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EC REP

REF 1097811

1077336 R02
JJB 03/22/2012



BiPAP A40

USER MANUAL

PHILIPS
RESPIRONICS

FOR HOME CARE SERVICE PROVIDER USE ONLY

Accessing Prescription Setting Screens



The information on this page is ONLY for home care service providers. Remove this page from the manual before giving the manual to the patient.

Full and Limited Menu Access Modes

The ventilator has two levels of menu access, Full and Limited. Full Menu Access allows you to alter all available settings. Limited Menu access permits the user to alter only those prescription settings that affect patient comfort, such as Rise Time or Flex, if they are available as part of the prescription. Turning the Lock settings off in Full Menu Access mode allows users to modify them. See Chapter 5 for more information. The ventilator defaults to Full Menu Access mode.

When the device is in Limited Menu Access mode, use the following key sequence to enter Full Menu Access mode:

1. From the Standby or Monitor screen, press the Down button and the Alarm Indicator/Audio Pause button simultaneously for several seconds. This temporarily places the device in Full Menu Access mode.
2. If you perform this key sequence from the Monitor screen, the Main Menu appears. If you perform it from the Standby screen, the Setup screen appears.
3. An audible indicator sounds indicating you are now in Full Menu Access mode.
4. You can access the Options menu and permanently change the Menu Access setting to Full. Otherwise, the device will return to Limited mode once you exit the menu screens or if one minute passes without pressing any device buttons.

Note: Chapter 5 provides detailed descriptions of the Full and Limited Menu screens.

Note: Philips Respironics recommends that you set the device back to Limited Menu Access mode before returning it to the patient so patients cannot change their prescription settings.

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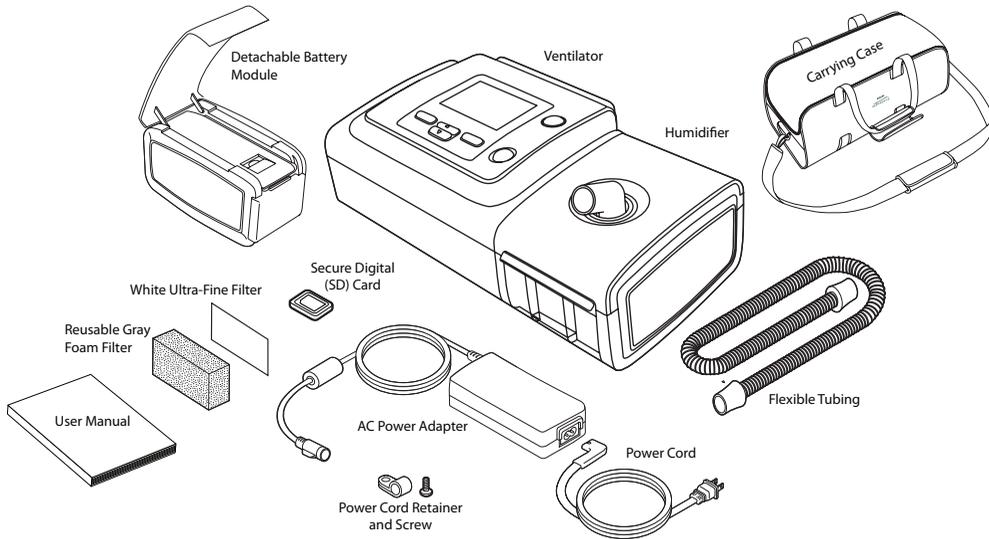
BiPAP A40

user manual

1. Introduction

1.1 Package Contents

The **BiPAP A40** system may include the following components. Some components are optional accessories that may not be packaged with the device.



1.2 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), Respiratory Insufficiency, or Respiratory Failure. 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.

1.3 Warnings and Cautions

Warnings

A warning indicates the possibility of injury to the user or operator.

Patient Monitoring	<p>Prior to placing a patient on the ventilator, a clinical assessment should be performed to determine:</p> <ul style="list-style-type: none"> • The device alarm settings • Needed alternative ventilation equipment • If an alternative monitor (i.e., an alarming Pulse Oximeter or Respiratory Monitor) should be used
Personnel Qualifications	<p>BiPAP A40 is a restricted medical device designed for use by Respiratory Therapists or other trained and qualified caregivers under the supervision of a physician.</p> <p>This manual serves as a reference. The instructions in this manual are not intended to supersede your health care professional's instructions regarding the use of the device.</p> <p>The prescription and other device settings should only be changed on the order of the supervising physician.</p> <p>The operator should read and understand this entire manual before using the device.</p>
SD Card Prescription Changes	<p>When making a therapy prescription or alarm setting change with the SD card, the health care professional must review and verify any prescription changes before using the device. The health care professional is responsible to ensure that the prescription settings are correct and compatible with the patient after using this feature. Installing the wrong prescription for a particular patient may result in improper therapy, lack of appropriate safety monitoring, and injury to the patient.</p>
Battery Back-up Power	<p>The ventilator has a two-stage low battery alarm. The medium priority alarm indicates that approximately 20 minutes of operation remain, and the high priority alarm indicates that less than 10 minutes of operation remain. Actual run time may be more or less than this and varies with battery age, environmental conditions, and therapy.</p> <p>Immediately seek an alternate power source when the "Low Battery" alarm appears. Complete power failure and loss of power is imminent.</p>
Operating and Storage Temperatures	<p>Do not use this device if the room temperature is warmer than 35° C (95° F) because the temperature of the airflow may exceed 43° C. This could cause thermal irritation or injury to the patient's airway.</p> <p>Do not use the device while positioned in a warm place, such as direct sunlight.</p>

Device Start-Up	Make sure the device is working properly at start-up (when entering standby mode). Always verify that the audible tone sounds and the alarm LEDs light red then yellow momentarily. Contact Philips Respironics or an authorized service center for service if these indications do not occur at start-up. See Chapters 4 and 5 for more information about device start-up.
Bacteria Filter	Philips Respironics recommends that a main line outlet bacteria filter be used whenever the device is used on multiple patients.
Therapy Modes/ Features	The AVAPS-AE mode is for non-invasive use on adult patients only.
Patient Circuits	The ventilator should only be used with patient interfaces (e.g., masks, circuits and exhalation ports) recommended by Philips Respironics. Proper operation of the device, including alarms, with other circuits has not been verified by Philips Respironics and is the responsibility of the health care professional or respiratory therapist.
	An exhalation port is required. Do not block the exhalation port. This can reduce airflow and result in rebreathing of exhaled air.
	At low expiratory pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing – some rebreathing may occur.
	When using a patient circuit with a full face mask, the mask must be equipped with a safety (entrainment) valve. Make sure that the safety (entrainment) valve is functioning properly with the ventilator.
Improperly Functioning Ventilator	If you notice any unexplained changes in the performance of the device, if it is making unusual sounds, if the device or detachable battery are dropped, if water is spilled into the enclosure, or if the enclosure is cracked or broken, discontinue use and contact Philips Respironics or an authorized service center for service. If you are a patient, please contact your home care service provider.
Circuit Disconnect	You should not rely on any single alarm to detect a circuit disconnect condition. The Low Minute Ventilation and Apnea alarms should be used in conjunction with the Circuit Disconnect alarm.
	Test the operation of the circuit disconnect function whenever a change is made to the circuit. An increase in circuit resistance can prevent proper operation of some alarms.

Nurse Call and Remote Alarm System	The Nurse Call output of this device is designed only for use with SELV (Safety Extra Low Voltage) as described in IEC 60601-1. Do not connect the Nurse Call output of this device to potentially hazardous voltages as severe injury or death may result.
	The Nurse Call and Remote Alarm features should be considered a back-up to the device's alarm system. Do not rely solely on the Nurse Call feature.
	When using a remote alarm or nurse call system, make sure you fully test the connector and cable by verifying that: <ul style="list-style-type: none"> – Annunciated alarms on the ventilator are also annunciated on the remote alarm or nurse call system. – Disconnecting the remote alarm or nurse call cable from the ventilator or from the remote alarm or nurse call system results in an alarm notification at the remote alarm.
Power Cord	Route the power cord to the outlet in a way that will prevent the cord from being tripped over or interfered with by chairs or other furniture.
	Only use the power cords and nurse call cables recommended by Philips Respironics with the ventilator. Use of power cords and cables not supplied by Philips Respironics may cause overheating or damage to the device.
Accessories	When adding any components to the breathing system, the flow resistance and dead space of the added components (such as humidifiers and filters) should be carefully considered in relation to the potential for adverse effects on the patient's ventilatory management and device alarms.
	The use of accessories, transducers, and cables other than those specified by Philips Respironics may result in increased emissions or decreased immunity of the device.

Oxygen	When administering fixed-flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary, depending on the pressures, patient flows and circuit leak. Substantial leaks may reduce the inspired oxygen concentration to less than the expected value. Appropriate patient monitoring should be used, as medically indicated, such as an alarming pulse oximeter.
	When using oxygen with this system, the oxygen supply must comply with local regulations for medical oxygen.
	Do not connect the device to an unregulated or high pressure oxygen source.
	When using oxygen with this system, a Philips Respironics Pressure Valve must be placed at the device outlet. Failure to use the pressure valve could result in a fire hazard.
	Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
	Do not use the device near a source of toxic or harmful vapors.
	When using oxygen with this system, turn the device on before turning on the oxygen. Turn the oxygen off before turning the device off. This will prevent oxygen accumulation in the device. Explanation of the Warning: When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device's enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
EMC	Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. The device should not be used adjacent to or stacked with other equipment. For more information, contact your home care service provider.
	Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. See the EMC section of this manual for distances to observe between RF Generators and the ventilator to avoid interference.
Cleaning	To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the device.
	Never operate the device if any parts are damaged or if it is not working properly. Replace damaged parts before continuing use.
	Periodically inspect electrical cords and cables for damage or signs of wear. Discontinue use and replace if damaged.
	Repairs and adjustments must be performed by Philips Respironics-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly device damage.

Cautions

A caution indicates the possibility of damage to the device.

Electrostatic Discharge (ESD)	Do not use antistatic or conductive hoses or conductive patient tubing with the device.
Condensation	Condensation may damage the device. If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (operating temperature) before starting therapy.
Filters	A properly installed, undamaged gray foam filter is required for proper operation. Wash periodically and replace when damaged for proper operation.
Extension Cords	Do not use extension cords with this device.
Device Placement	Do not place the device in or on any container that can collect or hold water.
	Do not place the device directly onto carpet, fabric, or other flammable materials.
	Do not plug the device into an outlet controlled by a wall switch.
Humidifier	The heated humidifier can only be used when the ventilator is connected to AC power. It cannot be used with a battery.
External Battery	Do not use the same external battery to operate both the ventilator and any other equipment such as power chairs.
	An external battery should only be connected to the ventilator using the Philips Respironics External Battery Cable. This cable is fused, pre-wired, and properly terminated to ensure safe connection to a standard deep cycle lead acid battery. Use of any other adapter or cable may cause improper operation of the ventilator.
Cleaning	Do not immerse the device or allow any liquid to enter the enclosure or the inlet filter.
	Do not steam autoclave the ventilator. Doing so will destroy the ventilator.
	Do not use harsh detergents, abrasive cleaners, or brushes to clean the ventilator system.

Notes

- This product does not contain natural latex rubber or dry natural rubber in patient or operator accessible areas or in the air path or breathing circuit.

1.4 Contraindications

The BiPAP A40 ventilator is not a life support device.

The device is contraindicated for both invasive use and pediatric use when in AVAPS-AE mode.

