UPDATE URGENT Medical Device Recall Notice

All OmniLab Advanced + (OLA+) devices
Interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm

This document is intended for physicians, health care professionals, distributors and users of these medical devices. This letter 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.

Purpose of this Letter

This letter is an update to the previous Medical Device Recall Notice, *2024-CC-SRC-006-B*, sent in June 2024, regarding interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm condition. Philips Respironics is issuing this updated letter to inform all customers that the risk to patient safety is not increased due to the Ventilator Inoperative Alarm condition, and therefore the use of the OmniLab Advanced + (OLA+) devices can continue.

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

Philips Respironics observed increased complaints related to a Ventilator Inoperative Alarm condition occurring in a software platform shared between A-Series and OLA+ devices. Some complaints, unrelated to OLA+, were associated with unexpected health outcomes. This led Philips Respironics to issue communications for A-Series (2023-CC-SRC-039) and OLA+ (2024-CC-SRC-006) to alert all customers while investigating the complaints related to the Ventilator Inoperative Alarm condition. Since issuing those communications, Philips Respironics' investigation has indicated there have not been any unexpected health outcomes for the intended patient population of OLA+ devices.

The products using this software platform are designed with a Ventilator Inoperative Alarm condition. Specifically, the device software monitors for scenarios which may trigger this alarm condition and is designed to shut down the device if therapy cannot be delivered to the proper specifications. If the device enters a Ventilator Inoperative Alarm condition, a corresponding audible and visual alarm will alert the patient or caregiver.

2. Hazard/harm associated with the issue.

OLA+ devices remain safe for use under the supervision of clinicians where professional intervention can be taken in the event of a Ventilator Inoperative Alarm condition.

Philips Respironics has received ten (10) reports of Ventilator Inoperative alarm occurrences with OLA+ devices. However, there were no reports of serious injury or death and the risk to patient safety is not increased. Therefore, the OLA+ devices can continue to be used in supervised clinical settings.

3. **Products in scope and how to identify them.**
   - All OmniLab Advanced + (OLA+) devices, all of which are designed with a Ventilator Inoperative Alarm condition, are in scope of the Medical Device Recall Notice (UMDRN).

- Refer to labeling on the device (as shown below) and the User Manual.

Figure 1 Device Name Location

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

Actions for Physicians/Healthcare Professionals:

- Review of the OLA+ User Manual is essential to understanding the intended use and performance of the device.
- In the event of a Ventilator Inoperative Alarm condition, follow the steps in **Appendix A:** *Instructions on Performing the Hard Reboot* to restore device function.
- Complete the response form attached if this came directly to you from Philips Respironics.

Actions for Distributors/Respiratory leader/Biomed:

- Distribute this Urgent Medical Device Recall Notice (UMDRN) to the identified customer list (e.g. physicians, clinicians).
- Distributors should have customers complete and return the Customer Response form to your organization for your reconciliation purposes within 30 days.
- Complete and return the response form attached to Philips Respironics following completion of your reconciliation activities.

5. Actions planned by Philips Respironics

Philips Respironics will continue to monitor all reports of device malfunction related to the OLA+ device per the Philips Respironics Post Market Surveillance process.

If you need any further information or support concerning this topic, please contact your local Philips Respironics

representative: 1-800-345-6443, prompts 4, 5 or email at respironics.clinical@philips.com.

This notice has been reported to the appropriate Regulatory Agencies.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

Philips Respironics regrets any inconveniences. We are committed to improving people's health around the world.

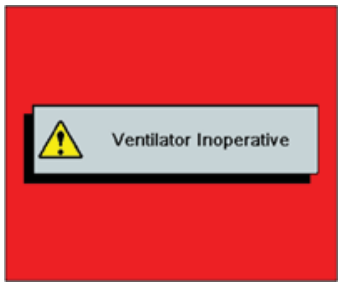
Sincerely,

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

Attachments:
Appendix A: *Instructions on Performing the Hard Reboot*

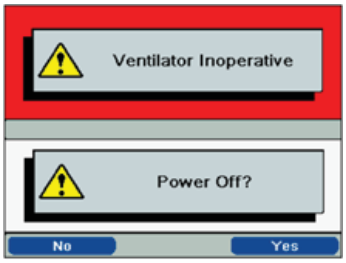
Performing a Hard Reboot

If a Ventilator Inoperative alarm occurs, the display screen turns red and the Ventilator Inoperative message appears on-screen, as shown below.



To perform the hard reboot, please follow the instructions below:

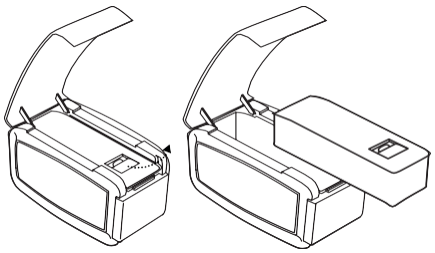
1. **Disconnect from the device.**
2. **Power off the therapy device.**
   - Press the Start/Stop button (⏻).
   - If the ventilator display is operational, the "Power Off" confirmation screen will appear, as shown below.



   - Select the button on the right side, "Yes" to shut off the device and silence the alarm.
3. **Unplug the power cord from the wall or from the device itself.**
4. **If the device does not have a detachable battery pack or an external battery pack, skip Step 5. If the device does have a detachable battery pack or an external battery pack, continue to Step 5.**
5. **Remove the battery from the therapy device.**

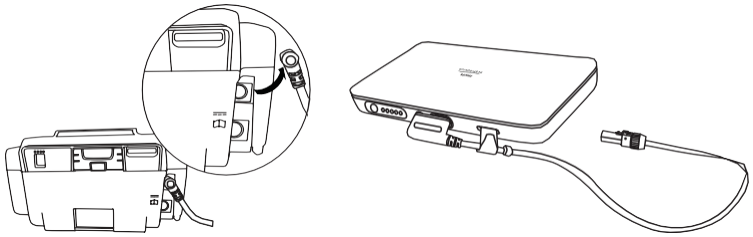
Detachable Battery Pack

- If the detachable battery pack is used, open the battery compartment at top of the detachable battery module accessory.
- Lift battery out using release lever on top of the battery (see below).

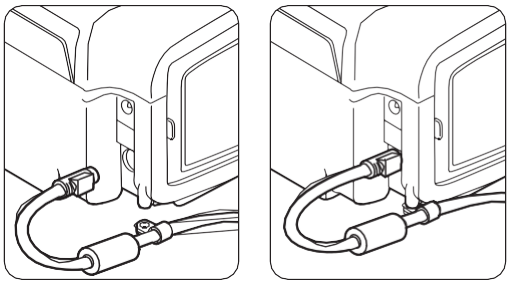


Li Ion Battery Pack

- If an external battery pack is used, unplug the battery pack cord from the back of the ventilator (see below).



6. **Disconnect the device from the power source (battery and/or power cord) for at least 30 seconds.**
7. **After 30 seconds, reconnect the device to the applicable power source (battery and/or power cord).**
8. **Plug the power cord in to the wall or to the therapy device itself.**



9. **Power on the device by pressing the Start/Stop button (⏻).**
10. **Once the ventilator powers back on, therapy may be restarted.**