Provider Newsflash
September 2024

FDA Recall – Breas Medical

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has posted a Class I recall notice of a recall by Breas Medical for an update to the use instructions for their newly manufactured Vivo 45 LS ventilators due to the potential for elevated formaldehyde levels found after internal testing found the potential for a short-term increase in formaldehyde exposure. Use of the affected product and short-term exposure to formaldehyde emissions may cause serious adverse health consequence.

What do I need to do?

- Please review the following recall notice: Ventilator Correction: Breas Medical Updates Use Instructions for Vivo 45 LS due to Potential Elevated Formaldehyde Levels in Newly Manufactured Ventilators | 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.