

Philips Respironics 磁扣型面罩修正措施 - 更新禁忌症和警告事項常見問答集 (「常見問答集」)

2022 年 12 月 23 日

本通知包含重要資訊，說明如何以安全的方式繼續使用您的磁扣型面罩。

- 請將本通知以及 Philips Respironics 磁扣型面罩修正措施 - 更新禁忌症和警告事項相關常見問答集 (「常見問答集」)，轉知貴單位中有必要知悉相關內容的所有人員。請務必正視本通知可能的影響。
- 請保留一份副本，與磁扣型面罩的使用說明 (IFU) 一同收存。

1. 給 DME、經銷商及醫生：哪裡可以找到本次修正措施的詳細資訊？
 - 有關本次修正措施的詳細資訊可查看 Philips Respironics 網址：
<https://www.usa.philips.com/healthcare/e/sleep/communications/magnet-notification>
2. 給患者：哪裡可以找到本次修正的詳細資訊/支援及購置不含磁性頭具扣的面罩或無磁性頭具扣？
 - 有關本次修正措施的詳細資訊可查看 Philips Respironics 網址：
<https://www.usa.philips.com/healthcare/e/sleep/communications/magnet-notification>
 - 如欲購置不含磁性頭具扣的面罩或無磁性頭具扣，請聯絡你的設備供應商。
3. 禁忌症及警告事項分別是什麼？

「禁忌症」是指使用裝置的風險明顯大於可能的效益，應避免使用該裝置的情況。「警告事項」則是提醒患者應注意的情況，否則可能導致死亡或嚴重傷害。此外，警告事項也可能包括潛在的嚴重不良反應和安全性風險。簡而言之，禁忌症是告訴使用者，什麼情況不應使用裝置，警告事項則是告訴使用者，在使用裝置時如何避免危害。

4. 禁忌症和警告事項的更新內容為何？

Philips Respironics 已更新現有的禁忌症及警告事項，加入以下內容：

禁忌症：對於有以下可能受磁場影響之植入物的患者，以及可能與該患者近距離接觸的家庭成員、照護者、同睡者，禁止使用面罩，植入物包括但不限於：

- 心律調節器
- 植入式心臟除顫器 (ICD)
 - 神經刺激器
 - 放置於上肢、軀體或更高處 (例如頭頸部) 且帶有磁性的金屬植入物/電極片/閥
 - 腦脊髓液 (CSF) 支架 (例如 VP (腦室腹膜) 支架)
 - 動脈瘤夾
 - 金屬線圈栓塞
 - 腦內動脈血管內血流擠壓裝置
 - 金屬製顱板、螺絲、顱骨開孔蓋及骨頭取代裝置
 - 眼內金屬碎片
 - 眼部植入物 (例如青光眼植入物、視網膜植入物)
 - 部分帶有金屬的隱形眼鏡
 - 帶有植入性磁鐵用於恢復聽覺或平衡的植入物 (例如植入式耳蝸、植入式耳骨聽覺裝置，以及腦幹聽力誘發植入物)
 - 金屬製假牙
 - 金屬製消化道夾
 - 金屬支架 (例如用於動脈瘤、冠狀動脈、氣管分支、膽道的支架)

- 植入式端口及幫浦(例如胰島素幫浦)
- 舌下神經刺激器
- 標示為不適用於MR(磁振)環境的裝置
- 未標示可用於MR環境或未評估於磁場環境中使用是否安全的磁性金屬植入物。

警告：面罩中的磁性頭具夾含有兩塊磁鐵，磁場強度為0.4 T。除禁忌症中列明的設備外，請確保面罩與可能受磁場影響的其他醫療植入物或醫療器材保持至少6吋(約15.24公分)距離，以免受到局部磁場影響。這也包括可能與使用面罩之患者近距離接觸的家庭成員、照護者、同睡者。

