Provider Newsflash
October 2024

FDA Recall – Baxter Healthcare

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class I recall notice of Baxter Healthcare updates to the use instructions for all lots of Life2000 ventilation systems with software version 06.08.00 after identifying that this ventilator may fail to issue a Low Gas Pressure alarm if the pressure gas source (Life2000 compressor, oxygen cylinder or wall source) is not connected to the ventilator and turned on **before** starting the ventilator. The firm is currently working on a software update to address this issue and will contact all customers to update their devices once it is available. This notice does not involve device removal.

What do I need to do?

- Please review the following recall notice: Ventilator Correction: Baxter Healthcare Updates Use Instructions for Life2000 Ventilation System Due to Risk of No Low Gas Pressure Alarm | 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 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.