PHILIPS

URGENT Medical Device Recall Notice

All BiPAP A30 and BiPAP A40 devices

Interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm

Updated Information for Device Distributors and Healthcare Providers

Philips Respironics previously distributed Urgent Medical Device Recall Notice (UMDRN) *2023-CC-SRC-039-C* in October 2024 to all users of BiPAP A30 and BiPAP A40 devices, which provided an update for Urgent Medical Device Recall Notice 2023-CC-SRC-039 regarding interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm condition. Based on feedback from global regulators, Philips Respironics is issuing this letter as an additional update to that UMDRN.

The purpose of this updated notice is to clarify the patient population who **cannot tolerate** interruptions or loss of therapy. For patients who **cannot tolerate** interruption or loss of therapy an alternative ventilator is required. This determination should be made under the guidance of a physician.

For users who **can tolerate** therapy interruptions, as previously communicated, the device can continue to be used, or an alternate device will be made available at the customer's discretion.

For further information on the options listed above, please see **Section 5:** *Actions planned by Philips Respironics*.

It is important to note that BiPAP A30 and BiPAP A40 devices are not intended for life support and are not intended to ventilate patients suffering from respiratory failure.

Please review this letter in its entirety, as some information may be new or updated from what was previously communicated.

PHILIPS

URGENT MEDICAL DEVICE RECALL NOTICE

All BiPAP A30 and BiPAP A40 devices

Interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm

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.

Purpose of this Letter

The purpose of this letter is to provide customers and healthcare providers with critical information pertaining to use of the products, in accordance with the intended use, to prevent risk to the patient. In addition, this letter provides updated actions that Philips Respironics will be taking to address the Ventilator Inoperative alarm issue.

Philips Respironics advises 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. It is important to note that these devices are not life support devices and do 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

The products in scope are designed with a Ventilator Inoperative condition, which occurs when the ventilator detects an unrecoverable condition that may affect therapy. If the device enters a Ventilator Inoperative condition, a corresponding audible and visual alarm will alert the patient or caregiver. The device is designed to shut down if the condition indicates that the device cannot deliver therapy to the proper specifications; the device monitors for scenarios which may trigger a Ventilator Inoperative condition. Despite having a very low probability of occurrence, interruptions and/or loss of therapy due to a Ventilator Inoperative condition have been reported to result in serious health outcomes that were not expected for the intended patient population. Twelve (12) reports included an allegation of serious injury, and eight (8) cases reported a patient death associated with this issue.

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.

As of January 2025, Philips Respironics has received 1,518 in-use complaints related to Ventilator Inoperative alarm occurrences.

PHILIPS

3. Products in scope and how to identify them

- All BiPAP A30 and BiPAP A40 Devices, all of which are designed with a Ventilator Inoperative condition, are in scope of this UMDRN.
- Refer to labeling on the device (as shown below) and the Instructions for Use or User Manual.

Figure 1 Device Name Location

- 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

The following actions are advised to ensure that the device is prescribed and used in accordance with the intended use for which the device was designed.

Actions for All Recipients:

- Review the intended use for devices in scope of this issue. These devices are not intended to ventilate patients suffering from respiratory failure. Please note the clarifications to the intended use for BiPAP A40 Devices as detailed in **Appendix A1:** *Intended use for BiPAP A40 devices only*.

- Please note that all device models in scope of this issue are not indicated to be used as life support devices (**Appendix A2:** *Contraindications and Warnings*).

Actions for Physicians/Healthcare Professionals:

- Philips Respironics is recommending that physicians/healthcare professionals assess whether the patients under their care, who are using the devices in scope, 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 in therapy, Philips Respironics recommends the following two options:

    - **Option 1:** The device can continue to be used.

        - If a Ventilator Inoperative alarm occurs, the hard reboot option can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, please see **Appendix A3:** *Instructions on Performing the Hard Reboot.*

OR

- **Option 2:** The device distributor may be contacted for the alternative device options being presented by Philips Respironics as outlined in **Section 5**: *Actions planned by Philips Respironics*.

