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URGENT Field Safety Notice

Philips Respironics – Sleep and Respiratory Care

Notification To DMEs/Distributors/Prescribers

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 XX, 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 Customer,

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 Field Safety Notice is intended to inform you that Philips Respironics is updating its existing contraindications and warnings to the following:

Contraindication: *Use of the mask is contraindicated in patients with metallic splinters in the eye and the following metallic implants: brain shunts, aneurysm clips, pacemakers, implantable cardioverter defibrillators (ICD), defibrillators, VP shunts, and certain neurostimulators used in and around the neck.*

Warning: *Magnets with a magnetic field strength of 400mT are used in the mask. With the exception of the devices identified in the contraindication, ensure the mask is kept at least 2 inches (5 cm) away from any other active medical implant or medical device that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields.*

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

The affected masks contain magnets which can potentially affect the functioning of certain implanted medical devices, such as metal splinters in the eyes, brain shunts, aneurysm clips, pacemakers, implantable cardioverter defibrillators (ICD), defibrillators, VP shunts, and certain neurostimulators used in and around the neck, or any implanted medical device affected by magnets.

2. Describe the hazard/harm associated with the issue

With the exception of the devices identified in the contraindication, if the mask magnets are placed less than 2 inches away from an implanted metallic device the magnets may cause the device to not perform as intended, which may result in a serious injury. There have been nine (9) reports of serious injuries associated with this issue.

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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. Describe the actions that should be taken by the customer in order to prevent risks for patients

As a DME, distributor, or prescriber of these masks, **you must take the following action:**

4.1. This field safety notice and copies of the included patient version of the field safety notice and Facts and Questions document need to be provided to all those who need to be aware within your organization and to any organizations where the affected devices have been transferred. Additionally, all patients using the affected devices need to be given copies of the included patient version of the field safety notice and Facts and Questions document. As Philips Respironics sells these products through DMEs/distributors and prescribers, we may not have the contact information to reach all patients.

4.2. Fill out the Business Reply Form that is provided with this field safety notice per the instructions in the form. This form serves as official acknowledgement that you have received this field safety notice and completed the actions required for this medical device correction.

4.3. If patients do not have implanted medical devices, or metallic splinters in their eyes, then no action related to patients is needed.

4.4. Patients who have implanted medical devices that may interact with magnets and who use one of the affected masks identified in this field safety notice should be made aware of the potential interaction between the masks and their device(s) as noted in the contraindication/warning listed above. Patients should consult their physician to determine if another mask should be used for their therapy. Philips Respironics customer service can be contacted to learn more about non-magnetic mask options.

4.5. If a patient experiences any of the issues discussed above, they should contact a healthcare provider immediately.

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

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

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6. **If you need any further information or support concerning this issue, please contact your local Philips Respironics representative.** <Philips Respironics representative contact details to be completed by the Markets Q&R teams>. 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 Respironics or the local competent authority <localized by Philip Markets Q&R teams> Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

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
1090641	XS Amara View Mask w/HGR, JPN
1090642	S Amara View Mask w/HGR, JPN
1090643	M Amara View Mask w/HGR, JPN
1090644	L Amara View Mask w/HGR, JPN
1090651	XS Amara View Mask SE w/HGR, JPN
1090652	S Amara View Mask SE w/HGR, JPN
1090653	M Amara View Mask SE w/HGR, JPN
1090654	L Amara View Mask SE w/HGR, JPN
1090662	S Amara View Mask w/HGR, INTL
1090663	M Amara View Mask w/HGR, INTL
1090664	L Amara View Mask w/HGR, INTL
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-RTL
1136626RTL	Amara View Full Face Magnetic Clips

Wisp and Wisp Youth Nasal Mask	
Part #	**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
1094060	WISP MASK, CLEAR FRAME, W/ HDGR, INTL
1094061	WISP MASK, FABRIC FRAME, W/ HDGR, INTL
1094062	WISP MASK, CLEAR FRAME, W/ HDGR, INTL SE
1094070	WISP MASK, CLEAR FRAME, W/ HDGR, JPN SE
1094071	P, WISP MASK, FABRIC FRAME, W/ HDGR, JPN
1094072	S/M, WISP MASK FABRIC FRAME, W/ HDGR JPN
1094073	L, WISP MASK, FABRIC FRAME, W/ HDGR, JPN
1109298	WISP YOUTH MASK, FABRIC, W/MAG CLIPS DOM
1113954	XL, Wisp Mask, Fabric Frame, w/ HDGR, JP
1117119	MW, Wisp Mask, Fabric Frame, w/ HDGR, JP
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
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

