URGENT Medical Device Recall

All OmniLab Advanced + (OLA+) devices
Interruptions and/or loss of therapy due to a Ventilation 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.

Purpose of this Letter

The purpose of this letter is to advise you that Philips Respironics is voluntarily recalling, Philips Respironics OmniLab Advanced + (OLA+) devices after receiving eight (8) complaints regarding interruptions and/or loss of therapy. Philips is recommending that physicians/healthcare professionals review this notification and assess whether the patients under their care are able to tolerate interruptions of therapy with this device to ensure that they continue to receive the most appropriate therapy.

There have been no reports of serious injury or death, to date. It is important to note that the OmniLab Advanced + is not a life support device. OmniLab Advanced + does not need to be removed from service as a result of this letter.

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

When the ventilator detects an internal error or a condition that may affect therapy, the device will shut down if the cause of the failure indicates that the device cannot deliver therapy.

This may manifest in the following two ways:

- When there are three (3) reboots (restarts) within a 24-hour period, (stops providing therapy, screen goes blank during the reboot, and there is a single audible alert), the device will enter a Ventilator Inoperative state (therapy stopped, audible and visual alarms present).

OR

- The device may enter a Ventilator Inoperative state without a reboot (restart) preceding this condition.

2. Hazard/harm associated with the issue.

If the device enters the ventilator inoperative state, interruption and/or loss of therapy may occur. This may lead to anxiety, confusion/disorientation, increased/decreased respiratory rate (RR), dyspnea, tachycardia (high heart rate), abnormal chest wall movement, mild to severe hypoxemia/low oxygen saturation, hypercarbia/respiratory acidosis, hypoventilation, respiratory failure, or potentially death in the most vulnerable patients. Symptoms can include nausea and vomiting, tiredness (fatigue) or lethargy, shortness of breath, increased work of breathing, dizziness, slow, shallow or labored breathing, bluish skin, lips or nails (cyanosis), coughing, wheezing, headaches, and paranoia.

3. **Affected products and how to identify them.**
   - All OmniLab Advanced + (OLA+) devices are affected.
   - Refer to labeling on the device (as shown below) and the Instructions for Use or User Manual.

Figure 1: Device Name Location

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

As indicated in the IFU for affected devices (**Appendix A:** *Contraindications and Warnings*), the affected devices are not indicated to be used as life support devices.

Actions for Physicians/Healthcare Professionals:

- Refer to **Appendix B:** *Guidance for physicians/healthcare professionals related to Urgent Medical Device Recall Notice 2024-CC-SRC-006-B*
- Complete the response form attached if this came directly to you from Philips Respironics.
- **Follow these Steps if Ventilator Inoperative Alarm Occurs:**

  For facility-based clinicians, if a Ventilator Inoperative Alarm occurs, immediately remove the patient from the device and connect them to an alternate source of ventilation.

- As an optional step/action, you may attempt to perform a "hard reboot" (forced device restart) that may temporarily restore device function. The details and instructions for performing this hard reboot are contained in **Appendix C:** *Instructions on Performing the Hard Reboot.*

Actions for Distributors/Respiratory leader/Biomed/Sleep Labs: Complete and return the response form attached.

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

Philips Respironics is currently investigating this issue and will implement appropriate actions to prevent recurrence.

If you need any further information or support concerning this issue, please contact your local Philips Respironics representative: 1-800-345-6443, prompts 4, 5 or email at respironics.clinical@philips.com

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

Sincerely,

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

Attachments:
Appendix A: *Contraindications and Warnings*
Appendix B: *Guidance for physicians/healthcare professionals related to Urgent Medical Device Recall Notice 2024-CC-SRC-006-B*
Appendix C: *Instructions on Performing the Hard Reboot*

Appendix A: *Contraindications and Warnings*

1.4 Contraindications

The OmniLab Advanced + is not a life support device.

The device system should not be used on patients with the following conditions:

- Patients without a spontaneous respiratory drive
- Existing respiratory failure (failure to treat; risk of increased work of breathing due either to incomplete reversal of upper airway obstruction or to breathing at high lung volume, leading to worsening respiratory failure)
- Pneumothorax or pneumomediastinum
- Emphysematous bullae or a past history of pneumothorax (risk of pneumothorax)
- Acute decompensated cardiac failure or hypotension, particularly if associated with intravascular volume depletion (risk of further hypotension or reduction in cardiac output)
- Massive epistaxis or previous history of massive epistaxis (risk of recurrence)
- Pneumocephalus, recent trauma or surgery (ex. pituitary or nasal) that may have produced cranio-nasopharyngeal fistula (risk of entry of air or other material into the cranial cavity)
- Acute sinusitis, otitis media, or perforated ear drum
- Acute or unstable cardiac failure
- Nocturnal or resting angina (risk of infarction or arrhythmias)
- Unstable arrhythmias
- Severely obtunded or heavily sedated patients
- At risk for aspiration of gastric contents
- Impaired ability to clear secretions

If patients are dehydrated or volume depleted, or have persistent atrial fibrillation, their cardiac filling pressures may be low. In these cases, as with any CPAP or ventilatory support, use of the device may lead to a dangerous reduction in cardiac output. The device should not be used in patients who are dehydrated, or volume depleted and should be used with extreme care in patients with atrial fibrillation.

