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BiPAP AVAPS

USER MANUAL



BIPAP AVAPS user manual

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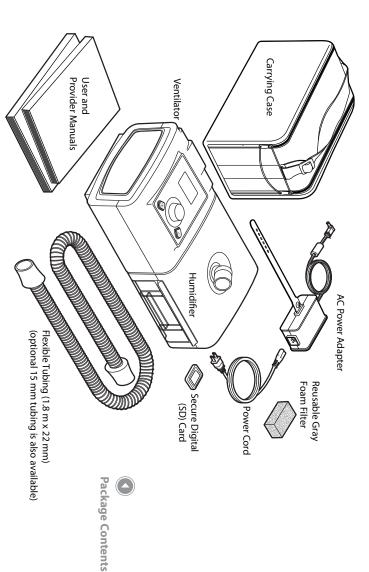
user manual

1. Introduction

This chapter provides an overview of the device.

Package Contents

(e.g., humidifier) are optional accessories that may not be packaged with the device. The BiPAP AVAPS system may include the following components. Some components



Intended Use

hospital or home. with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. This device may be used in the weighing over 66 lbs (30 kg) and pediatric patients 7 years or older and weighing over 40 lbs (18 kg) The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to treat adult patients

Warnings and Cautions

Caution: US federal law restricts this device to sale by or on the order of a physician.



Warnings

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

(
Device Usage	This device is not intended for life support. The device provides Positive
	Pressure Ventilation and is indicated for assisted ventilation. The device
	does not provide ventilation with guaranteed $V_{\scriptscriptstyle T}$ delivery. Patients requiring
	ventilation at a predetermined V _T are not candidates for Pressure Support
	ventilation.
Personnel	This manual serves as a reference. The instructions in this manual are not
Qualifications	intended to supersede your health care professional's instructions regarding
	the use of the device.
	The prescription and other device settings should only be changed on the
	order of the supervising physician.
	The operator should read and understand this entire manual before using
	the device.
Patient	The device should be used only with masks and connectors recommended
Circuits	by Philips Respironics or with those recommended by the health care
	professional or respiratory therapist. A mask should not be used unless the
	device is turned on and operating properly. The exhalation port(s) associated
	with the mask should never be blocked.
	Explanation of Warning: The device is intended to be used with special
	masks or connectors that have exhalation ports to allow continuous flow of
	air out of the mask. When the device is turned on and functioning properly,
	new air from the device flushes the exhaled air out through the mask
	exhalation port. However, when the device is not operating, enough fresh air
	will not be provided through the mask, and exhaled air may be rebreathed.

in the presence of an open flame. Do not connect the device to an unregulated or high pressure oxygen source. Do not use the device near a source of toxic or harmful vapors.
the mask may reduce the inspired oxygen concentration to less than the expected concentrations. Appropriate patient monitoring should be implemented. Oxygen supports combustion. Oxygen should not be used while smoking or
If administering fixed-flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary depending on the pressure setting, patient breathing pattern, and leak rate. Substantial leaks around
Supplemental oxygen cannot be used with the heated tube accessory. The safety pressure valve is not compatible with this set-up, and could result in a fire hazard.
When using oxygen with this system, a Philips Respironics Pressure Valve (REF 302418) must be placed at the air outlet port. Failure to use the pressure valve could result in a fire hazard. Refer to the pressure valve instructions for use for proper use.
Oxygen When using oxygen with this system, the oxygen supply must comply with
rebreathing of exhaled air. Verify the operation of the Patient Disconnect alarm with any changes in the
The device does not have an alarm to detect occlusion of the exhalation port. Before each use, inspect the patient circuit to verify that the port is
At low EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
is the case with most ventilators with passive exhalation ports, when power is lost, sufficient air will not be provided through the circuit, and exhaled air may be rebreathed.
Patient In the event of a power or device failure, audible and visual alarm signals will activate. The device must be disconnected from the patient immediately. As

Operating Temperatures	Do not use this device if the room temperature is warmer than 95° F (35° C). If the device is used at room temperatures warmer than 95° F, the temperature
	of the airflow may exceed 109° F (43° C). This could cause irritation or injury to your airway.
	Do not operate the device in direct sunlight or near a heating appliance
	because these conditions can increase the temperature of the air coming out
Bacteria Filter	If the device is used by multiple persons (such as rental devices), Philips
	Respironics recommends that a low-resistance, main flow bacteria filter (Part
	Number 342077) be installed in-line between the device and the circuit
	tubing to prevent device contamination.
Improperly	If you notice any unexplained changes in the performance of the device, if it
Functioning	is making unusual sounds, if it has been dropped or mishandled, if water is
Ventilator	spilled into the enclosure, or if the enclosure is cracked or broken, disconnect
	the power cord and discontinue use. Contact your home care provider.
	The use of accessories, transducers and cables other than those specified,
	with the exception of transducers and cables sold by Philips Respironics
	as replacement parts for internal components, may result in increased
	Ellissions of decleased illinutility.
	This device should not be used adjacent to or stacked with other equipment
	and that if adjacent or stacked use is necessary, the device should be observed
	to verify normal operation in the configuration in which it will be used.
	Operation of the device may be adversely affected by:
	 Electromagnetic fields exceeding the level of 3 V/m in the test conditions of EN 60601-1-2
	 Operation of high frequency (diathermy) equipment
	 Defibrillators, or short wave therapy equipment
	Radiation (e.g., x-ray, CT scan)
	 Magnetic fields (e.g., MRI)
	 Mobile RF communication equipment
	 The use of accessories, transducers and cables other than
	those specified, with the exception of transducers and cables sold by Philips Respironics
Power Cord	Be sure to 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.
	This device is activated when the power cord is connected.

Maintenance	Never operate the device if any of the parts are damaged or if it is not
	working properly. Have any damaged parts replaced before continuing use.
	Electrical cords, cables, and the power supply device should be periodically
	inspected for damage or signs of wear. Replace any damaged parts before using.
	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.
Cleaning	To avoid electric shock, unplug the device before cleaning it.
	Do not immerse the device in any fluids or spray the device with water or
	cleaners. Clean the device with a cloth dampened with an approved cleaner.
Humidifier	For safe operation, the humidifier must always be positioned below the
	breathing circuit connection at the mask and the air outlet on the device.
	The humidifier must be level for proper operation.



A Cautions

A caution indicates the possibility of damage to the device.

Electrostatic	Pins of connectors should not be touched. Connections should not be
Discharge	made to these connectors unless ESD precautionary procedures are
(ESD)	used. Precautionary procedures include methods to prevent build-up of
	electrostatic charge (e.g., air conditioning, humidification, conductive floor
	coverings, non-synthetic clothing), discharging one's body to the frame of
	the equipment or system or to earth or a large metal object, and bonding
	oneself by means of a wrist strap to the equipment or system or to earth.
	Before operating the device, ensure that the SD card cover is replaced
	whenever any of the accessories such as the Link Module or modem are not
	installed. Refer to the instructions that came with your accessory.
	Do not use antistatic or conductive hoses or conductive patient tubing with
	the device.
EMC	All Medical Electrical Equipment needs special precautions regarding
Information	EMC and needs to be installed and put into service according to the EMC
	information provided in Chapter 7: EMC Information.
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.
	Do not operate the device outside of the operating temperature range
	shown in the Specifications chapter.