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

1.5 Patient Precautions

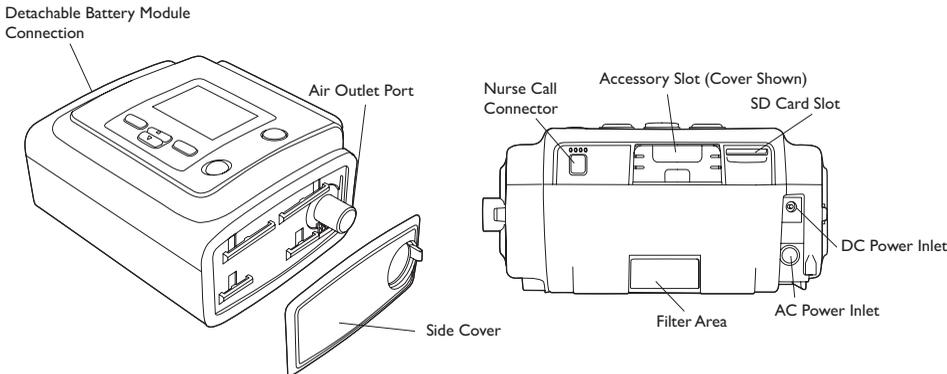
- Immediately report any unusual chest discomfort, shortness of breath, or severe headache.
- If skin irritation or breakdown develops from the use of the mask, refer to the mask instructions for appropriate action.
- The following are potential side effects of non-invasive positive pressure therapy:
 - Ear discomfort
 - Conjunctivitis
 - Skin abrasions due to non-invasive interfaces
 - Gastric distention (aerophagia)

1.6 System Overview

The BiPAP A40 ventilator can provide non-invasive or invasive ventilation. The device augments patient breathing by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This therapy is known as Bi-level ventilation. Bi-level ventilation provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), when you inhale, and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), when you exhale. The higher pressure makes it easier for you to inhale, and the lower pressure makes it easier for you to exhale. The device can also provide a single pressure level, known as CPAP (Continuous Positive Airway Pressure).

The ventilator can be operated using AC power, a detachable battery, or an external battery. See Chapter 4 for more information.

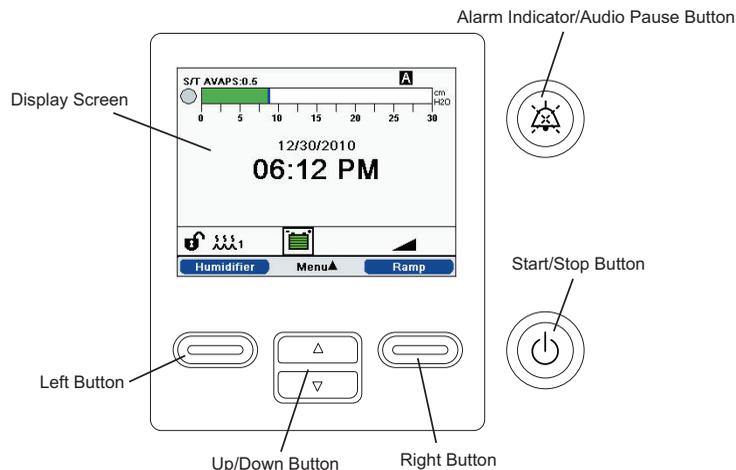
Several accessories are available for use with the device. Contact your home care service provider to purchase any accessories not included with your system. The following figure illustrates some of the device connectors and features, described in the table that follows.



Feature	Description
Air Outlet Port	Connect the flexible tubing here.
SD Card Slot	If applicable, insert the optional SD card here.
Accessory Slot (with cover)	If applicable, an optional accessory such as the Broadband Oximetry modem can be installed here. Refer to the instructions supplied with your accessory. When not using an accessory, the cover must be in place on the device.
AC Power Inlet	Connect the AC power adapter here.
DC Power Inlet	Connect an external battery here using the Philips Respironics DC power cord.
Filter Area	A reusable, gray foam filter must be placed in the filter area to screen out normal household dust and pollen. A white ultra-fine filter can also be used for more complete filtration of very fine particles.
Nurse Call Connector	Connect a nurse call or remote alarm system to the device by connecting a nurse call or remote alarm adapter cable to this connector.
Side Cover	If using a humidifier with the device, this side cover can be easily removed with the release tab before attaching the humidifier. Refer to the Humidifier Manual for more information.
Detachable Battery Module Connection	If you are using the Philips Respironics Detachable Battery Module, attach the Battery Module here and insert the battery into the module. See the instructions included with the Detachable Battery Module for more information.

1.6.1 Control Buttons

The figure below shows the display screen and primary control buttons on the device.



Feature	Description
Display Screen	Shows therapy settings, patient data, and other messages.
Start/Stop Button	Pressing this button when the device is off causes the device to enter Standby mode. Pressing this button while therapy is being delivered displays a pop-up screen that allows you to either turn the device off or return to Standby mode.
Alarm Indicator/ Audio Pause Button	This button serves two purposes: it temporarily silences the audible portion of an alarm, and it also acts as an alarm indicator. See Chapter 3 for more information.
Up/Down Button	This button allows you to navigate the display menu and edit device settings.
Left and Right Buttons	These buttons allow you to select display options or perform certain actions specified on-screen.

1.7 Symbols

The following symbols appear on the device.

Symbol	Description
	Start/Stop
	Alarm Indicator/Audio Pause
	For Airline Use. Complies with RTCA/DO-160F section 21, category M.
	DC Power
	AC Power Supply: connection for the AC/DC power supply
	DC Battery Voltage: connection for an external battery
	Consult accompanying instructions for use.
	Type BF Applied Part
	Class II (Double Insulated)
IP22	Exposure Protection
	Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC.

1.8 Traveling with the System

For your convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adaptor may be required to make your power cord compatible with the power outlets of the country to which you are traveling.

1.8.1 Airline Travel

The device is suitable for use on airlines when it is operating from an AC or DC power source.

Note: The device is not suitable for airline use with any modems or humidifiers installed.

1.9 How to Contact Philips Respironics

To have your device serviced, contact Philips Respironics Customer Service department at 1-724-387-4000 or +49 8152 93060.

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2. Therapy Modes and Features

2.1 Device Therapy Modes

Therapy Modes	Description
CPAP	Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle.
S	Spontaneous Pressure Support; A Bi-level therapy mode where breaths are patient-triggered and patient-cycled. The device triggers to IPAP (Inspiratory Positive Airway Pressure) in response to spontaneous inspiratory effort and cycles to EPAP (Expiratory Positive Airway Pressure) during exhalation. The device also cycles a patient-triggered breath if no patient exhalation effort is detected for 3 seconds. The level of Pressure Support delivered is determined by the difference between the IPAP and EPAP settings ($PS = IPAP - EPAP$)
S/T	Spontaneous/Timed Pressure Support; A Bi-level therapy mode where each breath is patient-triggered and patient-cycled or machine-triggered and machine-cycled. S/T mode is similar to S mode, except that the device also will enforce a set minimum breath rate by, if necessary, providing machine (time) triggered breaths. For these breaths, the inspiratory time is also a set value.
T	Timed Pressure Support; A Bi-level therapy mode where breaths are machine-triggered and machine-cycled. T mode provides mandatory pressure assist with bi-level pressures. The patient's breathing rate has no effect on the machine rate or pressure levels. The trigger to IPAP is determined by the breath rate setting, and the cycle time is determined by the inspiratory time setting.
PC	Pressure Control Pressure Support; A Bi-level therapy mode where each breath is patient or machine-triggered and machine-cycled. PC mode is similar to S/T mode, except that all breaths are machine-cycled. This is a pressure-limited, machine or patient-triggered, time-cycled mode. The cycle time is determined by the Inspiratory Time setting.

AVAPS-AE	<p>A novel Bi-level therapy mode that provides an automatically adjusting EPAP, Pressure Support, and back-up breath rate.</p> <p>In AVAPS-AE mode, the device monitors the patient’s upper airway resistance and automatically adjusts the delivered EPAP required to maintain a patent airway.</p> <p>In this mode, the AVAPS feature is always enabled. This allows the device to automatically adjust Pressure Support to maintain a target tidal volume. (Refer to the description of AVAPS in Section 2.2, Therapy Features.) The required Pressure Support is delivered above the automatic EPAP setting.</p> <p>Additionally, when the Breath Rate is set to Auto, the device will automatically adjust the back-up breath rate based on the patient’s spontaneous respiratory rate.</p>
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2.2 Therapy Features

If prescribed for you, the device provides the following therapy features.

2.2.1 AVAPS

Average Volume Assured Pressure Support (AVAPS) is a feature available in the S, S/T, PC, and T modes. (In AVAPS-AE mode, the AVAPS feature is always enabled.) AVAPS helps patients maintain a tidal volume (VT) equal to or greater than the target tidal volume (Tidal Volume setting) by automatically controlling the pressure support (PS) provided to the patient. The AVAPS feature adjusts PS by varying the IPAP level between the IPAP Min and IPAP Max settings (or Pressure Support Min and Pressure Support Max in AVAPS-AE mode). AVAPS will retain the learned PS for the patient so that each time therapy is started the PS will start at the learned PS.

The AVAPS algorithm in the BiPAP A40 contains an improvement to more accurately achieve and maintain the target tidal volume. The muscle effort of a spontaneous breath typically results in a larger tidal volume than a machine breath delivered at the same pressure. The new AVAPS algorithm will adjust the pressure slightly on machine delivered breaths to compensate for this difference, and throughout the night, the algorithm will “learn” the correct amount of pressure adjustment to apply to machine triggered breaths.

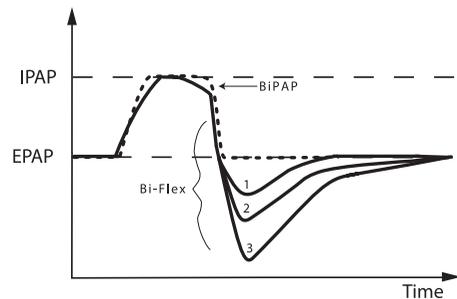
If IPAP Max is reached and the target tidal volume is not achieved, the Low Tidal Volume alarm activates (if enabled).

2.2.1.1 AVAPS Rate

The AVAPS Rate setting allows you to adjust the maximum rate at which the pressure support automatically changes to achieve the target tidal volume. The actual rate may be less than this maximum setting depending on how far the current estimated tidal volume is from the target tidal volume. A higher rate allows the AVAPS algorithm to change pressure support faster to meet the target tidal volume. It can be set from 0.5 cmH₂O per minute to 5.0 cmH₂O per minute in increments of 0.5 cmH₂O per minute.

2.2.2 Bi-Flex Comfort Feature

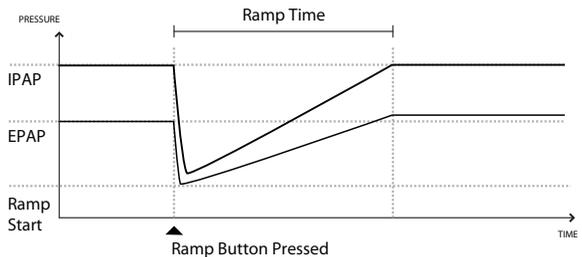
If enabled, the device provides a comfort feature called Bi-Flex in S mode only. The Bi-Flex attribute adjusts therapy by inserting a small amount of pressure relief during the latter stages of inspiration and during active exhalation (the beginning part of exhalation). Bi-Flex levels of 1, 2, or 3 progressively reflect increased pressure relief that will take place at the end of inspiration and at the beginning of expiration.



2.2.3 Ramp

The device is equipped with an optional ramp feature. The ramp feature is designed to offer lower pressures when activated and then gradually increase to allow the patient to fall asleep.

