


Certain Philips Respironics Masks for BiPAP, CPAP Machines Recalled Due to Safety Issue with Magnets That May Affect Certain Medical Devices: FDA Safety Communication

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The U.S. Food and Drug Administration (FDA) is alerting patients, caregivers, and health care providers that Philips Respironics (Philips) recalled certain masks (<https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2022/20220906-philips-respironics-alerts-customers-worldwide-of-updated-instructions-and-labeling-of-specific-sleep-therapy-masks-that-contain-magnetic-headgear-clips-due-to-potential-risk-of-serious-injury.html>).  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) used with bilevel positive airway pressure (also known as Bilevel PAP, BiPAP, or BPAP) machines and continuous positive airway pressure (CPAP) machines due to a serious safety concern. The recalled masks have magnets (placements shown by black circles in the picture below) and can cause potential injuries or death when use of a recalled mask with magnets interferes with certain implanted metallic medical devices and metallic objects in the body.

These potential adverse events can occur in people who use the masks, or in people near a person using the mask. Additionally, the recalled Philips masks may be used with other manufacturers' BiPAP and CPAP machines. Users of any BiPAP or CPAP machine should check to see whether their mask is one of the recalled Philips masks.

Device Description

The recalled masks are worn by a patient when using a BiPAP or CPAP machine and have magnetic headgear clips to hold them in place. The recalled masks are for single patient use in the home or multi-patient use in the hospital or other clinical environments. The recalled masks are for patients weighing more than 66lbs (30kg), except for the Wisp Youth Nasal Mask and Therapy Mask 3100 NC/SP which are for patients seven years of age and older weighing more than 40lbs (18kg).

- Figure 1: Amara View Full Face Mask
- Figure 2: DreamWisp Nasal Mask
- Figure 3: DreamWear Full Face Mask
- Figure 4: Wisp and Wisp Youth Nasal Mask
- Figure 5: Therapy Mask 3100 NC/SP



Figure 1:
Amara View
Full Face
Mask



Figure 2:
DreamWisp
Nasal Mask



Figure 3:
DreamWear
Full Face
Mask



Figure 4:
Wisp and
Wisp Youth
Nasal Mask



Figure 5:
Therapy
Mask 3100
NC/SP

The Magnets in the Recalled Masks May Affect Certain Metallic Medical Devices or Metallic Objects in the Body Presenting a Potential Risk

The recalled masks have magnets that can potentially cause injury or death if people who use them, or people near a person using a recalled mask, have certain implanted metallic medical devices or metallic objects in the body, such as:

- Pacemakers
- Implantable cardioverter defibrillators
- Metallic stents (such as aneurysm, coronary, tracheobronchial, and biliary)
- Neurostimulators (such as hypoglossal nerve stimulators)
- Magnetic metallic implants, electrodes, and valves placed in upper limbs, torso, neck, or head
- Cerebral spinal fluid shunts (such as ventriculoperitoneal shunt)
- Aneurysm clips
- Embolic coils
- Intracranial aneurysm intravascular flow disruption devices
- Metallic cranial plates, screws, burr hole covers, and bone substitute devices
- Ocular implants (such as glaucoma implants and retinal implants; intraocular lenses placed during cataract surgery are not impacted)
- Certain contact lenses with metal
- Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants)
- Magnetic denture attachments
- Implantable ports and pumps (such as insulin pumps)

- Metallic gastrointestinal clips
- Certain metallic joint replacements
- Devices labeled as Magnetic Resonance (MR) Unsafe
- Magnetic metallic implants not labeled for MR or not evaluated for safety in a magnetic field
- Metallic splinters in the eye
- Metallic shrapnel in the body

If the magnets affect the functioning or induce movement of certain implanted metallic medical devices or metallic objects in the body, the potential risks may include:

- For cerebral spinal fluid and ventriculoperitoneal shunts: potential increased pressure on the eye or brain, which may be fatal.
- For aneurysm clips: disrupted suture lines or clip separation, which may be fatal.
- For pacemakers: heart block or irregular heartbeat, which may be fatal.
- For cardioverter defibrillators: may fail to shock, which may be fatal.
- For neurostimulators: compression of the brain, seizures, or lead migration, which may be fatal.

Medical Device Reports


Manufacturers, such as Philips, are required to submit medical device reports (MDRs) when information reasonably suggests that their device may have caused or contributed to a death or serious injury, or has malfunctioned and that device or a similar device they manufacture would likely cause or contribute to a death or serious injury if the malfunction were to recur. Health professionals, consumers, and patients may voluntarily submit reports of device adverse events and malfunctions to the FDA.

