacturing guidelines (at least once a week, wash mask, tubing, water chamber with soap and water. Change out filters per guidelines given by the durable medical equipment (DME) company depending upon your device).

There is a Philips Respironics portal available to register the devices to check if they have been impacted and enroll in their repair/replacement program. You may call 1-877-907-7508 or visit the website http://www.Philips.com/SRC-update for further information.

If your CPAP/BiPAP machine is over 5 years old, you may also be eligible for a replacement CPAP/BiPAP machine at this time.

We will continue to follow this dynamic situation closely and strive to keep you informed as we receive updates.

Thank you.