Extension Cords	Do not use extension cords with this device.
Device	Do not place the device in or on any container that can collect or hold water.
Placement	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.
Air Filter	A properly installed, undamaged reusable foam inlet filter is required for
	proper operation.
	Operating the device with a dirty filter may keep the system from working
	properly and may damage the device.
	A dirty inlet filter may cause high operating temperatures that may affect
	device performance. Regularly examine the inlet filter as needed for
	integrity and cleanliness.
	Never install a wet filter into the device. You must ensure sufficient drying
	time for the cleaned filter.
Cleaning	Do not immerse the device in liquid or allow any liquid to enter the
	enclosure or inlet filter.

Notes

- Additional warnings, cautions and notes are located throughout this manual.
- Please see the "Limited Warranty" section of this manual for information on warranty coverage.

Contraindications

following conditions apply to you, consult your physician before using the device: The device is contraindicated on patients without a spontaneous respiratory drive. If any of the

- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Diagnosed with acute sinusitis or otitis media
- Allergy or hypersensitivity to the mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

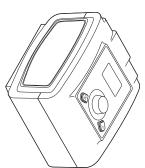
H₂O is possible. should understand that this device can deliver the pressure ranges indicated in the Control When assessing the relative risks and benefits of using this equipment, the health care professional Accuracy table in chapter 6. In the event of certain fault conditions, a maximum pressure of 40 cm

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 noninvasive positive pressure therapy:
- Ear discomfort
- Conjunctivitis
- Skin abrasions due to noninvasive interfaces
- Gastric distention (aerophagia)

System Overview

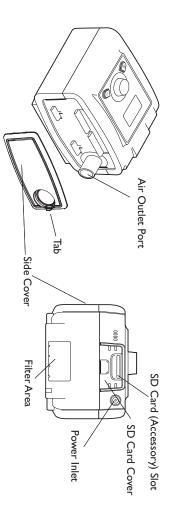
The BiPAP AVAPS device is intended to augment patient breathing by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This therapy is known as Bi-level 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 a single pressure level, known as CPAP (Continuous Positive Airway Pressure).



comfort feature provides increased pressure relief during the expiratory phase of breathing, and the air pressure will gradually increase until the prescription pressure is reached. Additionally, the Flex comfortable. The ramp function allows you to lower the pressure when trying to fall asleep. The When prescribed, the device can also provide features to help make your therapy more AVAPS feature helps you maintain a target V $_{_{
m T}}$

purchase any accessories not included with your system. Several accessories are also available for use with the device. Contact your home care provider to

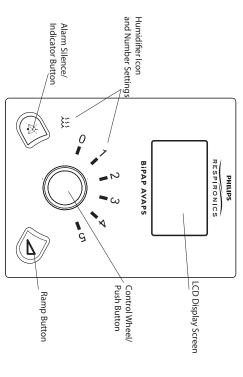
The figure below illustrates some of the device features, described in the table below.



Feature	Description
Air Outlet Port	Connect the flexible tubing here. Note: Heated Tubing should only be connected to the Air Outlet Port of the compatible System One Heated Humidifier and not to the Air Outlet Port of the therapy device.
SD Card (Accessory) Slot	If applicable, insert the optional SD card here.
SD Card Cover	If applicable, the optional accessories such as a Link Module or Modem can be installed here. Refer to the instructions supplied with your accessory. When not using an accessory, this cover must be in place on the device.
Power Inlet	Connect the power supply cord here.
Filter Area	A reusable, gray foam filter must be placed in the filter area to screen out normal household dust and pollen.
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.

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. The startup screen is shown temporarily when the device is first powered.
Humidifier lcon	This Icon lights up (different colors) when the optional humidifier and/or heated tube is attached and heat is being applied. White means classic
	humidification is selected. Blue means System One humidification is selected. Orange means the heated tube is attached. Please refer to the humidifier user manual for more information.
Humidifier Numbers	The humidifier number settings are only visible when the humidifier is attached and therapy is active. You can use the control wheel to change
	the number settings for the humidifier. When the heated tube is being used with the humidifier, these numbers will control the heated tube temperature setting.
Control Wheel/ Push Button	Turn the Wheel to toggle between options on the screen. Press the Wheel to choose an option. Primary function is to turn airflow on/off. Pressing the Wheel also resets alarms.
Ramp Button	When the airflow is on, this button allows you to activate or restart the ramp function. This button lights up when therapy is active or during specific alerts.
Alarm Silence/ Indicator Button	Silences the audible portion of the alarm for a period of time and indicates an alarm condition.

Available Therapy Modes

The table below describes the therapy modes available on the device:

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 triggers machine-triggered breaths based on a set breath rate and cycles machine-cycled breaths based on a set inspiratory time if the patient does not spontaneously breathe within a set time.
Т	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. Therefore, the inspiratory time may be triggered by the patient or by the device, but IPAP will be pressure-limited with a set cycle time determined by the Inspiratory Time setting.

Available Therapy Features

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

AVAPS

not aware of breath to breath pressure changes. value gradually. This occurs over several minutes. The rate of change is slow, so that the patient is minimum (IPAP Min) and maximum (IPAP Max) settings. AVAPS averages $V_{\scriptscriptstyle T}$ and changes the PS (PS) provided to the patient. The AVAPS feature adjusts PS by varying the IPAP level between the tidal volume (Tidal Volume setting in the AVAPS) by automatically controlling the pressure support PC, and T modes. It helps patients maintain a tidal volume (V_{τ}) equal to or greater than the target If enabled, Average Volume Assured Pressure Support (AVAPS) is a feature available in the S, S/T,

achieved, the Low Tidal Volume alarm activates. if the target tidal volume is exceeded. If IPAP Max is reached and the target tidal volume is not Conversely, as patient effort increases, AVAPS will reduce PS. IPAP will not fall below IPAP Min, even The IPAP level will not rise above IPAP Max, even if the target tidal volume is not reached As patient effort decreases, AVAPS automatically increases PS to maintain the target tidal volume.

Bi-Flex Comfort Feature

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

Ramp

patients can fall asleep more comfortably. If enabled, the device is equipped with a linear ramp function. The Ramp feature will reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so

Rise Time

comfortable setting for the patient. Rise time cannot be adjusted when Bi-Flex is enabled. rise time while a setting of 6 is the slowest. Providers should adjust the rise time to find the most pressure increase that will take place at the beginning of inspiration. A setting of 1 is the fastest pressure setting. Rise time levels of 1, 2, 3, 4, 5, or 6 progressively reflect slowed response of the amount of time it takes the device to change from the expiratory pressure setting to the inspiratory If enabled, the device provides a feature called Rise Time in S, S/T, T, and PC modes. Rise time is the

Symbols

The following symbols appear on the device and power supply.

Symbol	Description
1	Consult accompanying instructions for use.
1	AC Power
;]	DC Power
IP22	Drip Proof Equipment
	Caution, consult accompanying documents.
	ESD Warning Symbol
	Class II (Double Insulated)
≫	Type BF Applied Part
	For indoor use only
\otimes	Do not disassemble
*	For Airline Use. Complies with RTCA DO-160F section 21, category M.

80W REF	-CE 60W REF	R ONLY
Use only with the Heated Tubing compatible 80W power supply 1091399. (can also be used when Heated Tubing is not in use)	Use only with the standard 60W power supply 1091398. (not for use with Heated Tubing)	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

How to Contact Philips Respironics

To have your device serviced, contact your home care provider. If you need to contact Philips Respironics directly, call the Customer Service department at 1-724-387-4000 or 1-800-345-6443.