As of August 30, 2022, Philips reported 14 serious injuries and 0 deaths related to the use of the recalled masks. The reported injuries included pacemaker failure leading to pacemaker replacement, a need for shunt adjustment, resetting of automatic implantable cardioverter defibrillator, arrhythmia, cognitive changes, headaches, change in heart rate (tachycardia, bradycardia), convulsions (seizures), and irregular blood pressure.

Although MDRs are a valuable source of information, this passive surveillance system has limitations. The incidence, prevalence, or cause of an event cannot typically be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about details such as frequency of device use. Because of these limitations, MDRs comprise only one of the FDA's several important postmarket surveillance data sources. These reports,

along with data from other sources, can contribute important information to a medical device's benefit-risk assessment. The FDA continues to review and assess the MDRs and will keep the public informed as new information becomes available.

Recommendations for Patients and Caregivers

- **Stop use** of the recalled mask and switch to a non-magnetic mask if available, if you or someone near you when using the recalled mask have any of the implanted metallic medical devices or metallic objects in the body listed above that may be affected by the magnets in the masks.
- Ensure the recalled mask is kept at least 6 inches away from metallic medical implants, metallic objects in the body, and medical devices that can be impacted by the magnetic fields.
- Consult with your health care provider to determine if another mask can be used for therapy and to decide if the plan for your care and treatment should change as a result of this safety issue.
- Contact your health care provider immediately, if you experience any issues related to your medical device and report the issue through the FDA's MedWatch Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).
- Contact Philips Respironics' customer service at 1-800-345-6443 or visit their website at www.usa.philips.com (<http://www.usa.philips.com/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) for more information about non-magnetic mask options.
- Properly dispose of the recalled mask after you have another alternative mask.
- You may continue using the mask, if you or someone near you when using the recalled mask, do **not** have any of the implanted metallic medical devices or metallic objects in the body listed above that may be affected by the magnets in the masks.

Recommendations for Health Care Providers

- Tell patients to **stop use** of the recalled mask and switch to a non-magnetic mask if available, if they or someone near them when using a recalled mask have any of the implanted metallic medical devices or metallic objects in the body listed above that may be affected by the magnets in the masks.
- Ensure the recalled mask is kept at least 6 inches away from metallic medical implants, metallic objects in the body, or medical devices that can be impacted by the magnetic fields.
- Properly dispose of the recalled mask.
- Discuss the health risks associated with using the recalled masks with patients who may at risk for potential injury or death due to magnets affecting the function or

inducing movement of certain implanted metallic medical devices or metallic objects in the body.

- Do not prescribe use of the recalled masks on patients who have any of the implanted metallic medical devices or metallic objects in the body listed above that may be affected by the magnets in the masks. Prescribers should also ask about any other people who may be at risk for injury or death if they are near a recalled mask while it is being used.
- If you have any problems with a recalled mask or if you treat a patient who has been affected, report the issue through the FDA's MedWatch Voluntary Reporting Form (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).

FDA Actions

The FDA recognizes that patients rely on these devices and is closely monitoring the company's actions to ensure the issue is resolved given the impact on patients. The FDA continues to work with Philips to ensure the company takes appropriate steps to correct the recalled devices.

The FDA is assessing the health hazard presented by use of the recalled products, reviewing the strategy the company proposes to address the problem, and may take additional actions as appropriate.

The FDA is also evaluating the safety of magnets that may be present in masks or similar interfaces from other manufacturers that are used in sleep medicine and that may have the potential to impact patient safety. The FDA intends to alert these manufacturers if appropriate and take necessary steps to address any issues that may be identified.

The FDA will keep the public informed if significant new information becomes available.


Reporting Problems to the FDA

If you think you had a problem related to the recalled masks, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>), or call 1-800-332-1088 for more information on how to mail or fax the form.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you need any further information or support concerning this issue, please contact Philips Customer Care Solutions Center at 1-800-345-6443 or visit their website at www.usa.philips.com

(<https://www.usa.philips.com/healthcare/product/HCNOCTN181/customer-care-solutions-center-customer-care>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).

More information on medical device recalls, including [What is a Medical Device Recall](/medical-devices/medical-device-recalls/what-medical-device-recall) (</medical-devices/medical-device-recalls/what-medical-device-recall>), is available on FDA.gov.