BiPAP autoSV Advanced System One

USER MANUAL

PHILIPS
RESPIRONICS

Table of Contents

CAUTION: U. S. federal law restricts this device to sale by or on the order of a physician.

Intended Use

The BiPAP autoSV Advanced System One is intended to provide non-invasive ventilatory support to treat adult patients (>30 kg/66 lbs) with Obstructive Sleep Apnea and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing. This device may be used in the hospital or home.

Warnings

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

- This manual serves as a reference. The instructions in this manual are not intended to supersede the health care professional's instructions regarding the use of the device.
- The operator should read and understand this entire manual before using the device.
- This device is not intended for life support.
- The device should be used only with masks and connectors recommended 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) or entrainment valve associated with the mask should never be blocked. **Explanation of the 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 or entrainment valve. However, when the device is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed.
- If you are using a full face mask (a mask covering both your mouth and your nose), the mask must be equipped with a safety (entrainment) valve.
- When using oxygen with this system, a Philips Respironics Pressure Valve must be placed in-line with the patient circuit between the device and the oxygen source. The pressure valve helps prevent the backflow of oxygen from the patient circuit into the device when the unit is off. Failure to use the pressure valve could result in a fire hazard.
- 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.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- 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.
- Do not use the device near a source of toxic or harmful vapors.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Do not use this device if the room temperature is warmer than 35° C (95° F). If the device is used at room temperatures warmer than 35° C (95° F), the temperature of the airflow may exceed 43° C (109° F). 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 of the device.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, disconnect the power cord and discontinue use. Contact your home care provider.
- Periodically inspect electrical cords and cables for damage or signs of wear. Discontinue use and replace if damaged.
- To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the device. DO NOT immerse the device in any fluids.
- If the device is used by multiple persons (such as rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and the circuit tubing to prevent contamination.
- 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.
- For safe operation when using a humidifier, 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.
- The BiPAP autoSV Advanced System One device can deliver pressures up to 25 cm H_2O. In the unlikely event of certain fault conditions, pressures of up to 35 cm H_2O are possible.
- The data obtained when using an Oximetry module accessory is not considered to be diagnostic and is not to be used in the diagnosis of a patient's condition.
- 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 damage.
  Note: Please see the "Limited Warranty" section of this manual for information on warranty coverage.

Cautions

A Caution indicates the possibility of damage to the device.

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information. Contact your home care provider regarding EMC installation information.
- Mobile RF communications equipment can affect medical electrical equipment.
- Pins of connectors marked with the ESD warning symbol shall not be touched and connections shall not be made without special precautions. 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. It is recommended that all individuals that will handle this device understand these precautionary procedures at a minimum as part of their training.
- 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.
- Condensation may damage the device. If this 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.
- Do not use extension cords with this device.
- Do not place the device directly onto carpet, fabric, or other flammable materials.
- Do not place the device in or on any container that can collect or hold water.
- A properly installed, undamaged reusable foam inlet filter is required for proper operation.
- Tobacco smoke may cause tar build-up within the device, which may result in the device malfunctioning.
- Dirty inlet filters may cause high operating temperatures that may affect device performance. Regularly examine the inlet filters as needed for integrity and cleanliness.
- Never install a wet filter into the device. You must ensure sufficient drying time for the cleaned filter.
- Always ensure that the DC power cord securely fits into your therapy device prior to use. Contact your home care provider or Philips Respironics to determine if you have the appropriate DC cord for your specific therapy device.
- When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. Damage to the device may occur.
- Only use a Philips Respironics DC Power Cord and Battery Adapter Cable. Use of any other system may cause damage to the device.

Contraindications

The device should not be used if you have severe respiratory failure without a spontaneous respiratory drive.

If any of the following conditions apply to you, consult your physician before using the device:

- Inability to maintain an open 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

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)
- Contact your health care professional if symptoms of sleep apnea recur.

Symbol Key

The following symbols may appear on the device and power supply:

Symbol	Definition
	Consult accompanying instructions for use.
	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.
	Do not disassemble.
	For Airline Use. Complies with RTCA/DO-160F section 21, category M.
	Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC.
	Use only with the standard 60W power supply 1091398. (not for use with Heated Tubing)
	Use only with the Heated Tubing compatible 80W power supply 1091399. (can also be used when Heated Tubing is not in use)

System Contents

Your BiPAP autoSV Advanced System One may include the following items:

- Device
- User manual
- Carrying case
- Flexible tubing
- Power cord
- Power supply (60W REF 1091398, or 80W REF 1091399)
- SD card
- Side cover panel (optional)
- Reusable gray foam filter
- Disposable ultra-fine filter (optional)
- Humidifier (optional)

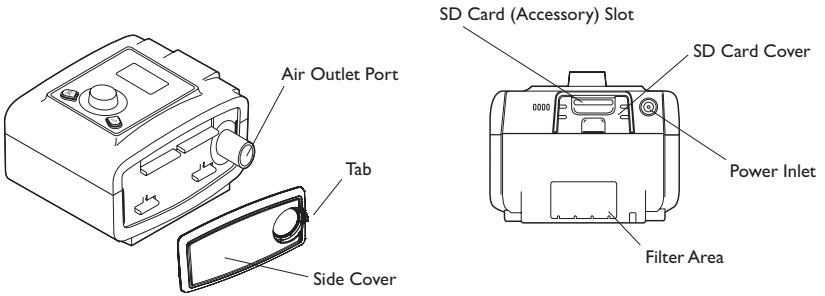
Note: If any of these items are missing, contact your home care provider.