- As indicated in the user manuals for the following devices: BiPAP A30 and BiPAP A40, these devices are not suitable for ventilator-dependent patients (i.e., patients who are dependent on artificial ventilation for their immediate life support). If interruptions of therapy **cannot** be tolerated:
  - **Transition patient to an alternative ventilator as soon as practicable.**
  - If a Ventilator Inoperative alarm occurs and an alternative ventilator is not available immediately, as a temporary measure, a hard reboot can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, please see **Appendix A3:** *Instructions on Performing the Hard Reboot.*
- Complete the response form attached if this came directly to you from Philips Respironics.

Actions for Patients and Users:

- If your physician has indicated you are a patient that **can tolerate** interruptions in therapy, please see the following options:
  - **Option 1:** The device can continue to be used.
    - If a Ventilator Inoperative alarm occurs, the hard reboot option can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, please see **Appendix A3:** *Instructions on Performing the Hard Reboot*.

OR

  - **Option 2:** Contact your device distributor for the alternative device options being presented by Philips Respironics as outlined in **Section 5:** *Actions planned by Philips Respironics*.

- If your physician has indicated you are a patient that **cannot tolerate** interruptions in therapy, please see the following:
  - Contact your physician to expedite transition to an alternative ventilator.
  - If a Ventilator Inoperative alarm occurs and an alternative ventilator **is not available immediately**, as a temporary measure, a hard reboot can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, please see **Appendix A3:** *Instructions on Performing the Hard Reboot*.

Actions for Distributors:

- Distribute this Urgent Medical Device Recall Notice (UMDRN) and all appendices to the

identified customer list (e.g. physicians, clinicians, and patient/users).

- See **Section 5**: *Actions planned by Philips Respironics* to contact Philips Respironics regarding your options.

- 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**

1. Philips Respironics is clarifying the labeled intended use of the BiPAP A40 by removing "Respiratory Failure." These devices are not intended to ventilate patients suffering from respiratory failure. This clarification is intended to prevent potential misinterpretation as the product is not designed or intended for life support applications**.** For further information on the clarified intended use, please see **Appendix A1:** *Intended use for BiPAP A40 devices only***.**

2. Based on patient conditions, Philips Respironics will present the following options to customers:

- **<u>Options for Patients Who Can Tolerate Interruptions in Therapy</u>**
  - **Continued Use:** For patients whose health conditions can withstand interruptions or loss of therapy, the device can continue to be used.
    - If a Ventilator Inoperative alarm occurs, the hard reboot option can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, **see Appendix A3**: *Instructions on Performing the Hard Reboot*.

OR

  - **Alternate Device:** Independent of a Ventilator Inoperative alarm, at the discretion of the patient, caregiver or physician, the customer will be provided with an alternative therapy device (DreamStation BiPAP S/T or DreamStation BiPAP AVAPS depending on availability – **please see the Intended Use below**) and then the device must be returned to Philips Respironics to minimize disruption in therapy.

    - **DreamStation BiPAP S/T Intended Use:**
      The BiPAP S/T device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home.
    - **DreamStation BiPAP AVAPS Intended Use:**
      The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home.

- **<u>Options for Patients Who Cannot Tolerate Interruptions in Therapy</u>**
  - **Financial Compensation:** For patients whose health conditions cannot withstand interruptions or loss of therapy, to offset the cost of alternative and appropriate therapy, the customer will be issued credit based on the depreciated value of the device.

- If a Ventilator Inoperative alarm occurs and an alternative life support ventilator **is not available** immediately, as a temporary measure, a hard reboot can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, **see Appendix A3:** *Instructions on Performing the Hard Reboot.*

Next Steps: The customer should contact Philips Respironics regarding an alternate device or financial compensation at the following: Respironics.repair@philips.com or 1800-345-6443 (Option 2).

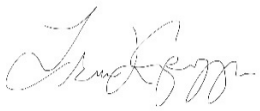
If you need any further information or support concerning this issue, please contact your local Philips Respironics representative: 1-800-345-6443, prompts 4, 5 or email at respironics.clinical@philips.com.

