

Masks with Magnets - FAQs for Updated Contraindication and Warning – for Patients, DMEs, Distributors, and Prescribers

August 29, 2022

1. 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.

2. 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*
- *Emboic 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.*

3. What Philips 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 and Wisp Youth, and Therapy Mask 3100 NC/SP with magnetic clips.
 - b. See Appendix for full part numbers list. All units distributed under the identified part numbers are affected by this issue.

4. What should I use instead of these products?
 - a. Amara View Minimal Contact Full-Face Mask and Wisp/Wisp Youth 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.

5. 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?
 - a. You should discuss the updated Contraindication and Warning with your physician.

6. I believe I have had adverse events or harm because of the magnets in my mask; what do I do?

STOP using the affected mask and contact a healthcare provider immediately. Report the event to the FDA MedWatch: The FDA Safety Information and Adverse Event Reporting Program, either online, or by regular mail, or by fax.

Appendix - Devices Impacted by This Issue:

| Amara View Minimal Contact Full-Face Mask | |
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| Part # | Description |
| 1090602 | S Amara View Mask w/HGR |
| 1090603 | M Amara View Mask w/HGR |
| 1090604 | L Amara View Mask w/HGR |
| 1090622 | S Amara View Mask w/ HGR, DOM |
| 1090623 | M Amara View Mask w/ HGR, DOM |
| 1090624 | L Amara View Mask w/ HGR, DOM |
| 1090670 | Amara View Mask w/HGR, FitPack |
| 1090696 | RP – Amara View Headgear, L |
| 1090697 | RP-Amara View Headgear, Standard |
| 1135080 | S AMARA VIEW MASK SE W/ HGR |
| 1135081 | M AMARA VIEW MASK SE W/ HGR |
| 1135082 | L AMARA VIEW MASK SE W/ HGR |
| 1136626 | Amara View Magnet Clip |
| 1090670RTL | AMARA VIEW MASK W/HGR, FITPACK |
| 1136626RTL | Amara View Full Face Magnetic Clips |

| Wisp and Wisp Youth | |
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| Part Number | Description |
| 1094050 | WISP MASK, CLEAR FRAME, W/ HDGR, DOM |
| 1094051 | WISP MASK, FABRIC FRAME, W/MAG CLIPS DOM |
| 1094053 | WISP MASK, USA, FABRIC FRAME, W/ HDGR |
| 1109298 | WISP YOUTH MASK, FABRIC, W/MAG CLIPS DOM |
| 1118060 | P, WISP MASK, CLEAR FRAME, W/ HDGR, DOM |
| 1118061 | S/M, WISP MASK CLEAR FRAME, W/ HDGR DOM |
| 1118062 | L, WISP MASK, CLEAR FRAME, W/ HDGR, DOM |
| 1118063 | XL, WISP MASK, CLEAR FRAME, W/ HGR, DOM |
| 1118064 | P, WISP MASK, FABRIC FRAME, W/ HDGR,DOM |
| 1118065 | S/M, WISP MASK FABRIC FRAME W/ HDGR,DOM |
| 1118066 | L, WISP MASK, FABRIC FRAME, W/ HDGR,DOM |
| 1118067 | XL, WISP MASK, FABRIC FRAME W/ HGR, DOM |
| 1120434 | Wisp/DreamWisp Magnetic Headgear Clip,RP |
| 1137360 | Wisp Nasal Lab Mask, Fabric Frame, DOM |
| 1137361 | Wisp Nasal Lab Mask, Clear Frame, DOM |
| 1137366 | S/M, Wisp Lab Mask, Fabric Frame, DOM |