You can also use the following addresses:

Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668

BIPAP AVAPS

2. Device Setup

Installing the Air Filter

insert it into the filter area. you receive the device, you must install it before using the device. To install the gray foam filter, One reusable gray foam filter is supplied with your device. If your filter is not already installed when normal household dust and pollen. It must be in place at all times when the device is operating. The device uses a gray foam filter that is washable and reusable. The reusable filter screens out

Where to Place the Device

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

Connecting the Breathing Circuit

To use the system, 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 Whisper Swivel II) port, or Philips Respironics interface with a separate exhalation device (such as the
- Philips Respironics 1.83 m (6 ft.) 22 mm flexible tubing or the optional 15 mm flexible tubing
- Philips Respironics headgear (for the mask)

Complete the following steps to connect your breathing circuit to the device:

1. Connect the flexible tubing to the air outlet on the side of the device.

of the bacteria filter. **Note**: If required, connect a bacteria filter to the device air outlet, and then connect the flexible tubing to the outlet

functional and deliver therapy. **Note**: When using the bacteria filter, the device performance may be affected. However, the device will remain

with the bacteria filter installed in-line, but at the opposing end of the tubing **Note**: When using the optional heated tubing, attach the heated tubing to the humidifier's modified air outlet port,

- Connect the tubing to the mask. Refer to the instructions that came with your mask
- $\dot{\omega}$ Attach the headgear to the mask if necessary. Refer to the instructions that came with your
- designed to exhaust CO_2 from the patient circuit. Do not block or seal the ports on the exhalation device. Warning: The exhalation device (Whisper Swivel II) or exhalation port (on masks with an integrated exhalation port) is

with a safety (entrainment) valve. You must ensure that the entrainment valve is functioning properly. **Warning:** If you are using a full face mask (a mask covering both your mouth and your nose), the mask must be equipped

Supplying AC Power to the Device

Complete the following steps to supply AC power to the device:

Plug the socket end of the power cord (included) into the power supply (also included).

the 80W power supply. Important! When you are using Heated Tubing with the compatible System One Heated Humidifier, you must use

- 5 Plug the pronged end of the power cord into an electrical outlet that is not controlled by a wall switch.
- $\dot{\omega}$ Plug the power supply cord's connector into the power inlet on the back of the ventilator.
- 4. Ensure that all connections are secure.

Important! To remove AC power, disconnect the power supply cord from the electrical outlet.

Note: See Chapter 4 for instructions on using DC Power.

Display Symbols

The following symbols may display on the device in place of text if the display language selected by your home care provider is "lcon."

		// 合 Clear Patient Data (in progress)		// 凸 ✓ Clear Patient Data Successfully	Comfort Setting	hPa/cmH ₂ O	Humidifier, Humidity Level	(i) Information	IDA D - IPAP Max	IFAF A	
ature	т По 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	(in progress)	. Failed		Successfully	Successfully	Successfully	Successfully lity Level	Successfully Jity Level	Successfully Jity Level	Successfully lity Level

<u> </u>		Leak Machine Hours Minute Ventilation Mode No No No Settings Available Off (disabled) On (enabled) Patient Disconnect Provider Mode Ramp Start Pressure Ramp Time Reset Therapy Hours Reset Blower Hours Reset Blower Hours Reset Blower Hours Respiratory Rate Rise Time Rise Time Lock SD Card Corrupted
	○ PAP	Mode
	×	No
	*	No Settings Available
		Off (disabled)
	יבן	On (enabled)
	Do	Patient Disconnect
	a)	Provider Mode
		Ramp Start Pressure
	1	Ramp Time
	<u></u> ⊕.	Reinsert SD Card
		Reset Therapy Hours
	№ ⊕	Reset Blower Hours
	RR	Respiratory Rate
	\	Rise Time
	1	Rise Time Lock
	△ [[]	SD Card Corrupted
	\triangle	SD Card Full

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res (pelection committed)	Tube Temperature	Tubing Type Lock	Tubing Type	Exhaled Tidal Volume	Tidal Volume	Ventilator Inoperative	Timed Inspiration	Therapy Hours	Therapy (Blower On)	Therapy (Blower Off)	System One Resistance Lock	System One Resistance	System One Humidification	Setup Parameter Display	Setup	SD Card Removed	SD Card is Write-Protected	SD Card Inserted: Prescription Rejected	SD Card Inserted: Prescription Accepted	SD Card Inserted: Writing Successful	SD Card Inserted: Writing in Progress	Description

Navigating the Device Screens

you back to the previous screen. option or setting that is highlighted. If you choose "Back" or the 🛨 icon on any screen, it will take Turn the Wheel to toggle between options and settings on the screen. Press the Wheel to choose an

depending on your prescription settings Note: The screens shown in this manual are examples only. Information on your device screens may be different

Note: Your device will either display in icon mode or text mode. Examples will be shown in both modes

Starting and Stopping the Device

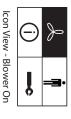
Supply power to the device.

which shows the total blower hours for the device in hours and minutes. current software version number. The Blower hours screen (\bigoplus in icon mode) will then appear, The first screen to display will be the Philips Respironics logo, followed by the screen showing the

The Main Menu screen appears, shown below







con View - Blower Off

Text View

Put on your mask assembly.

Note: If you are having trouble with your mask, refer to the instructions supplied with the mask

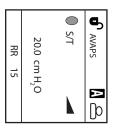
- 4. Turn the Wheel to toggle between the four options. Highlight Therapy or the igoplus icon. Press the Wheel to turn on the airflow and begin therapy. The Monitor Pressure screen will appear, described in detail in the next section.
- 5 If the device does not operate accordingly, contact your home care provider, as the alarm Verify that the device beeps and the alarm and ramp LEDs light up each time therapy is started. system may not be fully functional.
- 9 and headgear until the air leak stops. See the instructions provided with your mask for more information. Make sure that no air is leaking from your mask into your eyes. If necessary, adjust the mask

soon as possible. **Note**: A small amount of leak is normal and acceptable. Correct large mask leaks or eye irritation from an air leak as

- 7. may reduce tension on the mask. If you are using the device in a bed with a headboard, try placing the tubing over the headboard. This
- $\dot{\infty}$ Main Menu. Press and hold the Wheel for approximately 2 seconds to turn off therapy and return to the
- 9. accordingly, contact your home care provider, as the alarm system may not be fully functional. Verify that the device beeps when therapy is stopped. If the device does not operate

Monitor Pressure Screen

Pressure screen appears. From the Main Menu, if you select Therapy and then press the Wheel, the following Monitor



The Monitor Pressure screen displays the following items:

- Pressure
- Therapy Mode (CPAP, S, S/T, T, or PC)
- Timed Breath Indicator (
)
- Icon Bar
- Measured Parameters

Note: The Ramp symbol will also appear on the display if Ramp is active.

screen. Refer to the instructions provided with the accessory for more information. **Note**: If an accessory is attached to the therapy device, additional symbols may appear on the Monitor Pressure

conditions described in the following table exist. The top of the display shows a group of status symbols. The symbols will only appear if the

Symbol	Description
a	The Provider Access symbol indicates the device is in Provider mode.
AVAPS	The AVAPS symbol displays only when the AVAPS therapy feature is enabled by the provider.
FLEX	The Flex symbol displays only when the Bi-Flex therapy feature is enabled by the provider.
A	The Apnea alarm symbol displays only when the Apnea alarm is enabled by the provider.
Do	The Patient Disconnect symbol displays only when the Patient Disconnect alarm is enabled by the provider.