System Overview

The BiPAP autoSV Advanced System One device is intended to augment your breathing by supplying pressurized air through a circuit. It senses your breathing effort by monitoring airflow in the 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.

When prescribed, the device can also provide features to help make your therapy more comfortable. The ramp function allows you to lower the pressure when trying to fall asleep. The air pressure will gradually increase until the prescription pressure is reached. Additionally, the Bi-Flex comfort feature provides increased pressure relief during the expiratory phase of breathing.

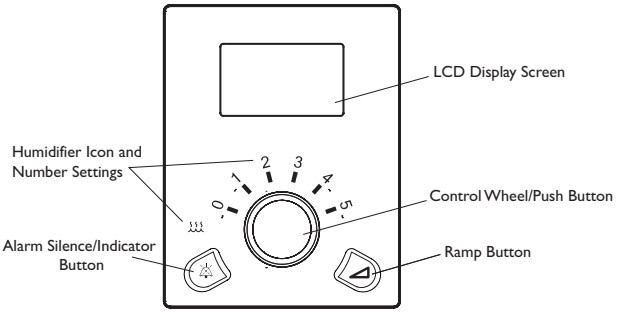
Several accessories are also available for use with the device. Contact your home care provider to purchase any accessories not included with your system.



This figure illustrates some of the device features, described in the following table.

Device Feature	Description
Air Outlet Port (conical, 22 mm)	Connect the 15 or 22 mm Philips Respironics flexible tubing here.
SD Card (Accessory) Slot	If applicable, insert the optional accessory 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 the accessory. When not using an accessory, this cover must be in place on the device.
Power Inlet	Connect the power cord here.
Filter Area	A reusable, gray foam filter must be placed in the filter area to screen out normal household dust and pollens. A white ultra-fine filter can also be used for more complete filtration of very fine particles.
Side Cover (optional)	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.

Control Buttons



This figure shows the primary control buttons on the device, described in the following table.

Feature	Description
Display Screen	Shows therapy settings, patient data, and other messages. The startup screen is shown temporarily when the unit is first powered.
Humidifier Icon	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 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.
Ramp Button	When the airflow is on, this button allows you to activate or restart the ramp function. When the airflow is off, this button allows you to activate the Mask Fit Check. 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 Features

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

Bi-Flex Comfort Feature

If enabled, the device provides a comfort feature called Bi-Flex. 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.

Ramp

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 patients can fall asleep more comfortably.

Rise Time

If enabled, the device provides a feature called Rise Time. 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 0, 1, 2, or 3 progressively reflect slowed response of the pressure increase that will take place at the beginning of inspiration. A setting of 0 is the fastest rise time while a setting of 3 is the slowest. Providers should adjust the rise time to find the most comfortable setting for the patient. Rise time cannot be adjusted when Bi-Flex is enabled.

Installing the Air Filters

CAUTION: A properly installed, undamaged gray foam filter is required for proper operation.

The device uses a gray foam filter that is washable and reusable, and an optional white ultra-fine filter that is disposable. The reusable filter screens out normal household dust and pollens, while the ultra-fine filter provides more complete filtration of very fine particles.

The reusable gray foam filter and the optional disposable ultra-fine filter are supplied with the device. If your filters are not already installed when you receive your 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, mesh-side facing in, towards 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.

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 port, or Philips Respironics interface with a separate exhalation device (such as the Whisper Swivel II)

  WARNING: If you are using a full face mask (a mask covering both your mouth and your nose), the mask must be equipped with a safety (entrainment) valve.
- Philips Respironics 22 mm (or 15 mm) flexible tubing, 1.83 m (6 ft.)
- Philips Respironics headgear (for the mask)

  WARNING: If the device is used by multiple persons (such as rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and the circuit tubing to prevent contamination.

To connect your breathing circuit to the device, complete the following steps:

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

   Note: Make sure the Tubing type setting (15 or 22) matches the tubing you are using (Philips Respironics 15 or 22 mm tubing). Make sure the Tubing type setting is 15 or 15H when the Heated Tube is connected.

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

   Note: 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.
3. Attach the headgear to the mask if necessary. Refer to the instructions that came with your headgear.

Where to Place the Device

Place the device 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, air conditioners).

CAUTION: Do not place the device directly onto carpet, fabric, or other flammable materials.

CAUTION: Do not place the device in or on any container that can collect or hold water.

Supplying AC Power to the Device

CAUTION: Condensation may damage the device. If this 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.

WARNING: 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.

WARNING: This device is activated when the power cord is connected.

IMPORTANT: If you are using your device with a humidifier, refer to the instructions included with your humidifier for details on how to power the device and humidifier.

Complete the following steps to operate the device using AC power:

1. Plug the socket end of the AC power cord (included) into the power supply (also included).
   IMPORTANT: When you are using Heated Tubing with the compatible System One Heated Humidifier, you must use the 80W power supply.
2. Plug the pronged end of the AC 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 device.
4. Ensure that all connections are secure.
   IMPORTANT: To remove AC power, disconnect the power supply cord from the electrical outlet.
   WARNING: Periodically inspect electrical cords and cables for damage or signs of wear. Discontinue use and replace if damaged.
   CAUTION: Do not use extension cords with this device.

