

**URGENT Field Safety Notice**

Trilogy Evo, Trilogy Evo O2, Trilogy EV300  
Loss of Power Alarm – Software Correction Update

18-APR-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 is a follow up communication to the Philips *URGENT Field Safety Notice* for the *Trilogy Evo, Trilogy Evo O2, and Trilogy EV300* 2024-CC-SRC-001 sent in March 2024 that could pose a risk for patients or users. This notice is intended to inform you about:

- Release of Software Version 1.06.06.00 to correct the Loss of Power alarm issue
- Trilogy Evo, Evo O2, and EV300 Firmware Upgrade Procedure
- Business Reply Form and actions required by customers

The following is a summary of the information previously communicated in March 2024 that will be corrected by Software Version 1.06.06.00, as well as mitigating steps you should be implementing until this software revision has been successfully downloaded.

Philips Respironics has become aware of a potential safety issue with Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices where the ventilator can issue a Battery Depleted or Loss of Power alarm while sufficient power is still available. This can result in a sudden loss of ventilation while the device alarms. Philips Respironics has received twenty-seven (27) reports of this malfunction and has observed no incidents of patient injury or harm.

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

All Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices are susceptible to this problem.

A software algorithm that calculates remaining battery life can malfunction and cause the device to either:

- A. Issue a Loss of Power alarm that stops CPAP or PSV therapy while operating on battery power alone.

- B. Issue a Battery Depleted alarm while continuing therapy if plugged into a permanent power source, such as AC or DC power.

This can only happen if all of the following conditions are met:

1. The device is operating in CPAP or PSV mode
2. The device is not able to detect the respiratory effort of the patient for at least ten minutes and fifty-five seconds

**Patients most vulnerable to this issue include neonatal and pediatric patients, patients recently removed from anesthesia, or other patients with low inspiratory effort due to their potential for minimally detectable respiratory effort.**

This malfunction is due to a software algorithm calculation error and is not a malfunction of the internal or detachable batteries. An alarm, which can stop therapy, may occur even if there is sufficient battery life remaining.

This malfunction will not happen in ventilation modes other than CPAP and PSV.

## 2. Hazard/harm associated with the issue

A Loss of Power event can cause irreversible harm to the most vulnerable patient populations, including death, if the associated alarm is not observed with the appropriate response. This is because the Loss of Power alarm will cause CPAP or PSV therapy to stop while the high priority alarm alerts the care provider to the issue.

## 3. Affected products and how to identify them

All Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices are susceptible to this problem.



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

Your device(s) may continue to be used safely in CPAP or PSV mode for all users if all safety measures are followed:

- Ensure the Backup Ventilation is set to ON and the apnea interval setting is correct and appropriate based on the clinical assessment of the patient. This will minimize the chances for a CPAP or PSV supported patient to encounter a loss of power malfunction.
- Keep the device plugged into AC or DC power to the greatest extent possible.

- Keep an alternative form of ventilation on standby. If the device must be unplugged for patient transport, plug the device back in as soon as you reach your destination.
- Do not leave a patient unsupervised while operating on battery power alone.
- Follow typical monitoring protocols for ventilated patients such as use of backup monitors, including pulse oximetry or heart rate.

Immediately plug the device into a power source if a Loss of Power alarm occurs. This includes AC power, DC power, or installing a fully charged detachable battery. If none of these power sources are available, then remove the detachable battery and put it back in. Each of these will clear the alarm and restart the ventilator.

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.

Philips has released a software correction for this issue (Software Version 1.06.06.00).

For DME/Homecare users: The software is available via the “My Philips for Professionals” website for customers to upgrade devices. Please refer to **Appendix A** for instructions on how to download the software correction.

For Hospital users: The software is available via InCenter. Please refer to **Appendix B** for instructions on how to download the software correction.

<For markets which require the software update to be delivered in a different manner, such as USB, please update the instructions above and in the Appendices as necessary and remove instructions not applicable to your market.>

## 5. Actions planned by Philips Respironics to correct the problem

Philips Respironics will be following up with customers to ensure devices have been updated to SW version 1.06.06.00.

If you need any further information or support concerning this issue, please contact your local Philips Respironics sales representative.

This notice has been reported to the appropriate Regulatory Agencies.

Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Thomas J. Fallon  
Head of Quality for Sleep and Respiratory Care

**URGENT Field Safety Notice**

**Reference:** Trilogy Evo Battery Failure Alarm  
Trilogy Evo, Trilogy Evo O2, and Trilogy EV300  
2024-CC-SRC-001 Rev B

**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]**

Philips Respironics will follow up with the person who submitted this form with a full list of devices that were sold to the customer and for periodic progress on device software updates.