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DreamWear Full Face Mask	
Part #	**Description**
1133344	S, DreamWear UTN Nsl/Full, Combo Pack
1133345	M, DreamWear UTN Nsl/Full, Combo Pack
1133370	S, DreamWear Full, Sm & Med Frm, INTL
1133371	M, DreamWear Full, Sm & Med Frm, INTL
1133372	L, DreamWear Full, Sm & Med Frm, INTL
1133373	MW, DreamWear Full, Sm & Med Frm
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, S. & M. Frm, GBL
1133380	S, DreamWear Full, M. Frm W/ HGR, GBL
1133381	M, DreamWear Full, Med Frm W/ HGR
1133382	L, DreamWear Full, Med Frm W/ HGR
1133383	MW, DreamWear Full, Med Frm W/ HGR
1133385	S, DreamWear Full, Sm Frm W/ HGR, GBL
1133386	M, DreamWear Full, Sm Frm W/ HGR
1133387	L, DreamWear Full, Sm Frm W/ HGR, GBL
1133388	MW, DreamWear Full, Sm Frm W/ HGR,
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
1133395	DreamWear Full, Demo Pack
1133400	FitPack, DreamWear Full, Med Frame
1133401	DreamWear Full, Med Frm W/O HGR, GBL
1133405	S, DreamWear Full, Med Frm W/O HGR
1133406	M, DreamWear Full, Med Frm W/O HGR
1133407	L, DreamWear Full, Med Frm W/O HGR
1133408	MW, DreamWear Full, Med Frm W/O
1133410	S, DreamWear Full, Sm Frm W/O HGR
1133411	M, DreamWear Full, Sm Frm W/O HGR
1133412	L, DreamWear Full, Sm Frm W/O HGR
1133413	MW, DreamWear Full, Sm Frm W/O HGR
1133415	S, DreamWear Full, Lg Frm W/O HGR, GBL
1133416	M, DreamWear Full, Lg Frm W/O HGR
1133417	L, DreamWear Full, Lg Frm W/O HGR, GBL
1133418	MW, DreamWear Full, Lg Frm W/O HGR
1133423	S/M, DreamWear Full, Sm Frm w/ HGR
1133424	S/M, DreamWear Full, Med Frm w/ HGR
1133425	S/M, DreamWear Full, Lg Frm w/ HGR
1133427	W, DreamWear Full, Med Frm W/ HGR
1133430	S, DreamWear Full Cushion, RP
1133431	M, DreamWear Full Cushion, RP
1133432	L, DreamWear Full Cushion, RP

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
1137921	FitPk, DreamWisp Nsl, MED Con W/ HGR INT
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
1137937	P, DreamWisp NSL, SM CON, W/HGR, INT
1137938	S, DreamWisp NSL, SM CON, W/HGR, INT
1137939	M, DreamWisp NSL, SM CON, W/HGR, INT
1137940	L, DreamWisp NSL, SM CON, W/HGR, INT
1137941	XL, DreamWisp NSL, SM CON, W/HGR, INT
1137942	P, DreamWisp Nsl, Med Con, W/HGR INT
1137943	S, DreamWisp Nsl, Med Con, W/HGR INT
1137944	M, DreamWisp Nsl, Med Con, W/HGR INT
1137945	L, DreamWisp Nsl, Med Con, W/HGR INT
1137946	XL, DreamWisp Nsl, Med Con, W/HGR INT
1137947	P, DreamWisp Nsl, S-M-L Con, W/HGR, JPN
1137948	S, DreamWisp Nsl, S-M-L Con, W/HGR, JPN
1137949	M, DreamWisp Nsl, S-M-L Con, W/HGR, JPN

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1133433	MW, DreamWear Full Cushion, RP
1133434	SW, DreamWear Full Cushion, RP
1133435	S, DreamWear Full Cushion, RP, JPN
1133436	M, DreamWear Full Cushion, RP, JPN
1133438	W, DreamWear Full Cushion, RP, JPN
1133450	DreamWear Full Headgear, RP
1133454	Headgear Magnet Clip, RP
1135275	S, DreamWear Full, Sm and Med Frm
1135276	M, DreamWear Full, Sm and Med Frm
1135277	SW, DreamWear Full,Sm and Med Frm
1135278	MW, DreamWear Full,Sm and Med Frm
1135327	S, DreamWear Full, Sm & Med Frm, KR
1135388	M, DreamWear Full, Sm & Med Frm, KR
1135389	SW, DreamWear Full, Sm & Med Frm, KR
1135390	MW, DreamWear Full, Sm & Med Frm
1137430	Fitpack, DreamWear Full Lab,Med Frm
1137431	Ext Sizepack,DreamWear Full Lab Msk
1137437	S, DreamWear Full Lab Msk,Med Frame
1137438	S, DreamWear Full Lab Mask,Sm Frame
1137439	M, DreamWear Full Lab Msk,Med Frame
1137440	COMBOPACK, DREAMWEAR FULL LAB
1140235	S, DreamWear Full, Med Frm W/ HGR
1143130	FitPack, DreamWear Full, Med Frame
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 Full Face Mask Kit, Small
1133376RTL	DreamWear Full Face Mask Kit, Medium
1133377RTL	DreamWear Full Face Mask Kit, Large
1133378RTL	DreamWear Face Mask Kit, M. 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, Medium

	Therapy Mask 3100 NC/SP
1144608	Therapy Msk 3100 NC, fitpack, w/HGR
1144610	Therapy Msk 3100 SP, fitpack, w/HGR
1145038	Therapy Msk 3100 NC, fitpack, w/HGR
1145039	Therapy Mask 3100 NC, fitpack, w/HGR
1145040	Therapy Mask 3100 NC, fitpack, w/HGR

