

Company Announcement/Recall – Philips Respironics Masks

Purpose of this communication:

- We are writing to inform you that the FDA has announced a recall by Philips Respironics for certain masks 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 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.

What do I need to do?

- Please review the following recall notice: [Certain Philips Respironics Masks for BiPAP, CPAP Machines Recalled Due to Safety Issue with Magnets That May Affect Certain Medical Devices: Letter to Health Care Providers | FDA](#)
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the 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.

Thank you in advance for your cooperation and continued partnership.