



Urgent Field Safety Notice ResMed Masks with Magnets - Potential Magnetic Interference with Certain Medical Devices

PHYSICIAN LETTER

Reference: MWM-2023-FSN-01

Date: 20 November 2023

Dear Physician/Doctor,

ResMed is providing you with important information regarding our masks with magnets, which may interact with some implants or certain medical devices. ResMed is **updating the Contraindications and Warnings** in our User Guides on the safe use of **ResMed masks with magnets**.

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 Contraindications

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 Warnings

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. Please **carefully read Appendix A** for labelling updates, as it includes further examples of implants or medical devices that may be affected by magnetic interference.

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.

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.

ResMed is making our masks without magnets available to your patient's healthcare professional for replacement.



Information for Physicians

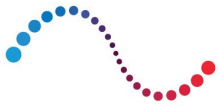
Newly contraindicated patients using ResMed masks with magnets need to seek an alternative mask without magnets in a timely manner. They are instructed to contact their healthcare professional for alternative mask options. If an alternative mask is not available, patients are instructed to consult with their physician on appropriate next steps regarding their therapy. The following considerations may be relevant in consultation with your patients:

- **Identify if the implant/medical device can be adversely affected by magnetic interference.** Some implants and medical devices are affected by magnetic fields as indicated in the updated Contraindication and Warning. This includes active medical implants that interact with magnets and metallic implants/objects containing ferromagnetic material.
- **Consider the effect of magnetic interference to the implant/medical device and the potential for harm.** Under the presence of magnetic fields, the effect and potential for harm varies across implants/medical devices and patient populations.
- **Consider the potential for magnetic interference of the mask magnets to occur during use.** Magnetic field exposure from the mask magnets (located in the frame and headgear clips) may occur during normal use, handling or inadvertently if clips detach during use. This applies to the patient and anyone in close physical contact while using the mask. As identified in the Warnings, users are warned to keep the magnets 6 inches (150mm) from implants or medical devices that may be adversely affected by magnetic interference.
- **Consider whether newly contraindicated patients may continue therapy until an alternative mask is available.** Some patients may not have an alternative mask readily available. On a case-by-case basis, you may want to discuss with the patient the benefits of continuing therapy against the risk of harm posed by magnetic interference. Ensure patients understand the continued need to switch to an alternative mask in a timely manner to minimise exposure to magnetic fields and the potential for adverse effects.

Refer to the implant/medical device Instructions for Use (IFU), or contact the implant/medical device manufacturer, for safety information relating to exposure to static magnetic fields and the potential clinical effects.

Note, patients new to therapy are subject to the updated labelling. To ensure these patients are informed during their mask selection, it is important to identify if they have an implant/medical device that may be adversely affected by magnetic interference and advise whether the use of masks with magnets is contraindicated. For those not contraindicated, the magnetic clips remain a beneficial feature for the regular fitting and use of masks.

Further information is also available at www.resmed.com/magnetupdate. Click on the Healthcare Professionals tab for relevant FAQs.



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Reporting an Adverse Event

If your patient has experienced an adverse event related to the use of ResMed masks with magnets, please visit www.resmed.com/contact or contact 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 appropriate actions are taken for affected patients.

Sincerely,

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

Dawn Y. Haake

Chief Quality Officer



APPENDIX A - LABELLING UPDATES

Contraindication

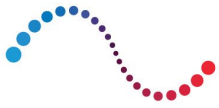
Masks with magnetic components are contraindicated for use by patients where they, or anyone in close physical contact while using the mask, have the following:

- 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.








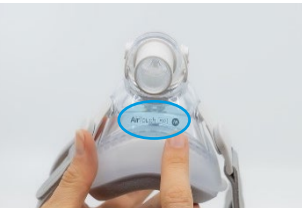


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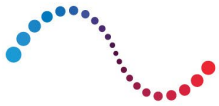
APPENDIX B - RESMED MASKS WITH MAGNETS

Note, product availability may differ in each country.



Magnet locations

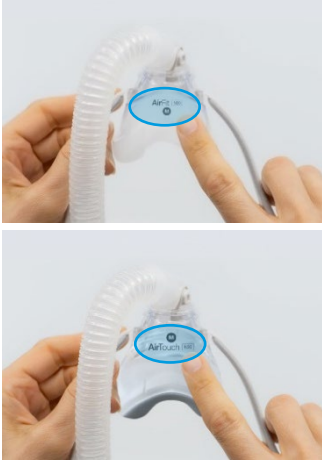





Products Affected	Location of Model Name	Location of Magnets
<p>AirFit™ F30i</p>		
<p>AirFit™ F30 Full face mask</p>		
<p>AirFit™ F20 Full face mask</p> <p>AirFit™ F20 Full face mask for Her</p> <p>AirTouch™ F20 Full face mask</p> <p>AirTouch™ F20 Full face mask for Her</p>	 	 



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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>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>		



What are FSNs and FSCAs?

A 'field safety notice' (FSN) is an important communication about the safety of a medical device that is sent to customers by a device manufacturer, or their representative.

FSNs tell you what you need to do to reduce the specified risks of using the medical device. They give you either new information or highlight/remind you about existing advice.

The actions are referred to as 'field safety corrective actions' (FSCAs).

If you receive a field safety notice from a manufacturer, **always act on it.**

Do not wait for a communication from the MHRA.

It is important that your organisation takes the actions detailed in the FSN and that you tell the manufacturer that you have received the FSN.

Your organisation's reply is the evidence that the manufacturer, and the MHRA, needs to monitor the progress of the corrective actions to ensure patient safety.

Without your reply the manufacturer can't know if their important message has been received and the MHRA may need to issue a safety communication.