

Dear Home Medical Products, Inc. Patients:

On September 7, 2022, Home Medical Products, Inc. ("HMP") received notification from medical device manager Philips Respironics issuing a voluntary recall for certain Philips Respironics mask used with bilevel positive airway pressure (also known as Bilevel PAP, BiPAP or BPAP) machines and continuous positive airway pressure (CPAP) machines. Philips Respironics is one of several manufacturers of medical devices from whom HMP, and many other suppliers of medical equipment nationwide, sources products.

What you need to know:1

- Five mask types are affected by this recall: the DreamWisp, DreamWear, Amara View, Wisp and Wisp Youth masks.²
- The recalled masks are worn by a person when using a BiPAP or CPAP machine and have magnets that connect the mask components to hold the device in place.
- The magnets can potentially affect the functioning of or cause movement of certain implanted metallic medical devices, which could result in injury or death to the mask user or people near the patient wearing the recalled mask, such as a bed partner, who have such devices.³
- Medical devices that could potentially be affected by these magnets include brain stents, aneurysm clips, pacemakers, implantable cardioverter defibrillators, ventriculoperitoneal shunts, ocular implants, magnetic denture attachments, insulin pumps, certain neurostimulators used in and around the neck, cochlear implants or any metallic implanted medical device affected by magnets.
- The magnets could also affect mask users who have metallic objects in their body, such as shrapnel or splinters in their eyes, including people near the patient wearing the affected mask, such as a bed partner.
- The FDA is providing <u>recommendations in a safety communication</u> for patients, caregivers and health care providers concerning use of the recalled masks with magnets, which patients may be using with Philips BiPAP and CPAP machines or those of other manufacturers.

What should you do:

- **STOP** using the affected mask, if the implant/medical device is contraindicated against the mask magnets.⁴ Consult your physician immediately to determine if another mask can be used for your therapy. In the interim, switch to a non-magnetic mask if available, for continued therapy. Properly dispose of the mask that has magnets after an alternative is obtained.
- If you, household members, caregivers, and bed partners who may be in close vicinity to you, do not have implanted medical devices, or metallic splinters in the eyes, then no action is needed.
- Household members, caregivers, and bed partners with a medical implant/device must ensure the mask is kept at least 6 inches (approx. 15.24 cm) away from the medical implant(s)/device(s).
- Contact Philips Respironics customer service for more information on non-magnetic mask options.
- Contact your health care provider immediately, if you experience any issues related to your medical device and <u>report the issue</u> <u>through the FDA's MedWatch Voluntary Reporting Form</u>.

HMP is actively reviewing its records to identify, and contact impacted patients. If your medical device is impacted by Philips Respironics' voluntary recall, then HMP will contact you soon to discuss your and your prescriber continuing treatment options. Additional information, including answers provided by Philips Respironics to Frequently Asked Questions, is available on the HMP website: <a href="https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https://https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//https//http

HMP provides safe, high quality, medically necessary products, and services to its patients. HMP remains committed to sourcing the safest, highest quality, therapeutically effective products available in the marketplace. Should you have any question about HMP's products and services, please do not hesitate to contact HMP.

Thank you for your attention to this important information.

HMP

¹https://www.fda.gov/news-events/press-announcements/certain-philips-respironics-masks-bipap-cpap-machines-recalled-due-safetyissue-magnets-may-affect

² For a more detailed list of the devices impacted by this issue, please see Figures 1 - 5 in the Philips Respironics Notification to Patients letter.

³ Please see Contraindication and Warning Section of the Philips Respironics Notification to Patients letter.

⁴ Please see Contraindication and Warning Section of the Philips Respironics Notification to Patients letter.