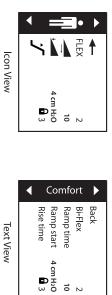
The bottom section of the display shows additional measured parameters which may include:

- Respiratory Rate (RR)
- Tidal Volume in milliliters (ml)
- Minute Ventilation (Min Vent) in liters per minute (lpm)
- Leak in lpm

Note: The measured parameters display one at a time on-screen.

Changing the Comfort Settings

and press the Wheel, the Comfort Settings screen below appears. professional may prescribe for you. From the Main Menu, when you highlight the Comfort option Your device is equipped with optional Flex, Ramp Time, and Rise Time features that your health care



Note: If no comfort settings are available, the Comfort Settings screen displays "No Settings Available."

cannot adjust any settings that are locked. Note: If your home care provider has locked a comfort setting, a lock symbol ($lackbox{n}$) appears next to the value. You

Flex Setting

relief, with higher numbers providing additional relief. therapy. Your home care provider can enable, lock, or disable this feature. When your provider increase or decrease the setting from 1 to 3. A setting of 1 provides a small amount of pressure enables Flex, a level will already be set for you on the device. If this is not comfortable, you can The Flex comfort setting allows you to adjust the level of pressure relief that you feel during

Ramp Time Setting

is 0 to 45 minutes This enables you to modify the Ramp time setting in 5 minute increments. The range for this setting

Ramp Start Setting

The device is equipped with an optional ramp feature that your home care provider can enable or more comfortably. increases (ramps) the pressure until your prescription setting is reached, allowing you to fall asleep disable. This feature reduces the air pressure when you are trying to fall asleep and then gradually

Note: If the ramp feature is disabled, nothing will happen when you press the Ramp button.

enabled, the Ramp icon () appears on the Monitor Pressure screen. the top of the device. Use the Ramp button as often as you like during the night. When Ramp is If ramp is enabled on your device, after you turn on the airflow, you can press the Ramp button on

CPAP setting (if in CPAP therapy mode) or the EPAP setting (for all other therapy modes) The Ramp Start pressure setting can be increased or decreased from 4 in increments of 1 to the

Rise Time Setting

comfort. A setting of 1 is the fastest rise time, while 6 is the slowest. for you, you can adjust the rise time from 1 to 6 to find the setting that provides you with the most Rise time is the time it takes for the device to change from EPAP to IPAP. If rise time is prescribed

Note: If Flex is enabled, the rise time setting will be fixed at 3.

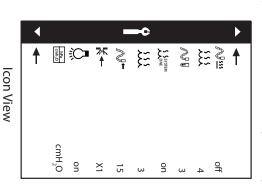
Language

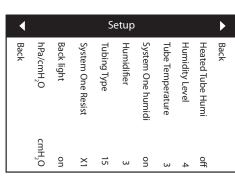
Mode" on the interface. mode". You can also turn off (0) text mode which means the device will display the "Icon This feature allows you to choose which language to display on the interface when in "Text

Note: Both "Icon Mode" and English "Text Mode" are shown throughout this guide for your reference

Setup Screen (— c)

screen will appear. The user can change settings in the Setup menu. From the Main Menu, highlight "Setup" or the icon and press the wheel. The following Setup





horizontally across the screen when highlighted. the screen will slide up and down accordingly. If the text is too long to completely fit on the screen, it will scroll **Note**: The screen will only show a few lines at a time. As you rotate the wheel to toggle over different options

Text View

The following options appear on the Setup screen:

Heated Tube Humidification

(0) this feature. This setting will only display if you are using the heated tube. You can enable (1) or disable

Humidity Level

changed from the Setup screen. choose the desired humidity setting for the humidifier: 1, 2 or 3. This setting can only be This setting will only display if you are using the heated tube. This setting allows you to

Tube Temperature

this will turn off both the humidifier and the heated tube. choose the desired temperature for the heated tube: 0, 1, 2, 3, 4 or 5. If you choose zero (0), This setting will only display if you are using the heated tube. This setting allows you to

Note: When using Heated Tubing, the control wheel can also be used to change this setting

SYSTEM ONE Humidification

display if the humidifier is attached. adjusting for changes in room temperature and room humidity. You can enable (1) or System One humidity control maintains a consistent mask humidity by monitoring and style of basic temperature controlled heated humidification will be used. This will only disable (0) this feature. If the System One humidity control has been disabled, the classic

Note: The System One Humidification option is only available if the Heated Tubing is removed or has been disabled.

Humidifier

display if the humidifier is attached. Please refer to the humidifier manual if using a humidifier. This setting allows you to view and choose the desired humidity setting. This will only

Note: The Humidifier option is only available if the Heated Tubing is removed or has been disabled

Tubing Type Setting

setting to the appropriate tubing type (15H) and you will not be able to change it.. Respironics 15 mm tubing. When using Heated Tubing, the device will automatically change this You can choose either (22) for the Philips Respironics 22 mm tubing, or (15) for the optional Philips This setting allows you to select the correct size diameter tubing that you are using with the device.

Note: If the Heated Tubing is removed, the device will default back to the previous tubing type setting.

15. If your device does not have the tubing type setting, you must use the Respironics 22 mm tubing selection. Warning: If you are using the optional Respironics 15 mm tubing, the device tubing type setting must be set to

SYSTEM ONE Resistance

you will not see this setting. screen will display a lock symbol (🙀) next to the setting. If your provider has disabled resistance, locked the resistance setting into place, you can view the setting but cannot change it, and the home care provider if you cannot find this resistance setting for your mask. If your provider has mask. Each Respironics mask may have a "System One" resistance control setting. Contact your This setting allows you to adjust the level of air pressure relief based on the specific Respironics

Backlight

You can enable or disable the button LED backlight on the device.

hPa/cmH₂O

You can select either hPa or cmH₂O as the default unit of measure on the device

Humidifier Preheat

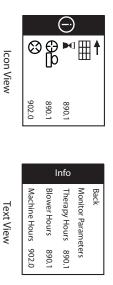
starting therapy When using a humidifier, the device can preheat the water tank for up to 30 minutes prior to

mode. The humidifier icon (Σ) will illuminate during this time. control wheel for 5 seconds. You will hear a single beep and the device will now be in preheat From the device Home screen, highlight "Therapy" or the $oldsymbol{f \Theta}$ icon, then press and hold down the In order to activate the preheat mode, the blower must be "off" and a humidifier must be attached

humidifier number selected in the setup menu (0, 1, 2, 3, 4, or 5) will now take effect. on the Home screen, preheat mode will end and the blower will turn "on" to begin therapy. The options from the Home screen. If you press the wheel while "Therapy" or the Θ icon is highlighted During the 30 minute preheat, you will still be able to use the control wheel to select other menu

Viewing the Information Screen

screen below appears. You cannot change settings on the Information screen. From the Main Menu, when you highlight the Info option and press the Wheel, the Information



information. Note: The Information screen is only for reference. Your home care provider may periodically ask you for this

Note: If an accessory is attached to the therapy device, additional items may appear on the Information screen. Refer to the instructions provided with the accessory for more information.

