UPDATED: URGENT Field Safety Notice

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

19 Feb 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,

This letter is to inform you of a new issue related to the use of non-pneumatic nebulizers with Trilogy Evo Platform ventilators (Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 ventilators collectively) as well as provide you with updates regarding two prior communications regarding these same devices. This FSN 2026-CC-SRC-002 includes the following issues:

- new information on non-pneumatic (e.g., vibrating mesh) nebulizers (FSN 2025-CC-SRC-020 – Vibrating Mesh Nebulizers)
- an update to a previously communicated Field Safety Notice regarding nebulized aerosol deposition on the internal flow sensor (FSN 2024-CC-SRC-013 – Flow Sensor Nebulized Aerosol Deposition), and
- an update to the Obstruction Alarm timing, communicated in an Important Product Notice (IPN 2024-CC-SRC-002 – Obstruction Alarm).

Philips Respironics has released a device software update (Version 1.06.15.00) to address FSN-2024-CC-SRC-013 and IPN 2024-CC-SRC-002 as well as update to User Manual addendum to address all three issues above.

Please note with this user manual addendum update, Philips Respironics is no longer permitting the use of non-pneumatic nebulizers with Trilogy Evo Platform ventilators.

These updates are required for continued safe and compliant operation of Trilogy Evo Platform ventilators. Additional details (provided in Appendix A), as well as the actions you need to perform, both immediately and during ongoing use, are included below.

Review this letter in its entirety, as some information may be new or updated from previous communications. A response form is included in this letter. It must be completed and returned as instructed to confirm receipt and understanding of this notice.

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

Philips Respironics has identified three issues affecting Trilogy Evo Platform ventilators - one new issue and two issues which have been previously communicated.

Use of Non-pneumatic (e.g., Vibrating Mesh) Nebulizers Prohibited *(new information)*
Analysis of the impact of nebulizers on performance of Trilogy Evo Platform ventilators revealed that using non-pneumatic nebulizers with Trilogy Evo Platform ventilators may result in a discrepancy between the set tidal volume and the tidal volume received by the patient. Non-pneumatic nebulizers change the airflow characteristics by adding liquid droplets, causing the ventilator's leak estimation calculation to be incorrect. This leads to under-delivery of therapy to the patient even though the graphic user interface does not display the change. This condition may occur with or without aerosol accumulation on the flow sensor. It is also not consistent with the requirements of ISO 80601-2-12[1]. There have been three (3) complaints reported for this issue, including one (1) with minor injury and two (2) with no injury reported.

Nebulizer Use and Flow Sensor Impact *(previously communicated)*
Depending on where a nebulizer is placed on the patent circuit, aerosol can enter the ventilator and accumulate on the internal flow sensor. Over time, this buildup may interfere with the sensor's ability to accurately measure airflow, leading to incorrect flow calculations and potentially impacting the therapy delivered to the patient. In these cases, the internal flow sensors should be replaced. Philips Respironics has conducted a 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, with three (3) resulting in serious injuries.

Obstruction Alarm Timing *(previously communicated)*
Analysis has shown that in some situations, the Obstruction Alarm does not trigger within the timeframe dictated by the relevant standards[2] – two (2) breath cycles or five (5) seconds. In certain ventilation modes, with or without backup rates, the alarm could be delayed by up to four (4) breaths. No complaints or adverse events, including injuries and deaths, were reported that were attributed to this issue.

[1] ISO 80601-2-12:2023, *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.*
[2] ISO 80601-2-12:2011 Clause 201.12.4.107 and ISO 80601-2-72:2015 Clause 201.12.4.107

2. Hazards and harms associated with these issues

Use of Non-pneumatic Nebulizers (e.g. Vibrating Mesh Nebulizers) Prohibited
The use of a non-pneumatic nebulizer may lead to under-delivery of volume and inaccuracies on the ventilator display. Potential harms include hypoventilation, low oxygen saturation, inadequate or inappropriate treatment, dyspnea, and other unspecified respiratory problems.

Nebulizer Use and Flow Sensor Impact
Aerosol deposits that accumulate on the flow sensor may cause over-delivery of tidal volume, under-delivery of FiO2, and in some cases a Ventilatory Inoperative condition. Potential harms in this situation may include over inflation of the lung, low oxygen saturation, hypoventilation, delay/absence of therapy and respiratory discomfort.

Obstruction Alarm Timing
Philips Respironics has assessed this issue and determined that it does not result in any risk to patients. In addition to the obstruction alarm, other medium and high priority alarm(s) will occur in the case of an obstruction. No adverse events, including death or injuries, have been reported. .

3. Affected products and how to identify them

All Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 models could be impacted by one or more of the issues described in this letter.

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

- Update all Trilogy Evo Platform ventilators with software version 1.06.15.00. The software is available as free download through our My Philips for Professionals (MyP4P) and InCenter websites. Refer to Appendix B of this letter for instructions on how to acquire the software and update devices.

