

FDA Recall – Philips Respironics, Inc.

Purpose of this communication:

- We are writing to inform you that Philips Respironics, Inc. is updating the use instructions for Bipap V30, A30, and A40 Devices due to the risk for a failure in the Ventilator Inoperative alarm, which can cause therapy interruption or loss.

The device may:

- Reboot intermittently for 5-10 seconds (stopping therapy, blank screen, single audible alert), then restart with the same patient settings.
- Reboot intermittently for 5-10 seconds (stopping therapy, blank screen, single audible alert), then restart with factory default settings.
- Enter a Ventilator Inoperative state (therapy stopped, audible and visual alarms present) after three reboots within 24 hours, or without a preceding reboot.

What do I need to do?

- Please review the following recall notice: [Philips Respironics Updates Use Instructions for Bipap-A30-A40-and-V30 Devices Due to Interruptions and/or Loss of Therapy](#)
- Notify impacted patients and facilitate the resolution of the recall, according to the guidelines issued by the manufacturer in the FDA 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.