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UPDATED: URGENT Field Safety Notice

Trilogy Evo, Trilogy Evo O2, Trilogy EV300
Flow Sensor Nebulized Aerosol Deposition

21-NOV-2024

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code
<modify title block format as needed>

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

<Dear Customer>

This letter is an update to the Field Safety Notice (FSN), *2024-CC-SRC-013*, (Trilogy Evo, Trilogy Evo O2, Trilogy EV300, Flow Sensor Nebulized Aerosol Deposition) previously communicated in September 2024 regarding Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices that have historically been used with an in-line nebulizer. As previously communicated, the use of in-line nebulizers 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 outlined below.

Philips Respironics has conducted an additional review of complaints and identified 2 complaints received in October 2024 related to in-line nebulizer use. There were no reports of injuries associated with these complaints. While Philips Respironics has not received any other specific complaints of device malfunctions resulting from in-line nebulizer use, we have performed a retrospective complaint review from product launch through 31 July 2024 and identified 928 complaints that, based on the symptoms reported in the complaint, may indicate the flow sensors were not performing as expected. Three (3) reports included allegations of serious injury. This is a reported incidence rate of less than 0.001%. No deaths have been reported.

The previous September 2024 communication was intended to provide information on the issue as well as guidance for proper placement of the in-line nebulizer. This update is intended to provide further guidance for customers to determine what immediate actions and service requirements are necessary for your devices. Please follow the added guidance provided within **Appendix B** of this letter, in addition to the guidance provided in the previously communicated FSN, which is repeated in this letter for convenience.

Please review this letter in its entirety, as some information is new or updated from what was previously communicated. Please complete and return the attached URGENT FIELD SAFETY NOTICE RESPONSE FORM to acknowledge receipt of this update.

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1. What the problem is and under what circumstances it can occur

Nebulized aerosols that accumulate over time have the potential to permanently impact the internal flow sensor. Any Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal, and Trilogy EV300 devices that have historically been used with an in-line nebulizer in certain configurations may be impacted. If your device has never been used with an in-line nebulizer, it is not affected by this issue and can continue to be used. For any device currently using an in-line nebulizer or if history of in-line nebulizer use is unknown, follow the guidance within this notice.

Circumstances that may result in aerosol deposition:

- When the in-line nebulizer is used with passive circuits for tidal volumes greater than or equal to 700 mL, or
- When the in-line nebulizer is placed at the dry side of the heated humidifier, or
- When the in-line nebulizer is placed at the "inspiratory port (to patient)" (device outlet), or
- When the in-line nebulizer is placed in any location *other than* those identified in the images in Section 4

Effects on the ventilator:

Modes	**Impact to therapy**	**Description**
Volume control modes (A/C-VC, SIMV-VC, MPV-VC) or AVAPS-AE mode or when AVAPS is enabled (with A/C-PC, S/T, PSV)	Therapy may be impacted	The device may deliver higher tidal volume than what is displayed onscreen despite the reported tidal volume onscreen aligning with the set value; Monitored pressures displayed on the screen are not impacted.
Use of Trilogy Evo O2, Trilogy Evo Universal, or Trilogy EV300 with a set FiO2 in all modes	Therapy may be impacted	The amount of oxygen delivered is calculated based on the flow measured by the flow sensor. The aerosol deposits can cause the flow sensor to under-measure flow, thus resulting in impacted devices under-delivering oxygen. Note: If using an optional external oxygen analyzer, the alarms and monitored delivery will alert users to the under delivery of oxygen.
Device is turned off or put into standby status	Therapy is impacted	Impacted devices may display a Ventilator Inoperative error message while in power off or standby mode. If this occurs, the error will prevent the device from providing therapy.

Pressure control (A/C-PC, ST/T, PSV, SIMV-PC, CPAP, MPV-PC)	No impact to therapy	In pressure control modes, therapy is not impacted. Pressure provided will be consistent with settings. Note: Monitored tidal volume displayed on the screen may be lower than what is being delivered to the patient. Delivered therapy is not impacted.

Those most vulnerable to this issue include ventilator dependent patients, infants, and pediatric patients who are being ventilated in a volume control mode.