| DreamWear | |
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| Part # | Description |
| 1133344 | S, DreamWear UTN Nsl/Full, Combo Pack |
| 1133345 | M, DreamWear UTN Nsl/Full, Combo Pack |
| 1133375 | S, DreamWear Full, Sm & Med Frm, GBL |
| 1133376 | M, DreamWear Full, Sm & Med Frm, GBL |
| 1133377 | L, DreamWear Full, Sm & Med Frm, GBL |
| 1133378 | MW, DreamWear Full, Sm & Med Frm |
| 1133380 | S, DreamWear Full, Med Frm W/ HGR |
| 1133381 | M, DreamWear Full, Med Frm W/ HGR |
| 1133382 | L, DreamWear Full, Med Frm W/ HGR, GBL |
| 1133383 | MW, DreamWear Full, Med Frm W/ HGR, GBL |
| 1133385 | S, DreamWear Full, Sm Frm W/ HGR, GBL |
| 1133386 | M, DreamWear Full, Sm Frm W/ HGR, GBL |
| 1133387 | L, DreamWear Full, Sm Frm W/ HGR, GBL |
| 1133388 | MW, DreamWear Full, Sm Frm W/ HGR, GBL |
| 1133390 | S, DreamWear Full, Lg Frm W/ HGR, GBL |
| 1133391 | M, DreamWear Full, Lg Frm W/ HGR, GBL |
| 1133392 | L, DreamWear Full, Lg Frm W/ HGR, GBL |
| 1133393 | MW, DreamWear Full, Lg Frm W/ HGR, GBL |
| 1133395 | DreamWear Full, Demo Pack |
| 1133400 | FitPack, DreamWear Full, Med Frame, GBL |
| 1133401 | DreamWear Full, Med Frm W/O HGR, GBL |
| 1133405 | S, DreamWear Full, Med Frm W/O HGR, GBL |
| 1133406 | M, DreamWear Full, Med Frm W/O HGR, GBL |
| 1133407 | L, DreamWear Full, Med Frm W/O HGR, GBL |
| 1133408 | MW, DreamWear Full, Med Frm W/O HGR, GBL |
| 1133410 | S, DreamWear Full, Sm Frm W/O HGR, GBL |
| 1133411 | M, DreamWear Full, Sm Frm W/O HGR, GBL |
| 1133412 | L, DreamWear Full, Sm Frm W/O HGR, GBL |
| 1133413 | MW, DreamWear Full, Sm Frm W/O HGR, GBL |
| 1133415 | S, DreamWear Full, Lg Frm W/O HGR, GBL |
| 1133416 | M, DreamWear Full, Lg Frm W/O HGR, GBL |
| 1133417 | L, DreamWear Full, Lg Frm W/O HGR, GBL |
| 1133418 | MW, DreamWear Full, Lg Frm W/O HGR, GBL |
| 1133430 | S, DreamWear Full Cushion, RP |
| 1133431 | M, DreamWear Full Cushion, RP |
| 1133432 | L, DreamWear Full Cushion, RP |
| 1133433 | MW, DreamWear Full Cushion, RP |
| 1133434 | SW, DreamWear Full Cushion, RP |
| 1133450 | DreamWear Full Headgear, RP |
| 1133454 | Headgear Magnet Clip, RP |
| 1137430 | Fitpack, DreamWear Full Lab,Med Frm, DOM |
| 1137431 | Ext Sizepack,DreamWear Full Lab Msk, DOM |
| 1137437 | S, DreamWear Full Lab Msk,Med Frame, DOM |
| 1137438 | S, DreamWear Full Lab Mask,Sm Frame, DOM |
| 1137439 | M, DreamWear Full Lab Msk,Med Frame, DOM |
| 1137440 | COMBOPACK, DREAMWEAR FULL LAB MASK |

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| 1137367 | L, Wisp Nasal Mask, Fabric Frame, DOM |
| 1137368 | S/M, Wisp Nasal Mask, Clear Frame, DOM |
| 1137369 | L, Wisp Nasal Mask, Clear Frame, DOM |
| 1137370 | COMBOPACK, WISP LAB MASK, DOM |
| 1138989 | P, WISP MASK,CLEAR FRAME, W/HDGR, 1118060 |
| 1138991 | L, WISP MASK, CLEAR W/ HDGR, DOM, 1118062 |
| 1138992 | XL,WISP MASK,CLEAR FRAME,W/ HGR,1118063 |
| 1138993 | P, WISP MASK,FABRIC FRAME,W/HDGR,1118064 |
| 1138994 | S/M,WISP MASK FABRICFRAME W/HDGR,1118065 |
| 1138995 | L, WISP MASK,FABRIC FRAME,W/HDGR,1118066 |
| 1138996 | XL,WISP MASK,FABRIC FRAME W/HGR, 1118067 |
| 1139009 | S/M,WISPMASK CLEAR FRAME,W/ HDGR 1118061 |
| 1094051RTL | WISP MASK, FABRICFRM,W/MAG CLIPS DOM-RTL |
| 1148366 | DreamWisp/Wisp Magnetic Clips - RTL |