5. 有哪些 Philips Respironics 產品受影響？

- a. DreamWear Full Face Mask、磁扣型 Amara View Minimal Contact Full-Face Mask、DreamWisp Nasal Mask with Over the Nose Cushion、Wisp/Wisp Youth Mask、磁扣型 Therapy Mask 3100 NC/SP。
- b. 完整的零件編號清單，請參閱緊急通知：醫療設備出廠後安全通知。

6. 我應該改用什麼替代產品？

- a. Amara View Minimal Contact Full-Face Mask 及 Wisp/Wisp Youth Nasal Mask 另有無磁性頭具扣，可替換磁性頭具扣。
- b. 無磁扣型 Amara View Minimal Contact Full-Face Mask 可替換 DreamWear Full Face Mask。
- c. DreamWear under-the-nose nasal mask、無磁扣型 Wisp Nasal Mask 及 Pico，可替換 DreamWisp Nasal Mask with Over the Nose Cushion。
- d. DreamWear 鼻底枕墊式鼻罩是 Therapy Mask 3100 NC 的替代品。
- e. DreamWear Silicone Pillows、Nuance 和 Nuance Pro 是 Therapy Mask 3100 SP 鼻枕的替代品。

7. 對於可以使用磁性頭具扣或無磁性頭具扣的面罩 (Amara View Minimal Contact Full-Face Mask 及 Wisp/Wisp Youth Nasal Mask)，如何取下磁性頭具扣，並扣上無磁性頭具扣？請依照 IFU 說明 (重述如下) 執行這些步驟。

Amara View Minimal Contact Full-Face Mask

取下磁性頭具扣：

- 握住磁性頭具扣並扭離框架，以斷開連接。拆下頭具凸片，順勢將磁扣從頭具取下。將頭具凸片穿過框架上頭具扣的連接點。重新扣上頭套凸片。

裝上無磁性頭具扣：

- 將下側頭帶的頭具凸片從頭具扣的掛鉤面，穿過頭具扣槽孔到頭具扣的外扁平面；將凸片扣住頭具。將頭具扣用力壓到框架上，將兩者連接。

Wisp/Wisp Youth Nasal Mask

取下磁性頭具扣：

- 將磁扣的末端拉離框架。拆下頭具凸片，順勢將磁扣從頭具取下。將扣在框架上的磁扣圓形底座從下方的槽孔推出，使其脫離面罩。將頭具凸片穿過框架下方(較短的框架臂)上的槽孔，重新扣上頭具凸片。

裝上無磁性頭具扣：

- 將底部頭帶的頭具凸片從頭具夾的圓扣面，穿過頭具夾槽孔到頭具夾的外扁平面；將凸片扣住頭具。將頭具夾壓入下方(較短)框架臂上的槽孔中，以連接至框架

8. 我有植入式醫療裝置，但還是想用磁扣型的面罩產品，或是醫生說我可以繼續使用磁扣型的面罩，我該怎麼做？

在繼續使用磁扣型面罩之前，您應與醫生討論禁忌症及警告事項的更新內容。

9. 我相信我因為面罩中的磁鐵而受傷；我該怎麼辦？

停止使用受影響的產品，並立即聯絡專業醫護人員。請致電飛利浦香港睡眠和呼吸護理熱線：(852) 2873 1232 向 Philips 報告或通報當地主管機關。

10. 如果 DME、經銷商及處方醫生決定繼續向患者分銷含磁鐵的口罩及口罩配件，他們需要根據醫療設備出廠後安全通知的條款分銷相關產品，並向購買者提供一份醫療設備出廠後安全通知和相關常見問題集的副本。

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

23 December 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.usa.philips.com/healthcare/e/sleep/communications/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.usa.philips.com/healthcare/e/sleep/communications/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 Field Safety Notice 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?

STOP using the affected mask and contact a healthcare provider immediately. Report the event to Philips by calling Hong Kong Sleep & Respiratory Care Service Hotline at (852) 2873 1232 or the local competent authority.

10. 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.