

UPDATED: URGENT Field Safety Notice

Trilogy Evo, Trilogy Evo O2, Trilogy EV300
Non-pneumatic Nebulizer Use, Flow Sensor Nebulized Aerosol Deposition, and Obstruction Alarm

13-APR-2026

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,

Philips Respironics is issuing this update to Field Safety Notice (FSN) 2026-CC-SRC-002, which was previously distributed regarding Trilogy Evo Platform ventilators (Trilogy Evo, Trilogy Evo O2 and Trilogy EV300 ventilators).

Since the initial communication, Philips Respironics has received feedback and questions from customers regarding the restriction on the use of non-pneumatic nebulizers (e.g., vibrating mesh nebulizers) as described in prior FSN 2026-CC-SRC-002 under reference bullet 2025-CC-SRC-020. Based on additional internal review and clinical evaluation, Philips Respironics has evaluated the risk versus benefit of continued use of the non-pneumatic nebulizers (e.g., vibrating mesh nebulizers). Based on this evaluation, Philips Respironics is revising its guidance to allow for the use of non-pneumatic nebulizers as long as the updated instructions for nebulizer placement and understanding of the warning contained in this Field Safety Notice are followed. Adherence to the revised guidance contained in this FSN will support continuity of care where alternative options may be limited or not appropriate in all care settings.

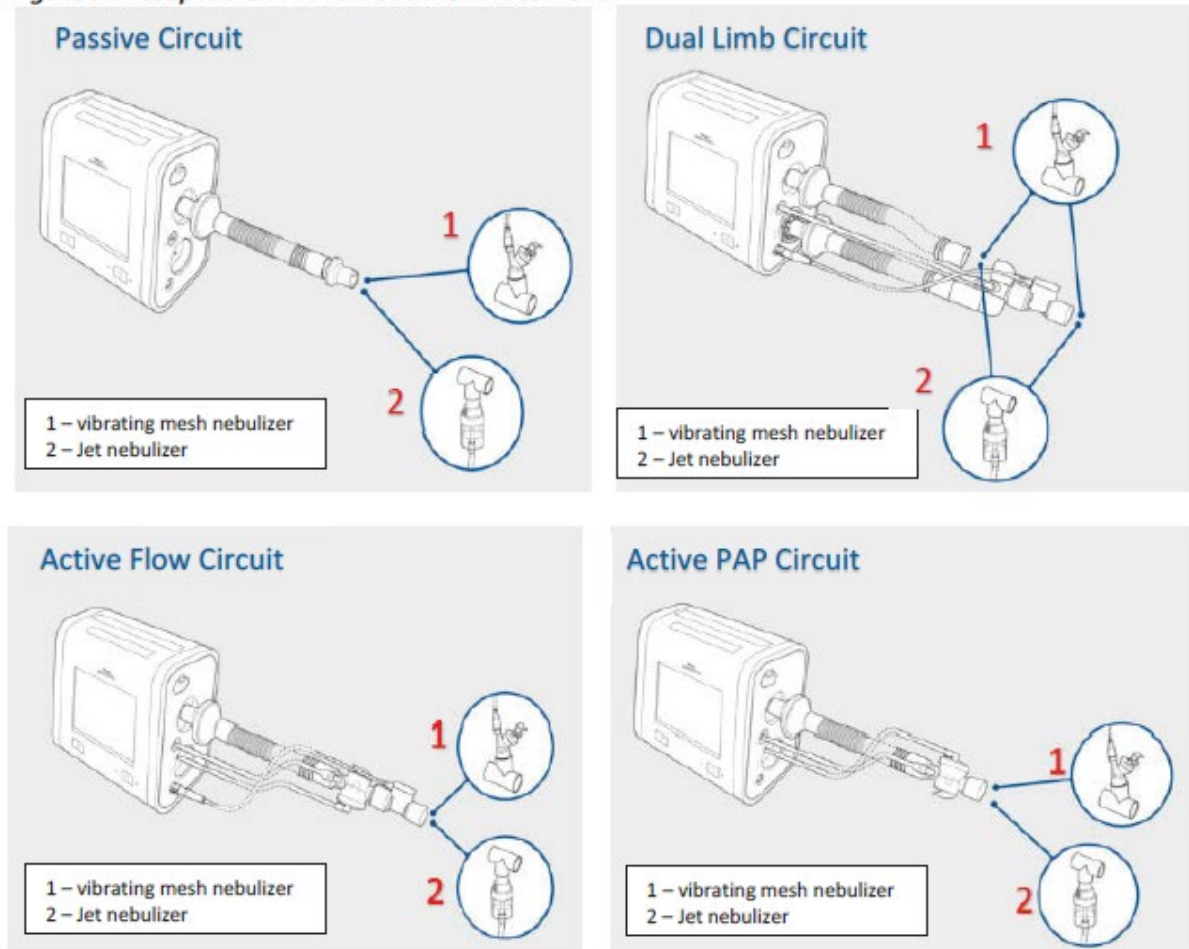
Therefore, this update provides clarification and revised guidance regarding the use of non-pneumatic nebulizers with Trilogy Evo Platform ventilators.

Specifically:

- Similar to pneumatic nebulizers, non-pneumatic nebulizers may be used as long as they are placed in accordance with the guidance and instructions on the proper location for a nebulizer on the various types of patient circuits. See “Figure 1: Acceptable In-Line Nebulizer Placement”
- **WARNING:** Ventilator accuracy can be adversely affected by changes to the inspired gas caused by the use of both pneumatic and non-pneumatic nebulizers.