The following items appear on the Information screen:

- Monitor Parameters Displays the available parameters.
- on and patient breathing has been detected. Therapy Hours - The device displays the total number of hours that the blower has been
- be reset by your home care provider. This setting allows the provider to track device Blower Hours - Displays the total number of hours that the blower has been on. It can usage between patients.
- Machine Hours Displays the total number of hours that the blower has been on. This cannot be reset by the home care provider.

Viewing the Monitor Parameters Screen

There are two ways to access the Monitor Parameters screen:

- From the Monitor Pressure screen, press the Alarm Silence and Ramp keys simultaneously for two seconds.
- From the Information screen, select the Monitor Parameters setting.

shown below. The parameters displayed in this screen are described in the following table. A sample screen is

Vte 200	cmH ₂ O 4.0
RR 10	6 %
	MinVent 6

Press the Wheel to exit the Monitor Parameters screen and return to the previous screen.

the instructions included with your accessory for more information. is attached to the therapy device. This box will be empty (as shown here) if no accessory is attached. Please refer to **Note:** The information displayed in the last box shown on the sample screen will vary depending on what accessory

Viewing Measured Parameters

choose which measured parameters you want displayed. The parameters below appear on both the appear one at a time. The Setup Parameter Display setting on the Setup screen allows you to measured parameter. The measured parameters that display on the Monitor Pressure screen only Monitor Pressure and Monitor Parameters screens. Several measured parameters can be viewed on-screen. The following table describes each

Parameter	Description
Pressure	Displays the current patient pressure.
Leak (條)	The estimated leak is the average leak value for the last 6 breaths. The display is updated at the end of each breath.
Respiratory Rate (RR)	Respiratory Rate (RR) This is the average of the previous 6 breaths. If the mode supports machine-triggered breaths, this display will be the total breathing rate (spontaneous breaths + machine breaths). The display is updated at the end of each breath.
Minute Ventilation (MinVent)	The estimated Exhaled Minute Ventilation is based on the average of the last 6 breaths. The display is updated at the end of each breath.
Exhaled Tidal Volume (Vte)	The estimated Exhaled Tidal Volume is obtained by the integration of patient flow. The display is updated at the end of each breath.

the instructions included with your accessory for more information. **Note:** If an accessory is attached to the therapy device, additional parameters may appear on-screen. Please refer to

BIPAP AVAPS

3. Device Alarms

This chapter describes the ventilator alarms and what you should do if an alarm occurs.

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.

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

Audible and Visual Alarm Indicators

When an alarm condition occurs:

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

highest priority alarm displays. the following order: high priority, medium priority, then low priority. When multiple priority alarms are active, the highest priority LED light displays and the highest priority audible indicator sounds. On the display screen, the last Note: If multiple alarms occur at the same time, only the highest priority alarm will be active. The precedence is in

Note: Informational messages are a lower precedence than alarms and will not display on the screen if any alarm is active

Alarm LED Indicators

The Alarm Silence/Indicator button lights up as follows whenever an alarm is detected:

- Red Flashing Indicator High priority alarm is detected.
- Yellow Flashing Indicator Medium priority alarm is detected
- Yellow Solid Indicator Low priority alarm is detected.

The Alarm Silence/Indicator button does not light up when informational messages display

Alert Audible Indicators

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

- Ventilator Inoperative When a ventilator inoperative alarm occurs, a continuous indicator as: audible indicator sounds. The alarm descriptions later in this chapter display this
- pattern, repeating one second on, then one second off. The alarm descriptions later in Power Failure – When a power failure occurs, a series of beeps sounds in a 1 beep this chapter display this indicator as: •
- High Priority When a high priority alarm is active, a series of beeps sounds in the following alarm descriptions later in this chapter display this indicator as: • • • continues until the cause of the alarm is corrected or the audible alarm is silenced. The pattern, which is repeated twice: 3 beeps, a pause, and then 2 more beeps. This indicator
- in a 3-beep pattern. This pattern repeats until the cause of the alarm is corrected or Medium Priority – When a medium priority alarm is active, a series of beeps sounds indicator as: • • • the audible alarm is silenced. The alarm descriptions later in this chapter display this
- alarm is silenced. The alarm descriptions later in this chapter display this indicator as: pattern. This pattern repeats until the cause of the alarm is corrected or the audible Low Priority – When a low priority alarm is active, a series of beeps sounds in a 2-beep
- Informational Messages and Confirmation Audible Indicators When an informational when the device detects that a certain action has been completed (for example, when message appears on screen, a brief, 1- beep audible indicator sounds. Additionally, sounds. The descriptions later in this chapter display this indicator as: • an SD card is inserted or removed from the device) a brief, 1- beep audible indicator

Silencing an Alarm

restart the silence period. is reactivated. Touching the Alarm Silence/Indicator button while the silence period is active will sound until the silence period expires. When the silence period expires, the alarm's audible alarm alarm occurs while the silence period is active, the audible alarm portion of the new alarm will not for one minute. An icon will appear on the screen when the alarm is silenced (🙇). If another You can silence an alarm by pressing the Alarm Silence/Indicator button. This will silence the alarm

Alarm Message Screens

to the most recent, highest priority alarm. When an alarm message is activated, an alarm screen is displayed, showing the text or icon specific

take precedence over lower priority alarms). same period of time, the alarm screen will display the higher priority alarm (higher priority alarms Resetting the alarm allows you to return to the previous screen. If multiple alarms occur during the Pressing the Control Wheel will reset the alarm and remove the alarm screen from the display.

Note: Pressing the Control Wheel resets all alarms.

Note: If the alarm pop-up is present, you cannot see the Monitor Pressure screen.

Alarm Summary Table

The following table summarizes all of the high, medium, and low priority alarms and informational messages.

Alarm	Priority	Audible Indicator	Visual Indicators	Device Action	User Action
Loss of Power	High	•	Red flashing button; Blank screen	Shuts down	Remove your mask. Check your power connections. Make sure there is power at the outlet or power source. Restore power to the device. If the alarm continues, contact your home care provider for service.
Ventilator Inoperative	High		Red solid button; Note: In the propertive of the properties of th	Shuts down	Remove your mask. Press the Alarm Silence/Indicator button to silence the alarm. Contact your home care provider for service.
Low Pressure Alarm	High	•	Red flashing button; Note: The pressure or - (if Icon option is selected) A hPa cm cm Hzo	Operates	This could be caused by an excessive leak or blockage or a device malfunction. Press the Alarm Silence/Indicator button to silence the alarm. Remove your mask. Check for the following: dirty inlet filters, blocked air intake, excessive leak in the patient circuit. If the alarm continues, contact your home care provider.
High Pressure	High	•	Red flashing button Name	Operates; If the alarm continues for 10 seconds, the alarm escalates to a Ventilator Inoperative alarm	This may be caused by a malfunctioning device. Press the Alarm Silence/Indicator button to silence the alarm. Remove your mask Remove power from the device. Restore power. If the alarm continues, contact your home care provider for service.