- Review the latest version of the User Manual Addendum - a copy is included with this letter. Ensure a copy of all product literature, including this User Manual Addendum, is included with every Trilogy Evo Platform ventilator in your fleet.

- Stop all use of non-pneumatic nebulizers, including vibrating mesh nebulizers, with all Trilogy Evo Platform ventilators.

- 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 are not to be used.

- If a Trilogy Evo Platform ventilator previously in your possession has been transferred, ensure this information is communicated to them, including the attached User Manual Addendum.

- 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 has released a software update and new User Manual Addendum to support the use of Trilogy Evo Platform ventilators to deliver safe and effective therapy to patients. A list of the changes to both items is included in Appendix A. We will continue to investigate ways to prevent and detect potential contamination of the internal flow sensor during nebulization.

Philips Respironics will be following up with customers to ensure that devices have been updated to this new version of software and new addendums (attached) have been disseminated.

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

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 Evo O2, Trilogy EV300, Flow Sensor Nebulized Aerosol Deposition, Obstruction Alarm, and Vibrating Mesh Nebulizers, C&R 2026-CC-SRC-002

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/State/ZIP/Country: _____

Customer Actions:

- Please return the completed form by fax to the number indicated below or email it to **[localization]** within 30 business days of receipt.
- Upon receipt of your signed acknowledgement, a list of all the impacted devices within your installed base will be provided by Philips Respironics
- **To prevent unnecessary risk for patients**, immediately update the device software following the instructions provided in this letter and refer to the User Manual addendum provided, or contact Philips representative for support.

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, Trilogy Evo Universal, and Trilogy EV300 ventilators.

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.

Appendix A

Detailed changes to the Trilogy Evo platform software and User Manual Addendum

Trilogy Evo software version 1.06.15.00 includes the following updates:

- On-screen guidance on the proper placement and use of a pneumatic nebulizer with a Trilogy Evo Platform ventilator has been added.

- A new button has been added to the bottom of the screen that leads to the same guidance as above.

- The alarm criteria related to the potential measurement drift of the internal flow sensors has been modified. Flow sensor drift may be an indication of aerosol deposition on the flow sensor. A Ventilator Service Required alarm has been implemented when the drift approaches a critical value. If the drift exceeds that value, a Ventilator Inoperative alarm will sound and the device will stop delivering therapy.

- A Ventilator Service Required alarm criteria has been added to signal when a mismatch is detected between the two (2) internal pressure control sensors. This may also indicate that the flow sensor is contaminated. An entry would be recorded in the error log if this alarm criteria was triggered.

- A correction was made to the timing of the Obstruction Alarm to meet standards requirements.

All previous software updates are included in this new software version. Devices can safely be upgraded from any previous version of 1.06 software to software 1.06.15.00.

The Trilogy Evo User Manual Addendums include the following updates:

For proper nebulizer usage

- A warning to not use non-pneumatic (e.g., vibrating mesh) nebulizers with Trilogy Evo Platform ventilators,

- restrictions on the use of pneumatic nebulizers based on flow rates and tidal volumes for certain circuit size and therapy mode combinations,

- guidance and illustrations on the proper location for a pneumatic nebulizer on the various types of patient circuits, and

- an updated description of the status bar showing and describing the new Nebulizer button.

For Obstruction Alarm changes

- An update to the test procedure to confirm the Obstruction Alarm will detect a circuit obstruction and
- Additional details on Obstruction Alarm triggering

Appendix B

Software update procedure for Trilogy Evo Platform Ventilators

Trilogy Evo software version 1.06.15.00 is available as a free download from the following websites:

For Homecare Customers – My Philips for Professionals (www.my.philips.com/s/)

For Hospital Customers - InCenter (https://philips.mizecx.com/login.html)

Details for accessing and downloading the appropriate software for your country are included below.

My Philips for Professionals (www.my.philips.com/s/)

If you do not have a MyP4P account, go to http:www.my.philips.com/s/ to create one.

1. To begin, you will need to provide Personal Information and Organization information. You will need to click on each box, fill out the required fields, and click save for each section.

2. If information is completed accurately, green check marks will appear. Click submit to complete the registration request.

3. Once your registration is approved, you will receive an email with instructions to activate your account.

4. Next, you will need to create a password. If information is completed accurately, green check marks will appear. Click submit.

5. Once the password has been submitted, you can click on the link to MyP4P to choose your SRC groups (this will determine what types of documents you will have access to.

6. First, you will choose your specialty – you will need to choose Sleep Therapy and Respiratory Care.

7. Next, you will choose your groups. Choose the SRC groups.

8. You will click on the Request Access hyperlink for each group you desire access. Then you will be prompted to enter your account number. For the Service Software group, you will need to open the ULA first and then check the box before you can click to request access.

