PHILIPS

URGENT Medical Device Correction Letter

Philips Respironics – Sleep and Respiratory Care
Notification to Patients

Amara View Minimal Contact Full-Face Mask
DreamWear Full Face Mask
DreamWisp Nasal Mask with Over the Nose Cushion
Wisp Nasal Masks and Wisp Youth Nasal Masks
Therapy Mask 3100 NC/SP

February 14, 2023

This document contains important information for the continued safe use of your Masks with Magnets

- Please review the following information and FAQs for Updated Contraindication & Warning – Philips Respironics Masks with Magnets Correction ("FAQs"). It is important to understand the implications of this communication.
- Please retain a copy with the Masks with Magnets Instruction for Use (IFU).

Dear Patient,

The following Philips Respironics patient interface devices (face and nasal masks) - Amara View Minimal Contact Full-Face Mask, DreamWear Full Face Mask, DreamWisp Nasal Mask with Over the Nose Cushion, Wisp Nasal Masks, Wisp Youth Nasal Masks, and Therapy Mask 3100 NC/SP - contain magnets.

This Urgent Medical Device Correction Letter is intended to inform you that Philips Respironics is updating its existing 'Contraindications' and 'Warning' of the above masks with magnets to the below.

Contraindication: *Use of the mask is contraindicated for patients and their household members, caregivers, and bed partners that may be in close vicinity to patients using the masks, that have implanted devices that may be affected by magnets, including but not limited to:*

- *Pacemakers*
- *Implantable cardioverter defibrillators (ICD)*
- *Neurostimulators*
- *Magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher (i.e. neck and head)*
- *CSF (cerebral spinal fluid) shunts (e.g., VP (ventriculo peritoneal) shunt)*
- *Aneurysm clips*
- *Embolic coils*
- *Intracranial aneurysm intravascular flow disruption devices*
- *Metallic cranial plates, screws, burr hole covers, and bone substitute devices*
- *Metallic splinters in the eye*
- *Ocular implants (e.g., glaucoma implants, retinal implants)*
- *Certain contact lenses with metal*
- *Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants)*
- *Magnetic denture attachments*
- *Metallic gastrointestinal clips*
- *Metallic stents (e.g., aneurysm, coronary, tracheobronchial, biliary)*
- *Implantable ports and pumps (e.g., insulin pumps)*
- *Hypoglossal Nerve Stimulators*
- *Devices labeled as MR (magnetic resonance) unsafe*
- *Magnetic metallic implants not labeled for MR or not evaluated for safety in a magnetic field*

Warning: *Magnets with a magnetic field strength of 400 mT are used in the mask. With the exception of the devices identified in the contraindication, ensure the mask is kept at least 6 inches (approx. 15.24 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. This includes household members, caregivers, and bed partners that may be in close vicinity to patients that use the masks.*

1. What the problem is and under what circumstances it can occur

- The affected masks contain magnets which can potentially affect the functioning and/or induce the movement/dislocation of medical implants or medical devices that can be impacted by the magnetic fields.
- See the Contraindication and Warning in this notice for additional details.

2. Describe the hazard/harm associated with the issue

- With the exception of the devices in the contraindication, if the mask magnets are placed less than 6 inches (approx. 15.24 cm) away from a metallic implant or device the magnets may cause the device to not perform as intended, which may result in a serious injury.
- As of October 14, 2022, there have been twenty-five reportable events suggesting that the mask magnets have impacted patients' medical devices which include: pacemaker interference, pacemaker failure leading to replacement, need of shunt adjustment, resetting of automatic implantable cardioverter defibrillator (AICD), seizures, defibrillator shutting off periodically, arrhythmia, irregular blood pressure, change in heartbeats, and cognitive issues.

3. Affected products and how to identify them

Figures 1 – 5 shows the images of the affected masks and Figure 6 (next page) contains their part numbers. The magnetic headgear clips on these masks are circled. Use the below images (Figures 1-5) and the Part Numbers (see Figure 6) in this letter, to determine if your or your patient's mask also uses magnetic headgear clips. These masks are intended to provide an interface for application of CPAP or bi-level therapy to patients.

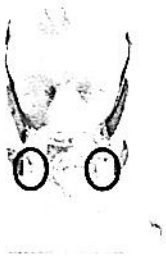

Figure 1: Amara View Full Face Mask

Figure 2: DreamWisp Nasal Mask

Figure 3: DreamWear Full Face Mask

Figure 4: Wisp and Wisp Youth Nasal Mask

Figure 5: Therapy Mask 3100 NC/SP

4. <u>Patients must take the following action to prevent risks</u>:

4.1. **STOP** using the affected mask if the implant/medical device is contraindicated against the mask magnets. Patients should consult their physician immediately to determine if another mask can be used for their 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.

4.2. 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.

4.3. 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).