2. Hazard/harm associated with the issue

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 FiO_2, under delivery of oxygen that is not recognized by the device may also occur. In certain cases, when the internal flow sensor is impacted and the ventilator is placed in standby or powered off, it may result in a ventilator inoperative condition.

Potential harms associated with the over-delivery of tidal volume may include volutrauma/barotrauma and/or respiratory discomfort. Potential harms associated with a delay in therapy or under delivery of oxygen may include respiratory discomfort, low oxygen saturation, and/or dyspnea.

3. Affected products and how to identify them

According to our records, you have received at least one Trilogy Evo, Trilogy Evo O2, or Trilogy EV300 device. Any devices historically used with an in-line nebulizer in certain configurations are susceptible to this problem.

If your device has never been used with an in-line nebulizer, it is not affected by this issue and can be used in accordance with the guidance in this notice.

Please note that the internal flow sensor is inside the device and cannot be inspected by customers for accumulation of aerosol deposits. The guidance provided in Section 4 below must be followed to determine the appropriate steps to take for your device(s).

4. Immediate actions that should be taken by the customer / user to prevent risks to patients

Note: The device operator is responsible for reading and understanding the instructions before use.
As previously communicated, the use of in-line nebulizers 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.

- For all Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 users, regardless of in-line nebulizer use:
  - 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.
  - As indicated in the IFU, if a Ventilator Inoperative error occurs, ensure an alternate source of ventilation is available.

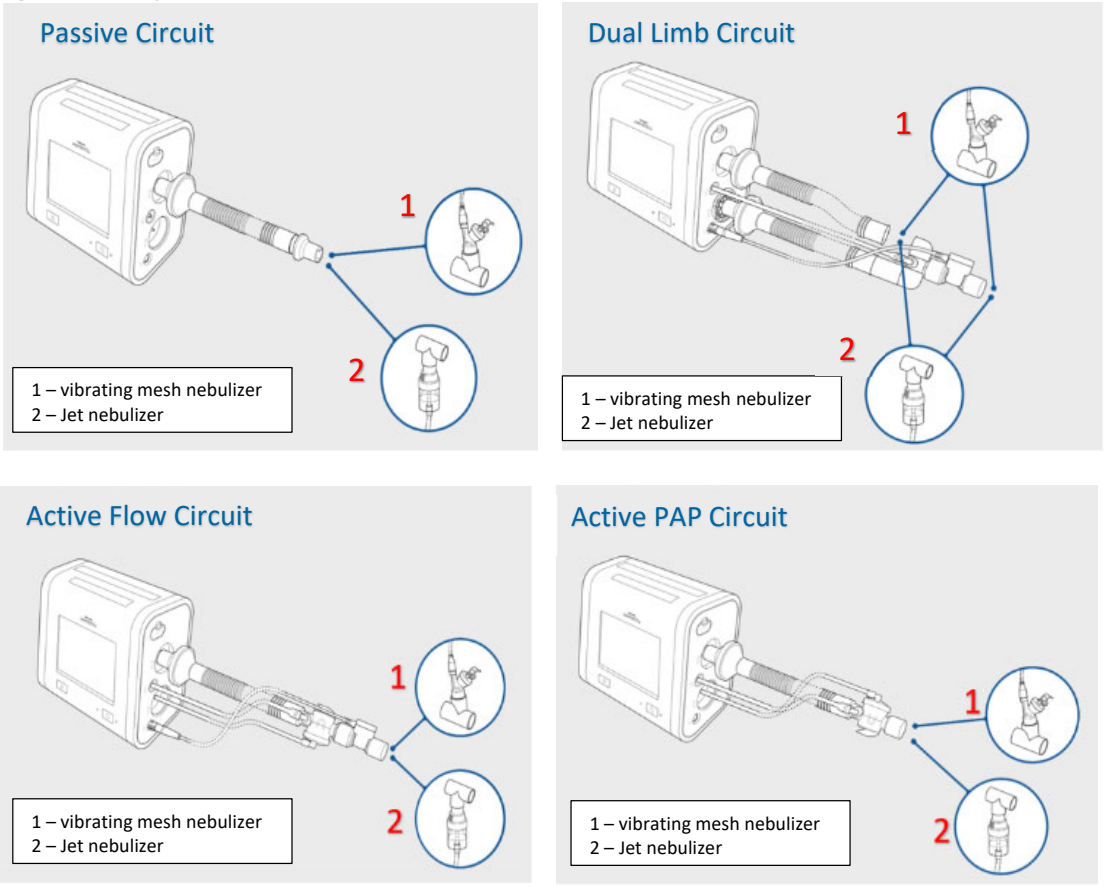
- Follow the guidance within this letter, including the updated guidance provided within **Appendix B**.

