Provider Newsflash
October 2024

FDA Recall – Philips Respironics, Inc.

Purpose of this communication:

- We are writing to inform you that the FDA has posted notice of a voluntary urgent medical device correction by Phillips Respironics, Inc. with instructions for additional user action and guidance regarding the use of in-line nebulizers with Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal, and Trilogy EV300 Ventilators. Phillips has determined that in some circumstances, the use of in-line nebulizers placed in certain locations may lead to aerosol deposits forming on the ventilator flow sensor. If aerosol deposits accumulate over time on the flow sensor, there is a possibility of patient impact due to one or more of the following conditions: the ventilator may become inoperative following stand by or powering off, leading to delay in therapy; and over-delivery of inhaled and exhaled air (tidal volume) and/or under-delivery of oxygen for devices with a specific concentration setting (FiO2).

- **What do I need to do?**
- Please review the following recall notice: Philips Respironics Issues Additional Usage Instructions for Trilogy Evo Ventilators Related to Use of In-Line Nebulizers | 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.

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