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
SRN:	AU-MF-000011753
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. **Further action for contraindicated patients is required.** 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.

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.

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.

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

Actions to be taken by Homecare 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 healthcare professional 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).

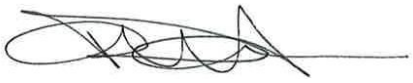
For alternative mask options, please contact your ResMed or Customer Service representative.

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,



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.

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 Homecare Provider / Hospital / Distributor	
Address of Homecare 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.

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

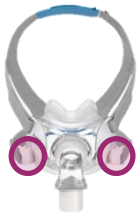
Keep the mask magnets at a safe distance of at least 6 inches (150 mm) away from implants or medical devices that may be adversely affected by magnetic interference. This warning applies to you or anyone in close physical contact with your mask. The magnets are in the frame and lower headgear clips, 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
AirFit™ F30*i*		
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 B - 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™ F20 NV		
AirFit™ N10 Nasal mask AirFit™ N10 Nasal mask **for Her**		

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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.