



FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a voluntary nationwide recall by Philips for specific Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam?utm_medium=email&utm_source=govdelivery
- 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 for your prompt attention and cooperation in this matter.