1137950	L, DreamWisp Nsl, S-M-L Con, W/HGR, JPN
1137951	XL, DreamWisp Nsl, S-M-L Con, W/HGR, JPN
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
1139332	P, DreamWisp Nsl, S-M Con, W/HGR KR
1139333	S, DreamWisp Nsl, S-M Con, W/HGR KR
1139334	M, DreamWisp Nsl, S-M Con, W/HGR KR
1139335	L, DreamWisp Nsl, S-M Con, W/HGR KR
1139336	XL, DreamWisp Nsl, S-M Con, W/HGR KR
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
1148913	P, DreamWisp Nsl, S-M Con, W/HGR CN
1148914	S, DreamWisp Nsl, S-M Con, W/HGR CN
1148915	M, DreamWisp Nsl, S-M Con, W/HGR CN
1148916	L, DreamWisp Nsl, S-M Con, W/HGR CN
1148917	XL, DreamWisp Nsl, S-M Con, W/HGR CN
1137942AP	P, DREAMWISP NSL, MED CON, W/HGR, AP
1137942CE	P, DREAMWISP NSL, MED CON, W/HGR, CE
1137942RC	P, DREAMWISP NSL, MED CON, W/HGR, RC
1137943AP	S, DREAMWISP NSL, MED CON, W/HGR, AP
1137943CE	S, DREAMWISP NSL, MED CON, W/HGR, CE
1137943RC	S, DREAMWISP NSL, MED CON, W/HGR, RC
1137944AP	M, DREAMWISP NSL, MED CON, W/HGR, AP
1137944CE	M, DREAMWISP NSL, MED CON, W/HGR, CE
1137944RC	M, DREAMWISP NSL, MED CON, W/HGR, RC
1137945AP	L, DREAMWISP NSL, MED CON, W/HGR, AP
1137945CE	L, DREAMWISP NSL, MED CON, W/HGR, CE
1137945RC	L, DREAMWISP NSL, MED CON, W/HGR, RC
1137946AP	XL, DREAMWISP NSL, MED CON, W/HGR, AP
1137946CE	XL, DREAMWISP NSL, MED CON, W/HGR, CE
1137946RC	XL, DREAMWISP NSL, MED CON, W/HGR, RC
1137916RTL	FITPK DREAMWISP NSL, MED CON W/HGR -RTL

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1145041	Therapy Mask 3100 NC, fitpack, w/HGR
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
1145049	Therapy Msk 3100 SP, fitpack, w/HGR,
1145050	Therapy Mask 3100 SP, fitpack, w/HGR
1145051	Therapy Mask 3100 SP, fitpack, w/HGR
1145052	Therapy Mask 3100 SP, fitpack, w/HGR
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
1145060	Therapy Mask 3100 NC-SP, demopack
1145061	Therapy Msk 3100 NC, lab fitpack, single
1145062	Therapy Msk 3100 SP, lab fitpack, single
1145063	Therapy Mask 3100 NC-SP, lab combo
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

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FIELD SAFETY NOTICE BUSINESS RESPONSE FORM

Reference: 2022-CC-SCR-001

Instructions: Complete and return all pages of this form within 30 days and return it to Philips Respironics by either of the following methods:

<Reply form return details to be completed by the Key Market / country Q&R teams>

Customer Name:_____

Street Address:_____

City/Postal Code/Country:_____

We acknowledge:

1. Receipt and understanding of the accompanying DME/Distributor/Prescriber Urgent Field Safety Notice and confirm that the notice has been provided to all those who need to be aware within your organization and to any organizations where the affected devices have been transferred.
2. Receipt of the patient version of the Field Safety Notice and "Facts and Questions" document and confirm that these documents have been provided to all patients using the affected devices.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date (DD/MM/YYYY):_____

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Masks with Magnets – Facts and Questions for Updated Contraindication and Warning – for Patients, DMEs, Distributors, and Prescribers

August XX, 2022

1. What is a contraindication versus a warning?
    a. 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 in patients with metallic splinters in the eye and the following metallic implants: brain shunts, aneurysm clips, pacemakers, implantable cardioverter defibrillators (ICD), defibrillators, VP shunts, and certain neurostimulators used in and around the neck.

    Warning:
    Magnets with a magnetic field strength of 400mT are used in the mask. With the exception of the devices identified in the contraindication, ensure the mask is kept at least 2 inches (5 cm) away from any other active medical implant or medical device that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields.

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.

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 can be used as an alternative to DreamWear Full Face.
    c. DreamWear under-the-nose nasal mask, Wisp with non-magnetic headgear clips, and Pico can be used as alternatives to DreamWisp Nasal Mask with Over the Nose Cushion.

5. Does this affect competitive products with magnets?
    a. The magnet type and strength used in Philips Respironics masks is consistent with those used across the CPAP mask industry. Similar issues have occurred with other products in the masks with magnets category. However, Philips Respironics cannot comment on the safety and efficacy of masks from other manufacturers.

6. I have an implanted 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.

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

    a. If you experience any of the issues discussed above, contact a healthcare provider immediately.