

Company Announcement/Recall – Phillips Trilogy Evo Ventilator

Purpose of this communication:

We are writing to inform you that the FDA has posted a Class I recall issued by Philips Respironics of certain serial numbers of their Trilogy Evo Ventilators, model numbers DS2110X11B. They are also recalling Repair Kits for Trilogy Evo muffler assembly, Part number 1135257, lot numbers between 210414 and 210524 due to the potential health risks from the polyester-based polyurethane (PE-PUR) sound abatement foam in the muffler assembly of the ventilators and the repair kits that was incorrectly used by a supplier. The ventilators and repair kits were manufactured and distributed from April 15, 2021 to May 24, 2021

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-trilogy-evo-ventilators-potential-health-risks-pe-pur-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 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.