

BiPAP autoSV Advanced System One

PROVIDER GUIDE



IMPORTANT! Remove this guide before giving the device to the patient. Only medical professionals should adjust pressure settings.

This guide must be used with the User Manual when used by a medical professional. Read and understand the User Manual, the Provider Guide, and all accessory manuals before setting up the device. This guide provides you with instructions on how to access and navigate the provider screens used to modify device settings.

Note: The screens shown throughout this guide are examples only. Actual screens may vary slightly.

Accessing the Provider Mode Screens


Accessing provider mode unlocks settings that cannot be modified by the user. To access provider mode:

1. Supply Power to the device. First, plug the socket end of the AC power cord into the power supply. Then plug the pronged end of the AC power cord into an electrical outlet that is not controlled by a wall switch. Finally, plug the power supply cord's connector into the power inlet on the back of the device.
2. Once the device is powered, the Main Menu appears, shown below. Turn the wheel to toggle between the four options and highlight "Setup".

Therapy	Bi-Flex
Info	Setup

Main Menu

Note: "Bi-Flex" shown above may also display a blank screen or "Rise Time" depending on your settings.

3. Once "Setup" is highlighted, press and hold both the Control Wheel and the Ramp Button  on the device for at least 5 seconds.
4. You will hear a quick double beep and the Provider Menu will appear, shown below. You are now in provider mode.

EXIT	Reminder
Info	Setup

Provider Menu

Navigating the Provider Mode Screens

To navigate these display 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: Choosing “EXIT” from the Provider Screen will exit provider mode and the device will return to the Home Screen in the patient mode.

Note: Provider mode will time out after 30 seconds of inactivity. The device will then automatically exit the provider mode and return to the Home Screen in the patient mode.

Provider Mode Screen Descriptions

The following sections will describe the options available under the 3 choices from the Provider Screen (Reminder, Setup, and Info).

Reminder Screen

From the Provider Menu, highlight “Reminder” and press the wheel. The following Reminder screen will appear:

Reminder	Back
	Reminder off 30 90 180 270 365

Reminder Screen

- **Reminder** - You can set a reminder on this screen that will let patients know when it is time to perform a certain task, such as replacing the mask. You can select one of the following settings: Off (no reminder is set), or you can set the device to display a reminder after 30, 90, 180, 270, or 365 days.

Note: You can set a specific patient reminder message using the EncorePro software, and put this message on the SD Card or send it to the patient’s device via a modem.


Setup Screen

From the Provider screen, highlight “Setup” and press the wheel. The following Setup screen will appear:


Setup	Back	
	Max pressure	4 - 25.0
	EPAP min	4 - Max pres
	EPAP max	EPAP min - Max Pres
	PS min	0 - (Max Pres - Max EPAP)
	PS max	PS min - (Max Pres - Min EPAP)
	BPM	Off Auto 4 - 30
	Ti	0.5 - 3.0
	Flex type	None Bi-Flex
	Bi-Flex	1 2 3
	Rise time	0 1 2 3
	Ramp time	0:00 - 0:45
	Ramp start	4 - EPAP Min
	Tubing Type Lock	on off
	Tubing Type	15 22
	SYSTEM ONE resistance	0 X1 X2 X3 X4 X5
	Lock SYSTEM ONE	on off
	SYSTEM ONE humidification	on off
	Humidifier	0 1 2 3 4 5
	Auto on	on off
	Patient disconnect alarm	0 15 60
	Apnea alarm	0 10 20 30 40
	Low min vent alarm	0 - 99
	Show AHI/leak/PB	on off
	Language	EN ES
	Humidifier LED Backlight	on off
Setup parameter displayed	None Leak RR MinVent Vte	
Back		

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.

