

URGENT Medical Device Correction

**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**

August 29, 2022

This document contains important information for the continued safe 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.

This Urgent Medical Device Correction 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.
- 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

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. Actions to be taken by patient to prevent risks

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. Actions planned by Philips to correct the problem

Philips Respironics is updating its existing Contraindication and Warning as provided in this correction letter.

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

This correction letter has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax. Philips regrets any inconvenience caused by this problem.

Sincerely,

Thomas J Fallon

Thomas Fallon
 Head of Quality Assurance
 Philips Respironics

Devices Impacted by This Issue - Figure 6:

| Amara View Minimal Contact Full-Face Mask | |
|---|-------------------------------------|
| 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 | |
|---------------------|--|
| 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 | |
|------------------|--|
| 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 |

| | |
|------------|---|
| 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 | |
|--|--|
| 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 |

| | |
|------------|---|
| 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 | |
|--------------------------------|--|
| 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 |