If ramp is activated with AVAPS enabled or in AVAPS-AE mode, it will reduce the maximum pressure support capability to IPAP Min or Pressure Support Min and ramp to the IPAP Max or Pressure Support Max. In AVAPS-AE mode, the EPAP will reduce to the EPAP Min setting but is not ramped, and Auto-EPAP adjusts the pressure according to the patient's needs. During the ramp period, the IPAP or pressure support applied will be adjusted by the AVAPS algorithm but will be constrained by the current maximum ramp pressure set point. The pressures (with exception of EPAP in AVAPS-AE mode) will then ramp up to the original prescribed settings over the ramp time period.

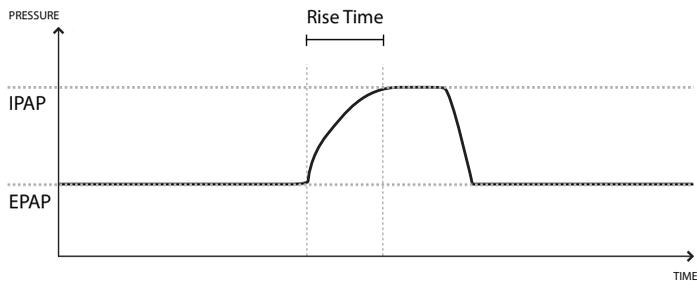


2.2.4 Rise Time

If enabled, the device provides a feature called Rise Time in S, S/T, T, PC, and AVAPS-AE modes. Rise time is the amount of time it takes the device to change from the expiratory pressure setting to the inspiratory pressure setting.

Rise time levels of 1, 2, 3, 4, 5, or 6

progressively reflect slowed response of the pressure increase that will take place at the beginning of inspiration. A setting of 1 is the fastest rise time while a setting of 6 is the slowest. Adjust the rise time to find the most comfortable setting for the patient. Rise time cannot be adjusted when Bi-Flex is enabled.



2.2.5 Digital Auto-Trak

An important characteristic of the device is its ability to recognize and compensate for unintentional leaks in the system and to automatically adjust its trigger and cycle algorithms to maintain optimum performance in the presence of leaks. This feature is known as Digital Auto-Trak.

The device continuously monitors flow and adjusts the estimate of patient flow as circuit leak changes. The compensation provides a better estimate of patient flow to be used to track patient breathing patterns and calculate flow-based parameters, such as exhaled tidal volume.

The device continually tracks breathing patterns and automatically adjusts sensitivity thresholds to ensure optimum patient and machine synchrony as breathing patterns change or as circuit leak varies.

Sensitive Auto-Trak is an enhancement to the Auto-Trak algorithm that improves patient and machine synchrony for patients with minimal respiratory effort. Sensitive Auto-Trak refines the baseline trigger and cycle sensitivity thresholds.

2.3 Therapy Event Detection

The device monitors breathing and detects apneas, hypopneas, and other therapy events (as available).

Event	Definition
Obstructed Airway Apnea/ Clear Airway Apnea Detection	An apnea is detected when there is an 80% reduction in airflow from baseline for at least 10 seconds or if there is no airflow detected for 10 seconds. During the apnea, one or more pressure test pulses are delivered by the device. The device evaluates the response of the patient to the test pulse(s) and assesses whether the apnea has occurred while the patient has a clear airway or an obstructed airway. The airway is determined to be clear if the pressure test pulse generates a significant amount of flow; otherwise, the airway is determined to be obstructed.
RERA Detection	RERA (Respiratory effort-related arousal) is defined as an arousal from sleep that follows a 10 second or longer sequence of breaths that are characterized by increasing respiratory effort, but which does not meet criteria for an apnea or hypopnea. Snoring, though usually associated with this condition, need not be present. The RERA algorithm monitors for a sequence of breaths that exhibit both a subtle reduction in airflow and progressive flow limitation. If this breath sequence is terminated by a sudden increase in airflow along with the absence of flow limitation, and the event does not meet the conditions for an apnea or hypopnea, a RERA is indicated.
Periodic Breathing	A persistent waning and waxing breathing pattern which repeats itself between 30 and 100 seconds. The nadir of the breathing pattern is characterized by at least a 40% reduction in airflow from an established baseline flow. The pattern must be present for several minutes before it can be identified as periodic breathing.
Hypopnea Detection	A hypopnea is detected when there is an approximately 40% reduction in airflow from baseline for at least 10 seconds.
Snore Detection	Vibration snore is disabled at pressures greater than 16 cmH ₂ O in CPAP mode. Vibration snore is disabled at IPAP settings greater than 20 cmH ₂ O or max pressure support (IPAP – EPAP) greater than or equal to 10 cmH ₂ O in bi-level modes. It is also disabled during any machine triggered breaths when EPAP settings are greater than or equal to 10 cmH ₂ O.
Large Leak	The level of leak is so large, it is no longer possible to determine respiratory events with statistical accuracy.

2.3.1 Event Detection in Modes with a Back-up Rate

If the device is in a mode that delivers its own backup breath, (S/T, PC, T, or AVAPS-AE mode), then the device will NOT deliver the test pulse. Instead, it will use the machine back-up breath and evaluate it for which (if any) type of apnea to score.

3. Ventilator Alarms

There are three types of alarms:

- High Priority – Require immediate response by the operator
- Medium Priority – Require prompt response by the operator
- Low Priority – Require operator awareness. These alarms alert you to a change in the ventilator status.

Additionally, the ventilator also displays informational messages and confirmation alerts that notify you of conditions that need attention but do not qualify as alarm conditions.

***Note:** If multiple alarms occur at the same time, all alarms are processed and displayed, but the alarms are ordered first by priority and then by occurrence, with the newest, highest priority alarms at the top of the list. The alarm precedence is in the following order: high priority, medium priority, low priority, and informational messages.*

***Note:** Not all alarms are available in every therapy mode; some alarms are mode-dependent.*

3.1 Audible and Visual Alarm Indicators

When an alarm condition occurs:

- The alarm LED indicator on the Alarm Indicator/Audio Pause button lights
- The audible alarm sounds
- A message appears on the screen describing the type of alarm

Each of these is described in detail below.

3.1.1 Alarm LED Indicators

The Alarm Indicator/Audio Pause button on the front of the ventilator lights up as follows whenever an alarm is detected:

- Red Flashing Indicator – When the device detects a high priority alarm, the Alarm Indicator/Audio Pause button flashes red.

- Yellow Flashing Indicator – When the device detects a medium priority alarm, the Alarm Indicator/Audio Pause button flashes yellow.
- Yellow Solid Indicator – When the device detects a low priority alarm, a solid yellow light appears on the Alarm Indicator/Audio Pause button.

The Alarm Indicator/Audio Pause button does not light up when informational messages or confirmation alerts display.

3.1.2 Audible Indicators

An audible indicator sounds whenever a power failure or a high, medium, or low priority alarm is detected. Additionally, an audible indicator sounds for informational messages and to confirm that certain actions have occurred (for example, when an SD card is inserted or removed from the device).

- Ventilator Inoperative Audible Indicator – When a ventilator inoperative alarm occurs, a continuous audible alarm sounds. The alarm descriptions later in this chapter display this indicator as: 
- Power Failure Audible Indicator – When a power failure occurs, a series of beeps sounds in a 1 beep pattern, repeating one second on, then one second off. The alarm descriptions later in this chapter display this indicator as:  
- High Priority Audible Indicator – When a high priority alarm is detected, a series of beeps sound in the following pattern, which is repeated twice: 3 beeps, a pause, and then 2 more beeps. This indicator continues until the cause of the alarm is corrected or the audible alarm is paused. The alarm descriptions later in this chapter display this indicator as:
    
- Medium Priority Audible Indicator – When a medium priority alarm is detected, a series of beeps sound in a 3-beep pattern. This pattern repeats until the cause of the alarm is corrected or the audible alarm is paused. The alarm descriptions later in this chapter display this indicator as:   
- Low Priority Audible Indicator – When a low priority alarm is detected, a series of beeps sound in a 2-beep pattern. This pattern repeats until the cause of the alarm is corrected or the audible alarm is paused. The alarm descriptions later in this chapter display this indicator as:  

- Informational Messages and Confirmation Audible Indicators – When an informational message appears on screen, a brief, 1- beep audible indicator sounds. Additionally, when the device detects that a certain action has been completed (for example, when the Start/Stop button is pressed to start therapy, or when an SD card is inserted or removed from the device) a brief, 1- beep audible indicator sounds. The alarm descriptions later in this chapter display this indicator as: ◇

Note: For the alarm indicators noted throughout this manual, each “diamond” represents an audible beep.

3.1.3 Alarm Messages

When the ventilator detects an alarm, the Alarms and Messages Screen is displayed showing a description of the alarm condition. When an alarm message appears, it will be highlighted in red if it is a high priority alarm or in yellow if it is a medium or low priority alarm. (The highlight color matches the alarm LED color on the Alarm Indicator/Audio Pause button.) If an alarm is manually reset by the user, the Alarms and Messages screen is removed and the Monitoring Screen is re-displayed. If the alarm self-cancels, the Alarms and Messages screen remains displayed, but the highlight for the active alarm is removed, the LED is unlit, and the audible alarm stops.

3.2 Silencing an Alarm

When an alarm occurs, you can temporarily silence the audible indicator by pressing the Alarm Indicator/Audio Pause button. The alarm is silenced for 60 seconds and then sounds again if the cause of the alarm has not been corrected. Each time you press the Alarm Indicator/Audio Pause button, another 60 second period is initiated.

When Audio Pause is active, the Alarm Indicator/Audio Pause symbol () appears if you are on the Monitor screen.

There is also a Pre-silence alarm feature. You can press the Alarm Indicator/Audio Pause button at any time to begin a 60 second silence period. If an alarm occurs during that time the audible indicator will not sound until the silence period ends.

3.3 Resetting an Alarm

The Reset button clears the currently active alarm(s) from the display and stops the LED and audible alarm indicator. This button should be selected after the situation causing the alarm(s) has been corrected. Pressing this button cancels all active alarms and restarts alarm detection.

The ventilator self-cancels certain alarms if the cause of the alarm is corrected, shutting off the alarm LED, the audible alarm, and the alarm background color. You can manually reset an alarm by pressing the Left button (Reset). An active alarm silence function is cancelled when any alarm is manually reset.

3.4 Alarm Descriptions

This section describes all of the ventilator alarms and informational messages.

3.4.1 Patient Alarms (User-Settable)

1. Circuit Disconnect Alarm

This is a high priority alarm. It occurs when the breathing circuit is disconnected or has a large leak. The device continues to operate. The alarm will automatically terminate when the circuit is reconnected or the leak is fixed.

2. Apnea Alarm

This is a high priority alarm. It occurs when the patient has not triggered a breath within the time specified in the apnea alarm setting. The device continues to operate. The alarm will automatically terminate when two consecutive patient breaths are detected that meet the apnea alarm time setting.

3. High Respiratory Rate Alarm

This is a high priority alarm. It occurs when the respiratory rate is greater than the High Respiratory Rate alarm setting. The device continues to operate. The alarm will automatically terminate when the measured respiratory rate is less than the High Respiratory Rate alarm setting.

4. Low Minute Ventilation Alarm

This alarm is a high priority alarm. It occurs when the patient's minute ventilation is less than the Low Minute Ventilation alarm setting. The device continues to operate. The alarm will automatically terminate when the calculated minute ventilation is greater than the Low Minute Ventilation alarm setting.

5. Low Tidal Volume Alarm

This is a high priority alarm. It occurs when AVAPS is enabled (or in AVAPS-AE mode) and the ventilator is unable to reach the target tidal volume setting. The device continues to operate. The alarm will automatically terminate when the target tidal volume is reached.

3.4.2 System Alarms

1. Loss of Power

This occurs when a complete power failure has occurred and power was lost while the device was providing therapy.

2. Ventilator Inoperative Alarm

This 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.

