Urgent Product Defect Correction

Philips Healthcare
Locked Bag 30
North Ryde
NSW 1670
Australia

Final Copy

September 2024

2024-CC-SRC-013

TGA Reference #:	RC-2024-RN-00850-1
Product / Device Name / Model #	Trilogy Evo, Trilogy Evo O2, and Trilogy EV300
ARTG Ref #	332200, 336800
Short Description	Flow Sensor Nebulised Aerosol Deposition

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 has become aware of a potential problem when using in-line nebulisers in certain configurations with Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices. The use of in-line nebulisers 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.

While Philips Respironics has not received any specific complaints of device malfunctions resulting from in-line nebuliser 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.

This Product Defect Correction Notice is intended to inform you about:

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

Nebulised aerosols that accumulate over time have the potential to permanently impact the internal flow sensor. Any Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices that have historically been used with an in-line nebuliser in certain configurations may be impacted.

If your device has never been used with an in-line nebuliser, it is not affected by this problem and can continue to be used. If using an in-line nebuliser, continue to use in accordance with the guidance in this notice.

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Circumstances that may result in aerosol deposition:

- When the in-line nebuliser is used with passive circuits for tidal volumes greater than or equal to 700 mL, or
- When the in-line nebuliser is placed at the dry side of the heated humidifier, or
- When the in-line nebuliser is placed at the "inspiratory port (to patient)" or (device outlet), or
- When the in-line nebuliser 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 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 analyser, 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. If this occurs, the error will prevent the device from turning therapy back on.

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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 problem include ventilator dependent patients, infants and pediatric patients who are being ventilated in a volume control.

2. Hazard/harm associated with the problem

Aerosol deposits that accumulate over time on the flow sensor may cause over-delivery of tidal volume. If using a Trilogy Evo O2, or Trilogy EV300 device with a set FiO_2, under delivery of oxygen that is not recognised 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

Affected Part numbers in Australia are listed below:

Model #	Device Description
IN2110X15B	Trilogy Evo Ventilator, Intl
IN2100X15B	Trilogy Evo Ventilator w/OBM, Intl
IN2200X15B	Trilogy EV300, International
AU2110X15B	Trilogy Evo, Australia

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 nebuliser in certain configurations are susceptible to this problem.

If your device has never been used with an in-line nebuliser, it is not affected by this problem and can continue to 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

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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 in order to prevent risks for patients

- <u>For all Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 users, regardless of in-line nebuliser use:</u>
  - 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 Ventilator Inoperative error occurs, ensure alternate source of ventilation is available

- <u>If using a Trilogy Evo O2 or Trilogy EV300 device with a set FiO_2</u>
  - Continuously monitor oximetry (SpO_2) 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.
  - 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 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 alternative ventilator if monitoring suggests FiO_2 is not being sufficiently delivered.

- <u>If using in-line nebuliser 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).

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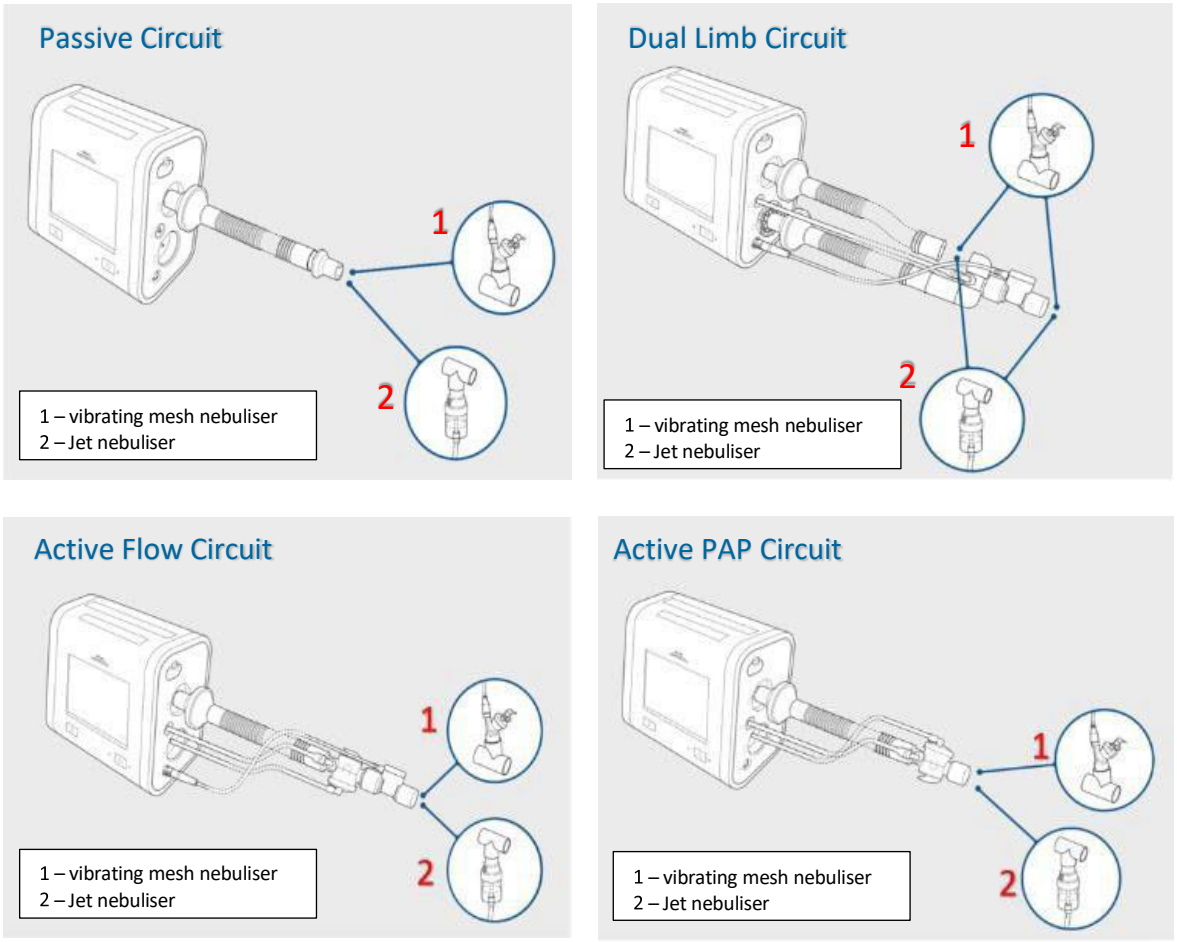
Figure 1: Acceptable In-Line Nebuliser Placement.



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

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

5. Actions planned by Philips Respironics to correct the problem

At this time, this communication is intended to provide awareness and understanding of the problem and immediate actions to be taken by the customer when using an in-line nebuliser.

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Philips Respironics understands that use of in-line nebulisers is common amongst ventilator patients and is working diligently to further understand the interaction between in-line nebulisers and the flow sensor within the Trilogy Evo devices. Philips Respironics is continuing to investigate this problem and will follow- up with customers to provide additional guidance and solutions as it becomes available during the next few months.

If you need any further information or support concerning this problem, please contact Philips Customer Support on 1800 830 517.

This notice has been reported to the appropriate Regulatory Agencies.

Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Princess Nochefranca
Quality Specialist
Philips Healthcare Australia and New Zealand

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Acknowledgement Form

Instructions: To acknowledge simply scan the QR Code below OR follow the link:

https://philips.efmfeedback.com/se/705E3ED8776E372E

If the above options are not available to you please Contact Philips Customer Support on 1800 830 517 and provide your verbal acknowledgement

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

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