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ResMed Notifies Customers About Updated Instructions and Labeling for Masks with Magnets Due to Potential Interference with Certain Medical Devices

ResMed's masks with magnets are safe when used in accordance with the updated Instructions for Use

SAN DIEGO, Dec. 20, 2023 (GLOBE NEWSWIRE) -- ResMed (NYSE: RMD, ASX: RMD) is conducting a voluntary global field action to update its guides for all masks with magnets to inform users about potential magnetic interference when magnets are near certain implants and medical devices in the body. This voluntary field correction does not require a return of a mask with magnets unless the patient is contraindicated. All ResMed masks containing magnets are safe when used in accordance with the [Field Safety Notice](#) and updated Instructions for Use in the guides of affected masks.

A patient is contraindicated 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).

Patients using the masks with magnets or anyone in close physical contact with mask magnets should keep the magnets at a safe distance of 6 inches (150 mm) away from implants or medical devices that may be adversely impacted by magnetic interference. Refer to the ResMed [Magnet Update](#) website for more information about the updates issued to contraindications and warning labels.

ResMed is notifying affected customers and providing guidance for specific actions. ResMed has provided a [patient letter](#) to healthcare providers that includes additional information regarding the contraindications and warnings for patients with the affected medical implants or devices. Patients should consult their physician and/or manufacturer of their implant or other medical device if they require additional information on the potential adverse effects of magnetic fields for their device.

For patients where they, or anyone in close physical contact, do not have a contraindicated device, no action is needed.

ResMed masks with magnets were distributed nationwide and globally from 2014 to November 2023. ResMed has submitted five reports of serious harm (medical intervention/hospitalization) that were potentially related to magnetic interference of a mask with a magnet with an implanted device to relevant regulatory authorities. To date, no permanent injuries or deaths have been reported.

The impacted Mask with Magnet product(s) can be identified by the model number: AirFit N10, AirFit F20, AirTouch F20, AirFit N20, AirTouch N20, AirFit F30, AirFit F30i on the cushion or frame of the masks.

ResMed voluntarily updated its contraindications and warning labels in response to new information obtained through post-market surveillance and industry practices. ResMed has notified the FDA and other global regulators where required.

Consumers with questions may contact ResMed at 1-800-424-0737, online at www.resmed.com/contact, or visit the Resmed [Magnet Update](#) website for more information. Adverse events experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either [online](#), by regular mail or fax. 1-800-332-1088 to request a form.

About ResMed

At ResMed (NYSE: RMD, ASX: RMD), we pioneer innovative solutions that treat and keep people out of the hospital, empowering them to live healthier, higher-quality lives. Our digital health technologies and cloud-connected medical devices transform care for people with sleep apnea, COPD, and other chronic diseases. Our comprehensive out-of-hospital software platforms support the professionals and caregivers who help people stay healthy in the home or care setting of their choice. By enabling better care, we improve quality of life, reduce the impact of chronic disease, and lower costs for consumers and healthcare systems in more than 140 countries. To learn more, visit ResMed.com and follow [@ResMed](#).

For media

+1 619.510.1281
news@resmed.com

For investors

+1 858.836.5000
investorrelations@resmed.com

