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 Ventilator Inoperative Alarm

Updated Information for Device Distributors and Healthcare Providers

<DD-MMM-YYYY>

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

This letter is an update to the previous Field Safety Notice, *2023-CC-SRC-039-B*, sent in <May or June, depends on Market> 2024, regarding interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm condition resulting in higher severity outcomes than predicted despite a very low probability of occurrence. The Ventilator Inoperative alarm is a design element present in the following devices: BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, and BiPAP A40 Pro. This letter is to inform users of the updated actions that Philips Respironics will be taking to address this issue.

Active Devices on the Market: Philips Respironics is proceeding with a plan for impacted products on the market to enable continued use where applicable. To provide users with appropriate therapy options, the following actions will be taken by Philips Respironics as listed below. Please note, this information can also be found in **Section 5:** *Actions planned by Philips Respironics*:

1. Philips Respironics is clarifying the labeled intended use of the BiPAP A40 and BiPAP A40 Pro by removing "Respiratory Failure." This clarification is intended to prevent potential misinterpretation as the product is not designed or intended for life support applications**. Please see the clarified intended use for the BiPAP A40 and BiPAP A40 Pro 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.

   Updated BiPAP A40 Pro Intended Use:

   - The BiPAP A40 Pro 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. This device is not intended for life support. It is not intended to be used as a transport ventilator. It is intended to be used both in the home and clinical settings such as hospitals, sleep laboratories, sub-acute care institutions, and portable applications such as wheelchairs and gurneys.

The clarification of the intended use for the BiPAP A40 and BiPAP A40 Pro devices can also be found in **Appendix A1:** *Intended use for BiPAP A40 BiPAP A40 Pro devices only***.**

- **Note:** This clarification is not applicable to the BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, and BiPAP A40 EFL as their intended use does not include Respiratory Failure. However, the same instructions in this FSN are applicable to these models and the same options are available.
- **Note:** Philips Respironics is not pursuing design changes relevant to these products for this issue.

2. Based on patient conditions, Philips Respironics will offer the following options to users:
   - For users who **can tolerate** therapy interruptions, the device can continue to be used or an alternate device will be made available at the user's discretion.
   - For users who **cannot tolerate** interruptions or loss of therapy, alternate therapy is required, and financial compensation for customers will be made available.

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

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

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 Ventilator 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.

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. Philips Respironics has received 1,351 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. 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 health outcomes that were not expected for the intended patient population.

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.

Philips Respironics has received 1,351 reports of Vent Inoperative alarm occurrences. Twelve (12) reports included an allegation of serious injury, and eight (8) cases reported a patient death associated with this issue out of approximately 100 million potential uses. <Local Market to add if necessary: This represents an incidence rate of less than 0.001192%.>

3. Products in scope and how to identify them

- All BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro Devices, all of which are designed with a Ventilator Inoperative condition, are in scope of this FSN.
- 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. Please note the clarifications to the intended use for BiPAP A40 and BiPAP A40 Pro Devices as detailed in **Appendix A1:** *Intended use for BiPAP A40 and BiPAP A40 Pro 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:

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

- Complete the response form attached if this came directly to you from Philips Respironics.

Actions for Patients and Users:

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

Actions for Distributors:

- Distribute this Field Safety Notification and all appendices to the identified customer list (e.g. physicians, clinicians, and patient/users).

- Contact Philips Respironics for alternate device options and/or financial compensation. For further information, **please see Section 5**: *Actions planned by Philips Respironics*.

- 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 and BiPAP A40 Pro by removing "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 BiPAP A40 Pro devices only***.**

2. Based on patient conditions, Philips Respironics will offer the following options to users:

   - **Options for Patients Who Can Tolerate Interruptions in Therapy**
     - **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 D**: *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 A-series device should 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.

- **Options for Patients Who Cannot Tolerate Interruptions in Therapy**
    - **Financial Compensation:** For patients whose health conditions cannot withstand interruptions or loss of therapy, the device should be returned to Philips Respironics and, 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 appropriate 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 D:** *Instructions on Performing the Hard Reboot.*

Next Steps: Please submit a request regarding an alternate device or financial compensation at the following: <Local Market to include the appropriate URL or email using the Global Customer Support Matrix>.

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>

This notice has been reported to the appropriate Regulatory Agencies.

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 A1: *Intended use for BiPAP A40 and BiPAP A40 Pro devices only*
Appendix A2: *Contraindications and Warnings*
Appendix B: *Guidance for physicians/healthcare professionals related to FSN 2023-CC-SRC-039-C*
Appendix C: *Guidance for Patients and Users related to FSN 2023-CC-SRC-039-C*
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-C

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
- Review and understand the new options Philips Respironics is offering. For further information, **please see Section 5**: *Actions planned by 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 devices in scope.

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 A1: *Intended use for BiPAP A40 and BiPAP A40 Pro devices only*

Applicable to BiPAP A40 and BiPAP A40 Pro:
Please note the Intended Use for the BiPAP A40 and BiPAP A40 Pro 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. 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.