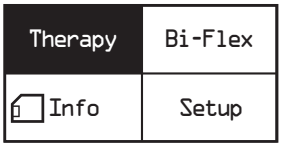
Navigating the Device Screens

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

Note: The screens shown throughout this manual are examples only. Actual screens may vary slightly. Examples are for reference only.

Starting the Device

1. Supply power to the device.
2. The first screen to display will be the Philips Respironics logo, followed by the screen showing the current software version number. The Blower hours screen will then appear, which shows the total blower hours for the device in hours and minutes.
2. Finally, the Home screen will appear, shown below.



Home Screen

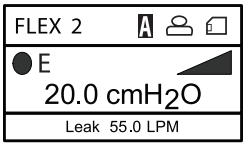
Note: "Bi-Flex" shown above will either display a blank screen or it will show "Bi-Flex" or "Rise time" depending on how the provider set up the device.

Note: The SD card icon will display next to "Info", if the SD card is inserted.

3. 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 options. Highlight "Therapy". Press the wheel to turn on the airflow and begin therapy. The Monitor Pressure screen will appear, described in detail in the next section.
   Note: If the "Auto on" feature is enabled, the device will automatically turn the airflow on whenever you apply the interface (mask) to your airway and begin to breathe into the interface.
5. Verify that the device beeps each time therapy is started. If the device does not operate accordingly, contact your home care provider, as the alarm system may not be fully functional.
6. Make sure that no air is leaking from your mask into your eyes. If necessary, adjust the mask and headgear until the air leak stops. See the instructions provided with your mask for more information.
   Note: A small amount of mask leak is normal and acceptable. Correct large mask leaks or eye irritation from an air leak as soon as possible.
7. If you are using the device in a bed with a headboard, try placing the tubing over the headboard. This may reduce tension on the mask.
8. From the Home Screen, highlight "Therapy" then press and hold the wheel for approximately 2 seconds to turn off therapy. Or, from the Monitor Pressure screen, press and hold the wheel for approximately 2 seconds to turn off therapy and return to the Home Screen.
9. Verify that the device beeps when therapy is stopped. If the device does not operate accordingly, contact your home care provider, as the alarm system may not be fully functional.

Monitor Pressure Screen

From the Main Menu, if you select Therapy and then press the wheel, the following Monitor Pressure screen appears. Example shown here.



The Monitor Pressure screen displays the following items:

- Pressure
- Timed Breath Indication
- I/E State Indication
- Ramp Indication
- Icon Bar
- Therapy Parameters

Note: Additional icons may appear if optional accessories are being used (such as the oximetry module). Refer to the manual that accompanies the accessory for more information.

The symbols will only appear if the conditions described in the following table exist.

Symbol	Description
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.
	The "Patient Disconnect" symbol displays only when the Patient Disconnect alarm is enabled by the provider.
	The "SD Card" symbol displays when the SD card is present.
	The "Timed Breath Indication" symbol displays during a machine triggered breath when the Breath Rate setting is not Off.
I or E	"I" is displayed above the pressure setting during IPAP (Inspiratory Positive Airway Pressure) and "E" is displayed during EPAP (Expiratory Positive Airway Pressure).
	The "Ramp" symbol displays while the Ramp function is active.

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

Ramp Feature

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

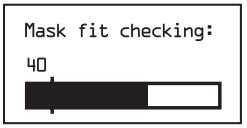
If ramp is enabled on your device, after you turn on the airflow, press the RAMP ( ) button on the top of the device. The Ramp icon ( ) will appear on the Monitor Pressure Screen. You can use the RAMP button as often as you wish during the night.

Note: If the Ramp feature is disabled and airflow is on, nothing will happen when you press the RAMP button.

Mask Fit Check Feature

The Mask Fit Check feature can be enabled or disabled by your home care provider. This feature allows you to check the fit of your mask prior to starting therapy. This is done by measuring the amount of leak.

Put on your mask assembly. If Mask Fit Check is enabled, before you turn on the airflow, press the RAMP ( ) button on the top of the device. Airflow will start and the Mask Fit Check screen will appear, shown below.



Mask Fit Check

The device will deliver a test pressure while the screen will count down 40 seconds. After the test, normal therapy will start and the screen will either display a checkmark (✓) or an X. The ✓ shows that the leak found allows for optimal performance of the device. The X shows that the leak may affect device performance, however, the device will remain functional and deliver therapy.

Note: If you choose to try to improve your mask fit, you can stop therapy, adjust the fit of your mask, and rerun the Mask Fit Check. Please refer to the instructions that came with your mask and headgear for the proper fitting procedure.

Humidifier Preheat

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

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

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

Bi-Flex/Rise time Screen

From the Home screen, highlight "Bi-Flex" or "Rise time" and press the wheel. The following screen will appear.