3. Low Battery Alarm

This is a high priority alarm that occurs in two stages. The medium priority alarm indicates that approximately 20 minutes of operation remain, and the high priority alarm indicates that less than 10 minutes of operation remain. Actual run time may be more or less than this and varies with battery age, environmental conditions, and therapy.

4. Pressure Regulation Alarm

This is a high priority alarm. It occurs when the ventilator cannot regulate pressure within an acceptable accuracy. The device continues to operate.

5. Low Circuit Leak Alarm

This is a high priority alarm. It occurs when the device detects that the exhalation port is partially or fully occluded.

6. High Temperature Alarm

This is a high priority alarm. It occurs when the device is close to reaching a high temperature limit. The device continues to operate.

7. AC Power Disconnected Alarm

This is a medium priority alarm. It occurs when the AC power source was lost, and the device has switched to DC (battery) power. The device continues to operate. The alarm terminates when the ventilator begins operating from AC power again.

8. Keypad Stuck Alarm

This is a low priority alarm. It occurs when a key becomes lodged inside the case of the device.

9. Replace Detachable Battery Alarm

The Replace Detachable Battery alarm occurs when the detachable battery is nearing the end of its useful life or a failure in the detachable battery that prevents it from charging or discharging has been detected. The alarm can be an informational message or a medium priority alarm. The device may continue to operate depending on the condition causing the alarm.

10. Insert SD Card Alarm

This is a low priority alarm. It occurs when a pulse oximeter is connected to the ventilator and there is no SD card inserted in the ventilator. The device continues to operate but no oximeter data is recorded on an SD card.

11. Card Error Info Message

This info message occurs when an unusable SD card is inserted into the ventilator. The device continues to operate but data cannot be logged onto the SD card.

12. Start On Battery Info Message

This info message indicates that the ventilator has started on battery power and no AC power is available. The device operator should verify that this is what is wanted.

13. Check AC Power Supply Info Message

This info message occurs when the AC power input to the ventilator is incorrect. The device continues to operate but therapy may not start.

14. Battery Disconnected Info Message

This info message occurs when the battery is disconnected from the ventilator while operating. The device continues to operate on AC power.

15. Battery Discharging Stopped Due to Temperature Info Message

This info message occurs when the detachable battery becomes overheated while providing power for the device. The device continues to operate. The battery is not used and the power source is switched to the next available power source.

16. Battery Not Charging Due to Temperature Info Message

This info message occurs when the detachable battery becomes too hot while charging or the device was in too cold or hot an environment before charging started. The device continues to operate. Battery charging stops until the battery cools or warms sufficiently.

17. Battery Not Charging Info Message

This info message occurs when the device has detected a condition that prevents the battery from accepting a charge. The device continues to operate. Battery charging stops.

18. Battery Depleted Info Message

This info message occurs when the external battery is fully depleted. The device continues to operate using the detachable battery if it is available.

19. Detachable Battery Disconnected Info Message

This info message occurs when the detachable battery power source is lost and the device has switched to an alternate power source. If detachable battery power returns, the ventilator will beep, but no message will appear on the display.

3.5 What to Do When An Alarm Occurs

Complete the following steps when an alarm occurs:

1. Whenever an alarm occurs, first always observe the patient and ensure that adequate ventilation and oxygenation (if appropriate) are available.
2. Look at the alarm indicators and listen to the audible Alarm Indicator/Audio Pause button (red or yellow) and whether the LED is solid or flashing.
3. Look at the display to check the alarm message that appears on-screen and whether it is highlighted in red or yellow.
4. Press the Alarm Indicator/Audio Pause button to temporarily silence the audible alarm. A visual indicator displays (). Or, press the Left (Reset) button to reset alarm. In case of Loss of Power, use the Alarm Indicator/Audio Pause button to both silence and terminate the alarm.
5. Look up the alarm in the alarm descriptions in this chapter to determine the source of the alarm and the appropriate action.

3.6 Alarm Summary Table

The following tables summarize the high, medium, and low priority alarms and informational messages.

3.6.1 Patient Alarms (User-Settable)

Alarm	Priority	Audible	Visual Indicators	Device Action	User Action
Circuit Disconnect	High	◇◇◇ ◇◇	Red flashing button; Circuit Disconnect message	Operates	Reconnect the patient circuit or fix the leak. If alarm continues to occur, contact your home care service provider. If the device will not exit circuit disconnect, switch to an alternate source of ventilation.
Apnea	High	◇◇◇ ◇◇	Red flashing button; Apnea message	Operates	Report the alarm to your home care service provider. Continue using device.
High Respiratory Rate	High	◇◇◇ ◇◇	Red flashing button; High Respiratory Rate message	Operates	Continue using device. If alarm continues, contact your home care service provider.
Low Minute Ventilation	High	◇◇◇ ◇◇	Red flashing button; Low Minute Ventilation message	Operates	Continue using device. If alarm continues, contact your home care service provider.
Low Tidal Volume	High	◇◇◇ ◇◇	Red flashing button; Low Vte message	Operates	Continue using device. If alarm continues, contact your home care service provider.

3.6.2 System Alarms

Alarm	Priority	Audible	Visual Indicators	Device Action	User Action
Ventilator Inoperative	High	■	Red flashing button; "Ventilator Inoperative" message	Shuts down if can't provide therapy safely. Or, continues to operate at a limited level.	Press Start/Stop button. If display is operational, Power Off confirmation screen appears. Select Right button to shut off device and silence alarm. Immediately remove patient from ventilator and connect them to alternate source of ventilation. Contact your home care service provider for service.
Pressure Regulation	High	◇◇◇ ◇◇	Red flashing button; Pressure Regulation message	Operates	Check for blockages or excessive leaks. If alarm continues, contact your home care service provider.
Low Circuit Leak	High	◇◇◇ ◇◇	Red flashing button; Low Circuit Leak message	Operates	Check for blockages in exhalation devices. Make sure the exhalation device is clean and functioning properly. If the alarm continues, contact your home care service provider.
High Temperature	High	◇◇◇ ◇◇	Red flashing button; High Temperature Message	Operates	Move device to cooler location. Make sure device is not close to a heat source. Make sure cooling vents are not blocked. If condition persists, contact your home care service provider.
Loss of Power	High	◇ ◇	Red flashing button; Blank screen	Shuts down	If using AC power, try plugging device into alternate AC power source. If loss of power continues, switch to DC power by connecting an external battery to the device. If there is still no power, connect patient to alternate source of ventilation and contact your home care service provider.

Alarm	Priority	Audible	Visual Indicators	Device Action	User Action
Low Battery (When Battery is Attached)	High	◇◇◇ ◇◇	High Priority-Red flashing button. Low Battery message. On Status panel, box around battery is red.	Operates	Switch to an alternate battery, or switch to AC power.
AC Power Disconnected (When Battery is Attached)	Medium	◇◇◇	Yellow flashing button; AC Power Disconnected message, and a box appears around battery in use.	Switches to alternate power source	Check AC power adapter and reconnect it if it has become disconnected. Make sure device is not connected to an overloaded AC circuit.
Stuck Key	Low	◇◇	Solid yellow button; Keypad Stuck message.	Operates	Check the keys to determine if they are lodged in the case. If alarm continues, place patient on alternate source of ventilation and contact your home care service provider.
Replace Detachable Battery	Info or Medium, depending on cause of alarm	◇ for Info ◇◇◇ for Medium	Replace Detachable Battery message appears. If battery is nearing end of useful life, message appears. If battery fails, message appears and button flashes yellow.	Operates	Switch to an alternate battery or AC power source while replacing the current detachable battery.
Insert SD Card (When Oximeter is Attached)	Low	◇◇	Solid yellow button; Insert SD Card message	Operates	Insert an SD card into the ventilator or remove the oximeter.

3.6.3 Informational Messages

Message	Priority	Audible	Visual Indicators	Device Action	User Action
Card Error	Info	◇	Card Error message	Operates	Remove SD Card and use another card, if available. Ensure card meets specifications. If condition persists, contact your home care service provider.
Start On Battery	Info	◇	Start On Battery message	Operates	Check battery status. Connect to AC power source as soon as possible.

Message	Priority	Audible	Visual Indicators	Device Action	User Action
Check AC Power Supply	Info	◇	Check AC Power Supply message	Operates	Connect ventilator to a battery and remove AC power. Replace the AC power supply. If condition persists, contact your home care service provider.
Battery Disconnected	Info	◇	Batt Disconnected message	Operates	Check the connection to the battery if not an intentional disconnection.
Battery Discharging Stopped Due to Temperature	Info	◇	Batt Discharge Stopped - Temp message	Operates	Move device to cooler location. Make sure device is not close to a heat source. Make sure cooling vents are not blocked. If condition persists, contact your home care service provider.
Battery Not Charging Due to Temperature	Info	◇	Batt Not Charging - Temp message	Operates	Make sure device is not close to a heat source. Make sure cooling vents are not blocked. Move device to a cooler location. If device is too cold, allow it to warm up. If condition persists, contact your home care service provider.
Battery Not Charging	Info	◇	Detach Battery Not Charging message	Operates	Replace the battery or find an alternate power source. If condition continues, contact your home care service provider.
Battery Depleted	Info	◇	External Battery Depleted message	Operates	Replace depleted battery with another or switch to AC power, if available. Recharge depleted battery.
Detachable Battery Disconnected	Info	◇	Detachable Batt Disconnected message, and a box appears around battery in use.	Switches to alternate power source	Check connection of the detachable battery to ventilator. Check the charge available on detachable battery and recharge battery if necessary.

4. Device Setup

4.1 Installing the Air Filter

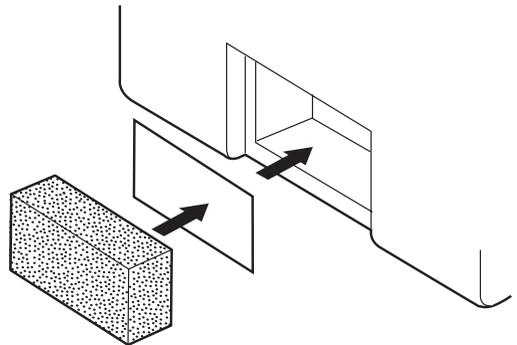
The device uses a gray foam filter that is washable and reusable, and a white ultra-fine filter that is disposable. The reusable filter screens out normal household dust and pollen, while the ultra-fine filter provides more complete filtration of very fine particles. The gray reusable filter must be in place at all times when the device is operating. The ultra-fine filter is recommended for people who are sensitive to tobacco smoke or other small particles. One reusable gray foam filter is supplied with your device. A disposable ultra-fine filter may also be included.

If your filter is not already installed when you receive the device, you must at least install the reusable gray foam filter before using the device. To install the filter(s):

1. If you are using the white disposable ultra-fine filter, insert it into the filter area first, with the smooth side facing toward the device.
2. Insert the required gray foam filter into the filter area after the ultra-fine filter.

Note: If you are not using the white disposable filter, simply insert the gray foam filter into the filter area.

Note: See Chapter 6 for information on how to clean and replace the air filter.



4.2 Where to Place the Device

Place the device upright on a firm, flat surface somewhere within easy reach of where you will use it, at a level lower than your sleeping position. Make sure the filter area on the back of the device is not blocked by bedding, curtains, or other items. Air must flow freely around the device for the system to work properly. Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, or air conditioners).