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 caused by this problem. 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 A1: *Intended use for BiPAP A40 devices only*
Appendix A2: *Contraindications and Warnings*
Appendix A3: *Instructions on Performing the Hard Reboot*

PHILIPS

Appendix A1: *Intended use for BiPAP A40 devices only*

Applicable to BiPAP A40:
Please note the Intended Use for the BiPAP A40 devices is being clarified by removing "Respiratory Failure." The device was not designed and is not intended for use as a life support ventilator, and it is acknowledged that "Respiratory Failure" could be misinterpreted as conflicting with this guidance. These devices are not intended to ventilate patients suffering from respiratory failure. Please review the clarified Intended Use below.

Updated BiPAP A40 Intended Use:
The BiPAP A40 ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. It is intended to be used in home, institutional/hospital, and portable applications such as wheelchairs and gurneys. It is not intended to be used as a transport ventilator, and is not intended for life support.

Not Applicable to BiPAP A30:
The change outlined above is not applicable to the BiPAP A30 as this device's intended use does not include "Respiratory Failure". However, the same instructions in this UMDRN are applicable to this model and the same options are available.

PHILIPS

Appendix A2: *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

BiPAP 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).

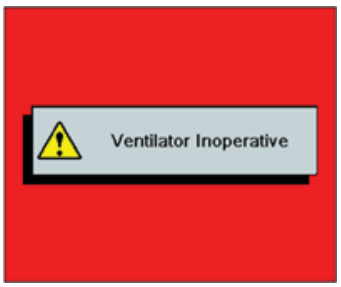
If the patient has any of the following conditions, consult their health care professional before using the device:
- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Diagnosed with acute sinusitis or otitis media
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

PHILIPS

Appendix A3: *Instructions on Performing the Hard Reboot*

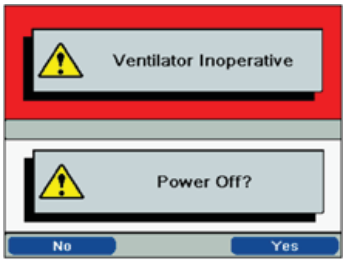
Performing a Hard Reboot

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:

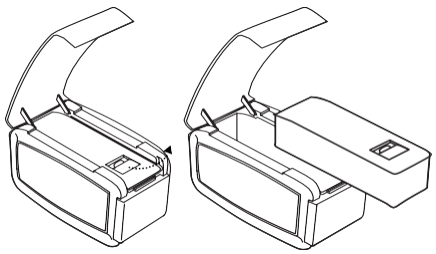
1. **Disconnect from the device.**
2. **Power off the therapy device.**
   - Press the Start/Stop button (⏻).
   - If the ventilator display is operational, the "Power Off" confirmation screen will appear, as shown below.



   - 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.**

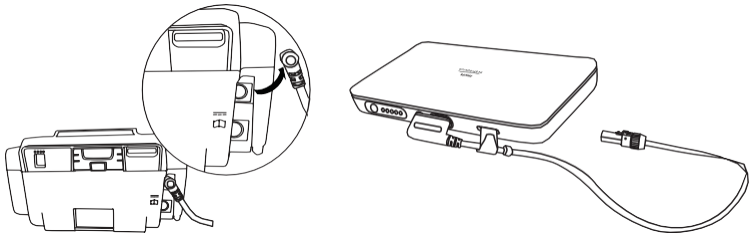
Detachable Battery Pack

- 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).

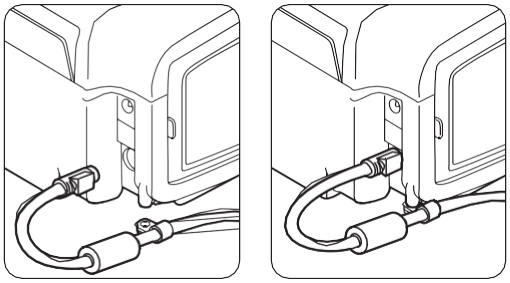


Li Ion Battery Pack

- 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.**