		> 0			
continues, contact your home care provider for service.		- or - (if Icon option is selected)			
or fix the leak. If the alarm					
button to silence the alarm.		Patient Disconnect			
the Alarm Silence/Indicator					
patient circuit is disconnected		>			Disconnect
This alarm occurs when the	Operates	Red flashing button	•	High	Patient
		Z!\↓ V _{TE}			
מפעורם:		>			
provider. Continue using your		selected)			
the alarm to your home care		- or - (if Icon option is			
Alarm Silence/Indicator button					
tidal volume setting. Press the		Low Tidal Volume			
unable to reach the target					
feature is enabled; This alarm			•		Volume
Only enabled if AVAPS therapy	Operates	Red flashing button	•	High	Low Tidal
		/ MinVent			
device.					
the alarm to your home care provider. Continue using your		- or - (if Icon option is			
silence the alarm. Report					
alarm setting. Press the Alarm Silence/Indicator button to		Low Minute Vent			
is less than or equal to the		>			ventilation
This alarm occurs when the	Operates	Red flashing button	•••	High	Low Minute
		$\triangle A$			
device.		selected)			
the alarm to your home care provider. Continue using your		or-lifloon option is			
silence the alarm. Report		Apnea			
therapy. Press the Alarm		→			
This alarm is generated when an apnea event occurs during	Operates	Red flashing button	•	High	Apnea
User Action	Device Action	Visual Indicators	Audible Indicator	Priority	Alarm

SD Card Full	SD Card Corrupted	Low Input Voltage
Low	Low	Medium
:	:	Indicator
Solid yellow button SD card full - or - (if Icon option is selected) M	Solid yellow button SD card corrupted - or - (if Icon option is selected)	Yellow flashing button Low Voltage - or - (if Icon option is selected) Ai
Operates	Operates	Ventilator Operates; Humidifier shuts down
This alarm occurs when the SD card is full. Press the Alarm Silence/Indicator button to silence the alarm. Remove the SD card and replace it.	This alarm occurs when a problem exists with the SD card. The data may be corrupted. Press the Alarm Silence/Indicator button to silence the alarm. Contact your home care provider with any questions.	The alarm is caused when input power at the device, either from an AC outlet or battery, falls below the acceptable limit for 10 seconds. Press the Alarm Silence/ Indicator button to silence the alarm. If the device is plugged into a wall outlet, unplug the device and then plug it back in. If the alarm continues to occur, contact your home care provider for service. If you are using a battery, replace the battery or plug the device into an AC outlet. If the alarm continues, contact your home care provider for service.

Audible Visual Indicators Device Indicator ••						
Audible Visual Indicators Device Indicator Action ••	needed.					
Audible Visual Indicators Action ••	30 seconds or until the user acknowledges it. No action is		- or - (if Icon option is selected)			
ority Audible Visual Indicators Action ••	This message occurs when the SD card is removed from	Operates	SD card removed	•	Info	SD Card Removed
ority Audible Visual Indicators Action ••						
Audible Visual Indicators Action Reinsert SD Card - or - (if Icon option is selected) SD card inserted: prescription accepted - or - (if Icon option is selected) Fig. 8 SD card inserted: Operates prescription is selected - or - (if Icon option is selected) SD card inserted: Operates prescription rejected - or - (if Icon option is selected) SD card inserted: Operates Operates prescription rejected - or - (if Icon option is selected) Operates Operates	30 seconds or until the user acknowledges. No action is		- or - (if Icon option is selected)			
Audible Indicator •• Reinsert SD Card -or - (if Icon option is selected) •• SD card inserted: operates prescription rejected -or - (if Icon option is selected) •• Operates operates operates operates prescription rejected -or - (if Icon option is selected)	This message occurs when the SD card is inserted into	Operates	SD card inserted	•	Info	SD Card Inserted
Audible Visual Indicators Device Indicator ••						
Audible Visual Indicators Device Indicator ••	home care provider for the correct prescription.		- or - (if Icon option is selected)			
Audible Visual Indicators Device Indicator Reinsert SD Card - or - (if Icon option is selected) SD card inserted: prescription accepted - or - (if Icon option is selected) Raccepted - or - (if Icon option is selected) Raccepted	This message occurs when the prescription is missing or incorrect. It is present for 30 seconds or until the user	Operates	SD card inserted: prescription rejected	•	Info	SD Card: Prescription Rejected
Audible Visual Indicators Device Indicator Reinsert SD Card - or - (if Icon option is selected) SD card inserted: prescription accepted - or - (if Icon option is selected)			<u></u>			
Audible Visual Indicators Device Indicator Reinsert SD Card - or - (if Icon option is selected) SD card inserted: prescription accepted Operates Operates Operates			- or - (if Icon option is selected)			
Audible Visual Indicators Device Indicator ••	This info message will be present for 30 seconds or until the user acknowledges it. No action needed.	Operates	SD card inserted: prescription accepted	•	Info	SD Card: Prescription Accepted
ority Audible Visual Indicators Device Indicator •• •• Reinsert SD Card - or - (if Icon option is selected)	SD card or contact your home care provider.					
ority Audible Visual Indicators Device Indicator •• Reinsert SD Card Operates	card and reinsert. If the alert continues to occur, replace the		- or - (if Icon option is selected)			
ority Audible Visual Indicators Device Indicator Action	device cannot read the SD card. The card may be inserted incorrectly. Remove the SD	(200	Reinsert SD Card	•		Remove and Reinsert
Audible Visual Indicators Device Indicator Action	This alarm occurs when the	Operates	>		l Ow	SD Card:
	User Action	Device Action	Visual Indicators	Audible Indicator	Priority	Alarm

Alarm	Priority	Audible Indicator	Visual Indicators	Device Action	User Action
Check Power Alert	Info	None	The following symbol -C!_	Shuts down	The power supply voltage is incorrect. Make sure that you are using the correct power supply with your device. If the alert continues to occur, contact your home care provider.
Humidifier Alert	Info	None	Humidifier LED icon will flash on the device.	Only displayed when both the humidifier and therapy is on.	Humidifier failure. Alert is present for 12 minutes or until the condition is fixed. Turn off airflow and reconnect the humidifier to the device according to the humidifier instructions. If the alert continues to occur, contact your home care provider.
Power Supply Alert	Info	None	Humidifier LED icon will flash for 30 seconds.	Only displayed when incorrect power supply is used with the heated tube.	Using wrong power supply. Alert is present for 30 seconds or until the condition is fixed. You must use the 80W power supply when using the heated tube. If the alert continues to occur, contact your home care provider.
Heated Tube Error Alert	Info	None	Humidifier LED icon will slowly flash for 30 seconds.	Alert present for 30 seconds or until condition is fixed.	Tubing may be overheating or malfunctioning. Alert is present for 30 seconds or until the condition is fixed. Turn off airflow and reconnect the heated tubing to the humidifier according to the humidifier instructions. If the alert continues to occur, contact your home care provider.
Humidifier Failure	Info	None	Flashing humidifier LED icon \$ \$ \$	Device operate; Humidifier shuts down	Alert is present for 12 minutes or until the condition is fixed. Turn off airflow and reconnect the humidifier to the device according to the humidifier instructions. If the alert continues to occur, contact your home care provider.

Troubleshooting

The table below lists some of the problems you may experience with your device and possible solutions to those problems.

