

FDA Recall – Philips Respironics Trilogy Evo Platform Ventilators

Purpose of this communication:

We are writing to inform you that Philips has identified three issues affecting Trilogy Evo Platform ventilators: (1) use of non-pneumatic (e.g., vibrating mesh) nebulizers, which can alter airflow characteristics and lead to inaccurate leak estimation and under-delivery of set tidal volume without indication on the user interface; (2) aerosol accumulation on the internal flow sensor, which may occur depending on nebulizer placement and can result in incorrect flow calculations, potentially causing over-delivery of tidal volume, under-delivery of FiO₂, or a Ventilatory Inoperative condition; and (3) delayed obstruction alarm activation, where in certain modes the alarm may not trigger within required standards and can be delayed by up to four breaths. Collectively, these issues may increase the risk of hypoventilation, low oxygen saturation, lung over-inflation, delayed or absent therapy, respiratory discomfort, and other adverse clinical outcomes. The affected devices include the Trilogy Evo (Model DS2110X11B, UDI-DI 00606959051942), Trilogy EV300 (Model DS2200X11B, UDI-DI 00606959052017), Trilogy Evo O2 (Model DS2100X11B, UDI-DI 00606959051997), and Trilogy Evo Universal (Model DS2000X11B, UDI-DI 00606959052000).

As of March 6, Philips has reported three serious injuries and no deaths associated with these issues.

What do I need to do?

- Please review the following recall notice from the FDA [here](#).
- Notify impacted patients to update all Trilogy Evo Platform ventilators to software version 1.05.15.00, discontinue all use of non-pneumatic nebulizers with these devices, and review the latest User Manual Addendum
- Confirm if you have any CareCentrix patients affected by this FDA Early Alert 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.