

安全緊急通知

ResMed 含磁鐵面罩 - 對某些醫療設備有潛在的磁場干擾

患者通知函

參考編號：MWM-2023-FSN-01

日期：2023 年 11 月 20 日

含磁鐵面罩使用者，您好：

ResMed 為您提供有關本公司含磁鐵面罩方面的重要資訊。這些含磁鐵面罩可能會影響部份植體或某些醫療設備。請您務必瞭解本通知函中所含資訊、視需要採取行動，並將其留存以備日後參考。

為回應來自最新行業實踐和全球安全資料的新訊息，ResMed 正在更新使用者指南中的**禁忌與警告內容**，以指引患者安全使用 **ResMed 含磁鐵面罩**。

- 禁忌：有以下狀況時，不得使用該面罩。
- 警告：辨識可能危險，並提供如何安全使用該面罩的資訊。

一般產品說明

這些面罩用於透過氣道正壓通氣（PAP）設備向患者輸送空氣。

ResMed 的部份面罩使用磁鐵，以便患者在平常佩戴面罩時，可輕易將頭帶與面罩框體扣合及解開。這對有身體殘障的患者尤其有益，包括那些有靈活性或視力障礙的患者。

哪些面罩受到影響？

下列 ResMed 面罩包含磁鐵，請注意，各國所供應面罩可能有所不同。如您並未使用下列任一面罩，則本函資訊與您無關。

面罩類型	受影響面罩
全罩式面罩	AirFit F20、AirFit F20 for Her AirTouch F20、AirTouch F20 for Her AirFit F30 AirFit F30i
鼻罩	AirFit N10、AirFit N10 for Her AirFit N20、AirFit N20 for Her AirTouch N20、AirTouch N20 for Her
無通氣孔面罩	AirFit F20 NV

請參閱**附錄 A** 以取得更多資訊，瞭解如何辨識您的 ResMed 面罩與磁鐵的具體位置。

有哪些變動？

在所有含磁鐵面罩的使用者指南中，ResMed 更新了磁場干擾的相關**禁忌與警告**。

更新版禁忌

包含磁性組件的面罩，禁止用於任何近距離接觸體內存在下列物體的患者及任何人士：

- 會受磁鐵影響的主動醫療植入物（即心律調節器、植入式心律整流除顫器（ICD）、神經刺激器、腦脊髓液（CSF）分流器、胰島素/輸液幫浦）
- 包含鐵磁性物質的金屬植入物/物體（即腦血管夾/干擾血流設備、栓塞線圈、支架、瓣膜、電極、使用植入磁鐵恢復聽力或平衡的植入物、眼部植入物、眼內金屬碎片）

更新版警告

如植體或醫療設備可能受磁干擾影響，請在面罩磁鐵與植體及設備間保持至少 6 英吋（150 公釐）的安全距離。本警告適用於與面罩有近距離接觸的患者或任何人。磁鐵位於面罩框及下側頭帶扣具內，其磁場強度最高可達 400mT。佩戴時，兩者將扣合以固定面罩，但入睡時可能會在無意間鬆脫。

如在外部磁場下改變功能，或包含會吸引/排斥磁場的鐵磁性物質（部份金屬植入物，如含有金屬的隱形眼鏡、牙科植體、金屬顱板、螺絲、鑽孔蓋和骨代用設備），植入物/醫療設備（包含禁忌症中列出的那些植入物和設備）可能會受到影響。請諮詢醫師與植體/其他醫療設備的製造商，以取得磁場潛在不良影響的相關資訊。

患者安全資訊

依據更新版的使用說明（包含**禁忌與警告**）使用時，ResMed 含磁鐵面罩安全無虞。

磁鐵靠近某些醫療植體/設備時（距離小於 6 英吋/150 公釐），磁干擾可能改變：

- 植體/醫療設備的功能；
- 磁鐵材質植體的位置；

在極少數情況下，這可能導致重傷或死亡。

有禁忌症患者可使用其他無磁鐵面罩，以避免磁干擾的潛在危害。其他使用 ResMed 含磁鐵面罩的患者皆可遵循更新版使用說明，繼續使用該面罩。

從 2014 年至 2023 年 11 月為止，ResMed 已於全球售出數千萬個含磁鐵面罩。在此期間，ResMed 已向相關監管機關提交了五（5）份可能與植入設備（包含植入式心律去顫器（ICD）與腦脊髓液（CSF）分流器）受磁場干擾有關的重傷（治療/住院）報告。目前尚無永久性傷害或死亡案例。



您需採取的行動

使用 ResMed 含磁鐵面罩且有禁忌症的患者

在您或任何與面罩使用時有近距離接觸者（如同床伴侶）的身上，如有以上**禁忌**所列出的醫療植體或金屬植入物：

- 及時將含磁鐵面罩更換為其他無磁鐵面罩。聯繫面罩供應商以瞭解可供選擇的替代面罩。
請注意，ResMed 正在為您的面罩供應商提供無磁鐵面罩，以做替換。
- 如沒有其他可用替代面罩，請諮詢您的醫師，以瞭解所進行治療的適當後續步驟。
- 收到替代面罩後，請將含磁鐵面罩棄置。