9. As you request access, a banner will appear at the top letting you know a request has been sent for you to receive access to the group.

10. When you are approved for the group(s) you signed up for, you will receive a confirmation email.

Downloading Software from the MyP4P website

1. Log onto https://www.my.philips.com/s/ with your customer account and password.

2. Click on the Group Documents tab.

3. Use the search tool and type: Trilogy Evo, Trilogy Evo O2, Trilogy Evo Universal, and Trilogy EV300.

4. Click on the applicable software version update (1.06.15.00). Read the description to be sure you are permitted to download the particular software revision for your country.

5. The file will automatically download. The file will be located in the folder where your downloads are stored, in a compressed, .zip format.

Once you have located the file on your computer, proceed below to the section titled **Unzipping the ventilatory software file and loading it to a USB flash drive.**

InCenter (https://philips.mizecx.com/login.html)

If you do not have an InCenter account, send an email to PCCI_CS_OPS@philips.com that includes:

Subject line: Request for access to InCenter Service P&S and Software Downloads for Respiratory Care-Ventilators.

Body: Company/institution full name
Street address
City, state, postal/zip code
Country
Telephone number
Email address
At least one ventilator serial number (to confirm that the request is from a valid customer).

Note: The InCenter team will process your request and email a temporary password within 72 hours.

Once you log into InCenter (https://philips.mizecx.com/login.html) create a password and access technical content for Hospital Respiratory Care products.

To download ventilator software from InCenter to the service PC, do the following:

1. Log on to InCenter: (https://philips.mizecx.com/login.html)
From the product tree section, select: **Hospital Respiratory Care > Ventilation > Trilogy**
Select the **Software tab**, and then select **Software Downloads**.
   - Select the appropriate software version approved for your in your country
1. *Note: Look for Software Version 1.06.15.00 when downloading the software. Read the description to be sure you are permitted to download the particular software revision based on your location.*

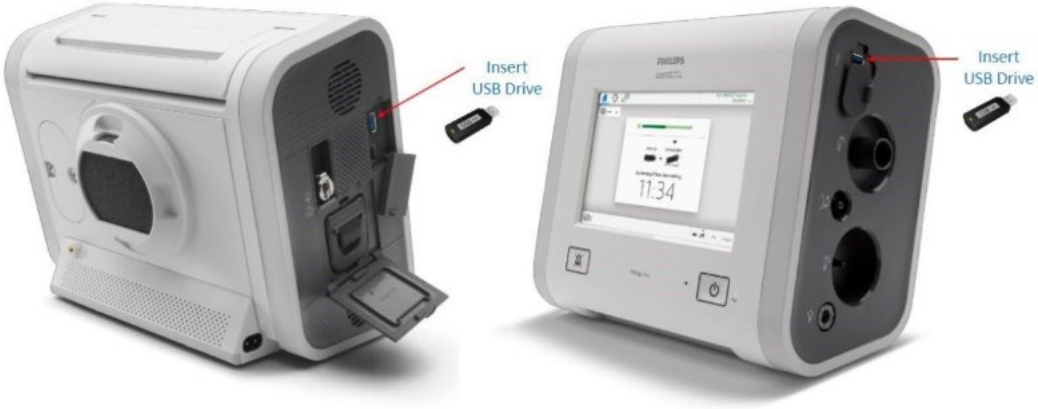
Unzipping the ventilator software file and loading it to a USB flash drive

Note: The USB flash drive must have a memory size of at least 2 GB and cannot contain any other files or folders.

- Locate the .zip file on your computer. Unzip the file, making the .exe file available.
- Connect the USB flash drive to the computer.
- Run the .exe file to self-extract the software update file. Select the USB flash drive location to unzip the file to. WinZip (or similar program) will copy the TrilogyEvo.upg file to the USB flash drive. Acknowledge any prompts and close the extraction program.
- The USB flash drive now contains the software update necessary for your Trilogy Evo Platform ventilator.

Updating the software on your device

1. Connect device to AC power. Press On/Off (Standby) button.
2. Insert the USB-drive in either of the two USB ports of your device.



3. Go to the OPTIONS window (wrench icon) > Data Transfer
4. The device will recognize the USB drive and will show the Software version on the “Install Software Update” box. Click on that box.
5. Confirm that you are upgrading the device to the latest version and click YES
6. Trilogy Evo is now installing the new software. Please wait.
7. A confirmation of Software installation complete will be shown. Press OK and turn the ventilator ON.

To confirm that the software has successfully downloaded, go to the OPTIONS window (wrench icon) and select INFORMATION. Locate the Software Version Number on the screen and confirm that the version is 1.06.15.00.

If you require assistance with any of the steps in this process …

Contact your Philips Representative at: 1-800-722-9377. Please select option 2, and request tech support. Please have at least one serial number for your device(s) available.