Updated BiPAP A40 Pro Intended Use:
The BiPAP A40 Pro 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. This device is not intended for life support. It is not intended to be used as a transport ventilator. It is intended to be used both in the home and clinical settings such as hospitals, sleep laboratories, sub-acute care institutions, and portable applications such as wheelchairs and gurneys.

Not Applicable to BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, and BiPAP A40 EFL:
The change outlined above is not applicable to the BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, and BiPAP A40 EFL as their intended use does not include "Respiratory Failure". However, the same instructions in this FSN are applicable to these models and the same options are available.

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 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.).

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

BiPAP 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-C*

Dear Physician/Healthcare Professional,

Philips Respironics issued the attached updated 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 Ventilator Inoperative Alarm*" to DME (Durable Medical Equipment) suppliers and medical institutions that have patients who are using these devices. To support physicians/ healthcare professionals who manage patients using ventilatory devices in the home setting, Philips Respironics is providing updated guidance regarding the continued use of these devices as well as alternative options for patients.

Philips Respironics 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:

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 D:** *Instructions on Performing the Hard Reboot***.**

OR

- **Option 2:** Submit a request at the following: < Local Market to include the appropriate URL or email using the Global Customer Support Matrix>, regarding alternate device options. For further information, **please see Section 5**: *Actions planned by Philips Respironics*.

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

As indicated in the IFUs for the following devices: BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, and BiPAP A40 Pro, 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:

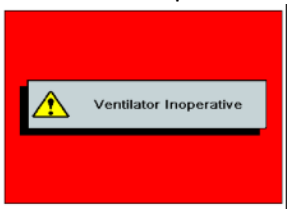
- **Transition patient to a ventilator that is indicated for life supporting ventilation as soon as practicable**.

- If a Ventilator Inoperative alarm occurs and an appropriate 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, **please see Appendix D:** *Instructions on Performing the Hard Reboot***.**

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

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.

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

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 D:** *Instructions on Performing the Hard Reboot***.**

OR

- **Option 2:** Submit a request at the following: <Local Market to include the appropriate URL or email using the Global Customer Support Matrix>, regarding alternate device options. For further information, **please see Section 5**: *Actions planned by Philips Respironics*.

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

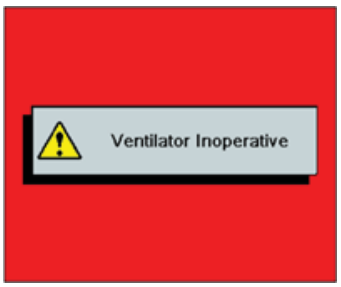
If your physician has indicated you are a patient that cannot tolerate interruptions in therapy, please see the following:

- Contact your physician to expedite transition to an appropriate life support ventilator.

- If a Ventilator Inoperative alarm occurs and an appropriate 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, **please see Appendix D:** *Instructions on Performing the Hard Reboot***.**

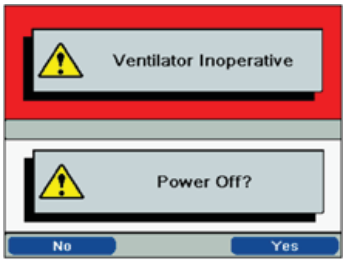
Performing a Hard Reboot

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:

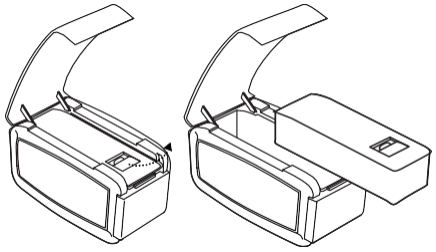
1. **Disconnect from the device.**
2. **Power off the therapy device.**
   - Press the Start/Stop button (⏻).
   - If the ventilator display is operational, the "Power Off" confirmation screen will appear, as shown below.



   - 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.**

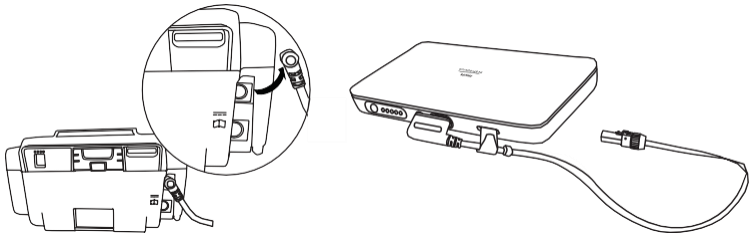
Detachable Battery Pack

- 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).

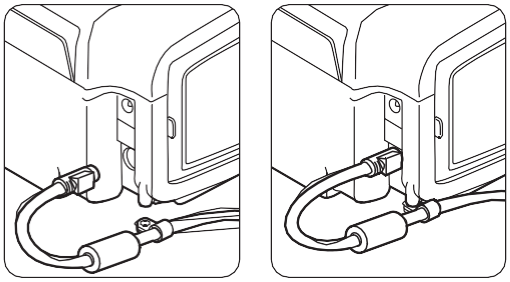


Li Ion Battery Pack

- 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.**