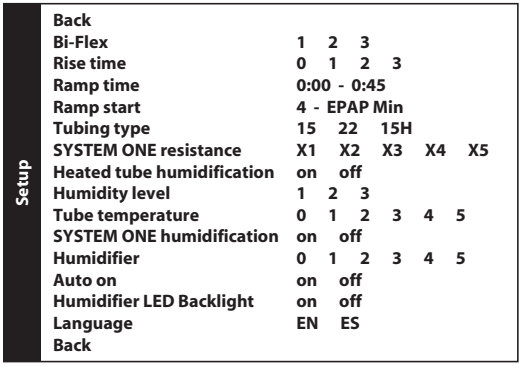
Note: This screen will be blank on the Home screen if your provider has not enabled Bi-Flex or Rise time on your device.

Flex Screen

- **Bi-Flex** - The Bi-Flex comfort feature allows you to adjust the level of air pressure relief that you feel when you exhale during therapy. Your home care provider can enable, lock or disable this feature. When your provider enables Bi-Flex, a level will already be set for you on the device. If this is not comfortable, you can increase or decrease the setting. The setting of "1" provides a small amount of pressure relief, with higher numbers providing additional relief. If the provider has disabled this feature, this setting will not display.
  Note: This same setting is also available under the "Setup" screen.
- **Rise time** - The Rise time comfort feature is the time it takes for the device to change from EPAP to IPAP. If Rise time is prescribed for you, you can adjust the Rise time from 0 to 3 to find the setting that provides you with the most comfort. A setting of 0 is the fastest Rise time, while 3 is the slowest. This setting will not display if your provider has not enabled Rise time on your device.
  Note: This same setting is also available under the "Setup" screen.

Setup Screen

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



Setup Screen

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

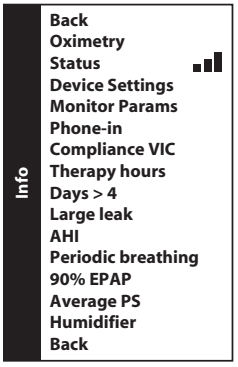
- **Bi-Flex** - The Bi-Flex comfort feature allows you to adjust the level of air pressure relief that you feel when you exhale during therapy. Your home care provider can enable, lock or disable this feature. When your provider enables Bi-Flex, a level will already be set for you on the device. If this is not comfortable, you can increase or decrease the setting. The setting of "1" provides a small amount of pressure relief, with higher numbers providing additional relief. If the provider has disabled this feature, this setting will not display.
  Note: This same setting is also available under the "Flex/Rise time" screen.
- **Rise time** - The Rise time comfort feature is the time it takes for the device to change from EPAP to IPAP. If Rise time is prescribed for you, you can adjust the Rise time from 0 to 3 to find the setting that provides you with the most comfort. A setting of 0 is the fastest Rise time, while 3 is the slowest. This setting will not display if your provider has not enabled Rise time on your device.
  Note: This same setting is also available under the "Flex/Rise time" screen.
- **Ramp time** - This enables you to modify the Ramp time setting in 5 minute increments. The range for this setting is 0 to 45 minutes.
- **Ramp start** - This displays the Ramp starting pressure. You can increase or decrease the Ramp starting pressure from 4 cm H_2O to the minimum EPAP setting in 0.5 cm H_2O increments. This will only display if your provider has enabled Ramp on your device.
- **Tubing Type** - This setting allows you to select the correct size diameter tubing that you are using with the device. You can choose either (22) for the Philips Respironics 22 mm tubing, or (15) for the Philips Respironics 15 mm tubing. When using the heated tube with the humidifier, the device will automatically change this setting to the appropriate tubing type (15H) and you will not be able to change it. If your provider has locked this setting into place, you can view the setting but cannot change it, and the screen will display a lock symbol ( ) next to the setting.
  Note: If the Heated Tubing is removed, the device will default back to the previous tubing type setting.
- **SYSTEM ONE resistance ( )** - 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 control setting. Contact your home care provider if you cannot find this resistance setting for your mask. If your provider has locked the resistance setting into place, you can view the setting but cannot change it, and the screen will display a lock symbol ( ) next to the setting. If your provider has disabled resistance, you will not see this setting.

- **Heated Tube humidification** - This setting will only display if you are using the heated tube with the humidifier. You can enable or disable this feature.
- **Humidity level** - This setting will only display if you are using the heated tube with the humidifier. This setting allows you to choose the desired humidity setting for the humidifier: 1, 2 or 3. This setting can only be changed from the Setup screen.
- **Tube temperature** - This setting will only display if you are using the heated tube with the humidifier. This setting allows you to choose the desired temperature for the heated tube: 0, 1, 2, 3, 4 or 5. If you choose zero (0), this will turn off both the humidifier and the heated tube.
  Note: When using Heated Tubing with the humidifier, the control wheel can also be used to change this setting.
- **SYSTEM ONE humidification** - System One humidity control maintains a consistent mask humidity by monitoring and adjusting for changes in room temperature and room humidity. You can enable or disable this feature. If the System One humidity control has been disabled, the classic style of basic temperature controlled heated humidification will be used. This will only display if the humidifier is attached.
- **Humidifier** - This setting allows you to choose the desired humidity setting: 0, 1, 2, 3, 4 or 5. If the System One humidity control has been disabled, the classic style of basic temperature controlled heated humidification will be used and the display will show: 0, C1, C2, C3, C4 or C5 for these settings. This will only display if the humidifier is attached. Please refer to the humidifier manual if using a humidifier.
- **Auto on** - You can enable this feature if you want the device to automatically turn the airflow on whenever you apply the interface (mask) to your airway. You can also disable this feature.
- **Humidifier LED Backlight/Ramp Backlight** - You can enable or disable the LED backlight for the humidifier number settings and Ramp button on the device.
  Note: If the humidifier is not attached, this feature will display as "Ramp Backlight" and control the LED backlight for the Ramp button only.
  Note: If the Humidifier LED Backlight is enabled or disabled, the humidifier icon will always remains on (if humidifier is attached and heat is being applied), but will dim after 30 seconds of inactivity.
- **Language** - This feature allows you to choose which language to display on the interface. You can choose English (EN) or Spanish (ES).

