



Urgent Product Defect Correction

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

PATIENT LETTER

Reference: MWM-2023-FSN-01

TGA RECALL NUMBER: RC-2023-RN-00941-1

Date: 20 Nov 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

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 or call on 1300 305 705.

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
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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,



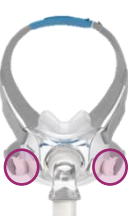
Dawn Y. Haake
Chief Quality Officer

APPENDIX A - RESMED MASKS WITH MAGNETS

Note, product availability may differ in each country.

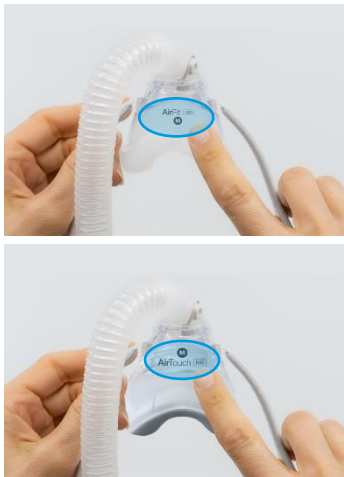


Magnet
locations

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
AirFit™ N20 Nasal mask AirFit™ N20 Nasal mask for Her AirTouch™ N20 Nasal mask AirTouch™ N20 Nasal mask for Her		
AirFit™ N10 Nasal mask AirFit™ N10 Nasal mask for Her		