

## 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

日期：	2023 年 11 月 20 日
參考號：	MWM-2023-FSN-01
受影響的產品：	ResMed 所有含磁鐵面罩：AirFit N10、AirFit N10 for Her、AirFit N20、AirFit N20 for Her、AirTouch N20、AirTouch N20 for Her、AirFit F20、AirFit F20 for Her、AirFit F20 NV、AirTouch F20、AirTouch F20 for Her、AirFit F30、AirFit F30i。
	各國供應產品可能有所不同。請參閱 ResMed 所提供的含磁鐵面罩產品代碼單列清單。
受影響群體：	使用上述任一受影響產品，或使用禁忌症或可能受磁干擾之醫療設備時的患者或與患者有身體密切接觸的任何人。
	<b>需對禁忌症患者採取進一步行動。</b> 所有其他患者可繼續依據更新版的使用說明使用面罩。

### 一般產品說明

面罩為非侵入式介面，用於將氣流從持續正壓呼吸器（CPAP）或雙壓呼吸器等正壓呼吸道（PAP）設備輸送空氣。

ResMed 部份面罩使用磁鐵，以便患者在平常佩戴時，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。

### 更動說明

ResMed 正在更新其現有禁忌與警告，以進一步為患者與醫護專業人員提供 ResMed 含磁鐵面罩的安全使用資訊。這是為了回應售後監督與行業實踐的新資訊，其內容與靠近某些醫療設備時可能產生的磁場干擾有關。

#### 禁忌更新

在對先前頭內金屬動脈瘤止血夾及單眼或雙眼在眼部穿刺傷後留有金屬碎片之禁忌症的更新中，ResMed 進一步將以下更新並列入禁忌：患者或任何在使用面罩時近距離接觸者（如同床伴侶）的身上有下列植體時，禁止使用含磁鐵面罩：

- 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）

請注意，並非所有禁忌中所列型號或醫療設備都會受到外部磁場影響。只有那些與磁鐵相互作用或含有鐵磁材料的物質才存在潛在的磁干擾。

#### 警告更新

與磁鐵的安全距離已從 2 英吋（50 公釐）增加至 6 英吋（150 公釐），我們現在提醒患者將面罩磁鐵與可能受到磁干擾不利影響的植體或醫療設備保持安全距離。此警告適用於患者或任何與面罩磁鐵有近距離接觸的人。

請參閱附錄 A - 標籤更新以查看完整的禁忌與警告內容。



## 患者安全資訊

依據更新版的使用說明（包含禁忌與警告）使用面罩時安全無虞（請參閱附錄 A）。

在特定情況下，當磁鐵靠近某些醫療植體/設備時，潛在磁干擾可能影響醫療植體/設備的功能或其植入位置，這可能導致重傷或死亡。

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 已向相關的監管機關提交了五（5）份可能與植入設備（包含心律去顫器與腦脊髓液分流器植體）受到磁性干擾有關的重傷（治療/住院）報告。目前尚無永久性傷害或死亡案例。

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。

## 受影響的產品

ResMed 含磁鐵面罩列於附錄 B - ResMed 含磁鐵面罩。為方便辨識，面罩型號與磁扣在面罩上的位置已標記於所提供圖片中。此資訊也已透過患者通知函提供給患者。

所有其他 ResMed 無磁鐵面罩皆不受影響。

每位客戶將收到一份受影響 ResMed 含磁鐵面罩產品代碼的清單，其中包含唯一設備識別碼（如有需要）。

## ResMed 的行動

受影響的含磁鐵面罩使用者指南中，ResMed 正在更新使用說明（IFU）的禁忌與警告章節。

此外，本通知的進一步相關資訊將在 [www.resmed.com/magnetupdate](http://www.resmed.com/magnetupdate) 網站提供。

ResMed 將與客戶協調，為禁忌症患者更換不含磁鐵的替代面罩。

## 醫療保健提供者、醫院和經銷商應採取的行動

1. 將線上（若有）或本通知最後的確認表填寫完畢寄回。
2. 立即給處方醫師和/或任何其他相關醫護專業人員提供一份本通知與醫師函，以通知更新標籤內容（禁忌與警告）。
3. 立即給所有目前使用 ResMed 含磁鐵面罩的患者提供一份患者通知函，以通知更新標籤內容（禁忌與警告）。

*請注意，患者通知函已指引禁忌症患者聯繫其面罩供應商以取得替換面罩。*

4. 及時為禁忌症患者提供無磁鐵的替換面罩。沒有可用的替換面罩時，請通知患者諮詢其醫師。
5. 如患者需要有關磁場對某些設備的潛在不良影響（如警告所說明）的其他資訊，指引患者諮詢其醫師和/或植體/其他醫療設備製造商。