Info Screen

From the Home screen, highlight "Info" and press the wheel. The following Info screen will appear. The user cannot change settings in the Info menu.

Note: These screens are only for reference. Your home care provider may periodically ask you for this information.



Info Screen

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

- **Oximetry** - This screen displays the Oximetry parameters.
  Note: This option is only shown when an optional Oximetry module is attached.
- **Status** - This displays information sent from a peripheral (SD card , modem , etc.). If two peripherals are attached, two lines will appear with corresponding icons.

  Note: This will not display if no peripherals are being used.
- **Device Settings** - This screen allows you to view the current device settings. Maximum pressure, EPAP min, EPAP max, BPM, PS min and PS max will display.
- **Monitor Parameters** - This screen displays all available measured therapy parameters. The following will display: Estimated Patient Pressure in cm H_2O, Leak ( ) in LPM, Minute Ventilation in LPM, Tidal Volume in mL, Respiratory Rate in BPM, and the pulse oximetry measurement if available on the device. Example shown below.

cmH_2O 4.0	 6	MinVent 6
Vte 200	RR 10	SpO_2 98

  Note: This screen will only display if the blower is on.
- **Phone-in** - This screen displays the total therapy hours for the device, the total blower hours, and the total number of days used when the sessions were greater than 4 hours since the device was last reset by the home care provider. This screen also displays a compliance check number used by your home care provider to validate that the data provided by you is the data taken from this screen. This setting only appears if your provider has enabled this feature.
- **Compliance VIC (Visual Inspection Check)** - This screen displays the start day and the total number of days used when the sessions were greater than 4 hours. This screen also displays a check code number used by your home care provider to validate that the data provided by you is the data taken from this screen.
- **Therapy hours** - The device is capable of recognizing the difference between the time the patient is actually receiving therapy and the time when the blower is simply running. This screen displays the amount of time the patient is actually receiving therapy on the device for the most recent 1 day time frame. It also displays the average amount of time the patient is actually receiving therapy on the device over a 7 day and a 30 day time frame (provided the device has at least 7 or 30 days of data respectively). If the device has only 5 days of data to use for the calculation, the 5 day average value will be seen under the 7 day display.
- **Days > 4** - This screen displays the cumulative number of device therapy sessions that exceeded 4 hours over a 1 day, a 7 day, and 30 day time frame.
- **Large leak** - During any given night, the device recognizes the percentage of time the patient was experiencing what it deemed to be a large leak. Large leak is defined as the level of leak that is so large, it is no longer possible to determine respiratory events with statistical accuracy. This screen displays the nightly value of percentage of time in large leak for the most recent 1 day time frame. It also displays the average of these individual nightly values of percentage of time in large leak over a 7 day and a 30 day time frame (provided the device has at least 7 or 30 days of data respectively). If the device has only 5 days of data to use for the calculation, the 5 day average value will be seen under the 7 day display. If you see a large increase in the percent of time in large leak indicated here, contact your home care provider for assistance. This screen only displays if your home care provider has enabled it.
- **AHI** - The device accumulates individual Apnea/Hypopnea Indices (AHI) for each session the patient used the device. This screen displays the nightly AHI value for the most recent 1 day time frame. It also displays the average of these individual nightly AHI values over a 7 day and a 30 day time frame (provided the device has at least 7 or 30 days of data respectively). If the device has only 5 days of data to use for the calculation, the 5 day average value will be seen under the 7 day display. This screen only displays if your home care provider has enabled it.

- **Periodic Breathing** - During any given night, the device recognizes the percentage of time the patient was experiencing periodic breathing. This screen displays the nightly value of periodic breathing for the most recent 1 day time frame. It also displays the average of these individual nightly values of periodic breathing over a 7 day and a 30 day time frame (provided the device has at least 7 or 30 days of data respectively). If the device has only 5 days of data to use for the calculation, the 5 day average value will be seen under the 7 day display. If you see a large increase in the percent of time in periodic breathing indicated here, contact your home care provider for assistance. This screen only displays if your home care provider has enabled it.
- **90% EPAP** - During any given night, the device recognizes the 90% EPAP (Expiratory Positive Airway Pressure) achieved by the Auto Algorithm. 90% EPAP is defined as the pressure at which the device spent 90% of the session time at or below. For example, if the device recognized airflow for 10 hours, and 9 hours were spent at or below 11 cm H_2O, and 1 hour was spent above 11 cm H_2O, then the 90% EPAP would be 11 cm H_2O. This screen displays the nightly value of 90% EPAP for the most recent 1 day time frame. It also displays the average of these individual nightly values of 90% EPAP over a 7 day and a 30 day time frame (provided the device has at least 7 or 30 days of data respectively). If the device has only 5 days of data to use for the calculation, the 5 day average value will be seen under the 7 day display.
- **Average PS** - Pressure Support is the difference between IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure). This screen displays the average of the Pressure Support values over a 1 day, 7 day, and 30 day time frame (provided the device has at least 7 or 30 days of data respectively). If the device has only 5 days of data to use for the calculation, the 5 day average value will be seen under the 7 day display.
- **Humidifier** - This screen will display 3 settings: power supply (either the 60W or 80W), Tubing type setting, and either the Humidifier setting or the Tube temperature setting (if using).

