

Manufacturer name:	Philips Respironics
About the Recall:	The use of in-line nebulizer placed in certain locations can result in aerosol deposits accumulating over time on the device's internal flow sensor. Impacted flow sensors may result in inaccurate flow measurements in circumstances. Aerosol deposits that accumulate over time on the flow sensor may cause over-delivery of tidal volume if using a Trilogy Evo O2, Trilogy Evo Universal, or Trilogy EV300 device with a set FiO2, under delivery of oxygen that is not recognized by the device may also occur. Potential harms associated with the over-delivery of tidal volume may include volutrauma/barotrauma and/or respiratory discomfort.
Products(s) numbers/models that are affected:	A picture or table list can go here.
URL Link(s) to Manufacturer Notice/Web Site:	www.usa.philips.com
Actions to be taken by customer/Patient:	<p>For all Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal, and Trilogy EV300 users, regardless of in-line nebulizer use:</p> <p>As indicated in the Instructions for Use (IFU), in volume control mode, ensure that the High Inspiratory Pressure (HIP) alarm is set appropriately and is compatible with your patient's condition</p> <p>* As indicated in the IFU, if Ventilator Inoperative error occurs, ensure alternate sources of ventilation is available</p> <p>* Follow the guidance</p> <p>If using a Trilogy Evo O2, Trilogy Evo Universal, or Trilogy EV300 device with a set FiO2</p>

* Continuously monitor oximetry (SpO₂) of the patient and follow your institution's protocol for monitoring of arterial blood gas measurements to ensure that the patient is receiving adequate oxygenation. For devices with software versions below 1.05.10.00, use an external FiO₂ analyzer to identify under delivery of oxygen for any patient where the oxygen blending module is used. Switch to an alternative ventilator if an external FiO₂ analyzer is not available.

* As indicated in the IFU, maintain an immediately available back-up device that will allow rapid transition to a different oxygen delivery method or alternative ventilator if monitoring suggests FiO₂ is not being sufficiently delivered.

If using in-line nebulizer treatments:

* The circuit must be configured properly.

* For prescriptions needing tidal volumes greater than 700 mL with a passive circuit, transition patient to alternate circuit (Active PAP, Active Flow, or Dual Limb).

* When tidal volumes greater than 700 mL are used with a passive circuit, nebulized aerosol deposition can occur even if the nebulizer is placed appropriately.

Contact your local DME provider for further guidance.

Should you have further questions or concerns you may reach out to Respironics directly at 1-800-345-6443 option 2 for repair.