Warning
Physicians should assess individual patient risks before prescribing autoSV therapy for patients with chronic, symptomatic heart failure (NYHA II-IV) with left ventricular ejection fraction below 45% and moderate to severe predominant central sleep apnea.
The physician should assess the relative risks and benefits of autoSV therapy on a case-by-case basis in patients with severe heart conditions including unstable angina or unstable arrhythmias.

Appendix B

Guidance for physicians/health care professionals related to Urgent Medical Device Recall Notice 2024-CC-SRC-006-B

Dear Physician/Healthcare Professional,

Philips recently sent an Urgent Medical Device Recall Notice, entitled "*All OmniLab Advanced + (OLA+) devices Interruptions and/or loss of therapy due to a Ventilation Inoperative Alarm*" to DME (Durable Medical Equipment) suppliers and medical institutions that have patients who are using these devices. A copy of this Urgent Medical Device Recall Notice is included with this letter.

To support physicians/healthcare professionals who manage patients using ventilatory devices in the home setting, Philips is providing additional guidance regarding the continued use of these devices.

Philips is recommending that physicians/healthcare professionals assess whether the patients under their care are able to tolerate interruptions of therapy to help ensure that they continue to receive the most appropriate therapy.

For Patients Who **Can** Tolerate Interruptions of Therapy:

If interruptions of therapy can be tolerated and the ventilator inoperative (vent inop) alarm occurs, the patient/lay caregiver will have instructions to remove the patient from the device and to place them on an alternative device.

- If they do not have an alternative device, they can contact their equipment provider or DME for assistance with obtaining an alternative device.

For Patients Who **Cannot** Tolerate Interruptions of Therapy:

If interruptions of therapy cannot be tolerated, **please consider writing a prescription for a ventilator that is indicated for life supporting ventilation**. OmniLab Advanced + (OLA+) devices are not suitable for a ventilator-dependent patient (i.e., patients who are dependent on artificial ventilation for their immediate life support).

If interruptions of therapy cannot be tolerated, the patients and lay caregivers are instructed to provide alternate ventilation AND contact the Equipment Supplier/DME for immediate device alternative.

Optional Step: Patients (or lay caregivers) may perform a "hard reboot" after a vent inop occurs:

The hard reboot **may** temporarily restore therapy to the patient which could allow them to continue to use the device while waiting for an alternative device from their DME or equipment supplier.

***Please refer to **Appendix C** (attached) for Instructions on Performing the Hard Reboot. ***

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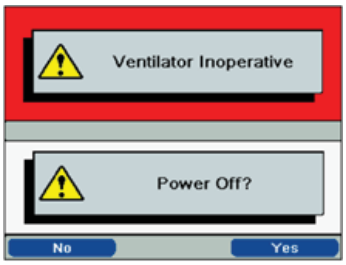
Performing a Hard Reboot

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

Warning: Immediately remove the patient from the ventilator and if required, connect them to an alternate source of ventilation. Contact your home care equipment provider for service.

Meanwhile, as an option you may follow these steps to try to temporarily restore ventilatory function while waiting for a replacement device and/or professional medical intervention.

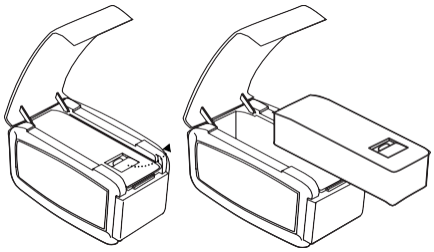
1. **Power off the therapy device.**
   - Press the Start/Stop button (⏻).
   - If the ventilator display is operational, the "Power Off" confirmation screen will appear, as shown below.



   - Select the button on the right side, "Yes" to shut off the device and silence the alarm.
2. **Unplug the power cord from the wall or from the device itself.**
3. **Remove the battery from the therapy device.**

Detachable Battery Pack

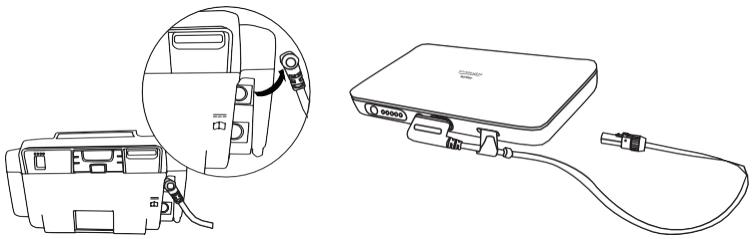
- If the detachable battery pack is used, open the battery compartment at top of the detachable battery module accessory.
- Lift battery out using release lever on top of the battery (see below).



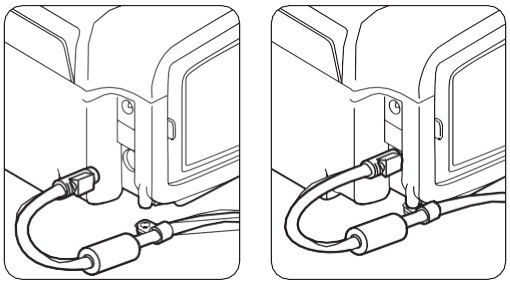
Respironics Inc.
1001 Murry Ridge Lane Murrysville,
PA 15668 USA

Li Ion Battery Pack

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



4. **Leave the battery disconnected from the ventilator for at least 30 seconds.**
5. **Reconnect the applicable battery in use.**
6. **Plug the power cord in to the wall or to the therapy device itself.**



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