4.3 Connecting the Breathing Circuit

You will need the following accessories in order to assemble the recommended circuit:

- Philips Respironics interface (nasal mask or full face mask) with integrated exhalation port, or Philips Respironics interface with a separate exhalation device (such as the Whisper Swivel II)
- Philips Respironics 22 mm or 15 mm flexible tubing
- Philips Respironics headgear (for the mask)

4.3.1 Connecting a Non-Invasive Circuit

Complete the following steps to connect a non-invasive breathing circuit to the device:

1. Connect the flexible tubing to the air outlet on the side of the device.
 - a. If required, connect a bacteria filter to the device air outlet, and then connect the flexible tubing to the outlet of the bacteria filter.
 - b. When using the bacteria filter, the device performance may be affected. However, the device will remain functional and deliver therapy.
2. Connect the tubing to the mask. Refer to the instructions that came with your mask.

4.3.2 Connecting an Invasive Circuit

1. Connect the flexible tubing to the air outlet on the side of the device.
 - a. If required, connect a bacteria filter to the device air outlet, and then connect the flexible tubing to the outlet of the bacteria filter.
 - b. When using the bacteria filter, the device performance may be affected. However, the device will remain functional and deliver therapy.

2. If using, connect an invasive humidifier or Heat Moisture Exchange filter (HME). An invasive humidifier meeting EN ISO8185 is recommended.
3. Connect the flexible tubing to the humidifier or HME, and then place an exhalation device (such as the Whisper Swivel II) in line on the patient end.
4. Connect a trach adapter to the exhalation device if needed, and then attach the patient's trachestomy tube.
5. Refer to Chapter 5 to set the System One Resistance setting to Invasive.

4.4 Supplying Power to the Device

The device can operate on AC or DC power. The ventilator accesses power from potential sources in the following order:

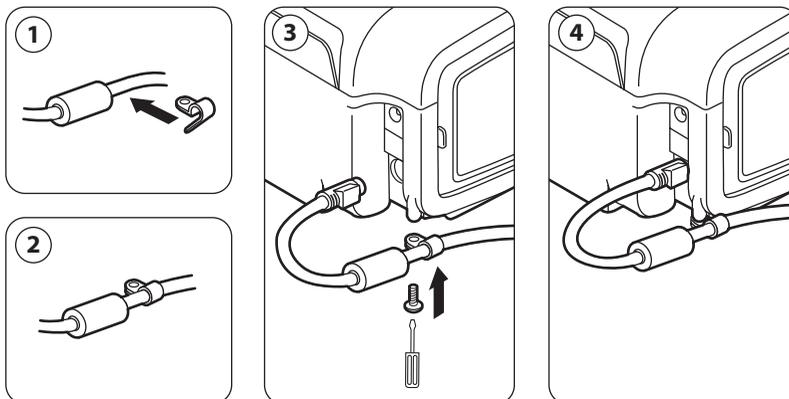
- AC Power
- External Battery
- Detachable Battery Pack

4.4.1 Using AC Power

An AC power cord and power supply is included with the device.

1. Plug the socket end of the power cord into the power supply.
2. Plug the pronged end of the power cord into an electrical outlet that is not controlled by a wall switch.
3. Plug the power supply cord's connector into the power inlet on the back of the ventilator.
4. Ensure that all connections are secure.

- There is an accessory clip that can be used to secure the power cord to prevent accidental disconnection. Route the cords through the clip and secure the clip to the enclosure of the device using the supplied screw, as shown.



Note: Some devices have a locking-type power connector. To avoid damage to the connector, when disconnecting the power cord, pull the connector at its base, not the cord, to disengage the lock.

4.4.2 Using DC Power

You can operate the ventilator using an external battery or detachable battery pack.

4.4.2.1 External Battery

The ventilator can operate from a 12 VDC lead acid battery using the Philips Respironics External Battery Cable. This cable is pre-wired and properly terminated to ensure safe connection of an external battery to the ventilator. Battery operating time depends on the characteristics of the battery and usage of the device.

Due to a variety of factors, including battery chemistry, age, and use profile, the capacity of the external battery as shown on the device display is only an estimate of the actual remaining capacity.

Refer to the instructions supplied with the External Battery Cable for detailed information on how to operate the device using an external battery.

4.4.2.2 Detachable Battery

Philips Respironics offers a detachable Lithium-Ion battery pack. You can connect the detachable battery to the device and recharge the battery using the Philips Respironics Detachable Battery Module. Refer to the instructions included with your Detachable Battery Pack and Detachable Battery Module for more information.

Note: The Detachable Battery pack will automatically recharge whenever it is connected to the therapy device and the device is running on AC power.

4.4.3 Device Power Source Indicators

There are many power source indicators on the device and the display screen. These indicators are described in detail below.

4.4.3.1 AC Power Indicators

When AC power is applied to the device and the airflow is off, the green AC LED indicator on the Start/Stop button lights. When AC power is applied and the airflow is on, the white AC LED indicator on the Start/Stop button lights.

4.4.3.2 DC Power Indicators

When DC power is applied to the device, battery symbols will appear on-screen to indicate the battery status. The detachable and external battery symbols will only appear on-screen if a detachable or external battery is attached to the device. The shading in the battery icon indicates the power remaining in the battery. Refer to the Display Symbols table in Chapter 5 for information on each battery symbol.

Battery	Symbol
External Battery	
Detachable Battery	

There are several DC power indicators that will display on-screen to indicate which battery is in use (if applicable), if the batteries are low, charging, or discharged, etc. The following table explains all of the DC power indicators.

DC Power Indicator	Description
Battery in Use Indicator 	A black box will appear around the battery that is in use. For instance, if the external battery is currently in use, the  symbol appears on-screen.
Green Fully Charged Battery Indicator	When a battery is charged to greater than 90% of its capacity, all of the bars in the battery symbol will appear in green.
Partially Charged Battery Indicator	When a battery symbol is partially charged, some of the bars in the battery symbol will appear in green, while others will be clear. For instance, if the external battery is 50% charged, the following symbol displays on-screen: 
Yellow Low Battery Indicator (Medium Priority)	When the device detects that an in-use battery's charge is low (has approximately 20 minutes of charge left), the inside of the box surrounding the battery symbol turns yellow. (In addition, a medium priority alarm message will display indicating "Low Battery." See Chapter 3 for more information. The yellow indicator is for the last available battery source.
Red Low Battery Indicator	When the device detects that an in-use battery's charge is nearly depleted (has approximately 10 minutes of charge left), the inside of the box surrounding the battery symbol turns red. In addition, a high priority alarm message displays indicating "Low Battery." See Chapter 3 for more information. The red indicator is for the last available battery source.
Yellow Battery Recharging Symbol 	Whenever AC power is applied to the device, the detachable battery will recharge as needed. If the detachable battery is being recharged, the  symbol displays.

5. Viewing and Changing Settings

5.1 Navigating the Menu Screens

To navigate through all of the menu screens and settings:

- Use the Up/Down button to scroll through the menu.
- Use the Left and Right buttons to perform the actions specified on the on-screen buttons.

5.2 Using the Keypad Lock Feature

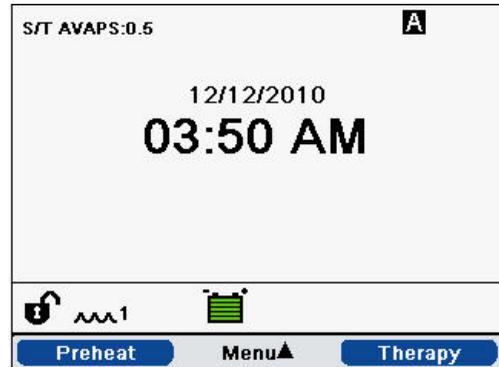
***Note:** When Keypad Lock is enabled, the Alarm Indicator/Audio Pause and Start buttons continue to function normally.*

1. Access the Keypad Lock feature from the Options menu. It is intended to prevent accidental changes to device settings. This feature locks the navigation keys (Up, Down, Stop, Left, and Right).
2. If the keypad is locked, you must unlock it before you can enter the Menu. When you press one of the navigation keys, a Keypad Unlock message displays. To unlock the keypad, hold the Right button down for 5 seconds. Or press the Left (Cancel) button to cancel the Keypad Unlock action.
3. An audible indicator sounds when the keypad is successfully unlocked. Once the display is unlocked, you can enter the Menu as you normally would by pressing the Up button.
 - There is a keypad lock inactivity time-out period. After you have unlocked the keypad as indicated, the keypad will re-lock after five minutes of inactivity.

The keypad automatically unlocks if an alarm or informational message occurs and remains unlocked while alarms are active.

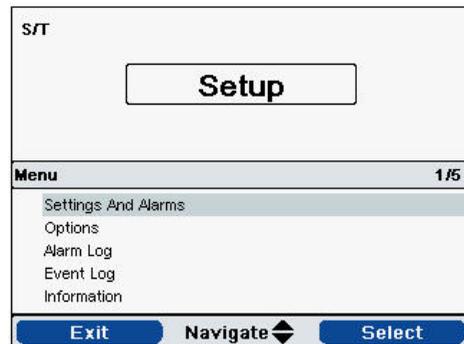
5.3 Accessing the Standby Screen

1. After you press the  button, the Startup screen appears momentarily, indicating the device name and software version.
2. The Standby screen then appears, shown here. It displays the date and time, therapy mode, a patient accessory panel (if a patient accessory is attached), a status panel, and the soft key panel.
3. You can perform the following actions from the Standby screen :
 - a. If a humidifier is connected, you can activate the humidifier preheat function by pressing the Left (Preheat) key. See the Accessories chapter for more information.
 - b. If an accessory module is attached, you can monitor the connection to any attached patient accessory.
 - c. Access the menu by selecting the Up (Menu) key.
 - d. Initiate therapy by selecting the Right (Therapy) key. Selecting this key starts the airflow and displays the Monitoring screen.



5.4 Accessing the Setup Screen

1. There are two ways to access the Setup screen:
 - Select Menu from the Standby screen
 - Perform the Provider Menu Access Key Sequence from the Standby screen
2. You can access the device and therapy settings from this screen. The menu options vary based on your device setup. A sample screen is shown here.



5.5 Accessing the Monitor Screen

The Monitor screen appears after you press the Therapy key on the Standby screen. There are two versions of this screen: Simple View and Detailed View. Samples of both screens are shown to the right.

5.5.1 Monitor Screen Content

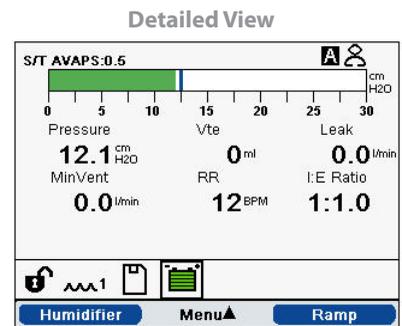
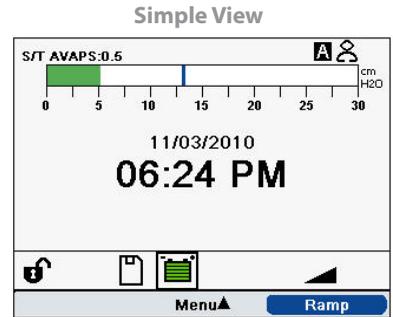
The Monitor screen is divided into several panels, the Monitor panel, Date and Time panel, Patient Accessory panel (if attached), and the Status panel.

In Simple View, the Monitor screen displays the following:

1. Monitor Panel
 - a. Therapy mode
 - b. Flex or AVAPS (if enabled), display next to the therapy mode, along with the value setting
 - c. Patient breath indicator displays below the therapy mode
 - d. Peak pressure symbol appears on the graph according to the maximum Patient Pressure reached during each breath
 - e. A bar graph displays the current pressure level
 - f. If enabled, alarm status indicators for Audio Pause, Apnea, and Circuit Disconnect display in the upper right corner
2. The Date/Time panel shows the current date and time.
3. The Patient Accessory panel displays when an accessory is connected to the device. See the Accessories chapter for more information.
4. The Status panel displays certain symbols that indicate features being used, such as Ramp, as well as battery status.

