Respiratory Institute





Mount Sinai Integrative Sleep Medicine Service

RE: Philips CPAP Mask Recall September 2022

Dear Patients & Providers:

The Mount Sinai - National Jewish Respiratory Institute and Mount Sinai Integrative Sleep Medicine Service would like to alert patients that certain Philips Respironics masks used with continuous positive airway pressure (CPAP) and bilevel positive airway pressure (Bilevel PAP, BiPAP, or BPAP) machines have been recalled due to a serious safety concern.

These recalled masks have strong magnets that can cause potential injuries or death when the magnets interfere with certain implanted metallic medical devices and/or metallic objects in the body. Pictures and model numbers of the recalled masks can be seen here, with the locations of the magnetic clips circled:



While Mount Sinai did not directly dispense these masks to patients, we will do our best to assist with this process. We want to assure you that our first priority remains the safety of our patients.

Discontinuation of these masks is recommended for patients who have, or are in close vicinity to household members, caregivers, or bed partners with, implanted magnetic devices. These include (but are not limited to) the following:

Pacemakers, Implantable cardioverter defibrillators (ICD), neurostimulators, screws, ocular implants, implants to restore hearing or balance, implantable ports and pumps (such as insulin pumps), hypoglossal nerve stimulators, devices labeled as MR (Magnetic Resonance) unsafe, and magnetic metallic implants not evaluated for safety in a magnetic field. (Please see comprehensive list here)

RECOMMENDED NEXT STEPS (for those with a recalled mask <u>and</u> an implanted magnetic device, or those with a recalled mask in close vicinity to patients with implanted magnetic devices):

- **1.** <u>ALL PATIENTS SHOULD CONTACT the home care/durable medical equipment (DME) company that provided your mask for additional information and replacement of your mask</u>
- 2. In addition to contacting your DME for a mask replacement, if **EITHER** or **BOTH** of the below apply to you, please contact your provider **BEFORE** discontinuing mask use:
 - a. You are using a life-sustaining ventilator device (such as a Trilogy)
 - b. You become very sleepy with sustained vigilance tasks such as driving or operating heavy equipment

Philips Respironics is working with home care/durable medical equipment (DME) suppliers to ensure that safe replacements can be provided to our patients who are affected by this recall. We will continue to provide more information as soon as we have it and we appreciate your understanding and patience as we navigate this challenge. If you have further questions, please contact your primary provider or your Respiratory Institute sleep/pulmonary physician at 212-241-5656.