Nothing happens	There is no power	If you are using AC power, check the outlet and
when you apply	at the outlet or	verify that the device is properly plugged in. Make
power to the device.	the device is	sure there is power available at the outlet. Make
The backlight on the	unplugged.	sure the AC power cord is connected correctly to
buttons does not		the power supply and the power supply cord is
light.		securely connected to the device's power inlet. If
		the problem continues to occur, contact your home
		care provider. Return both the device and power
		supply to your provider so they can determine if the
		problem is with the device or power supply.
		If you are using DC power, 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 provider.
The airflow does not	There may be a	Make sure the device is powered correctly.
turn on.	problem with the	Make sure "Therapy" or (1) is highlighted when
	blower.	pressing the control Wheel to start airflow. If the
		with your device. Contact your home care provider
		for assistance.
The device display is	The device has	Unplug the device. Reapply power to the device. If
erratic.	been dropped or	the problem continues, relocate the device to an
	mishandled, or	area with lower EMI emissions (away from electronic
	the device is in	equipment such as cellular phones, cordless phones,
	an area with high	computers, TVs, electronic games, hair dryers, etc.).
	Electromagnetic	If the problem still occurs, contact your home care
	Interference (EMI)	provider for assistance.
	emissions.	

Problem	Why It Happened	What To Do
The Device will not turn off.	The correct blower off sequence was not followed.	Select Therapy to go back to the Monitor Pressure screen. Push and hold the knob for 2 seconds.
The Ramp feature does not work when	Your home care provider did not	If Ramp has not been prescribed for you, the Ramp feature will not work.
you press the Ramp	prescribe Ramp	If your provider has enabled Ramp but the feature
button.	for you, or your pressure is already	still does not work, check the pressure setting on your Monitor Pressure screen. If the pressure is set
	set to the minimum	to the minimum setting, or the starting pressure
	setting.	is the same as the prescribed pressure, the Ramp feature will not work.
The airflow is much warmer than usual.	The air filters may be dirty.	Clean or replace the air filters.
	The device may be	The temperature of the air may vary somewhat based on your room temperature. Make sure the
	operating in direct	device is properly ventilated. Keep it away from
	sunlight or near a	bedding or curtains that could block the flow of air
	heater.	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.
The airflow pressure feels too high or too low.	The Tubing type setting may be incorrect.	Make sure the Tubing type setting (22 or 15) matches the tubing that you are using (Philips Respironics 22 or 15 mm tubing). If you are using the Heated Tubing, this setting will be 15H and you cannot change it.

Problem	Why It Happened	What To Do
Tube Temperature is	Incorrect power	Make sure the 80W power supply is being used.
turned on in "Setup"	supply is being	This can be confirmed by looking at the power
screen but Heated	used (60W is used	supply for the 60W or 80W symbols. This can also
Tubing is not warm.	instead of 80W).	be checked by looking at the "Humidifier" settings
		under the "Setup" screen.
Tube Temperature	Heated Tubing is	Inspect Heated Tubing for damage and reconnect.
is turned on in	attached incorrectly	If the problem continues, contact your home care
"Setup" screen but	or damaged.	provider.
Humidifier LED does		
not stay orange.		
The mask feels	This could be due to	Make sure you are properly fitted with the correct
uncomfortable	improper headgear	size mask. If the problem continues, contact your
to wear, there	adjustment or	home care provider to be fitted with a different
is significant air	improper mask	mask.
leakage around	fitting.	
the mask, or you		
experiences other		
mask-related issues.		
You have a runny	This may be caused	Contact your home care provider.
nose.	by a nasal reaction	
	to the airflow.	

BiPAP AVAPS

4. Accessories

optional accessories, always follow the instructions enclosed with the accessories. your home care provider for additional information on the available accessories. When using the There are several accessories available for your BiPAP AVAPS system, such as a humidifier. Contact

Adding a Humidifier with or without Heated Tubing

adding moisture to the airflow. your home care provider. A humidifier and heated tube may reduce nasal dryness and irritation by You can use the heated humidifier and the heated tube with your device. They are available from

Note: Refer to the humidifier's instructions for complete setup information.

SD Card

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

Note: The SD card does not need to be installed for the device to work properly. The SD card records device usage information on the SD card. Contact your home care provider if you have any questions about the SD card. information for your home care provider. You can refer to the Device Alarms chapter of this manual for more

Supplemental Oxygen

Please note the warnings in Chapter 1 when using oxygen with the device. Oxygen may be added anywhere in the patient circuit provided that a pressure valve is used.

Shielded DC Cord

how to operate the device using DC power. with the Shielded DC Cord, enables the device to be operated from a 12 VDC free-standing battery. ational vehicle, boat, or motor home. The Philips Respironics DC Battery Adapter Cable, when used Refer to the instructions supplied with the Shielded DC Cord and adapter cable for information on The Philips Respironics Shielded DC Cord can be used to operate this device in a stationary recre-

Caution: When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. The device may not work properly if connected while the vehicle's engine is running.

damage to the device or vehicle. **Caution:** Only use a Philips Respironics Shielded DC Cord and Battery Adapter Cable. Use of any other system may cause

Carrying Case

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

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

a different power cord or an international plug adapter may be required to make your power cord care provider for additional information. compatible with the power outlets of the country to which you are traveling. Contact your home If you are traveling to a country with a line voltage different than the one you are currently using,

Note: If you are using a humidifier with the device, the humidifier should be emptied before traveling

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

user manual

5. Cleaning the Device

Follow the instructions below to clean the device. If you are using the device on multiple users, complete the following steps before each new user.



Marning: 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.

- Unplug the device before cleaning.
- Clean the outside of the device only. Use a cloth with one of the following cleaning agents to clean the exterior of the device.
- Mild detergent
- 70% Isopropyl Alcohol
- DisCide Towelettes
- 10% Chlorine bleach solution
- $\dot{\omega}$ Allow the device to dry completely before plugging in the power cord
- 4. Inspect the device and all circuit parts for damage after cleaning. Replace any damaged parts.

Cleaning or Replacing the Filters

replace it with a new one every six months Under normal usage, you should clean the gray foam filter at least once every two weeks and

- If the device is operating, stop the airflow. Disconnect the device from the power source.
- Remove the filter from the enclosure by gently squeezing the filter in the center and pulling it away from the device.
- $\dot{\omega}$ Examine the filter for cleanliness and integrity.

- 4. Wash the gray foam filter in warm water with a mild detergent. Rinse thoroughly to remove all torn, replace it. (Only Philips Respironics-supplied filters should be used as replacement filters.) detergent residue. Allow the filter to air dry completely before reinstalling it. If the foam filter is
- 5. Reinstall the filter.

Cleaning the Tubing

detergent. Rinse thoroughly. Air dry. For the 15 or 22 mm flexible tubing, gently wash the tubing in a solution of warm water and a mild Clean the flexible tubing before first use and daily. Disconnect the flexible tubing from the device.

Note: Refer to the humidifier manual for the instructions on how to clean the heated tube.

Service

The device does not require routine servicing.