- <u>If using a Trilogy Evo O2 or Trilogy EV300 device with a set FiO_2</u> the aerosol deposits can cause the flow sensor to under-measure flow, thus resulting in impacted devices under-delivering oxygen.

  - 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 1.06.10.00, use an external FiO_2 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 FiO_2 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 alternate ventilator if monitoring suggests FiO_2 is not being sufficiently delivered.

- <u>If using in-line nebulizer treatments:</u>
  - The circuit must be configured as pictured in the images in **Figure 1** below.
  - 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 as pictured.

Figure 1: Acceptable In-Line Nebulizer Placement



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The above images are also located separately in Appendix A for reference.

This notice must be distributed to all members of your organization responsible for setting up and supervising patients that use these devices. This notice must also be distributed to any organizations to which you have further distributed Trilogy Evo, Trilogy Evo O2, or Trilogy EV300 devices.

5. Actions planned by Philips Respironics to correct the problem

This updated communication is intended to provide further guidance for immediate actions and service requirements necessary for your devices. Philips Respironics is working diligently on a labeling update to further mitigate this issue and will continue to follow-up with customers as additional information and solutions become available during the next few months.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed/verified by the Market/Business>*

This notice has been reported to the appropriate Regulatory Agencies.

Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Tracie Capozzio
Sr. Director, Head of Quality Therapy Platforms
Sleep and Respiratory Care

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URGENT Field Safety Notice

Reference: Flow Sensor Nebulized Aerosol Deposition
Trilogy Evo, Trilogy Evo O2, and Trilogy EV300
2024-CC-SRC-013

Instructions: Please complete and return this form to Philips Respironics promptly and no later than 30 days after receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and management of the necessary steps to avoid the issue. This form can be completed by filling out the required fields, scanning, and emailing to **[localization]**

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the Trilogy Evo, Trilogy Evo O2, or Trilogy EV300 device. Additionally:

☐ I am unsure of the status of some or all of the Trilogy Evo, Trilogy Evo O2, or EV300 devices under my care as it relates to the issue described in the Field Safety Notice. Inspection or servicing of some or all equipment is required.

☐ Protocols within my organization's care network ensure that either 1) in-line nebulizers are always used at the patient end of ventilator circuits; or 2) in-line nebulizers are not used on patients under my care.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx>