如要瞭解可選擇的替代面罩，請聯絡 ResMed 或客服專員。



**製造商**

ResMed Pty Ltd  
1 Elizabeth Macarthur Drive  
Bella Vista 2153  
Australia

感謝您在此事上的支援，為確保客戶和患者瞭解最新的標籤更新內容，考慮採取行動實屬必要。含磁鐵面罩上市國家的所有相關主管（監管）機關皆已知悉此客戶通知。

如有任何疑問，請聯繫您當地的 **ResMed** 聯絡窗口。

謹啟

**Dawn Y. Haake**

品質總監



## 客戶確認表格

現場安全緊急通知回覆表 - ResMed 含磁鐵面罩及某些醫療設備潛在的磁干擾

為遵守監管行動的可追溯性要求，請完整填寫此表格並儘快以電子郵件發送至 [magnetresponse@resmed.com](mailto:magnetresponse@resmed.com)。

我確認收到本現場安全通知，並確認我已閱讀並理解其內容。

我將依指示/視情況轉發此資訊。

ResMed 參考編號	MWM-2023-FSN-01
醫療保健提供者/醫院/經銷商名稱	
醫療保健提供者/醫院/經銷商地址	

名稱	
職位	
電子郵件地址/電話號碼	
簽名	
日期	

由於您所購買的含磁鐵面罩為現場安全通知產品，您因身為相關註冊聯絡人而收到本通知。您的資訊以及在上述表格中輸入的資料將根據我們的監管報告義務進行專門處理。該資料將由 ResMed 安全儲存，並僅出於遵守我們監管要求的目的而保留，且在最後一次適用銷售後最多保留 15 年。根據我們的隱私聲明（可於 <https://www.resmed.com/privacy> 查看），您所在地區之外經過培訓的 ResMed 監管及品質團隊成員可存取此資料。有關個人資料處理的更多資訊，請通過 [privacy@resmed.com](mailto:privacy@resmed.com)，聯繫我們。

## 附錄 A - 標籤更新

### 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）

### 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，以取得磁場可能產生影響的相關資訊。

**附錄 B - 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
<b>AirFit™ F30i</b>		
<b>AirFit™ F30</b> Full face mask		
<b>AirFit™ F20</b> Full face mask <b>AirFit™ F20</b> Full face mask for Her <b>AirTouch™ F20</b> Full face mask <b>AirTouch™ F20</b> Full face mask for Her	 	

附錄 B - 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><b>AirFit™</b> N20 Nasal mask</p> <p><b>AirFit™</b> N20 Nasal mask for Her</p> <p><b>AirTouch™</b> N20 Nasal mask</p> <p><b>AirTouch™</b> N20 Nasal mask for Her</p>		
<p><b>AirFit™</b> F20 NV</p>		
<p><b>AirFit™</b> N10 Nasal mask</p> <p><b>AirFit™</b> N10 Nasal mask for Her</p>		



## URGENT FIELD SAFETY NOTICE

# ResMed Masks with Magnets and Potential Magnetic Interference with Certain Medical Devices

Date:	20 November 2023
Reference:	MWM-2023-FSN-01
Products Affected:	All lots of ResMed masks with magnets: AirFit N10, AirFit N10 for Her, AirFit N20, AirFit N20 for Her, AirTouch N20, AirTouch N20 for Her, AirFit F20, AirFit F20 for Her, AirFit F20 NV, AirTouch F20, AirTouch F20 for Her, AirFit F30, AirFit F30i.  Product availability may differ in each country. Refer to the separate masks with magnets product code list provided by ResMed.
Population Affected:	Patients where they, or anyone in close physical contact while using one of the above affected products, have a contraindicated medical device or a medical device that may interfere with magnets.  <b>Further action for contraindicated patients is required.</b> All other patients may continue to use the mask in accordance with the updated Instructions for Use.

### General Product Description

The mask is a non-invasive interface, used for channelling airflow to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device.

Magnets are used in some ResMed masks to facilitate 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.

### Description of Change

ResMed is updating its existing contraindications and warnings to further inform patients and healthcare professionals on the safe use of ResMed masks with magnets. This is in response to new information obtained through post-market surveillance and industry practices related to possible magnetic interference when in close proximity to certain medical devices.

#### Update to Contraindication

In an update to the previously contraindicated metallic aneurysm hemostatic clips in the head and metallic splinters in one or both eyes following a penetrating eye injury, ResMed is further contraindicating the use of its masks with magnets for patients where they, or anyone in close physical contact while using the mask (e.g., bed partner), 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)

*Note, not all models or manufactured variants of medical devices listed in the contraindications are affected by external magnetic fields. Only those that interact with magnets or contain ferromagnetic materials present the potential for magnetic interference.*





### Update to Warning

The safe distance to the magnets has been increased from 2 inches (50 mm), and patients are now warned to keep the mask magnets at a safe distance of **6 inches (150 mm)** away from implants or medical devices that may be adversely impacted by magnetic interference. This applies to patients, or anyone in close physical contact with the mask magnets.