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6. Specifications

Environmental

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

Physical

Dimensions: $7"L \times 5.5"W \times 4"H$ (18 cm x 14 cm x 10 cm)

Approximately 3 lbs (1.36 kg)

Standards Compliance

This device is designed to conform to the following standards:

- IEC 60601-1: Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
- Requirements and tests $Safety\ and\ Essential\ Performance-Collateral\ standard:\ Electromagnetic\ compatibility-like the compatibility$ IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: General Requirements for Basic
- IEC 60601-1-8: Medical Electrical Equipment Part 1-8: General Requirements for Basic guidance for alarm systems in medical electrical equipment and medical electrical systems Safety and Essential Performance – Collateral standard: General Requirements, tests and
- equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-11: Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral standard: Requirements for medical electrical
- and Essential Performance, Part 6. Home care ventilatory support devices ISO 10651-6: Lung Ventilators for Medical Use – Particular Requirements for Basic Safety
- RTCA DO-160F Section 21, Category M; Emission of Radio Frequency Energy

Electrical

AC Power Consumption (with 60W power supply): 100 to 240 VAC, 50/60 Hz, 2.1 A

AC Power Consumption (with 80W power supply): 100 to 240 VAC, 50/60 Hz, 2.0 A

DC Power Consumption: 12 VDC, 5.0 - 6.67 A

There are no user-replaceable fuses.

Type of Protection Against Electric Shock: Class II

Degree of Protection Against Electric Shock: Type BF Applied Part

Degree of Ingress Protection: Device Drip Proof

(Device and AC power supply):

Mode of Operation: Continuous

Pressure

Pressure Increments: 4.0 to 30.0 cm H_2O (in 1.0 cm H_2O increments)

Flex Therapy Feature: Off, 1, 2, 3

Control Accuracy

Parameter	Range	Accuracy
IPAP	4 – 30 cm H ₂ O	$\pm 2.5 \text{ cm H}_2\text{O*}$
EPAP	$4 - 30 \text{ cm H}_2\text{O}$	$\pm 2.5 \text{ cm H}_2\text{O*}$
CPAP	4 – 20 cm H ₂ O	$\pm 2.5 \text{ cm H}_2\text{O*}$
Breath rate	0 to 30 BPM	greater of \pm 1 BPM or \pm 10% of setting
Inspiration time	0.5 to 3 seconds	\pm (10% of setting + 0.1 second).

with Whisper Swivel II). *Pressure measured at the patient connection port with or without the humidifier (no patient flow,

Displayed Parameter Accuracy

Parameter	Accuracy	Resolution	Range
Estimated Leak Rate	$\pm (5+15\% \text{ of reading}) \text{ LPM}$	1 LPM	0 to 200 LPM
Exhaled Tidal Volume	\pm (25+15% of reading) ml	5 ml	0 to 2000 ml
Respiratory Rate	Greater of ±1 BPM or ±10% of reading 1 BPM		0 to 60 BPM
Exhaled Minute Ventilation $\pm (1+15\% \text{ of reading}) \text{ LPM}$	±(1+15% of reading) LPM	1 LPM	0 to 99 LPM

Spontaneous Breathing During Power Failure Conditions

	Passive Circuit	Passive Circuit
30	<1.0	<1.0
09	<2.8	<2.8

Noise

Minimum Alarm Sound Level: 45 dB(A)

Disposal

Dispose of the device in accordance with local regulations.

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

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	Compliance Level	Electromagnetic Environment -
	Level		Guidance
Electrostatic	±6 kV contact	±6 kV contact	Floors should be wood, concrete or
Discharge (ESD)			ceramic tile. If floors are covered with
	±8 kV air	±8 kV air	synthetic material, the relative humidity
IEC 61000-4-2			should be at least 30%.
Electrical fast	±2 kV for power supply lines	±2 kV for supply mains	Mains power quality should be that of a
Transient/burst			typical home or hospital environment.
	±1 kV for input-output lines	±1 kV for input/output lines	
IEC 61000-4-4			
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a
IEC 61000-4-5			typical home or hospital environment.
	±2 kV common mode	±2 kV for common mode	
Voltage dips, short	<5% ∪ _⊤	<5% U _⊤	Mains power quality should be that of a
interruptions and voltage	(>95% dip in U_T) for	(>95% dip in U_T) for	typical home or hospital environment.
variations on power supply	0.5 cycle	0.5 cycle	If the user of the device requires
input lines	40% U _T	40% U _T	continued operation during power mains
	(60% dip in $U_{\overline{r}}$) for	(60% dip in $U_{\scriptscriptstyle T}$) for 5 cycles	interruptions, it is recommended that the
IEC 61000-4-11	5 cycles	70% U_T (30% dip in U_T) for	device be powered from an uninterruptible
	70% U _⊤ (30% dip in	25 cycles	power supply or a battery.
	$U_{\scriptscriptstyle T}$) for 25 cycles	<5% $U_{\scriptscriptstyle T}$ (>95% dip in $U_{\scriptscriptstyle T}$) for	
	<5% U _T (>95% dip in U _T) for	5 sec	
	5 sec		
Power frequency (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be
magnetic field			at levels characteristic of a typical location
			in a typical hospital or home environment.
IEC 61000-4-8			
NOTE: U_T is the a.c. mains volt	NOTE: \mathbf{U}_{T} is the a.c. mains voltage prior to application of the test level	st level.	

use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment. Guidance and Manufacturer's Declaration - Electromagnetic Immunity – This device is intended for

Interference may occur in the vicinity of equipment marked with the following symbol: $(\c M)$			
level in each frequency range. ^b			
electromagnetic site survey ^a , should be less than the compliance			
Field strengths from fixed RF transmitters, as determined by an			
uie i econimiente a sepai autori utazance in metera (iii).			
the proposed of counties distance is motors (m)			
in watts (W) according to the transmitter manufacturer and d is			
where P is the maximum output power rating of the transmitter			
	3 V/m	80 MHz to 2.5 GHz	IEC 61000-4-3
d = 2.3 √P 800 MHz to 2.5 GHz		3 V/m	Radiated RF
d = 1.2 √P 80 MHz to 800 MHz			
		150 kHz to 80 MHz	IEC 61000-4-6
d = 1.2 √P	3 Vrms	3 Vrms	Conducted RF
Recommended separation distance			
equation applicable to the frequency of the transmitter.			
the recommended separation distance calculated from the			
used no closer to any part of the device, including cables, than			
Portable and mobile RF communications equipment should be			
Electromagnetic Environment -Guidance	Compliance Level	IEC 60601 Test Level	Immunity Test

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

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

a Ь Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m. operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur

the maximum output power of the communications equipment. communications equipment (transmitters) and this device as recommended below, according to electromagnetic interference by maintaining a minimum distance between portable and mobile RF 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 Recommended Separation Distances between Portable and Mobile RF Communications Equipment

Rated Maximum Power	Separation	Separation Distance According to Frequency of Transmitter	uency of Transmitter
Output of Transmitter		3	
*	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2 √P	d = 1.2 √P	d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	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 separation distance for 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,

BIPAP AVAPS

Limited Warranty

is found after investigation by Respironics, Inc. Service. Respironics, Inc. reserves the right to charge an evaluation fee for any returned device as to which no problem or workmanship. The Respironics, Inc. Service department shall examine any devices returned for service, and damage caused by accident, misuse, abuse, alteration, water ingress, and other defects not related to material customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, perform in accordance with the product specifications for a period of two (2) years from the date of sale by Respironics, Inc. warrants that the system shall be free from defects of workmanship and materials and will

authorized distributers. the right to charge dealers for warranty service of failed product not purchased directly from Respironics or This warranty is non-transferable by unauthorized distributers of Respironics, Inc. products and reserves

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

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

Respironics, Inc. at: 1001 Murry Ridge Lane

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

Murrysville, Pennsylvania 15668-8550 1-724-387-4000