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.
- A list of all the impacted devices within your installed base for verification will be provided by Philips Respironics once this notice is signed and returned.
- Read this Urgent Field Safety Notice and update the software of all impacted devices in accordance with the software update instructions.

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.

**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

### Firmware Upgrade Procedure for DME/Homecare Users

<For markets which require the software update to be delivered in a different manner, such as USB, please update the instructions as necessary and remove instructions not applicable to your market.>

To download Software 1.06.06.00 for DME/Homecare users, please follow the instructions below.

*Note: MyP4P is not compatible with Internet Explorer. Access MyP4P using Microsoft Edge, Chrome, or Firefox browsers.*

If you have not previously created an account on My Philips for Professionals (MyP4P), you will need to register before downloading software version 1.06.06.00. For any issues regarding the registration process for MyP4P, please contact [respironics.service.operations@philips.com](mailto:respironics.service.operations@philips.com).

#### **For new users:**

To get started with MyP4P, you will need to register. The following instructions will guide you through the process.

Use the following link to register

[Registration | Philips](#)

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.

**This section will outline the steps to download the latest software using a USB stick:**

**A. Download of Software from MyP4P website**

*Note: MyP4P is not compatible with Internet Explorer. Access MyP4P using Microsoft Edge, Chrome, or Firefox browsers.*

1. Log onto <https://www.my.philips.com/> 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 EV300.  
*Note: Filters can also be used to narrow the search by product and/or document type.*
4. Click on the applicable software version update (1.06.06.00). The file will automatically download.  
*Note: the file is in a compressed format (.zip).*

**B. Downloading Trilogy Evo SW to USB**

1. Connect a USB flash drive to the PC. (Minimum memory size should be 2 GB or greater).
2. Save the device Upgrade zip file to a known location.
3. Unzip the file and an .exe file will be available.
4. Run the .exe file to self-extract the software update file.
5. During the self-extraction, select the USB flash drive location to unzip the file to.
6. Winzip will copy the TrilogyEvo.upg file to the USB flash drive. Acknowledge the prompts and close WinZip.
7. The USB flash drive will then contain the software update file necessary to upgrade the device software.

**C. Upgrading the SW on your device**

1. Insert the USB-drive in any of the two USB ports of your device.



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

If any issues are encountered when registering your account or downloading the software, please contact [Respironics.service.operations@philips.com](mailto:Respironics.service.operations@philips.com).

## Appendix B

### Firmware Upgrade Procedure for Hospital Users

<For markets which require the software update to be delivered in a different manner, such as USB, please update the instructions as necessary and remove instructions not applicable to your market.>

To download Software 1.06.06.00 for Hospital users, please access InCenter using the link below  
<https://philips.mizecx.com/login.html>

#### If you do not have an InCenter account:

1. Send an email to [PCCI\\_CS\\_OPS@philips.com](mailto:PCCI_CS_OPS@philips.com) that includes:
  - Subject line: Request for access to InCenter Service P&S and Software Downloads for Respiratory Care-Ventilators.
  - Customer full name Company/institution  
Street address  
City, state, postal/zip code  
Country
  - Telephone number
  - Email address
  - Ventilator serial number (to confirm that the request is from a valid customer).  
*NOTE: The InCenter team processes your request and emails a temporary password to you within 72 hours.*
2. Once you log into InCenter (<https://philips.mizecx.com/login.html>), create a password and access technical content for Hospital Respiratory Care products.

#### A. Downloading ventilator software from InCenter

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

1. Log on to InCenter: (<https://philips.mizecx.com/login.html>)
2. From the product tree section, select: **Hospital Respiratory Care > Ventilation > Trilogy**
3. Select the **Software tab**, and then select **Software Downloads**.
4. Select the appropriate software version approved for use in your country.  
*Note: Please look for Software Version 1.06.06.00 when downloading the software relevant to the Loss of Power Alarm.*

**NOTE:** The USB flash drive cannot contain folders or any other files, only the software file.

5. Save the software file to a USB flash drive.

#### B. Upgrading the software on your device

1. Insert the USB-drive in any of the two USB ports of your device.



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

## Appendix C

### Additional Updates Included in SW Version 1.06.06.00

In addition to the update for the Loss of Power Alarm issue, the following fixes are also addressed in SW version 1.06.06.00. **Please note that these fixes do not impact safety.**

1. Update to HIP/LIP - HEP/LEP technical Alarm threshold to eliminate nuisance alarms.
2. Added high priority Vent Service Required alarm criteria to detect contamination on flow sensor mesh.
3. Additional fixes to address software errors, as well as data corruption and transfer of data with Care Orchestrator (CO) and Care Orchestrator Essence (COE).