

Provider Newsflash March 2024

FDA Recall – Sleepnet Corportation CPAP & BiPAP Masks with Magnets

Purpose of this communication:

• We are writing to inform you that effective immediately the FDA has issued a notice of a voluntary recall by Sleepnet Corporation of their Mojo, Mojo 2, iQ 2, and Phantom 2 CPAP and BiPAP Masks with Magnets due to the potential for interference with certain medical devices. When a magnet comes into close proximity to certain medical implants or metallic implants, it could interfere with the performance or the position of the implant, potentially resulting in serious injury or death. The affected products include all lot/UDI numbers of their Mojo Full Face Vented Mask, Mojo 2 Full Face Vented Mask, Mojo 2 Full Face Vented Mask, Mojo 2 Full Face AAV Non-Vented Mask, iQ 2 Nasal Mask, and Phantom 2 Nasal Mask.

What do I need to do?

- Please review the following recall notice: <u>Sleepnet Corporation Issues Worldwide Recall of CPAP and</u> <u>BIPAP Masks with Magnets Due to Potential Interference with Certain Medical Implants | FDA</u>
- 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.