In Detailed View, the same information is shown, except instead of displaying the Date and Time panel, the screen displays the following measured parameters:

- Patient Pressure
- Exhaled Tidal Volume



- Leak
- Minute Ventilation
- Respiratory Rate
- I:E Ratio

Note: When an oximeter is connected, the current SpO₂ and Heart Rate readings will only display on the Patient Accessory panel if Detailed View is turned on. When Detailed View is turned off, only a heart icon displays to indicate that the oximeter is connected and show the data status. The data values will not display.

5.6 Changing Settings in Provider Menu Access Mode

1. Press the Up key to enter the Menu screens from the Standby or Monitor screens. The Main Menu screen appears.
2. Choose from the following selections on the Main Menu screen:
 - Safely Remove SD Card: This option will appear if an SD card is inserted in the ventilator. Select this option when you want to remove the SD card. When the “Remove SD Card” confirmation message appears, remove the card. If you press the left (cancel) button or don’t remove the card within 30 seconds, the confirmation message will close and the ventilator will continue writing to the card.
 - Settings and Alarms: View and change prescription settings and alarms.
 - Options: View and change device settings, such as Full or Limited Access mode, Detailed View, Language, etc.
 - Alarm Log: View a list of the 20 most recent alarms that have occurred.
 - Event Log: View a list of all events that have occurred, such as ventilator setting changes, ventilator inoperative conditions, alarms, etc.
 - Information: View detailed information about the device, such as the device’s software version and serial number.
 - Clear Patient Data: This option appears on the Setup screen, when the airflow is off and the device is in Standby. It allows you to clear all patient data stored in the device memory and the device SD Card, if inserted. It also clears the Modem SD Card data. However, this will not clear the alarm log. The alarm log must be cleared separately.

5.6.1 Changing Device Settings and Alarms

1. From the Main Menu screen, use the Up/Down key to highlight the Settings and Alarms item.
2. Press the Right key to select Settings and Alarms.

The device settings are listed below, along with the therapy modes in which they are available. The following settings are common to all therapy modes:

- Therapy Mode
- Ramp Length
- System One Humidification
- Humidifier
- Tubing Type Lock
- Tubing Type
- System One Resistance Lock
- System One Resistance
- Circuit Disconnect
- Apnea
- Low Minute Ventilation
- High Respiratory Rate

The settings below are specific to the modes listed in the table.

Therapy Setting	Therapy Modes					
	CPAP	S	S/T	T	PC	AVAPS-AE
Trigger Type	X	X	X		X	X
Auto-Trak	X	X	X		X	X
Auto-Trak [Sensitive]	X	X	X		X	X
Flow Trigger	X	X	X		X	X
Flow Trigger Sensitivity	X	X	X		X	X
Flow Cycle Sensitivity	X	X	X			X
CPAP	X					
Flex Lock		X ³				
Flex		X ³				
AVAPS		X ²	X	X	X	
AVAPS Rate		X ¹	X ¹	X ¹	X ¹	X
Tidal Volume		X ¹	X ¹	X ¹	X ¹	X
IPAP Max Pressure		X ¹	X ¹	X ¹	X ¹	
IPAP Min Pressure		X ¹	X ¹	X ¹	X ¹	
IPAP		X	X	X	X	
EPAP		X	X	X	X	
Breath Rate			X	X	X	X
Inspiratory Time			X	X	X	X ⁴
Maximum Pressure						X
Pressure Support Max						X
Pressure Support Min						X
EPAP Max Pressure						X
EPAP Min Pressure						X
Rise Time Lock		X	X	X	X	X

Therapy Setting	Therapy Modes					
	CPAP	S	S/T	T	PC	AVAPS-AE
Rise Time		X ²	X	X	X	X
Ramp Start Pressure	X	X	X	X	X	
Low Tidal Volume Alarm		X ¹	X ¹	X ¹	X ¹	X

1. Only available when AVAPS is enabled.
2. AVAPS and Rise Time are not available when Flex is enabled.
3. Flex is not available when AVAPS is enabled.
4. Inspiratory time is only available in AVAPS-AE when the breath rate is set between 1 and 40 BPM.

5.6.1.1 Therapy Settings

1. Mode

Change the Mode setting to one of the following therapy modes:

- CPAP
- S
- S/T
- T
- PC
- AVAPS-AE

2. Trigger Type

The device can be set to trigger breaths based on automatic flow thresholds or specific flow settings. Change the Trigger Type to one of the following options: **Auto-Trak**, **Auto-Trak [Sensitive]** or **Flow Trigger**.

If Flow Trigger is selected then two set points will be available for adjustment: Flow Trigger Sensitivity and Flow Cycle Sensitivity.

- **Flow Trigger Sensitivity (Expiration to Inspiration)**

The Flow Trigger Sensitivity may be adjusted from 1 to 9 l/min in 1 l/min increments. The flow trigger initiates when the patient's inspiratory effort creates a flow equal to or greater than the flow sensitivity setting.

- **Flow Cycle Sensitivity (Inspiration to Expiration)**

The Flow Cycle Sensitivity may be adjusted from 10 to 90% in 1% increments. As flow begins to decrease during inspiration, if the patient flow is less than the flow cycle set point, the device will cycle to expiration.

3. CPAP

Increase or decrease the CPAP pressure setting from 4 to 20 cm H₂O in increments of 0.5.

4. Flex Lock

Select Off to allow users to adjust the Flex setting. Or, select On so users cannot adjust their Flex setting.

5. Flex

This setting is not available if AVAPS is enabled. Set Flex to 1, 2, or 3 to enable the setting. A setting of 1 provides a small amount of pressure relief, with higher numbers providing additional relief. Select Off to disable the setting. The patient also has access to this setting, if Flex Lock is off. However, if Flex is "Off", the user cannot adjust it.

6. AVAPS

Select On or Off to enable or disable AVAPS.

7. AVAPS Rate

If AVAPS is enabled, the AVAPS Rate may be adjusted from 0.5 to 5.0 cmH₂O/minute in 0.5 cmH₂O increments.

8. Tidal Volume

If AVAPS is enabled (or in AVAPS-AE mode), you can adjust the target tidal volume from 200 to 1500 ml in 10 ml increments.

9. IPAP Max Pressure

This setting displays if AVAPS is enabled. Increase or decrease the setting from 4 to 40 cm H₂O in increments of 0.5. The IPAP Max Pressure must be equal to or greater than the IPAP Min value.

10. IPAP Min Pressure

This setting displays if AVAPS is enabled. Increase or decrease the setting from 4 to 40 cm H₂O in increments of 0.5. The IPAP Min Pressure must be equal to or greater than the EPAP value, and it must be less than or equal to the IPAP Max Pressure.

11. IPAP

This setting displays if AVAPS is Off. Increase or decrease the Inspiratory Positive Airway Pressure (IPAP) from 4 to 40 cm H₂O in increments of 0.5. You cannot set the IPAP setting lower than the EPAP setting. IPAP is limited to 25 cm H₂O when the Flex feature is enabled.

12. EPAP

Increase or decrease the Expiratory Positive Airway Pressure (EPAP) from 4 to 25 cm H₂O in increments of 0.5.

13. Breath Rate

Use the Breath Rate setting to establish the minimum rate of mandatory breaths that the ventilator will deliver per minute.

Increase or decrease the Breath Rate setting in increments of 1, as follows:

- S/T and PC modes: from 0 to 40 BPM
- T mode: from 4 to 40 BPM
- AVAPS-AE mode: Auto or from 0-40 BPM

Note: Setting the Breath Rate to 0 turns the setting off.

14. Inspiratory Time

Adjust the Inspiratory Time setting from 0.5 to 3.0 seconds in 0.1 second increments. Inspiratory Time is the duration for the inspiratory phase of a mandatory breath.

15. Maximum Pressure

This setting displays in AVAPS-AE mode. AVAPS-AE limits the pressure delivery to the Maximum Pressure setting. Increase or decrease the setting from 6 to 40 cmH₂O in increments of 0.5 cmH₂O.

16. Pressure Support Max

This setting displays in AVAPS-AE mode. Increase or decrease the setting from 2 to 36 cmH₂O in increments of 0.5 cmH₂O. The Pressure Support Max Pressure must be equal to or greater than the Pressure Support Min value.

17. Pressure Support Min

This setting displays in AVAPS-AE mode. Increase or decrease the setting from 2 to 36 cmH₂O in increments of 0.5 cmH₂O. The Pressure Support Min Pressure must less than or equal to the Pressure Support Max value.

18. EPAP Max Pressure

This setting displays in AVAPS-AE mode. Increase or decrease the setting from 4 to 25 cmH₂O in increments of 0.5 cmH₂O. The EPAP Max pressure settings must be equal to or greater than the EPAP Min Pressure value.

19. EPAP Min Pressure

This setting displays in AVAPS-AE mode. Increase or decrease the setting from 4 to 25 cmH₂O in increments of 0.5 cmH₂O. The EPAP Min Pressure must less than or equal to the EPAP Max value.

20. Rise Time Lock

Select Off to allow users to adjust their Rise Time setting or On to prevent users from adjusting the setting.

21. Rise Time

Adjust the rise time from 1 to 6 to find the most comfortable setting for the patient. Rise time is the time it takes for the device to change from EPAP to IPAP. A lower setting indicates a slower rise time while a higher setting means a faster rise time. The patient also has access to this setting if Rise Time Lock is off.

22. Ramp Length

Disable Ramp by selecting Off, or increase or decrease the Ramp Length setting from 5 to 45 minutes in 5-minute increments. When you set the ramp length, the device increases the pressure from the value set on the Ramp Start Pressure screen to the pressure setting over the length of time specified here.

23. Ramp Start Pressure

This setting displays in CPAP, S, T, or PC modes. Increase or decrease the ramp start pressure in increments of 0.5 from 4 cm H₂O to the pressure setting. The patient also has access to this setting, unless the ramp length is set to Off.

24. System One Humidification

Select On to enable or Off to disable this humidification feature. System One humidity control maintains a consistent mask humidity by monitoring and adjusting for changes in room temperature and room humidity.

25. Humidifier

Increase or decrease this setting from 0-5 in increments of 1. When the setting is 0, the humidifier is off. 0 is the lowest humidity setting while 5 is the highest setting.

26. Tubing Type Lock

Select Off to allow users to change the tubing type in user mode. Or, select On so users cannot adjust their tubing type.

27. Tubing Type

This setting allows you to select the correct size diameter tubing that you are using with the device. Select 22 mm for the Philips Respironics 22 mm tubing, or 15 mm for the optional Philips Respironics 15 mm tubing. The patient also has access to this setting if Tubing Type Lock is off.

28. System One Resistance Lock

Select Off to allow users to modify the System One resistance setting. Or, select On so users cannot adjust their System One resistance.

29. System One Resistance

Select from 0-5, or Invasive, to set the System One resistance. Choose "0" to turn System One Resistance compensation off. Choose "Invasive" if you are using an invasive circuit with the device. This setting allows you to adjust the level of air pressure relief based on the specific Philips Respironics mask. Each Philips Respironics mask may have a "System One" Resistance Lock setting. The patient also has access to this setting if System One Resistance Lock is off.

Note: When the device is in AVAPS-AE mode, the invasive option under System One Resistance is not available.

30. Circuit Disconnect Alarm

This setting enables or disables the circuit disconnect alarm. If enabled, an audible alarm will sound when a large, continuous air leak (such as mask removal) has been detected in the circuit.

Select Off to disable the alarm. Or, choose 15 or 60 seconds. Selecting 15 or 60 means that the alarm will sound after the circuit has been disconnected for that amount of time.

31. Apnea Alarm

This setting enables or disables the apnea alarm. If enabled, an audible alarm will sound when an apnea is detected.