- For customers who have updated 1.06.15.00 release, the User Interface only refers to pneumatic nebulizers – these instructions also apply to non-pneumatic nebulizers.

Figure 1: Acceptable In-Line Nebulizer Placement



This update **does not change the previously communicated information** regarding:

- Nebulized aerosol deposition on the internal flow sensor (FSN 2024-CC-SRC-013 – Flow Sensor Nebulized Aerosol Deposition), and
- Obstruction Alarm timing (IPN 2024-CC-SRC-002 – Obstruction Alarm).

Please review this letter carefully, as it contains **updated guidance regarding nebulizer use**. The specific nebulizer model should be selected and provided by the healthcare provider according to medication requirements. Philips Respironics cannot make clinical recommendations. Any questions regarding patient management should be directed to the appropriate clinical professionals. A response form is included and must be completed and returned as instructed to confirm receipt and understanding of this update.

1. What the problems are and under what circumstances they can occur

Use of non-pneumatic (e.g., Vibrating Mesh) Nebulizers (C&R 2025-CC-SRC-020)

Following the issuance of our Field Safety Notice regarding the use of Non-Pneumatic (e.g., Vibrating Mesh) Nebulizers with the Trilogy Evo device, we have become aware of the patient and operational impact associated with the restriction. At the time of the initial FSN issuance, the restriction on non-pneumatic (vibrating mesh) nebulizers was based on observed impacts to ventilator performance, including potential changes in delivered therapy accuracy due to aerosolized medication affecting the inspired gas.

Following evaluation of the risk versus benefit and customer feedback on real-world clinical, patient, and operational impact, Philips Respironics is revising its guidance to allow for the use of non-pneumatic nebulizers as long as the updated instructions and warning contained in this Field Safety Notice are followed.

2. Hazards and harms associated with nebulizer use (pneumatic or non-pneumatic)

Exercise caution when using a nebulizer (pneumatic or non-pneumatic) with the Trilogy Evo, Trilogy Evo O2 and Trilogy EV300. Nebulizers may impact ventilator performance depending on the type of nebulizer, circuit configuration and therapy mode.

When a nebulizer (pneumatic or non-pneumatic) is used inline with a passive circuit during AC-VC, SIMV or AVAPS modes, clinicians should be aware of possible discrepancies in tidal volume delivery and monitoring. In adult active PAP and adult dual limb circuits, non-pneumatic nebulizers have not demonstrated impact on ventilator performance or displayed parameters based on available testing. In contrast, pneumatic nebulizers may affect ventilator performance across all circuit types.

During nebulization, volume delivery accuracy in AC-VC, SIMV, or AVAPS modes may be impacted by gas added by pneumatic nebulizers and, in certain configurations, changes in gas properties associated with non-pneumatic nebulizers. As a result, patient volume and flow monitoring displayed on the device may not reflect actual patient values and triggering sensitivity may be affected. In addition, aerosolized particles may impact circuit components including external flow sensor (EFS) (active flow and dual limb circuits) and passive exhalation valve (single limb circuits), mask or mask elbow. These discrepancies in delivery and monitoring can lead to potential harms such as hypoventilation, patient discomfort, and delayed clinical response. Any reduction in ventilator accuracy is expected to resolve once nebulization is complete.

3. Affected products and how to identify them

All Trilogy Evo, Trilogy Evo O2 and Trilogy EV300 models could be impacted by this letter.

4. Actions that should be taken by the customer or user in order to prevent risks for patients or users

- Follow the updated instructions contained within this notice regarding the use of non-pneumatic nebulizers
- Communicate this Urgent Field Safety Notice to anyone in your organization who interacts with a Trilogy Evo Platform ventilator, including clinicians, therapists, nurses, caregivers, and

patients. Ensure they are aware of the changes regarding the use of nebulizers with these ventilators and that non-pneumatic nebulizers may be used.

- If a Trilogy Evo Platform ventilator previously in your possession has been transferred, ensure this information is communicated to them.
- Complete the URGENT Field Safety Notice Response Form included later in this letter. This is required to verify that you have received and understand the content of this notice.
- Distributors should identify customer list and where appropriate, distribute this Field Safety Notification and all relevant appendices to physicians, clinicians, patients and/or users.

5. Actions planned by Philips Respironics to correct the problem

Philips Respironics will be issuing an update to the User Manual to include this guidance on the use of Non-Pneumatic (e.g., Vibrating Mesh) Nebulizers. In addition, Philips Respironics will be releasing a software update to reflect this guidance on the user interface to clarify that it applies to both, non-pneumatic and pneumatic nebulizers. The updates will be included in a future release to minimize user impact through repeated device and literature updates.

If you need any further information or support concerning this issue, If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI: +448000260086
NI: +448000260430
ROI: +3531800832340

Email: UKFCO@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

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

URGENT Field Safety Notice Response Form

Reference: Trilogy Evo, Trilogy EV300 and Trilogy Evo O2 Non-pneumatic Nebulizer Use, Flow Sensor Nebulized Aerosol Deposition, 2026-CC-SRC-002_B

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/Postcode/Country: _____

Customer Actions:

- Please return the completed and signed reply form to [UKI Quality CR@philips.com](mailto:UKI_Quality_CR@philips.com) within 30 business days of receipt.

We acknowledge receipt and understanding of the accompanying Urgent 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 and Trilogy EV300 ventilators.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to [UKI Quality CR@philips.com](mailto:UKI_Quality_CR@philips.com)