請注意，並非所有禁忌中所列型號或版本的醫療設備都會受到外部磁場影響。如不確定醫療設備/植體是否列於禁忌中，或需要磁場可能對特定設備造成之不良影響的額外資訊，請與您的醫師聯繫。

所有其他使用 ResMed 含磁鐵面罩的患者

如沒有需避免使用 ResMed 含磁鐵面罩的禁忌症，則您可繼續使用面罩，請確定自己遵循所有使用者說明，本通知函中的更新內容亦包含在內。

- 重要事項：更新版**警告**中說明，ResMed 含磁鐵面罩應與可能受磁干擾不良影響的植體或醫療設備至少需保持 6 英吋（150 公釐）距離。

如需前述變動的更多相關資訊，請瀏覽 www.resmed.com/magnetupdate。

報告不良事件

如您因使用 ResMed 含磁鐵面罩而發生不良反應，請瀏覽 www.resmed.com/contact，聯絡面罩供應商或國家監管（主管）機關。

製造商

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista 2153
Australia

感謝您的支持，為確保所有患者皆清楚相關更新內容，考慮採取行動實屬必要。

如有任何問題或疑慮或希望取得更多資訊，請聯繫您的面罩供應商或醫師。

謹啟

Dawn Y. Haake
品質總監

附錄 A - ResMed 含磁鐵面罩

請注意，各國供應產品可能有所不同。



磁鐵位置

受影響的產品	型號名稱位置	磁鐵位置
AirFit™ F30i		
AirFit™ F30 Full face mask		
AirFit™ F20 Full face mask AirFit™ F20 Full face mask for Her AirTouch™ F20 Full face mask AirTouch™ F20 Full face mask for Her	 	 

附錄 A - ResMed 含磁鐵面罩（續）

請注意，各國供應產品可能有所不同。

受影響的產品	型號名稱位置	磁鐵位置
<p>AirFit™ N20 Nasal mask</p> <p>AirFit™ N20 Nasal mask for Her</p> <p>AirTouch™ N20 Nasal mask</p> <p>AirTouch™ N20 Nasal mask for Her</p>		
<p>AirFit™ F20 NV</p>		
<p>AirFit™ N10 Nasal mask</p> <p>AirFit™ N10 Nasal mask for Her</p>		



Urgent Field Safety Notice

ResMed Masks with Magnets - Potential Magnetic Interference with Certain Medical Devices

PATIENT LETTER

Reference: MWM-2023-FSN-01

Date: 20 November 2023

Dear Patient,

ResMed is providing you with important information regarding our masks with magnets, which may interact with some implants or certain medical devices. It is important that you understand the information contained in this letter, take action if necessary, and keep it for future reference.

In response to new information from latest industry practices and global safety data, ResMed is **updating the Contraindications and Warnings** in our User Guides to instruct patients on the safe use of **ResMed masks with magnets**.

- Contraindications: conditions under which the mask is not to be used.
- Warnings: identify a possible hazard and provide information on how to safely use the mask.

General Product Description

These masks are used to deliver air to a patient from a positive airway pressure (PAP) device.

Magnets are used in some ResMed masks to provide a simple and easy way for patients to attach and detach the headgear to the mask frame when regularly fitting the mask for use. This can be notably beneficial to patients with disabilities, including those facing dexterity or vision impairment.

Which masks are affected?

The following ResMed masks contain magnets, please note that mask availability may differ in each country. If you do not use one of the masks identified below, this letter does not apply to you.

Mask type	Affected masks
Full face mask	AirFit F20, AirFit F20 for Her AirTouch F20, AirTouch F20 for Her AirFit F30 AirFit F30i
Nasal mask	AirFit N10, AirFit N10 for Her AirFit N20, AirFit N20 for Her AirTouch N20, AirTouch N20 for Her
Non vented mask	AirFit F20 NV

See **Appendix A** for more information on identifying your ResMed mask and the specific location of the magnets.



What has changed?

ResMed is updating the **Contraindications** and **Warning** relating to magnetic interference, in its User Guides for all masks with magnets.

Updated Contraindications

Masks with magnetic components are contraindicated for use by patients where they, or anyone in close physical contact while using the mask, have the following:

- Active medical implants that interact with magnets (i.e., pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, cerebrospinal fluid (CSF) shunts, insulin/infusion pumps)
- Metallic implants/objects containing ferromagnetic material (i.e., aneurysm clips/flow disruption devices, embolic coils, stents, valves, electrodes, implants to restore hearing or balance with implanted magnets, ocular implants, metallic splinters in the eye)

Updated Warning

Keep the mask magnets at a safe distance of at least 6 inches (150 mm) away from implants or medical devices that may be adversely affected by magnetic interference. This warning applies to you or anyone in close physical contact with your mask. The magnets are in the frame and lower headgear clips, with a magnetic field strength of up to 400mT. When worn, they connect to secure the mask but may inadvertently detach while asleep.