| DreamWisp Nasal Mask with Over the Nose Cushion | |
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| Part # | Description |
| 1137916 | Fitpk DreamWisp Nsl, MED Con W/HGR GBL |
| 1137918 | FitPk DreamWisp Nsl, MED Con W/O HGR GBL |
| 1137922 | P, DreamWisp Nsl, Med Con W/O HGR GBL |
| 1137923 | S, DreamWisp Nsl, Med Con W/O HGR GBL |
| 1137924 | M, DreamWisp Nsl, Med Conn W/O HGR GBL |
| 1137925 | L, DreamWisp Nsl, Med Con W/O HGR GBL |
| 1137926 | XL, DreamWisp Nsl, Med Con W/O HGR GBL |
| 1137927 | P, DreamWisp NSL, SM CON, W/HGR, GBL |
| 1137928 | S, DreamWisp NSL, SM CON, W/HGR, GBL |
| 1137929 | M, DreamWisp NSL, SM CON, W/HGR, GBL |
| 1137930 | L, DreamWisp NSL, SM CON, W/HGR, GBL |
| 1137931 | XL, DreamWisp NSL, SM CON, W/HGR, GBL |
| 1137932 | P, DreamWisp Nsl, Med Con, W/HGR, GBL |
| 1137933 | S, DreamWisp Nsl, Med Con, W/HGR, GBL |
| 1137934 | M, DreamWisp Nsl, Med Con, W/HGR, GBL |
| 1137935 | L, DreamWisp Nsl, Med Con, W/HGR, GBL |
| 1137936 | XL, DreamWisp Nsl, Med Con, W/HGR, GBL |
| 1137953 | LABPK DreamWisp ALL CON S/M/L CUSH W/HGR |
| 1137954 | P/XL LABPK DreamWisp LAB PACK, S/L con |
| 1137955 | Combo LabPK DreamWisp |
| 1137964 | DreamWisp HEADGEAR, RP |
| 1137965 | DreamWisp LARGE HEADGEAR, RP |
| 1137966 | DreamWisp RS HEADGEAR, RP |
| 1144344 | DreamWisp RS HEADGEAR-Lab, RP |
| 1144345 | DreamWisp LARGE HEADGEAR-Lab, RP |
| 1144346 | DreamWisp HEADGEAR - Lab, RP |
| 1144502 | FitPack, DreamWisp, USA |
| 1148409 | DreamWisp Headgear (RS)- RTL |
| 1148410 | DreamWisp HEADGEAR, RP- RTL |
| 1148411 | DreamWisp LARGE HEADGEAR, RP- RTL |
| 1137916RTL | FITPK DREAMWISP NSL, MED CON W/HGR -RTL |

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| 1140235 | S, DreamWear Full, Med Frm W/ HGR, USA |
| 1143130 | FitPack, DreamWear Full, Med Frame, USA |
| 1144347 | DreamWear Full Headgear - Lab, RP |
| 1146593 | S, DreamWear Full Cushion, RP - RTL |
| 1146594 | M, DreamWear Full Cushion, RP - RTL |
| 1146595 | L, DreamWear Full Cushion, RP - RTL |
| 1146596 | MW, DreamWear Full Cushion, RP - RTL |
| 1146597 | DreamWear Full Headgear, RP - RTL |
| 1148363 | DreamWear Full Face Magnet Clip - RTL |
| 1133375RTL | DreamWear Mask, S. Cushion w/ Frame (S&M) |
| 1133376RTL | DreamWear Mask, M. Cushion w/ Frame (S&M) |
| 1133377RTL | DreamWear Full Face Mask Kit, L. Cushion |
| 1133378RTL | DreamWear Full Face Mask Kit, M. Wide Cushion |
| 1133430RTL | S, DREAMWEAR FULL CUSHION, RP-RTL |
| 1133431RTL | M, DREAMWEAR FULL CUSHION, RP-RTL |
| 1133432RTL | DreamWear Full Face Cushion, Large |
| 1133433RTL | DreamWear Full Face Cushion, Med. Wide |

