

December 19, 2023

URGENT: IMPORTANT FIELD SAFETY NOTICE

Dear valued client;

Recently, ResMed informed our office of a Field Safety Notice for their Continuous Positive Airway Pressure (CPAP) masks they have manufactured that contain magnets. This Field Safety Notice is specific for clients who have contraindications that could be interfered with by the magnets. These contraindications include:

- Active Metal Implants that interact with magnets (i.e., pacemakers, implantable cardioverter defibrillators, neurostimulators, cerebrospinal fluid shunts, insulin/infusion pumps)
- Metallic Implants or 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)

If you do not have any of the above contraindications, please disregard this notice.

If you have one or more of the contraindications listed above, please carefully review the attached patient letter from ResMed. This letter contains additional information about this Field Safety Notice, as well as a list of the CPAP masks containing magnets.

Once you confirm if you are currently using a ResMed CPAP mask with magnets, **please contact our office at (867)667-7120,** and ask for <u>Kate.</u> Our team will register you online with ResMed, and they will send a magnet free replacement mask, of your choice, at no cost. Once your mask arrives, we will contact you directly for pick up.

Please note, we currently do **NOT** have any of the ResMed replacement CPAP masks without magnets in our office. ResMed will send a magnet free replacement mask for each patient who requires one, at no cost, as we register each individual online.

If you require a mask in the interim, we do have alternate CPAP masks without magnets available for purchase. If you'd like to purchase a new mask, please let our office know so we can best accommodate your needs.



Please consult with your physician to discuss your implant and/or other medical device if you require additional information on the potential adverse effects of magnetic fields for your particular device.

ResMed has also updated their warning to reflect the contraindications of the magnetic masks:

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

'ResMed's masks with magnets are safe when used in accordance with the updated Instructions for Use including the Contraindications and Warnings.'

For updates on this Field Safety Notice, please visit www.resmed.com/magnetupdate.

All questions and concerns regarding this Field Safety Notice can be emailed directly to sheri@truenorthrespiratory.com.

Thank you,

Sheri Kostelnik

Compliance Coordinator

Sheri@truenorthrespiratory.com