Device Alerts

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 device status.

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

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.

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

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).

- Device Inoperative - When a device inoperative alarm occurs, a continuous audible indicator sounds. The alarm descriptions later in this manual display this indicator as: ▬▬▬
- Power Failure - 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 manual display this indicator as: • •
- High Priority - When a high priority alarm is active, a series of beeps sounds 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 silenced. The alarm descriptions later in this manual display this indicator as: • • • • • • • • • • •
- Medium Priority - When a medium priority alarm is active, a series of beeps sounds in a 3-beep pattern. This pattern repeats until the cause of the alarm is corrected or the audible alarm is silenced. The alarm descriptions later in this manual display this indicator as: • • •
- Low Priority - When a low priority alarm is active, a series of beeps sounds in a 2-beep pattern. This pattern repeats until the cause of the alarm is corrected or the audible alarm is silenced. The alarm descriptions later in this manual 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 an SD card is inserted or removed from the device) a brief, 1-beep audible indicator sounds. The descriptions later in this manual display this indicator as: •

Silencing an Alarm ( )

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

Alarm Message Screens

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

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

Alert Summary Table:

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

Alarm / Alert	Priority	Audible Indicator	Visual Indicators	Device Action	User Action
Loss of Power	High	• •	Red flashing button; Blank screen	Shuts down	Remove your mask. Press the Alarm Silence/Indicator button to silence the alarm. 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.
Device Inoperative	High	▬▬▬	Red solid button; "Device Inoperative"	Shuts down	Remove your mask. Press the Alarm Silence/Indicator button to silence the alarm. Contact your home care provider for service.

Alarm / Alert	Priority	Audible Indicator	Visual Indicators	Device Action	User Action
Low Pressure	High	• • • • •	Red flashing button; "Low Pressure"	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.
Low Speed	High	• • • • •	Red flashing button; "Low Blower Speed"	Operates	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.
High Pressure	High	• • • • •	Red flashing button; "High Pressure"	Operates; If the alarm continues for 10 seconds, the alarm escalates to a Device 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.
Low Pressure Support	High	• • • • •	Red flashing button; "Low Pressure Support"	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.
Apnea	High	• • • • •	Red flashing button; "Apnea"	Operates	This alarm is generated when an apnea event occurs during therapy. Press the Alarm Silence/Indicator button to silence the alarm. Report the alarm to your home care provider. Continue using your device.
Low Minute Ventilation	High	• • • • •	Red flashing button; "Low Minute Vent"	Operates	This alarm occurs when the calculated minute ventilation is less than or equal to the alarm setting. Press the Alarm Silence/Indicator button to silence the alarm. Report the alarm to your home care provider. Continue using your device.

Alarm / Alert	Priority	Audible Indicator	Visual Indicators	Device Action	User Action
Patient Disconnect	High	• • • • •	Red flashing button; "Patient Disconnect"	Operates	This alarm occurs when the patient circuit is disconnected or has a large leak. Press the Alarm Silence/Indicator button to silence the alarm. Reconnect the patient circuit or fix the leak. If the alarm continues, contact your home care provider for service.
Low Input Voltage	Medium	• • •	Yellow flashing button; "Low Voltage"	Device Operates; Humidifier shuts down	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.
SD Card Corrupted	Low	• •	Solid yellow button; "SD card corrupted Reformat card?"	Operates	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. Choose "yes" to reformat the card. If you choose "no" the card will not be reformatted. Note: Any information on the card will be lost when reformatted. Contact your home care provider with any questions.
SD Card Full	Low	• •	Solid yellow button; "SD card full"	Operates	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.
SD Card: Remove and Reinsert	Low	• •	Solid yellow button; "Reinsert SD Card"	Operates	This alarm occurs when the device cannot read the SD card. The card may be inserted incorrectly. Remove the SD card and reinsert. If the alert continues to occur, replace the SD card or contact your home care provider.
SD Card: Prescription Rejected	Low	• •	Solid yellow button; "SD card inserted: prescription rejected"	Operates	This message occurs when the prescription is missing or incorrect. Contact your home care provider for the correct prescription.

Alarm / Alert	Priority	Audible Indicator	Visual Indicators	Device Action	User Action
SD Card: Prescription Accepted	Info	•	"SD card inserted: prescription accepted"	Operates	This info message will be present for 30 seconds or until the user acknowledges it. No action needed.
SD Card Removed	Info	•	"SD card removed"	Operates	This message occurs when the SD card is removed from the device. It is present for 30 seconds or until the user acknowledges it. No action is needed.
Check Power Alert	Info	none	The following symbol 	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 orange for 30 seconds then return to solid blue. 	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 orange for 30 seconds then return to solid blue. 	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.

