

## FAQs

As of October 18, 2022

### **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**

#### ***What is Philips Respironics' notification in connection with its sleep therapy masks with magnetic clips about?***

- This is a voluntary notification to inform users of specific sleep therapy masks containing such magnetic clips of the updated instructions and labeling. The already present warnings have been strengthened and contraindications have been added.
- Use of the mask is only contraindicated for patients and their household members, caregivers and bed partners that may be in close vicinity to patients using the masks, that have implanted metallic medical devices/metallic objects that may be affected by magnets.
- These masks may continue to be used 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. Based on Philips Respironics' analysis, this means that in most patient populations, approximately 95 percent of the patients should be able to continue using the mask as they have been.

#### ***Why is Philips Respironics issuing this notification?***

- This is a voluntary notification to users of specific CPAP or Bi-Level PAP therapy masks containing magnetic clips to inform them of the updated instructions and labeling, including the strengthened warning and added contraindication.
- All users should read and follow Philips Respironics' voluntarily updated warning and added contraindication described in the notification.
- This represents a new and industry-leading practice.



### ***Why does FDA consider the mask magnet notification a recall?***

- This notification is considered a recall notification in the US, and a field safety notice outside the US. Under US medical device regulations, a 'recall' may include a wide range of actions, such as the removal of product from the field and/or a correction of product in the field (e.g., providing updated labeling information).
- Therefore, in the US a 'recall' does not necessarily mean a removal from service of affected units unless specified. This is a voluntary notification - a correction - to inform users of specific sleep therapy masks containing such magnetic clips of the updated instructions and labeling. The already present warnings have been strengthened and contraindications have been added, and these masks may continue to be used according to the updated instructions and labeling.

### ***Is this the start of a field action to replace all masks with magnets that are in use?***

- No, this is a voluntary notification to inform users of specific sleep therapy masks containing such magnetic clips of the updated instructions and labeling. The already present warnings have been strengthened and contraindications have been added.
- Patients should only stop using the masks with magnets if the implanted metallic medical device/metallic object is contraindicated against the mask magnets. These patients should consult their physician immediately to determine if another mask can be used for their therapy.
- The masks with magnets may continue to be used 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. Based on Philips Respiration's analysis, this means that in most patient populations, approximately 95 percent of the patients should be able to continue using the mask as they have been.

### ***Are Philips Respiration's masks with magnetic headgear clips safe to use?***

- Yes, these masks are safe and may continue to be used 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.
- The magnetic headgear clips are used to attach the headgear straps to the masks, which is a method that is commonly used in the sleep therapy devices industry. Such magnetic clips are also used in the wearable electronics industry.
- Patients should only stop using the masks with magnets if the implanted metallic medical device/metallic object is contraindicated against the mask magnets. These patients should consult their physician immediately to determine if another mask can be used for their therapy.

### ***What is the field strength of the magnetic clips?***

- The field strength of the magnetic clips is less than 400 mT. The application of Philips Respiration's magnetic headgear clips and straps - according to the previous, as well as the current updated instructions and labeling - complies with the guidelines from the International Commission of Non-Ionizing Radiation Protection (ICNIRP), as well as the ISO 14117:2019-09 standard, for use of magnetic elements in proximity of implanted medical devices.

***Does Philips Respironics' portfolio also include masks that do not contain magnetic clips?***

- Yes, Philips Respironics' portfolio also includes sleep therapy masks that do not contain magnetic headgear clips.

***Will Philips Respironics continue to distribute masks with magnetic clips?***

- Yes, following the implementation of the updated instructions and labeling, Philips Respironics will continue to distribute masks with magnetic clips.

***What will Philips Respironics do to support affected patients?***

- Affected patients with questions may contact Philips Respironics' customer service at 1-800-345-6443, (Monday – Friday; 8:30 AM ET to 8:00 PM ET) for more information about non-magnetic mask options. Patients may also contact their Durable Medical Equipment (DME) provider, which supplied the masks affected by this notice. Philips Respironics will work with DME providers and intends to provide a replacement mask without magnetic clips from within its mask portfolio for those patients who are currently affected by the added contraindication.

***What is the potential risk of serious injury that Philips Respironics is warning about?***

- Use of the mask is only contraindicated for patients and their household members, caregivers and bed partners that may be in close vicinity to patients using the masks, that have implanted metallic medical devices/metallic objects that may be affected by magnets.
- More than 17 million masks containing magnetic clips have been distributed by Philips Respironics between 2015 and 2021. As of September 2022, Philips Respironics has received 14 reports of patients suggesting that the mask magnets may have impacted their medical devices including pacemaker interference, pacemaker failure leading to replacement, need of shunt adjustment, resetting of automatic implantable cardioverter defibrillator, seizures, defibrillator shutting off periodically, arrhythmia, irregular blood pressure, change in heartbeats, and cognitive issues. Philips Respironics has not received any reports of patient death in connection with this matter.