Respiratory Institute





10 East 102nd Street Fifth Floor New York, NY 10029 800-563-3498 212-241-5656 www.therespiratoryinstitute.org

RE: ResMed masks with magnets

December 2023

Dear Patients and Providers:

The Mount Sinai – National Jewish Health Respiratory Institute and the Center for Sleep Medicine have received a notice from the medical equipment company ResMed of a **serious safety concern with certain masks** used with continuous positive airway pressure (CPAP) and bilevel positive airway pressure (bilevel PAP, BiPAP, or BPAP) machines.

Although patients received these masks from a durable medical equipment (DME) company and not from Mount Sinai, we, as providers, are forwarding this information to inform our patients about ResMed's recommendations for determining next steps and whether mask replacement is needed. Patient safety is our first priority. The following is the information that ResMed shared with us:

These masks contain magnets that may interfere with the functioning of certain implants and/or medical devices. Pictures and model numbers of the affected masks can be seen here, with the locations of the magnets circled:

Products Affected	Location of Model Name	Location of Magnets
Air Fit [™] [F30 <i>i</i>]		
Air Fit [™] F30		
AirFit [™] F20 Full face mask AirFit [™] F20 Full face mask for Her AirTouch [™] F20 Full face mask AirTouch [™] F20	ALCO O	
Full face mask for Her		

Respiratory Institute





10 East 102nd Street Fifth Floor New York, NY 10029 800-563-3498 212-241-5656 www.therespiratoryinstitute.org

Products Affected	Location of Model Name	Location of Magnets
AirFit [™] N20 Nasal mask AirFit [™] N20 Nasal mask for Her	Arg.	
AirTouch [™] N20 Nasal mask AirTouch [™] N20 Nasal mask for Her	Actual miles	
Air Fit [™] F20 NV	Airg a	
AirFit™ N10 Nasal mask AirFit™ N10 Nasal mask for Her		

At this time, ResMed's safety alert says:

Discontinuation of these masks is recommended for patients who have, or are in close vicinity to, household members, caregivers, or bed partners with certain implanted/metallic devices. These include (but are not limited to) the following:

- Active medical implants that interact with magnets (i.e., pacemakers, implantable cardioverter defibrillators, neurostimulators, cerebrospinal fluid 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)

Respiratory Institute





10 East 102nd Street Fifth Floor New York, NY 10029 800-563-3498 212-241-5656 www.therespiratoryinstitute.org

Patients are recommended to keep the mask magnets at a distance of at least six 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.

RECOMMENDED NEXT STEPS (for those with a ResMed mask with magnets <u>and</u> an implanted magnetic device, or those with an affected mask in close vicinity to patients with implanted magnetic devices):

- 1. **ALL PATIENTS SHOULD CONTACT** the home care/durable medical equipment (DME) company that provided your mask for additional information and replacement of your mask.
- 2. In addition to contacting your DME for a mask replacement, if **EITHER** or **BOTH** of the below apply to you, please contact your provider **BEFORE** discontinuing mask use:
 - a. You are using a life-sustaining ventilator device (such as a Trilogy)
 - b. You become very sleepy with tasks requiring sustained vigilance, such as driving or operating heavy equipment, when off CPAP/BPAP therapy

ResMed will be making replacement masks without magnets available to home care/durable medical equipment suppliers. They will also be updating the Contraindications and Warning sections of the Instructions for Use in the user guides of affected masks with magnets. Further information is also available on Updated Information on Masks with Magnets for Mask Users [www.resmed.com/magnetupdate].

We will continue to provide more information as soon as we have it, and appreciate your understanding and patience as we navigate this challenge.

If you have further questions, please contact your primary provider or your Respiratory Institute sleep/pulmonary physician at 212-241-5656.

Thank you