

URGENT Field Safety Notice

All BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro devices
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 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.

Philips Respironics has received 888 complaints regarding interruptions and/or loss of therapy in the Philips Respironics BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro 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 affected products feature a Ventilator Inoperative alarm, which occurs 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.

The above scenarios could result in interruption and/or loss of therapy which 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 to look for that would represent the above scenario 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.

Philips Respironics has received 888 reports of vent inop alarm occurrences. Ten (10) reports included an allegation of serious injury, and seven (7) cases reported a patient death associated to this issue out of approximately 100 million potential uses. <Local Market to add if necessary: This represents an incidence rate of less than 0.00088%.>

3. Affected products and how to identify them.

- All BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro devices are affected.
- Refer to labeling on the device (as shown below).



Figure 1 Device Name Location

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

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 FSN 2023-CC-SRC-039-B**
- Complete the response form attached if this came directly to you from Philips Respironics.

Actions for Patients and Users:

- **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.

For home-based patients, if a Ventilator Inoperative Alarm occurs, immediately remove the device and connect to an alternative device, if available. Contact your home care equipment provider for service and/or an alternative device.

- 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 D**, *Instructions on Performing the Hard Reboot*.
- Refer to **Appendix C**: *Guidance for Patients and Users related to FSN 2023-CC-SRC-039-B*

Actions for Distributors:

- Identify customer list and where appropriate, please distribute this Field Safety Notification and all relevant appendices to physicians, clinicians, patients and/or users.
- 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: *<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

Attachments:

Appendix A: *Contraindications and Warnings*

Appendix B: *Guidance for physicians/healthcare professionals related to FSN 2023-CC-SRC-039-B*

Appendix C: *Guidance for Patients and Users related to FSN 2023-CC-SRC-039-B*

Appendix D: *Instructions on Performing the Hard Reboot*

URGENT FIELD SAFETY NOTICE RESPONSE FORM

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

Reference: 2023-CC-SRC-039-B

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">

Appendix A: Contraindications and Warnings

BiPAP A40:

1.4 Contraindications

The BiPAP A40 ventilator is not a life support device.

AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg (22 lbs.).

If the patient has any of the following conditions, consult their health care professional before using the device in a non-invasive mode:

- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Diagnosed with acute sinusitis or otitis media
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

A30 EFL, BiPAP A40 Pro and BiPAP A40 EFL:

1.3 Contraindications

The BiPAP A40 Pro and BiPAP A40 EFL devices are not life support devices.

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

- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Diagnosed with acute sinusitis or otitis media
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

If the patient has any of the above conditions, consult their health care professional before using the device in a non-invasive mode.

(BiPAP A40 Pro) AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg (22 lbs.).

A30:

1.4 Contraindications

This ventilator is not suitable for a ventilator-dependent patient (i.e., patients who are dependent on artificial ventilation for their immediate life support).

If the patient has any of the following conditions, consult their health care professional before using the device:

- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Diagnosed with acute sinusitis or otitis media
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

Hybrid A30:

1.4 Contraindications

The BiPAP Hybrid A30 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.

Appendix B: Guidance for physicians/health care professionals related to FSN 2023-CC-SRC-039-B

Dear Physician/Healthcare Professional,

Philips recently sent a Field Safety Notice, entitled “*BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro 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 Field Safety 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**. As indicated in IFU, A30/A40 ventilators 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:

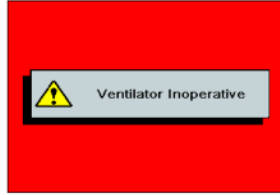
The hard reboot **may** temporarily restore therapy to the patient which could allow them to continue to use the device while waiting for an alternative device from their DME or equipment supplier.

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

Appendix C: Guidance for patients/users related to FSN 2023-CC-SRC-039-B

Background:

The ventilator has an alarm called “Ventilator Inoperative”. If it occurs, ventilation will stop and a constant beeping alarm will sound. The alarm silence button will flash red, and a message will appear on the device screen displaying “Ventilator Inoperative” like shown below.



Please share and discuss the attached physician letter (Appendix B) and the FSN (Field Safety Notice) with your physician/health care professional for their awareness and to allow them to make relevant recommendations for your treatment.

What to do if the Ventilator Inoperative Alarm Happens:

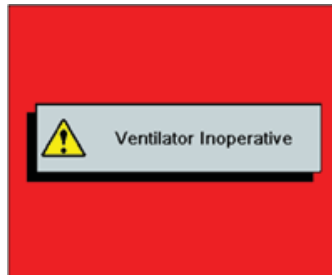
If this ventilator inoperative alarm occurs, immediately remove the ventilator and if required, connect to an alternate source of ventilation. Contact your home care equipment provider or DME (Durable Medical Equipment) for service and assistance.

Optional Step:

You (or someone taking care of you) can perform a “hard reboot” (or restart) on your ventilator which may allow for temporary usage of the device until you can be placed on an alternative ventilator.

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


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

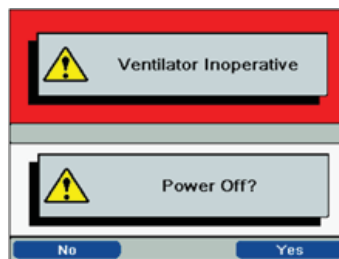


Warning: Immediately remove the patient from the ventilator and if required, connect them to an alternate source of ventilation. Contact your home care equipment provider for service.

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.



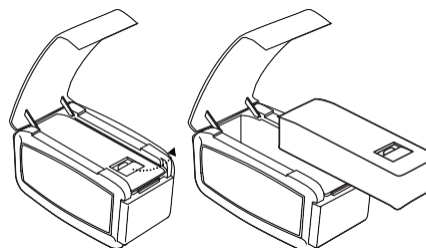
- Select the button on the right side, “Yes” to shut off the device and silence the alarm.

2. Unplug the power cord from the wall or from the device itself.

3. Remove the battery from the therapy device.

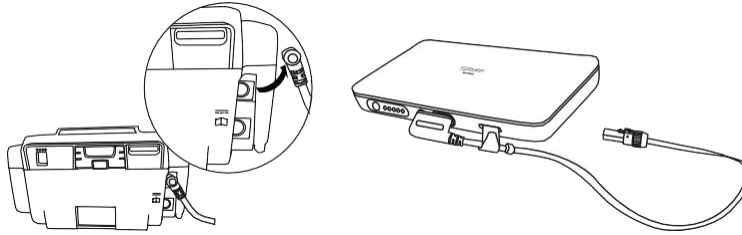
Detachable Battery Pack

- 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).

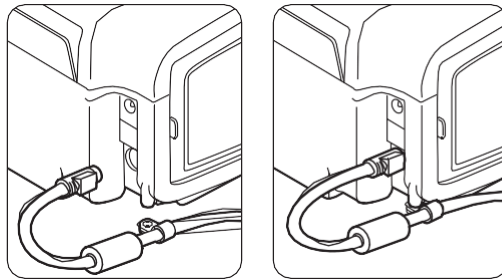


Li Ion Battery Pack

- 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.