

Provider Newsflash May 2024

FDA Recall - Philips Respironics, Inc.

Purpose of this communication:

• We are writing to inform you that effective immediately the FDA has issued a Class I recall of all Philips Respironics Trilogy Evo Ventilators (Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal, and Trilogy EV300) distributed from March 20, 2019 to February 16, 2024 except for those with the latest software version 1.05.06.00 installed. Due to an issue with the previous software, the algorithm that calculates remaining battery life can malfunction causing the ventilators to issue a "Battery Depleted" or "Loss of Power" alarm while sufficient power is still available. This results in a sudden loss of ventilation while the device alarms and may result in ventilator power down with no delivery of therapy to the patient even though the battery is not depleted.

What do I need to do?

- Please review the following recall notice: <u>Philips Respironics, Inc. Recalls Trilogy Evo Continuous</u> <u>Ventilators due to a Software-Related Possible Power Malfunction | 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 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.