Refer to **Appendix A - Labelling Updates**, for complete contraindications and warnings.

### **Patient Safety Information**

The masks are safe when used in accordance with the updated Instructions for Use, including the Contraindications and Warnings (refer to Appendix A).

Under certain circumstances when a magnet is in close proximity to certain medical implants/devices, potential magnetic interference could affect the performance or implanted position of the medical implant/device which has the potential to lead to serious injury or death.

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 ICD and CSF shunt implants) to relevant Regulatory Authorities. No permanent injuries or deaths have been reported.

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

### **Products Affected**

ResMed's masks with magnets are shown in **Appendix B - ResMed Masks with Magnets**. For ease of identification, the model of the mask and the magnetic clip positioning on the mask are highlighted in the images provided. This information is also provided to patients in the Patient Letter.

All other ResMed masks without magnets are not affected.

Each customer will receive a list of affected ResMed masks with magnet product codes (including the Unique Device Identifier, where required).

### **Actions by ResMed**

ResMed is updating the contraindications and warning sections of the Instructions for Use (IFU) in the user guides of affected masks with magnets.

In addition, further information related to this notice will be made available at [www.resmed.com/magnetupdate](http://www.resmed.com/magnetupdate).

ResMed will coordinate with customers for a replacement alternative mask without magnets for contraindicated patients.

### **Actions to be taken by Healthcare Providers, Hospitals and Distributors**

1. Complete and return the acknowledgment form online (where available) or at the end of this notice.
2. Immediately provide a copy of this notice and the physician letter to prescribing physicians, and/or any other relevant healthcare professionals, notifying them of the updated labelling (contraindications and warning).
3. Immediately provide a copy of the patient letter to all patients currently using a ResMed mask with magnets, notifying them of the updated labelling (contraindications and warning).

*Note, patients are instructed in the patient letter to contact their mask provider for a replacement mask if they are now contraindicated.*



4. Provide a replacement mask for contraindicated patients to an alternative mask without magnets in a timely manner. Where an alternative mask is not available, inform patients to consult with their physician.
5. Instruct patients to consult their physician and/or manufacturer of their implant / other medical device if they require additional information on the potential adverse effects of magnetic fields for their particular device (as described in warnings).

**For alternative mask options, please contact your ResMed or Customer Service representative.**

**Manufacturer**

ResMed Pty Ltd  
1 Elizabeth Macarthur Drive  
Bella Vista 2153  
Australia

We appreciate your support in this matter and consider this action necessary to ensure that our customers and patients are aware of the latest labelling updates. All relevant Competent (Regulatory) Authorities from countries where masks with magnets have been commercialised have been informed about this communication to customers.

For any questions, please contact your local ResMed contact.

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



## CUSTOMER ACKNOWLEDGEMENT FORM

### Reply form to Urgent Field Safety Notice – ResMed Masks with Magnets and Potential Magnetic Interference with Certain Medical Devices

To enable compliance to Regulatory action traceability requirements, please complete this form in full and send it back by email as soon as possible to [magnetresponse@resmed.com](mailto:magnetresponse@resmed.com).

**I confirm receipt of this field safety notice and I confirm that I have read and understood its content.**

**I will forward this information as instructed/appropriate.**

ResMed Reference	MWM-2023-FSN-01
Name of Healthcare Provider / Hospital / Distributor	
Address of Healthcare Provider / Hospital / Distributor	

Name	
Position	
Email address / Phone number	
Signature	
Date	

You received this notice as a registered contact relating to the purchase of mask with magnets subject to a field safety notice. Your information, as well as the data entered in the above form, is exclusively processed in the context of our regulatory reporting obligations. The data will be securely stored by ResMed and retained only for the purpose of complying with our regulatory requirements, and at most for 15 years after the last applicable sale. This data may be accessed by trained ResMed regulatory and quality team members outside of your region in conformity with our privacy notice available at <https://www.resmed.com/privacy/>. For any further information regarding the processing of personal data, please contact us at [privacy@resmed.com](mailto:privacy@resmed.com).



## APPENDIX A - LABELLING UPDATES

### Contraindication

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)

### 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.

## APPENDIX B - RESMED MASKS WITH MAGNETS

Note, product availability may differ in each country.

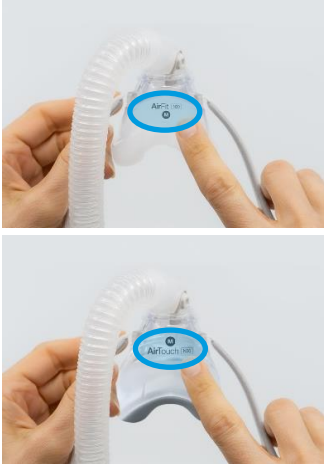





Magnet locations

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

**APPENDIX B - RESMED MASKS WITH MAGNETS (CONTINUED)**

Note, product availability may differ in each country.

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