

Provider Newsflash September, 2022

FDA Recall Update: Philips Respironics BiPAP Machines

Purpose of this communication:

We are writing to inform you that we have updated information related to the Newsflash sent on August 31, 2022 regarding recalled BiPAP machines. The FDA has now published notice of a Class 1 recall of certain Philips Respironics A-Series BiPAP A30, A-Series BiPAP A40, A-Series BiPAP V30 Auto and OmniLab Advanced machines distributed from August 5, 2020 to September 1, 2021. These machines may contain a plastic contaminated with a non-compatible material. If that plastic is in the device motor, it may release certain chemicals of concern called volatile organic compounds (VOC's). The plastic may also cause the machine to fail and stop working suddenly during use which may also lead to serious injury or death. Only machines with serial numbers identified in the company's communications located at Medical Device Recalls (fda.gov) are affected by this recall.

What do I need to do?

- Please review the following recall notice: <u>Philips Respironics Recalls Certain BiPAP Machines for</u>
 <u>Plastic Issue that May Expose Patients to Certain Chemicals of Concern | 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 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.