Troubleshooting

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

Problem	Why It Happened	What to Do
The airflow does not turn on.	There may be a problem with the blower.	Make sure the device is powered correctly. Make sure "Therapy" is highlighted when pressing the control wheel to start airflow. If the airflow does not turn on, there may be a problem with your device. Contact your home care provider for assistance.
You have a runny nose.	This may be caused by a nasal reaction to the airflow.	Contact your home care provider.

Problem	Why It Happened	What to Do
The device's display is erratic.	The device has been dropped or mishandled, or the device is in an area with high Electromagnetic Interference (EMI) emissions.	Unplug the device. Reapply power to the device. If the problem continues, relocate the device to an area with lower EMI emissions (away from electronic equipment such as cellular phones, cordless phones, computers, TVs, electronic games, hair dryers, etc.). If the problem still occurs, contact your home care provider for assistance.
Nothing happens when you apply power to the device. The backlights on the buttons do not light.	There is no power at the outlet or the device is unplugged.	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. Make sure 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 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 adaptor 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 Ramp feature does not work when you press the Ramp button.	Your home care provider did not prescribe Ramp for you, or your prescription pressure is already set to the minimum setting.	If Ramp has not been prescribed for you, discuss this feature with your home care provider to see if they will change your prescription. If your provider has enabled Ramp, but the feature still does not work, check the pressure setting on the Monitor Pressure screen. If it is set to the minimum setting (4.0 cm H_2O), or the starting pressure 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. The device may be operating in direct sunlight or near a heater.	Clean or replace the air filters. The temperature of the air may vary somewhat based on your room temperature. Make sure that the device is properly ventilated. Keep the device 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. If the problem continues, contact your home care provider.
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.
Tube Temperature is turned on in "Setup" screen but Heated Tubing is not warm. Tube Temperature is turned on in "Setup" screen but Humidifier LED does not stay orange (changes to blue).	Incorrect power supply is being used (60W is used instead of 80W). Heated Tubing is attached incorrectly or damaged.	Make sure the 80W power supply is being used. This can be confirmed by looking at the power supply for the 60W or 80W symbols. This can also be checked by looking at the "Humidifier" settings under the "Info" screen. Inspect Heated Tubing for damage and reconnect. If the problem continues, contact your home care provider.
The mask feels uncomfortable to wear, there is significant air leakage around the mask, or you experience other mask-related issues.	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 provider to be fitted with a different mask.

Accessories

There are several accessories available for your BiPAP autoSV Advanced System One device such as a humidifier, Oximetry module or a modem. Contact your home care provider for additional information on the available accessories. When using optional accessories, always follow the instructions enclosed with the accessories.

CAUTION: Pins of connectors marked with the ESD warning symbol shall not be touched and connections shall not be made without special precautions. 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. It is recommended that all individuals that will handle this device understand these precautionary procedures at a minimum as part of their training.

Adding a Humidifier with or without Heated Tubing

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

WARNING: 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.

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

Using the SD Card

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

Note: If the SD card is inserted in the device, the SD card icon ( ) will display next to "Info" on the Home screen and it will also display in the lower left corner of the Therapy screen.

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

Adding Supplemental Oxygen

Oxygen may be added at the mask connection. Please note the warnings listed below when using oxygen with the device.

WARNINGS:

- When using oxygen with this system, a Philips Respironics Pressure Valve must be placed in-line with the patient circuit between the device and the oxygen source. The pressure valve helps prevent the backflow of oxygen from the patient circuit into the device when the unit is off. Failure to use the pressure valve could result in a fire hazard.
  Note: Refer to the pressure valve's instructions for complete setup information.
- 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.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- 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.

Supplying DC Power to the Device

The Philips Respironics DC Power Cord can be used to operate this device in a stationary recreational vehicle, boat, or motor home. The Philips Respironics DC Battery Adapter Cable, when used with the DC Power Cord, enables the device to be operated from a 12 VDC free-standing battery.

CAUTION: Always ensure that the DC power cord securely fits into your therapy device prior to use. Contact your home care provider or Philips Respironics to determine if you have the appropriate DC cord for your specific therapy device.

CAUTION: When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. Damage to the device may occur.

CAUTION: Only use a Philips Respironics DC Power Cord and Battery Adapter Cable. Use of any other system may cause damage to the device.

Refer to the instructions supplied with the DC Power Cord and adapter cable for information on how to operate the device using DC power.

Service

The device does not require routine servicing.

WARNING: If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, disconnect the power cord and discontinue use. Contact your home care provider.

Traveling with the System

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.

For your convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment and is suitable for airline use. It may be helpful to bring this manual along with you to help security personnel understand the BiPAP autoSV Advanced System One 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. Contact your home care provider for additional information.

Airline Travel

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

Note: It is not suitable for airline use with any of the modems or humidifiers installed in the unit.

Home Cleaning

Cleaning the Device

WARNING: To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the device. DO NOT immerse the device in any fluids.

