

Provider Newsflash January 2024

FDA Recall - ResMed, Ltd.

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a Class I recall
of ResMed's AirFit and AirTouch Continuous Positive Airway Pressure (CPAP) Masks with magnets
distributed from January 2020 to November 20, 2023. The recall is due to possible magnetic
interference with certain medical devices. Under certain circumstances when a magnet is in close
proximity (less than 2 inches) to certain medical implants and devices, it might disrupt their function
or position, possibly causing serious harm or death.

What do I need to do?

- Please review the following recall notice: <a href="https://www.fda.gov/medical-devices/medical-d
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.