Select Off to disable the alarm. Or, increase or decrease the setting from 10 to 30 seconds in 10 second increments. For example, a setting of 10 means that the alarm will sound if the time between spontaneous breaths exceeds 10 seconds.

32. Low Tidal Volume Alarm

Select On to enable or Off to disable the Low Tidal Volume alarm. When the alarm is enabled, an audible indicator sounds if target tidal volume can't be reached. This alarm is only available when AVAPS is enabled (or in AVAPS-AE mode).

33. Low Minute Ventilation Alarm

This setting enables or disables the Low Minute Ventilation alarm. The alarm activates when the calculated minute ventilation is less than or equal to this setting. Select Off to disable this alarm, or increase or decrease the setting from 1 l/min to 99 l/min in increments of 1.

34. High Respiratory Rate Alarm

This setting enables or disables the High Respiratory Rate alarm. The alarm activates when the measured respiratory rate reaches or exceeds this setting. Select Off to disable this alarm, or increase or decrease the setting from 1 BPM to 60 BPM in increments of 1.

5.6.2 Changing Options Menu Settings

1. From the Main Menu screen, use the Up/Down key to highlight the Options item.
2. Press the Right key to select Options.

5.6.2.1 Options Settings

The following settings are available on the Options menu.

1. Menu Access

Select Full or Limited menu access. Full menu access allows home care service providers to access all ventilator and prescription settings. Limited menu access allows users to access only certain settings and does not allow them to change prescription settings.

2. Detailed View

Turn Detailed View On or Off using this setting. Detailed view displays additional therapy information on the Monitor screen.

3. Language

Select the Language that the software will appear in (English, French, German, etc.). The information on the screens will display in the language selected here.

4. Pressure Units

Select the pressure units that will display on the screens. You can choose either cm H₂O or hPa. All pressure units on the screens will display in the unit of measure selected here.

5. Breath Indicator

Select Patient or Machine to choose whether the breath indicator flashes on-screen during a patient-triggered breath or a machine-triggered breath. The default is Machine.

6. Keypad Lock

Select On to enable or Off to disable the Keypad Lock feature.

7. Keypad Backlight

Turn the backlight On or Off using this setting. Whenever you press the  button to begin therapy, the keypad backlight temporarily lights up. Once therapy is being provided, the keypad will be lit according to this Keypad Backlight setting. If the setting is On, the backlight remains on while therapy is provided. If the setting is Off, the backlight remains off while therapy is provided.

Note: The Keypad Backlight setting does not turn the Start/Stop button on or off.

8. Screen Brightness

Adjust the brightness of the screen backlight from 1 – 10, with 1 being the dimmest setting and 10 being the brightest.

9. Screen Saver

You can change the screen saver to reduce power consumption or dim the screen in a dark room. The following settings are available:

- Dim: The display's backlight is decreased, so that the display is still visible but not as bright.
- Breath: The display appears as a black screen, with only the patient breath indicator and manometer visible.
- Off: No screen saver displays and the display's backlight remains lit.

If enabled, the screen saver displays after 5 minutes of no keypad activity. Pressing any button on the device will exit the screen saver. Additionally, any alarm or informational message will also exit the screen saver.

10. Date Format

Select either mm/dd/yyyy or dd/mm/yyyy as the date format that will display on the device screens.

11. Time Format

Select either an AM/PM time format (hh:mm AM) or 24 Hour time format (hh:mm) For example, 2:49 PM or 14:49.

12. Month

The month defaults to the current month. The adjustable range is from 1 (January) – 12 (December).

13. Day

The day defaults to the current day. The adjustable range is from 1 – 31. The maximum value is based on the selected month.

14. Year

The year defaults to the current year. The adjustable range is from 2000 – 2099.

15. Hour

The hour defaults to the current hour. The adjustable range is from 12 AM – 12 PM or 0-23, depending on the selected Time Format.

16. Minute

The minute defaults to the current minute. The adjustable range is from 0 – 59.

17. Blower Hours

Displays the number of hours that the blower has been active since the last time this value was reset. You can reset this value to zero if desired (e.g., each time you give the device to a new patient).

Note: The Machine Hours displayed on the Information screen indicates the total number of hours that the blower has been working over the life of the device. This value cannot be reset.

18. Therapy Hours

This setting displays the total time the patient receives therapy. You can reset this value.

5.6.3 Viewing the Alarm Log

1. From the Main Menu screen, use the Up/Down key to highlight the Alarm Log item.
2. Press the Right key to select Alarm Log.

The alarm log displays the alarms in chronological order with the most recent events displayed first. It lists the 20 most recent alarms or messages that appeared on the device display.

The alarm log can be cleared when in Full Menu access mode, but not when the device is in Limited Menu access mode. Press the Right (Clear) key to clear the alarm log.

Note: Depending on how many alarms have occurred, the alarm log may be up to 4 pages long.

5.6.4 Viewing the Event Log

1. From the Main Menu screen, use the Up/Down key to highlight the Event Log item.
2. Press the Right key to select Event Log.

The event log displays a list of all events that have occurred, in chronological order with the most recent events displayed first. The event log is available in Full Menu access mode but not in Limited Menu access mode.

3. If desired, press the Right (Clear) key to clear the event log.

5.6.5 Viewing Device Information

1. From the Main Menu screen, use the Up/Down key to highlight the Information item.
2. Press the Right key to select Information.

The Information screen provides you with a summary of the current prescription settings, device settings, and system settings. You can use the Up/Down buttons to scroll through the information.

You can also view the Information screen by holding the **Down** key for 5 seconds when in the Monitor screen. This causes the detailed view of the Monitor Screen and the Information Screen to be displayed temporarily.

5.7 Updating Prescriptions Using the SD Card

You can update the patient's prescription using the SD Card. The prescription update can occur either when the ventilator is off or on.

1. Insert an SD Card with a valid prescription into the device. A **“Change Prescription?”** message appears on the display.
2. Select **Yes** to start the prescription update process. Select **No** to cancel the prescription update process and return to the previous display.
3. Select **Page** to review the entire prescription. Select **Cancel** to cancel the prescription update process and return the screen to the initial state before the prescription update started.
4. Once the entire prescription has been reviewed, a screen displays with the option to Cancel or OK the changes. Select **OK** to complete the prescription update and display the Prescription Change confirmation screen. Select **Cancel** to cancel the prescription update process and return the screen to the initial state before the prescription update started.

If the SD card is removed at any time during the prescription update, the process aborts and the screen returns to the initial state before the prescription update started.

A message appears on the display if errors occur during this process. For details on the possible prescription errors, refer to Chapter 8, Troubleshooting.

5.8 Changing Settings in Limited Menu Access Mode

The settings available to users are limited when the device is set to Limited access mode.

1. Press the Up key to enter the Menu screens from the Standby or Monitor screens. The Main Menu screen appears.
2. Choose from the following selections on the Main Menu screen:
 - **Safely Remove SD Card:** This option appears if an SD card is inserted in the ventilator. Select this option when you want to remove the SD card. When the “Remove SD Card” confirmation message appears, remove the card. If you press the Left (Cancel) button or don't remove the card within 30 seconds, the confirmation message will close and the ventilator will continue writing to the card.
 - **My Settings:** View and change certain prescription settings, such as rise time or ramp starting pressure, if these settings were enabled by your provider.

- Options: View and change certain device settings, such as keypad lock or keypad backlighting.
- Alarm Log: View a list of the 20 most recent alarms that have occurred.
- Information: View detailed information about your device, such as the device's software version and serial number.

5.8.1 Changing My Settings Menu Items

1. From the Main Menu screen, use the Up/Down key to highlight the My Settings item.
2. Press the Right key to select My Settings. The My Settings screen will appear.

Follow the general instructions below to navigate and change any of the therapy settings.

1. From the My Settings screen, use the Up/Down button to navigate to the setting you want to change and highlight it.
2. To modify a setting once it is highlighted, press the Right (Modify) button.
3. Use the Up/Down (Edit) button to scroll through the available settings. Press Down to decrease the setting, or press Up to increase the setting.
4. Once you have chosen the setting you want, press the Right (OK) button to save the new setting. Or, if you decide not to change the setting, press the Left (Cancel) button.
5. You can now either navigate to the next setting you want to change using the Up/Down (Navigate) button, or exit the My Settings menu by pressing the Left (Finish) button to return to the Main Menu.

You can change the following settings in the My Settings menu, if they are enabled by your home care service provider. Refer to the Therapy Settings section earlier in this chapter for details about each setting.

- Tubing Type
- Rise Time
- Ramp Start Pressure
- Flex
- System One Resistance
- Humidifier

5.8.2 Options Menu Items in Limited Access Mode

The following settings are included in the Options menu when the device is in Limited access mode. Refer to the Options Settings section earlier in this chapter for details on each setting.

- Keypad Lock
- Keypad Backlight
- LCD Brightness
- Screen Saver
- Date Format
- Time Format
- Month
- Day
- Year
- Hour
- Minute

5.9 Display Symbols

The following table defines symbols that may appear on-screen.

Symbol	Description
	Apnea alarm enabled
AVAPS: 1	AVAPS enabled, and the AVAPS rate setting (e.g., 1)
	Audio Pause is active
	Circuit Disconnect alarm is enabled
	External Battery is full and in use
	External Battery is at 80% capacity
	External Battery is at 60% capacity

Symbol	Description
	External Battery is at 40% capacity
	External Battery is at 20% capacity
	External Battery has less than 20 minutes left
	External Battery has less than 10 minutes left
	External Battery is empty
FLEX: 1	FLEX enabled and FLEX setting (e.g., 1)
	Full Menu Access Mode (Provider mode)
	Humidifier is connected and Humidifier setting (e.g., 1)
	Bad humidifier state (flashing symbol displays)
	Ramp
	SD Card Inserted
	SD Card Error (Bad memory card inserted)
	Writing to SD Card

Note: Refer to the instructions included with your detachable battery for descriptions of the detachable battery symbols that appear on-screen when the battery is installed in the device.

6. Cleaning and Maintenance

6.1 Cleaning the Ventilator

The ventilator's exterior surface and the exterior of the detachable battery pack compartment and battery pack (if using) should be cleaned before and after each patient use and more often if needed.

1. Unplug the device and clean the front panel and exterior of the enclosure as needed using a clean cloth dampened with water and a mild detergent.
2. Inspect the device and tubing for damage after cleaning. Replace any damaged parts.
3. Allow the device to dry completely before plugging in the power cord.

6.1.1 Cleaning and Disinfection for Multiple Users

Warning: If you are using the device on multiple users, discard and replace the bacteria filter each time the device is used on a different person.

When using the device on multiple users, complete the following steps to clean and disinfect the device before each new user.

1. Unplug the device before disinfecting.
2. Disinfect the outside of the device only. Use a cloth with one of the following cleaning agents to clean the exterior of the device:
 - Hydrogen Peroxide, 3%
 - 91% Isopropyl Alcohol
 - Vinegar, 5% acidity
 - Water
 - Chlorine bleach, household, 5.25% sodium hypochlorite, 1 to 5 part reduction with water

- DisCide Towelettes

3. Allow the device to dry completely before plugging in the power cord.

6.2 Cleaning and Replacing the Air Inlet Filter

Under normal usage, you should clean the gray foam filter at least once every two weeks and replace it with a new one every six months. The white ultra-fine filter is disposable and should be replaced after 30 nights of use or sooner if it appears dirty. DO NOT clean the ultra-fine filter.