| Therapy Mask 3100 NC/SP | |
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| Part # | Description |
| 1144608 | Therapy Msk 3100 NC, fitpack, w/HGR, GBL |
| 1144610 | Therapy Msk 3100 SP, fitpack, w/HGR, GBL |
| 1145044 | XS, Therapy Mask 3100 NC, w/oHGR, GBL |
| 1145045 | S, Therapy Mask 3100 NC, w/oHGR, GBL |
| 1145046 | M, Therapy Mask 3100 NC, w/oHGR, GBL |
| 1145047 | L, Therapy Mask 3100 NC, w/oHGR, GBL |
| 1145048 | MW, Therapy Mask 3100 NC, w/oHGR, GBL |
| 1145055 | XS, Therapy Mask 3100 SP, w/oHGR, GBL |
| 1145056 | S, Therapy Mask 3100 SP, w/oHGR, GBL |
| 1145057 | M, Therapy Mask 3100 SP, w/oHGR, GBL |
| 1145058 | L, Therapy Mask 3100 SP, w/oHGR, GBL |
| 1145059 | MW, Therapy Mask 3100 SP, w/oHGR, GBL |
| 1145060 | Therapy Mask 3100 NC-SP, demopack, GBL |
| 1145061 | Therapy Msk 3100 NC, lab fitpack, single |
| 1145062 | Therapy Msk 3100 SP, lab fitpack, single |
| 1145063 | Therapy Mask 3100 NC-SP, lab combo, GBL |
| 1145064 | XS, Therapy Mask 3100 NC, cushion, RP |
| 1145065 | S, Therapy Mask 3100 NC, cushion, RP |
| 1145066 | M, Therapy Mask 3100 NC, cushion, RP |
| 1145067 | L, Therapy Mask 3100 NC, cushion, RP |
| 1145068 | MW, Therapy Mask 3100 NC, cushion, RP |
| 1145069 | XS, Therapy Mask 3100 SP, cushion, RP |
| 1145070 | S, Therapy Mask 3100 SP, cushion, RP |
| 1145071 | M, Therapy Mask 3100 SP, cushion, RP |
| 1145072 | L, Therapy Mask 3100 SP, cushion, RP |
| 1145073 | MW, Therapy Mask 3100 SP, cushion, RP |
| 1145074 | Therapy Mask 3100 NC-SP, frame, RP |
| 1145459 | XS, Therapy Mask 3100 NC, w/HGR, GBL |
| 1145460 | S, Therapy Mask 3100 NC, w/HGR, GBL |
| 1145461 | M, Therapy Mask 3100 NC, w/HGR, GBL |
| 1145462 | MW, Therapy Mask 3100 NC, w/HGR, GBL |
| 1145463 | L, Therapy Mask 3100 NC, w/HGR, GBL |
| 1145464 | XS, Therapy Mask 3100 SP, w/HGR, GBL |
| 1145465 | S, Therapy Mask 3100 SP, w/HGR, GBL |
| 1145466 | M, Therapy Mask 3100 SP, w/HGR, GBL |
| 1145467 | MW, Therapy Mask 3100 SP, w/HGR, GBL |
| 1145478 | L, Therapy Mask 3100 SP, w/HGR, GBL |
| 1145916 | Therapy Mask 3100 NC, lab fitpack, GBL |
| 1145917 | Therapy Mask 3100 SP, lab fitpack, GBL |