

URGENT Field Safety Notice

Trilogy Evo, Trilogy Evo O2, Trilogy EV300
Loss of Power Alarm

26-FEB-2024

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 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 (20) reports of this malfunction and has observed no incidents of patient injury or harm. This URGENT Field Safety Notice is intended to inform you about:

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.

5. Actions planned by Philips Respironics to correct the problem

Philips Respironics is developing a software correction that will remedy this issue. It will be released for download by all device users in the second quarter of 2024. When available, you will receive an additional notification advising how to access and install the software on your devices.

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

customer.support.nordic@philips.com

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

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 **Post_Mkt_Nordic@philips.com**

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: _____

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): _____

Please email this completed and signed form to:

Post_Mkt_Nordic@philips.com