1. If the device is operating, stop the airflow. Disconnect the device from the power source.
2. Remove the filter(s) from the enclosure by gently squeezing the filter in the center and pulling it away from the device.
3. Examine the filter(s) for cleanliness and integrity.
4. Wash the gray foam filter in warm water with a mild detergent. Rinse thoroughly to remove all detergent residue.
5. Allow the filter to air dry completely before reinstalling it. If the foam filter is torn or damaged, replace it. Only Philips Respironics-supplied filters should be used as replacement filters.
6. If the white ultra-fine filter is dirty or torn, replace it.
7. Reinstall the filters, inserting the white ultra-fine filter first if applicable.

6.3 Cleaning the Reusable Tubing

1. Clean the tubing daily.
2. Disconnect the flexible tubing from the device.
3. Gently wash the tubing in a solution of warm water and a mild detergent.
4. Rinse thoroughly and air dry.

6.4 Service

The device does not require routine servicing.

7. Accessories

There are several accessories available for your BiPAP A40 device. Contact your home care service provider for additional information. When using the accessories, always follow the instructions included with them.

7.1 Humidifier

You can use the provided integrated humidifier with your device. A humidifier may reduce nasal dryness and irritation by adding moisture to the airflow.

When the device is in Standby, if the integrated humidifier is connected and the humidifier parameter setting is greater than 0, the Left key is labeled **Preheat**. Selecting this key initiates the humidifier preheat function and changes the humidifier icon to the “heating active” icon. Selecting this key again while the preheat function is active ends the pre-heat function. After the heater plate reaches the desired temperature, the Preheat feature automatically shuts off.

7.2 SD Card

The system comes with an SD card inserted in the SD card slot on the back of the device to record information for the home care service provider. Your provider may ask you to periodically remove the SD card and send it to them for evaluation.

To remove the SD card:

1. Select the “Safely Remove SD Card” option from the main menu
2. After the “Remove SD Card” confirmation message appears, remove the card.

To write an Event Log to the SD card:

1. Access the Setup screen in Full Menu Access mode.

2. Select the “Write Event Log to SD Card” option from the main menu.
 - a. While writing is in progress, a confirmation box with the message “Writing in Progress” appears.
 - b. When writing is complete, a confirmation box with the message “Writing Successful” appears.
 - c. If the write could not happen, a confirmation box with the message “Writing Failed” appears.

Note: *The SD card does not need to be installed for the device to work properly.*

Note: *Use only SD cards available from Philips Respironics.*

For details on updating a prescription using the SD card, see Chapter 5.

7.3 Supplemental Oxygen

Oxygen may be added anywhere in the patient circuit provided that a pressure valve is placed in-line between the device and the oxygen source. Refer to the oxygen warnings in Chapter 1 when using oxygen with the device.

7.4 Nurse Call System

You can use an institutional Nurse Call system with your device. There are several Philips Respironics cables available to connect a nurse call system to the ventilator. Refer to the instructions included with your cable assembly for details.

7.5 Remote Alarm Unit

You may use a Philips Respironics Remote Alarm unit with your device. There is a dedicated adapter cable assembly for connecting the device to the Remote Alarm unit. Refer to the instructions included with your Remote Alarm unit and adapter cable assembly for details.

7.6 Oximeter

You can connect the recommended oximetry device to the ventilator to monitor SpO₂ and heart rate levels. When an oximeter is connected, the Patient Accessory panel appears on the Standby and Monitor screens. A heart icon will indicate that the oximeter is connected and show the data status. When the device has Detailed View turned on, the panel also displays the current SpO₂ and Heart Rate readings. If bad data is being read from the oximeter, dashes appear next to the SpO₂ and Heart Rate indicators.

Note: Use only the oximetry device available from Philips Respironics.

7.7 Philips Respironics DirectView Software

You can use the Philips Respironics DirectView software to download the prescription data from the SD card to a computer. DirectView can be used by clinicians to receive and report stored data from the SD card. DirectView does not perform any automatic scoring or diagnosing of a patient's therapy data.

7.8 Philips Respironics Encore Software

You can use the Philips Respironics Encore software to download prescription data from the SD card to a computer. Encore can be used by clinicians to receive and report stored data from the SD card.

7.9 Carrying Case

A carrying case is available for transporting your ventilator. When traveling, the carrying case is for carry-on luggage only. The carrying case will not protect the system if it is put through checked baggage.

7.10 Detachable Battery and Detachable Battery Module

A rechargeable Lithium-Ion detachable battery is available for the BiPAP A40 device. You can connect the battery to the device and recharge it using the Detachable Battery Module. See the instructions included with your detachable battery and Detachable Battery Module for more information.

7.11 BiPAP A Series Roll Stand

There is a roll stand available for use with your BiPAP A40 device. Please see the instructions included with your roll stand for more information.

7.12 In-Use Bag

An In-Use bag is available for use with your BiPAP A40 device. The bag is not for use with the humidifier. The bag is designed to attach the ventilator to a wheelchair. Please see the instructions included with the in-use bag for more information.

8. Troubleshooting

This chapter lists some of the problems you may experience with your device and possible solutions to those problems.

Question: Why isn't my device turning on? The backlight on the buttons does not light.

Answer: If you are using AC power:

- Check the outlet and verify that the device is properly plugged in.
- Make sure there is power available at the outlet and that the AC power cord is connected correctly to the power supply and the power supply cord is securely connected to the device's power inlet.

If you are using an external power source:

- Make sure your DC power cord and battery adapter cable connections are secure.
- Check your battery. It may need recharged or replaced.
- If the problem persists, check the DC cord's fuse following the instructions supplied with your DC cord. The fuse may need to be replaced.

If the problem still occurs, contact your home care service provider.

Question: Why isn't the airflow turning on?

Answer: Make sure the device is powered correctly.

- Verify that you are not in Standby mode. The airflow remains off while in Standby.
- Press the Therapy button to ensure that therapy is on.
- If problem persists, contact your home care service provider for assistance.

Question: Why is the airflow much warmer than usual?

Answer: The air filters may be dirty. Clean or replace the air filters.

- The temperature of the air may vary somewhat based on your room temperature. Make sure the device is properly ventilated. Keep it away from bedding or curtains that could block the flow of air around the device.
- Make sure the device is away from direct sunlight and heating equipment.
- If using the humidifier with the device, check the humidifier settings. Refer to the humidifier instructions to make sure the humidifier is working properly.

Question: Why does the mask feel uncomfortable?

Answer: This could be due to improper headgear adjustment or improper mask fitting.

- Make sure you are properly fitted with the correct size mask.
- If the problem continues, contact your home care service provider to be fitted with a different mask.

Question: Why did my prescription change fail when I updated my prescription using the SD card?

Answer: There are three possible error messages that will appear if the prescription change fails when using an SD card:

- Prescription Change Failed: Remove the card and have the prescription replaced with a valid prescription.
- Prescription Failed – Serial Number: Remove the card and have the prescription replaced with the prescription with the correct serial number.
- Prescription Failed – Version: Remove the card and have the prescription replaced with a prescription in the correct version.

Question: Why isn't my detachable battery charging when it is inserted into the Detachable Battery Module and the ventilator is running on AC power?

Answer: The battery may not charge if the device is too hot or too cold or is operating at an ambient temperature outside of the specified valid range. Or, the device may not have enough power to charge the battery if the humidifier is in use.

- Make sure the device is not too close to a heat source.
- Ensure the cooling air vents are not blocked.
- Bring the ventilator to ambient room temperature.
- Allow the battery to charge while the device is in Standby or while the airflow is on and humidifier is off.
- Use the optional Philips Respironics Detachable Battery Charger to charge your battery.
- If the problem continues, contact an authorized service representative or Philips Respironics to have the device serviced. Please have the model number and serial number ready when you call. If you are a patient, please contact your home care service provider.

9. Technical Specifications

Environmental

	Operating	Storage
Temperature	5° C to 35° C (41° F to 95° F)	-20° C to 60° C (-4° F to 140° F)
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure	101 kPa to 77 kPa (approximately 0-2286 m/0-7500 ft)	N/A

Physical

Dimensions: 8.75" W x 7.25" L x 4.25" H

Weight: Approximately 4.4 lbs

Standards Compliance

This device is designed to conform to the following standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 10651-6: Lung ventilators for medical use -- Particular requirements for basic safety and essential performance -- Part 6: Home care ventilatory support devices
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing (Biocompatibility)
- RTCA/DO-160F section 21, category M; Emission of Radio Frequency Energy

Electrical

AC Voltage Source:	100 to 240 VAC, 50/60 Hz, 1.2 A
DC Power Source:	12 VDC, 5.0 A (External Battery) 24 VDC, 4.2 A (Power Supply)
Type of Protection Against Electric Shock:	Class II (To be used with external Class II power supply only)
Degree of Protection Against Electric Shock:	Type BF Applied Part
Degree of Protection against Ingress of Water:	Drip Proof, IP22
Mode of Operation:	Continuous

SD Card and SD Card Reader

Use only SD cards and SD card readers available from Philips Respironics, including the following:

SanDisk® Card Reader/Writer - SanDisk ImageMate - REF SDDR-99-A15

Control Accuracy

Parameter	Range	Accuracy
IPAP	4 – 40 cm H ₂ O	± 2.5 cm H ₂ O*
EPAP	4 – 25 cm H ₂ O	± 2.5 cm H ₂ O*
CPAP	4 – 20 cm H ₂ O	± 2.5 cm H ₂ O*
Breath rate	0 to 40 BPM	greater of ± 1 BPM or ±10% of setting
Inspiration time	0.5 to 3 seconds	± (10% of setting + 0.1 second)

Specifications listed are based on using a standard patient circuit (Philips Respironics 15 or 22 mm tubing; Whisper Swivel II).

*Pressure measured at the patient connection port with or without the integrated heated humidifier (no patient flow).

Displayed Parameter Accuracy

Parameter	Accuracy	Resolution	Range
Estimated Leak Rate	N/A	0.1 LPM	0 to 175 LPM
Exhaled Tidal Volume	Greater of ± 20 ml or $\pm 20\%$ of reading	1 ml	0 to 2000 ml
Respiratory Rate	Greater of ± 1 BPM or $\pm 10\%$ of reading	1 BPM	0 to 60 BPM
Exhaled Minute Ventilation	Calculation based on Exhaled Tidal Volume and Respiratory Rate	0.1 LPM	0 to 25 LPM
Estimated Patient Pressure	± 2.5 cmH ₂ O	0.1 cmH ₂ O	0 to 40 cm H ₂ O
I:E Ratio	Calculation based on Inspiratory time and Expiratory time	0.1	9.9:1 to 1:9.9

* Displayed parameter accuracies are based on ambient bench top conditions at an altitude of nominally 380 meters. All flow based parameters are expressed in volumetric flow.

** Pressure measured at the patient connection port with or without the integrated heated humidifier (no patient flow).

Sound

Minimum Alarm Sound Level: 60 dB(A)

Note: *The sound level may be reduced when the device is used in the In-Use bag.*

Breathing Resistance During Power Fail or Fault Conditions

The resistance measurements include the complete system, with humidifier, outlet bacteria filter, and patient circuit.

Patient Flow (LPM)	Expiratory Resistance* (cm H ₂ O)	Inspiratory Resistance* (cm H ₂ O)
30	<1.5	<1.5
60	<3.7	<4.1

Disposal

Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC. Dispose of this device in accordance with local regulations.

10. EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains Not Applicable	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical home or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 26 MHz to 2.5 GHz	<p>$d = 1.2 \sqrt{\frac{P}{f}}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{\frac{P}{f}}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (meters)			
	150 kHz to 80 MHz outside ISM Bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM Bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

BiPAP A40

user manual

Limited Warranty

Respironics, Inc. warrants that the **BiPAP A40** system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Accessories and replacement parts, including, but not limited to, circuits, tubing, leak devices, exhaust valves, filters and fuses, are not covered under this warranty.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties – including any warranty of merchantability or fitness for the particular purpose – are limited to two years. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

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