carecentrix

Provider Newsflash
December, 2022

FDA Recall – Philips Respironics Trilogy Reworked Ventilators

Purpose of this communication:

- We are writing to inform you that effective immediately, the FDA has issued a Safety Communication to provide additional information on two recent issues that have resulted in a recall by Philips of certain reworked Philips Respironics Trilogy 100 and Trilogy 200 ventilators. These devices were previously recalled in June, 2021 due to the potential health risks from the PE-PUR foam used for sound abatement. The current recall is due to the potential for adhesion failure of the silicone sound abatement foam, installed to replace the PE-PUR foam, which may cause it to separate from the plastic backing and potentially cause it to move and block the air path in the ventilator reducing the air flow in the ventilator and could cause it to alarm. If the alarm is not recognized or acted upon, the patient could experience difficulty breathing, asphyxia, hypoventilation or hypoxemia which can be life threatening. Additionally, Philips observed residual PE-PUR sound abatement foam in some of the reworked Trilogy 100 and Trilogy 200 ventilators that were returned to customers. Further exposure to PE-PUR foam may cause potential health risks which can result in serious injury or permanent impairment.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/safety-communications/certain-reworked-philips-respironics-trilogy-100200-ventilators-recalled-due-potential-silicone-foam
- 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.