PHILIPS

URGENT Medical Device Recall

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

September 15, 2022

This document contains important information for the continued safe and proper use of your equipment

- Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.
- Please retain a copy with the equipment Instruction for Use.

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 and Wisp Youth Nasal Masks, and Therapy Mask 3100 NC/SP - contain magnets.

Philips Respironics is updating its existing contraindications and warnings to the following:

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.
- There have been fourteen (14) reports of patients suggesting that the mask magnets have impacted their 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

Images of the affected masks are shown below. The magnetic headgear clips on these masks are circled. These images may be used as reference 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. The part numbers for the affected masks and mask components that contain magnets are listed in Figure 6.

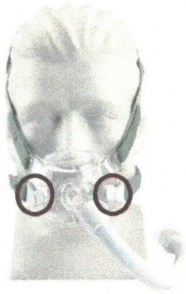

Figure 1: Amara View Full Face Mask

Figure 2: DreamWisp Nasal Mask

Figure 3: DreamWear Full Face Mask

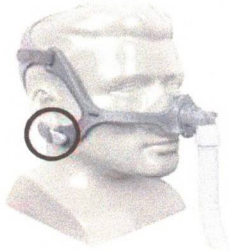

Figure 4: Wisp and Wisp Youth Nasal Mask

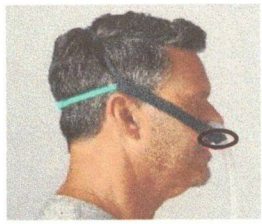

Figure 5: Therapy Mask 3100 NC/SP

4. Actions to be taken by patient to prevent risks

As a patient using these masks, **you must take the following action:**

You must take the following action:

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).

4.4. Contact Philips Respironics customer service for more information on non-magnetic mask options.

5. Describe the actions planned by Philips to correct the problem

Philips Respironics is updating its existing contraindication and warning as provided in this field safety notice.

1. **If you need any further information or support concerning this issue, please contact your local Philips Respironics representative.** For general issues or concerns, contact the Philips Customer Care Solutions Center at +1-800-345-6443.

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to Philips or the local competent authority. Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Thomas Fallon
Head of Quality
Philips Respironics