

FAQs for Updated Contraindication & Warning – Philips Respironics Masks with Magnets Correction (“FAQs”)

November 30, 2022

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

- Please review the following information and associated FAQs for Updated Contraindication & Warning – Philips Respironics Masks with Magnets Correction (“FAQs”) 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 Masks with Magnets Instruction for Use (IFU).

1. For DMEs, Distributors, and Prescribers: Where can I find additional information concerning this correction?
 - Philips Respironics website regarding this correction: <https://www.philips.com/magnet-notification>.
2. For Patients: Where can I find additional information/support concerning this correction and request a replacement mask without magnetic headgear clips or request non-magnetic headgear clips?
 - Philips Respironics website regarding this correction: <https://www.philips.com/magnet-notification>.
 - To request a replacement mask without magnetic headgear clips or request non-magnetic headgear clips, contact your equipment provider.
3. What is a Contraindication versus a Warning?

A ‘Contraindication’ is a condition under which the device should not be used because the risk of use clearly outweighs any possible benefit. A ‘Warning’ alerts the patient about a situation which, if not avoided, could result in death or serious injury. Additionally, a Warning may also describe potential serious adverse reactions and safety hazards. In short, a Contraindication tells the user when a device should not be used, and a Warning tells the user how to avoid sources of harm in the use of the device.

4. What is the updated Contraindication and Warning?

Philips Respironics is updating its existing Contraindications and Warnings to include 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.*

5. What Philips Respironics products are affected?

- a. DreamWear Full Face, Amara View Minimal Contact Full-Face Mask with magnetic clips, DreamWisp Nasal Mask with Over the Nose Cushion, Wisp/Wisp Youth Mask, and Therapy Mask 3100 NC/SP with magnetic clips.
- b. See Urgent Medical Device Correction Letters for full part numbers list.

6. What should I use instead of these products?

- a. Amara View Minimal Contact Full-Face Mask and Wisp/Wisp Youth Nasal Mask have non-magnetic headgear clip replacement parts that can be used in place of the magnetic headgear clips.
- b. Amara View Minimal Contact Full-Face Mask with non-magnetic headgear clips is an alternative to DreamWear Full Face.
- c. DreamWear under-the-nose nasal mask, Wisp with non-magnetic headgear clips, and Pico are alternatives to DreamWisp Nasal Mask with Over the Nose Cushion.
- d. DreamWear under-the-nose nasal mask is an alternative to Therapy Mask 3100 NC.
- e. DreamWear Silicone Pillows, Nuance, and Nuance Pro are alternatives to the pillows in Therapy Mask 3100 SP.

7. For the masks that can use either magnetic or non-magnetic headgear clips (Amara View Minimal Contact Full-Face Mask and Wisp/Wisp Youth Nasal Mask) how do you remove the magnetic headgear clips and attach the non-magnetic headgear clips? Follow the IFU instructions (restated below) to do these actions.

Amara View Minimal Contact Full-Face Mask

Removing the Magnetic Headgear Clips:

- Grip and twist the magnetic headgear clip away from the frame to disconnect. Detach the headgear tabs and slide the magnetic clips off of the headgear. Thread the headgear tabs through the clip connection points on the frame. Reattach the headgear tabs.

Attaching the Non-Magnetic Headgear Clips:

- Slide the bottom strap headgear tabs through the slot on the clip from the hook side through to the outer, flatter side; attach tab to headgear. Connect the headgear clip to the frame by pressing the clip firmly onto the frame.

Wisp/Wisp Youth Nasal Mask

Removing the Magnetic Headgear Clips:

- Pull the ends of the magnetic clip away from the frame. Detach the headgear tabs and slide the magnetic clip off the headgear. Push the circular end, still attached to the frame, out of the mask from bottom slot. Thread the headgear tabs through the slots on the bottom (shorter arms) of the frame. Reattach the headgear tabs.

Attaching the Non-Magnetic Headgear Clips:

- Slide the bottom strap headgear tabs through the slots on the clip from the round side through to the outer, flat side; attach tab to headgear. Connect the headgear clips to the frame by pressing them into the slots on the bottom (shorter) arms.

8. I have an implant/medical device and still want to use the mask with magnets OR my physician says I can continue to use a mask with magnets; what do I do?

You should discuss the updated Contraindication and Warning with your physician prior to continuing to use the mask with magnets.

9. I believe I have experienced harm because of the magnets in my mask; what do I do?
10. **STOP** using the affected mask and contact a healthcare provider immediately. Report the event to authority UK Medicines and Healthcare products Regulatory Agency or Ireland Health Products Regulatory Authority. Philips Respironics regrets any inconvenience caused by this problem.
11. Should DMEs, Distributors, and Prescribers decide to continue distributing masks and mask accessories with magnets to patients, they need to do so under the terms of the Field Safety Notices and provide a copy of the Field Safety Notice and associated FAQs to the purchaser.