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Field Safety Notice

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

<DD-MMM-YYYY>,

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code>

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 received complaints regarding interruptions and/or loss of therapy in the Philips Respironics OmniLab Advanced + (OLA+) devices. This URGENT Field Safety Notice is intended to inform you about:

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

The OmniLab Advanced + (OLA+) devices feature a Ventilator Inoperative alarm, which occurs when the ventilator detects an internal error or a condition that may affect therapy. This may manifest in the following ways:

- The device may reboot intermittently for 5-10 seconds (stops providing therapy, screen goes blank during the reboot, and there is a single audible alert), restarting therapy, and returning to delivering therapy with same patient settings.

OR

- The device may reboot intermittently for 5-10 seconds (stops providing therapy, screen goes blank during the reboot, and there is a single audible alert), restarting therapy, and returning to delivering therapy but with factory default settings.

OR

- When there are three (3) reboots within a 24-hour period, 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 preceding this condition.

2. Hazard/harm associated with the issue

Any of the above scenarios could result in interruption and/or loss of therapy which may lead to hypoventilation, mild to severe hypoxemia, hypercarbia, respiratory failure/insufficiency, or potentially death in the most vulnerable patients.

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3. Affected products and how to identify them

- All OmniLab Advanced + (OLA+) devices are affected.
- Refer to labeling on the device (as shown below).

- Refer to the device's Instructions for Use or User Manual.
- Contact the provider of your device and/or your supervising physician.

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

As a general reminder, prior to placing a patient on the ventilator, please refer to the user manual (including contraindications, see **Appendix A**) and perform a clinical assessment to ensure that:

- The device is appropriately set for patient requirements;
- Alternative ventilation equipment is available; and
- Where appropriate, alternative monitoring (i.e. an alarming Pulse Oximeter or Respiratory Monitor) is used.

Patients Requiring a Minimal Level of Ventilatory Support

- For patients whose health conditions can withstand interruptions or loss of therapy, **consider using**:
    - Patient monitoring equipment (i.e. an alarming Pulse Oximeter or Respiratory Monitor).
    - An alternate source of ventilation if you are concerned about adverse impact on their health.
- Contact Philips Respironics for assistance regarding the affected device.

Patients Requiring a Moderate Level of Ventilatory Support

- For patients whose health conditions may not be able to withstand interruptions or loss of therapy, **it is recommended that**:
    - Patient monitoring equipment is used (i.e. an alarming Pulse Oximeter or Respiratory Monitor).
    - The patient is removed from the device and placed on an alternate source of ventilation.
- Contact Philips Respironics for assistance regarding the affected device.

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Patients Requiring a High Level of Ventilatory Support

- For patients whose health conditions cannot withstand interruptions or loss of therapy, **it is strongly recommended that**:
    - Patient monitoring equipment is used (i.e. an alarming Pulse Oximeter or Respiratory Monitor) until the patient can be safely removed from the device.
    - A caregiver should closely monitor the patient.
    - The patient is removed from the device and placed on an alternate source of ventilation as soon as possible.
- Contact Philips Respironics for assistance regarding the affected device.

5. Actions planned by Philips Respironics to correct the problem

Philips Respironics is currently investigating this issue. Philips Respironics will be in contact as soon as additional appropriate actions have been determined.

As OmniLab Advanced + (OLA+) devices are included in the Sound Abatement Foam Field Action, the existing actions determined within the Sound Abatement Foam Remediation Update are applicable, they are as follows:

- Continue to wait for additional remediation options to become available.

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

Philips Respironics regrets any inconveniences caused by this problem. Please be assured that Philips Respironics has patient health and safety at the heart of what we do each and every day. We are committed to improving people's health around the world.

Sincerely,

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

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code>

Reference: 2024-CC-SRC-006

Instructions: Please complete and return this form to Philips Respironics promptly i.e., no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer Actions:

- Read and Acknowledge the Urgent Field Safety Notice
- Complete the form and return it to Philips Respironics

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all people that handle/use the affected device.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

<MARKET/Business to provide as appropriate - 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>

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Appendix A. Excerpt from OmniLab Advanced + (OLA+) User Manual "Contraindications"

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.