



Date March 1, 2024

URGENT: MEDICAL DEVICE RECALL

Mojo Full Face Mask, Mojo 2 Full Face Mask, iQ 2 Nasal Mask, and Phantom 2 Nasal Mask

Dear Valued Customer,

The purpose of this letter is to advise you that Sleepnet Corporation is voluntarily recalling masks with magnets which are intended to be used with positive airway pressure devices such as CPAP or bi-level: Mojo Full Face Vented Mask, Mojo Full Face Non Vented Mask, Mojo 2 Full Face Vented Mask, Mojo 2 Full Face Non Vented Mask, Mojo 2 Full Face AAV Non Vented Mask, iQ 2 Nasal Mask, and Phantom 2 Nasal Mask.

Reason for the Voluntary Recall:

This recall is being initiated based on information obtained from post market surveillance indicating a possible risk to patients and anyone in close physical contact with the mask, having an active medical implant or metallic implant that can be impacted by the magnetic field. The existing contraindications and warnings are being revised as a proactive measure to provide additional safety information to patients and healthcare professionals. To date, there have been no Medical Device Reports associated with the Sleepnet masks with magnets.

Risk to Health:

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. This could potentially lead to serious injury or death. Sleepnet Corporation has been distributing masks with magnets since 2006 and has not received any reports of injury or potential injury relating to the magnets.

Products Affected

The images below show the affected masks and location of the magnets. The location of the magnets on the mask and on the headgear clips are circled.



Phantom 2 Nasal Mask, part numbers 50182



iQ 2 Nasal Mask, part number 50169





Mojo Full Face Vented Mask and Mojo Full Face Non Vented Mask, part numbers 50835, 50836, 50837, 50838, 50920, 50921, 50922, 50923



Mojo 2 Full Face Vented Mask, Mojo 2 Full Face Non Vented Mask, and Mojo 2 Full Face AAV Non Vented Mask, part numbers 50817, 50818, 50819, 50820, 50912, 50913, 50914, 50915, 50941, 50942, 50943, 50944





Actions to be taken by the Customer/User:

1. If you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets, stop using the mask.
2. Contact your mask provider for a replacement mask that does not contain magnets.
3. If you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask does **NOT** have an active medical implant or metallic implant that will interact with magnets, you do not need to do anything.
4. If you are unsure whether or not you should use your mask with magnets, consult your physician or the manufacturer of your implant.
5. Continue using masks according to the updated instructions and labeling if patients or people in close proximity to them do not have implanted metallic medical devices or metallic objects in the body.

Product and Distribution Information:

Product	Product Description	Lot Number	UDI Number
50835	Mojo Full Face with Headgear, Small	All lot numbers	All UDI numbers
50836	Mojo Full Face with Headgear, Medium	All lot numbers	All UDI numbers
50837	Mojo Full Face with Headgear, Large	All lot numbers	All UDI numbers
50838	Mojo Full Face with Headgear, Extra Large	All lot numbers	All UDI numbers
50920	Mojo Non Vented Full Face Mask with Headgear, Small	All lot numbers	All UDI numbers
50921	Mojo Non Vented Full Face Mask with Headgear, Medium	All lot numbers	All UDI numbers
50922	Mojo Non Vented Full Face Mask with Headgear, Large	All lot numbers	All UDI numbers
50923	Mojo Non Vented Full Face Mask with Headgear, Extra Large	All lot numbers	All UDI numbers
50817	Mojo 2 Full Face Vented Mask, Small	All lot numbers	All UDI numbers
50818	Mojo 2 Full Face Vented Mask, Medium	All lot numbers	All UDI numbers
50819	Mojo 2 Full Face Vented Mask, Large	All lot numbers	All UDI numbers
50820	Mojo 2 Full Face Vented Mask, Extra Large	All lot numbers	All UDI numbers
50912	Mojo 2 Full Face Non Vented Mask, Small	All lot numbers	All UDI numbers
50913	Mojo 2 Full Face Non Vented Mask, Medium	All lot numbers	All UDI numbers
50914	Mojo 2 Full Face Non Vented Mask, Large	All lot numbers	All UDI numbers
50915	Mojo 2 Full Face Non Vented Mask, Extra Large	All lot numbers	All UDI numbers
50941	Mojo 2 Full Face AAV Non Vented Mask, Small	All lot numbers	All UDI numbers
50942	Mojo 2 Full Face AAV Non Vented Mask, Medium	All lot numbers	All UDI numbers
50943	Mojo 2 Full Face AAV Non Vented Mask, Large	All lot numbers	All UDI numbers
50944	Mojo 2 Full Face AAV Non Vented Mask, Extra Large	All lot numbers	All UDI numbers
50169	iQ 2 Nasal Vented Mask	All lot numbers	All UDI numbers
50182	Phantom 2 Nasal Vented Mask	All lot numbers	All UDI numbers



Actions by Sleepnet:

The existing contraindications and warnings are being revised as a proactive measure to provide additional safety information to patients and healthcare professionals.

New Contraindication

Do not use this mask if you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets. Implant examples include, but are not limited to, pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, aneurysm clips, metallic stents, ocular implants, insulin/infusion pumps, cerebral spinal fluid (CSF) shunts, embolic coils, metallic splinter, implants to restore hearing or balance with implanted magnets (such as cochlear implants), flow disruption devices, contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, bone substitute device, magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher, etc. If you have any questions regarding the implant, consult your physician or the manufacturer of your implant.

Updated Warning

Magnets are used in the mask and headgear clips with a field strength of 380mT. With the exception of the devices identified in the contraindication, ensure that the mask is kept at least 6 inches (approx. 16 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. This applies to you or anyone in close physical contact with your mask.

Authorized by:

A handwritten signature in blue ink that reads 'Jennifer Kennedy'.

Jennifer Kennedy
Director of Regulatory and Quality

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1-800-742-3646, extension 6611, Monday through Friday, 8:00 AM to 4:00 PM, Eastern Time.

Adverse reactions or quality problems 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 by fax.