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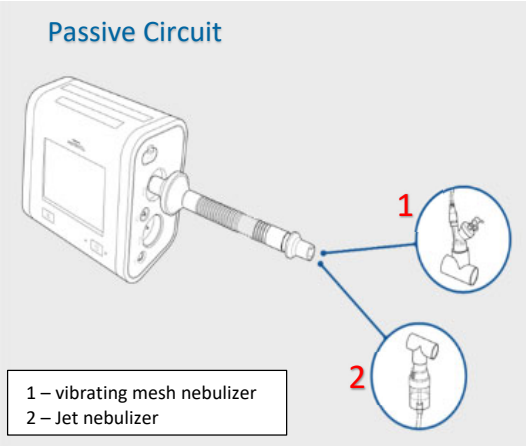
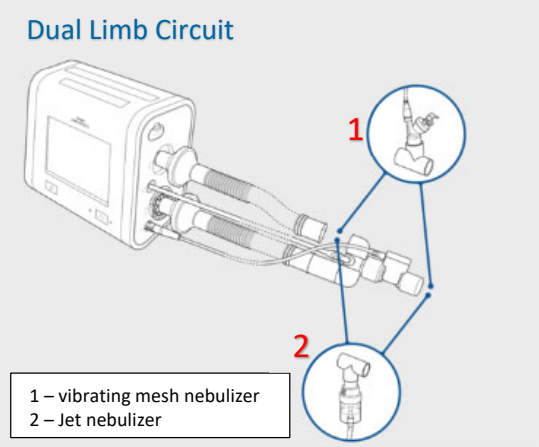
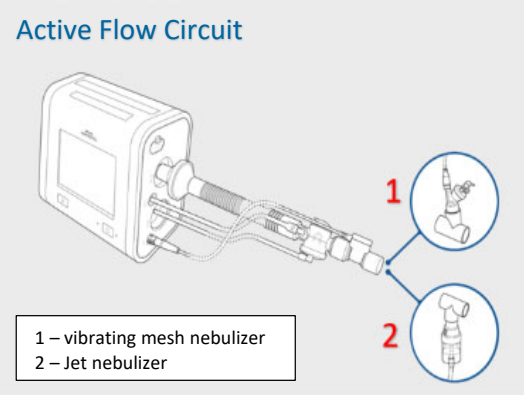
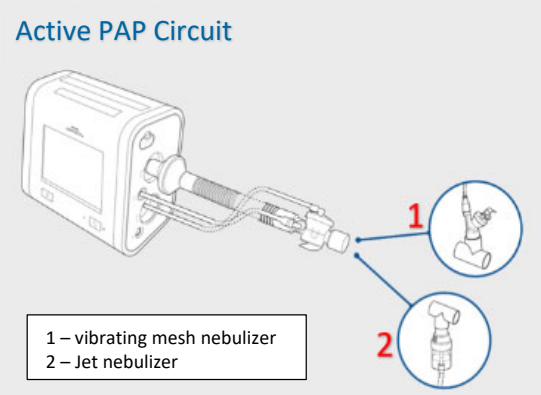
APPENDIX A
Appropriate Circuit Configurations for Use With In-Line Nebulizers

If using in-line nebulizer treatments, ensure the circuit is configured as shown in the images below.









Note: 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 as pictured.

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APPENDIX B
Guidance for Hospitals, DME and Homecare Providers

Please follow the guidance below to determine immediate actions for your devices.
Please note that the device operator is responsible for reading and understanding the instructions before use.

Immediate action is required for the scenarios listed below

- Devices, whether currently in use or not in use on a patient, where:
  - History of in-line nebulizer use or the placement of in-line nebulizer use is unknown
  - The in-line nebulizer has been placed at a location other than those identified in Figure1 of Section 4 of this notice.
- Device used with an In-line nebulizer for patients requiring tidal volumes greater than or equal to 700 mL with a passive circuit
- Devices being used with pressure control modes in which inspiratory pressure setting changes **have occurred** based on lower-than expected tidal volumes

ACTION: Transition the patient to an alternate form of ventilation. Refer to Table 1 below for available pathways for further analysis of the flow sensor. If you are transitioning to Trilogy Evo, Trilogy Evo O2, or trilogy EV300 device ensure it has been evaluated for use with an in-line nebulizer, in accordance with the guidance in this notice.

Consider prioritization of the most vulnerable patient populations:

- Ventilator dependent patients
- Infants and pediatrics

Table 1: Contact Pathways

Pathway	Contact
1	Philips Authorized Service Location (Bench Repair Facility or DME customers authorized to perform their own service)
2	Authorized Service Provider (for Hospital only)

To initiate the process for servicing your device, please *contact <details to be completed/verified by the Market/Business>* Philips Respironics will provide instructions for servicing product potentially impacted by flow sensor contamination.

For the scenarios listed below, continue to place the in-line nebulizer at the patient end of the circuit in accordance with the guidance in this notice.

- New devices or devices that have never been used with an in-line nebulizer
- In-line nebulizer used at patient connection port for tidal volumes less than or equal to 700 mL for all circuit types
- In-line nebulizer used at patient connection port for tidal volumes greater than or equal to 700 mL with Active PAP, Active Flow, or Dual Limb circuit
- Devices being used with pressure control modes in which **no** inspiratory pressure setting changes have occurred based on lower-than expected tidal volumes

Once the device has been serviced in accordance with this notice, it can be used with an in-line nebulizer placed at the patient end of the circuit, following the instructions provided.