Implants/medical devices, including those listed within contraindications, may be adversely affected if they change function under external magnetic fields or contain ferromagnetic materials that attract/repel to magnetic fields (some metallic implants, e.g., contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, and bone substitute devices). Consult your physician and manufacturer of your implant / other medical device for information on the potential adverse effects of magnetic fields.

Patient Safety Information

ResMed's masks with magnets are safe when used in accordance with the updated Instructions for Use including the **Contraindications** and **Warnings**.

When a magnet comes close to certain medical implants/devices (less than 6 inches / 150mm) there is potential for magnetic interference to change:

- the function of an implant/medical device
- the position of implants made of ferromagnetic material

In rare circumstances, this can lead to serious injury or death.

Contraindicated patients can avoid the potential harm from magnetic interference by using an alternative mask without magnets. All other patients using ResMed masks with magnets can continue to use the mask following the updated Instructions for Use.

From 2014 to November 2023, ResMed has sold tens of millions of masks with magnets globally. In this time, ResMed has submitted five (5) reports of serious harm (medical intervention /hospitalisation) that were potentially related to magnetic interference with an implanted device (including implantable cardioverter defibrillators (ICD) and cerebrospinal fluid (CSF) shunts) to relevant Regulatory Authorities. No permanent injuries or deaths have been reported.



Actions to be taken by you

Contraindicated patients using a ResMed mask with magnets

If you, or anyone in close physical contact while using the mask (e.g. bed partner), have an active medical implant or metallic implanted object that is identified within the **Contraindications** above:

- Replace your mask containing magnets with an alternative mask without magnets in a timely manner. Contact your mask provider for alternative mask options.
Note, ResMed is making our masks without magnets available to your mask provider for replacement.
- If an alternative mask is not available, consult your physician/doctor for appropriate next steps regarding your therapy.
- Dispose of the mask with magnets after you receive an alternative mask.

Note, not all models or variants of medical devices listed in the contraindications are affected by external magnetic fields. If you are not sure whether a medical device/implant falls under the Contraindications, or you require additional information on the potential adverse effects of magnetic fields for your particular device, please contact your physician/doctor.

All other patients using a ResMed mask with magnets

If you are NOT contraindicated from using a ResMed mask with magnets, you may continue to use the mask, ensuring you follow all user instructions, including the updates described in this letter.

- Importantly, ResMed masks with magnets are to be kept at least 6 inches (150mm) away from implants or medical devices that may be adversely affected by magnetic interference, as described in the updated **Warning**.

For more information regarding these changes please visit www.resmed.com/magnetupdate.

Reporting an Adverse Event

If you have experienced an adverse event related to the use of ResMed masks with magnets, please visit www.resmed.com/contact, contact your mask provider or the national Regulatory (competent) Authority.

Manufacturer

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista 2153
Australia

We appreciate your support and consider this action necessary to ensure that all patients are aware of these updates.

If you have any questions or concerns or would like more information, please contact your mask provider or physician/doctor.

Sincerely,

A handwritten signature in black ink, appearing to read "Dawn Y. Haake", with a horizontal line extending to the right.




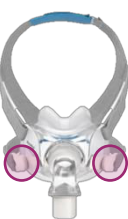



Dawn Y. Haake
Chief Quality Officer

APPENDIX A - RESMED MASKS WITH MAGNETS

Note, product availability may differ in each country.

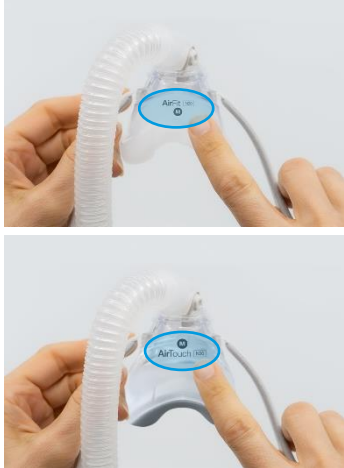





Magnet locations

Products Affected	Location of Model Name	Location of Magnets
AirFit™ F30i		
AirFit™ F30 Full face mask		
AirFit™ F20 Full face mask AirFit™ F20 Full face mask for Her		
AirTouch™ F20 Full face mask AirTouch™ F20 Full face mask for Her		

APPENDIX A - RESMED MASKS WITH MAGNETS (CONTINUED)

Note, product availability may differ in each country.

Products Affected	Location of Model Name	Location of Magnets
<p>AirFit™ N20 Nasal mask</p> <p>AirFit™ N20 Nasal mask for Her</p> <p>AirTouch™ N20 Nasal mask</p> <p>AirTouch™ N20 Nasal mask for Her</p>		
<p>AirFit™ F20 NV</p>		
<p>AirFit™ N10 Nasal mask</p> <p>AirFit™ N10 Nasal mask for Her</p>	