1. Unplug the device, and wipe the outside of the device with a cloth slightly dampened with water and a mild detergent. Let the device dry completely before plugging in the power cord.
2. Inspect the device and all circuit parts for damage after cleaning. Replace any damaged parts.

Cleaning or Replacing the Filters

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.

CAUTION: Dirty inlet filters may cause high operating temperatures that may affect device performance. Regularly examine the inlet filters as needed for integrity and cleanliness.

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. Allow the filter to air dry completely before reinstalling it. If the foam filter is torn, replace it. (Only Philips Respironics-supplied filters should be used as replacement filters.)
5. If the white ultra-fine filter is dirty or torn, replace it.
6. Reinstall the filters, inserting the white ultra-fine filter first if applicable.

CAUTION: Never install a wet filter into the device. You must ensure sufficient drying time for the cleaned filter.

Cleaning the Tubing

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

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

Disposal

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

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 Philips Respironics Customer Service department at 1-800-345-6443 or 1-724-387-4000. You can also use the following address:

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Specifications

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

Physical: Dimensions: 18 x 14 x 10 cm (7" L x 5.5" W x 4" H)
Weight (Device with power supply): Approximately 1.53 kg (3.37 lbs)

Standards Compliance This device is designed to conform to the following standards:
IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment
IEC 10651-6 Homecare Ventilatory Support Devices
EN 60601-1-2 Electromagnetic Compatibility
RTCA/DO-160F section 21, category M; Emission of Radio Frequency Energy

IEC 60601-1 Classification:
Type of Protection Against Electric Shock: Class II Equipment
Degree of Protection Against Electric Shock: Type BF Applied Part
Degree of Protection against Ingress of Water:
Device: Drip Proof, IP22
60W power supply: Drip Proof, IP22
80W power supply: Drip Proof, IP22
Mode of Operation: Continuous

Electrical: AC Power Consumption (with 60W power supply): 100 – 240 VAC, 50/60 Hz, 2.1 A
AC Power Consumption (with 80W power supply): 100 – 240 VAC, 50/60 Hz, 2.0 A
DC Power Consumption: 12 VDC, 6.67 A
Fuses: There are no user-replaceable fuses.

Noise: Minimum Alarm Sound Level: 45 dB(A)

Declared Dual-Number Noise Emissions Values: In accordance with ISO 4871
The measured A-weighted emission sound pressure level is 27 dB(A) with an uncertainty of 2 dB(A).
The measured A-weighted sound power level is 35 dB(A) with an uncertainty of 2 dB(A).
Note: These measurements apply to this device with an optional humidifier. Use of this device without a humidifier would result in measurements equal to or less than the stated values.
Note: Values determined according to noise test code given in ISO 17510-1:2007, using the basic standards ISO 3744 and ISO 4871.

Pressure Accuracy:
Pressure Increments: 4.0 to 25.0 cm H_2O (in 0.5 cm H_2O increments)
Pressure Stability:

	Static	**Dynamic < 10 cm H_2O**	**Dynamic ≥ 10.0 to 25 cm H_2O**
Device	± 0.5 cm H_2O	≤ 0.5 cm H_2O	≤ 1.0 cm H_2O
Device w/ Humidifier	± 0.5 cm H_2O	≤ 0.5 cm H_2O	≤ 1.0 cm H_2O

Control Accuracy:

Parameter	Range	Accuracy
Breath Rate	4 to 30 BPM	greater of ± 1 BPM or ± 10% of setting
Inspiration time	0.5 to 3 seconds	± (10% of setting + 0.1 second)

Displayed Parameter Accuracy:

Parameter	Accuracy	Resolution	Range
Estimated Leak Rate	± (5 + 15% of reading) LPM	1 LPM	0 to 200 LPM
Exhaled Tidal Volume	± (25 + 15% of reading) mL	1 mL	0 to 2000 mL
Respiratory Rate	greater of ± 1 BPM or ± 10% of reading	1 BPM	0 to 60 BPM
Exhaled Minute Ventilation	± (1 + 15% of reading) LPM	1 LPM	0 to 99 LPM

Maximum Flow Rate: (typical)

		Test pressures (cm H_2O)				
		4.0	**9.0**	**14.5**	**20.0**	**25.0**
22 mm tubing	**Measured pressure at the patient connection port (cm H_2O)**	3.7	8.8	13.5	19.1	24.0
	Average flow at the patient connection port (LPM)	90.5	145.9	158.5	151.6	133.0
15 mm tubing (heated or non-heated)	**Measured pressure at the patient connection port (cm H_2O)**	3.8	7.9	13.5	19.0	24.1
	Average flow at the patient connection port (LPM)	95.0	108.8	108.8	108.8	108.6

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.
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 ±1 kV for input/output lines	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 location in a typical hospital or home 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	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 $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol:

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 W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	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	0.23
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, objects, and people.

Limited Warranty

Respironics, Inc. warrants that the 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, water ingress, and other defects not related to material or workmanship. The Respironics, Inc. Service department shall examine any devices returned for service, and Respironics, Inc. reserves the right to charge an evaluation fee for any returned device as to which no problem is found after investigation by Respironics, Inc. Service.

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

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.

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:

1001 Murry Ridge Lane

Murrysville, Pennsylvania 15668-8550

1-724-387-4000

Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA

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