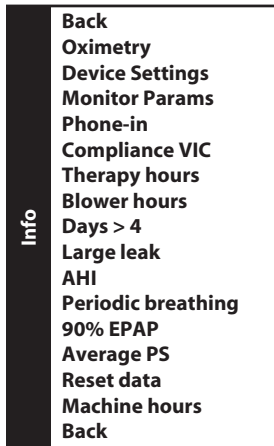
- **Max pressure** - This screen displays the current Maximum pressure setting. You can adjust the setting from 4 to 25 cm H₂O in 0.5 increments.
- **EPAP min** - This screen allows you to modify the Minimum EPAP setting. The setting specified here will be the minimum level of pressure applied during the expiratory breath phase. You may adjust the setting from 4 cm H₂O to the Maximum pressure setting.
- **EPAP max** - This screen allows you to modify the Maximum EPAP setting. The setting you specify here will be the maximum level of pressure applied during the expiratory breath phase. You may adjust the setting from the Minimum EPAP setting to the Maximum pressure setting.
- **PS min** - This screen allows you to modify the Minimum Pressure Support setting. This setting is the minimum difference that is permitted between IPAP and EPAP. You may adjust the setting from 0 cm H₂O to the difference between the maximum pressure setting minus the maximum EPAP setting.
- **PS max** - This screen allows you to modify the Maximum Pressure Support setting. The maximum pressure support is the maximum difference that is permitted between IPAP and EPAP. You may adjust the setting from PS min to the difference between the maximum pressure setting minus the minimum EPAP setting.
- **BPM** - This screen allows you to modify the Breaths Per Minute setting. You can choose between Off, Auto, or 4 through 30 in 1 BPM increments.
Note: This setting only displays if PS max is greater than zero.
- **Ti** - This screen allows you to modify the Inspiratory Time setting. You may adjust the setting from 0.5 to 3.0 seconds in 0.1 increments. This setting only displays if PS max is greater than zero and BPM is not set to Off or Auto.
- **Flex type** - This screen displays the comfort mode setting. You can select None or Bi-Flex.
- **Bi-Flex** - You can modify the Flex setting (1, 2 or 3) on this screen if you enabled Bi-Flex. The Bi-Flex comfort feature allows you to adjust the level of air pressure relief that the patient feels when exhaling during therapy. The setting of “1” provides a small amount of pressure relief, with higher numbers providing additional relief.
- **Rise time** - Rise time is the time it takes for the device to change from the expiratory pressure setting to the inspiratory pressure setting. This screen allows you to adjust the rise time so you can find the desired setting. A setting of “0” is the fastest rise time, while “3” is the slowest. This is only available if Flex type is set to None and PS max is greater than zero.
- **Ramp time** - This enables you to modify the Ramp time setting in 5 minute increments. The range for this setting is 0 (off) to 45 minutes.
Note: This setting only displays if EPAP min is greater than 4 cm H₂O.
- **Ramp start** - You can increase or decrease the ramp starting pressure in 0.5 cm H₂O increments. You may adjust the setting from 4 cm H₂O to the EPAP min setting.
Note: This setting only displays if Ramp time is not zero and EPAP min is greater than 4 cm H₂O.
- **Tubing type lock** - This enables you to lock the Tubing type setting if you do not want the patient to change it.
Note: If you lock this setting, the device defaults to a setting of 22, and the patient will not see the Tubing type setting.
- **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 Respironics 22 mm tubing, or (15) for the optional Respironics 15 mm tubing.
- **SYSTEM ONE resistance ( ←)** - This setting allows you to adjust the level of air pressure relief based on the specific Respironics mask. Each Respironics mask may have a “System One” resistance control setting. System One resistance compensation can be turned off by choosing the setting “0”.
Note: The patient also has access to this setting, if Lock SYSTEM ONE is off.
- **Lock SYSTEM ONE** - This enables you to lock the “System One” resistance control setting if you do not want the patient to change it.
Note: If you lock this setting, the patient will see a “lock” icon next to the 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 or disable this feature if you want the device to automatically turn the airflow on whenever the patient applies the interface (mask) to their airway.
- **Patient disconnect alarm** - You can enable this feature by choosing 15 or 60 seconds. The alarm will sound when a large, continuous air leak is detected in the circuit for longer than the specified setting. You can disable this feature by choosing “0”.
- **Apnea alarm** - This feature detects the cessation of spontaneous breathing. You can enable or disable the alarm by choosing 0 (off), 10, 20, 30, or 40 seconds. The alarm will sound when the time between patient-triggered breaths is greater or equal to the specified setting.
- **Low min vent alarm** - You can enable or disable this feature by choosing 0 (off) to 99 LPM (liters per minute) in 1 LPM increments. The alarm will sound when the calculated minute ventilation is less than or equal to the specified setting.
- **Show AHI/leak/PB** - You can select whether or not the Apnea/Hypopnea index, System Leak averages, and Periodic Breathing averages are displayed on the Patient Info screens.
- **Language** - This feature allows you to choose which language to display on the interface. You can choose English (EN) or Spanish (ES).
- **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.
- **Setup parameter displayed** - You can select which measured parameters will display on the Monitor Pressure screen. You can choose from None, Leak, RR, MinVent, or Vte. The following table describes each measured parameter. The measured parameters that display on the Monitor Pressure screen only appear one at a time.

PARAMETER	DESCRIPTION
Leak 	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)	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.

Info Screen

From the Provider screen, highlight “Info” and press the wheel. The following Info screen will appear.




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 Oximetry module is attached.


WARNING: The data displayed here and stored on the device SD card is not considered to be diagnostic and is not to be used in the diagnosis of a patient’s condition.

- **Device Settings** - This screen allows you to view the current device settings. The following will display: Maximum pressure in cm H₂O, EPAP min in cm H₂O, EPAP max in cm H₂O, Breaths Per Minute in BPM, PS min in cm H₂O, and PS max in cm H₂O.
- **Monitor Parameters** - This screen displays all available measured therapy parameters. The following will display: Estimated Patient Pressure in cm H₂O, Leak () in LPM, Minute Ventilation (MinVent) in LPM, Tidal Volume (Vte) in ml, Respiratory Rate (RR) in BPM, and the pulse oximetry (SpO₂) measurement if available on the device. Example shown below.

cmH ₂ O 4.0	 6	MinVent 6
Vte 200	RR 10	SpO ₂ 98

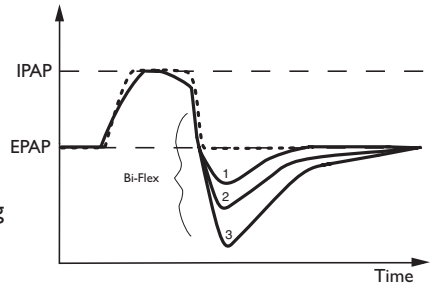
Note: This screen will only display if the blower is on.

- **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. This screen also displays a compliance check number you can use to validate that the data provided to you is the data taken from this screen.
- **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 you can use to validate that the data provided to 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 average amount of time the patient is actually receiving therapy on the device over a 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.
- **Blower hours** - This screen displays the number of hours that the blower has been active over the life of the device.
- **Days > 4** - This screen displays the cumulative number of device therapy sessions that exceeded 4 hours over 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 average of these individual nightly values of percentage of time in large leak over a 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.
- **AHI** - The device accumulates individual Apnea/Hypopnea indices (AHI) for each session the patient used the device. This screen displays the average of these individual nightly AHI values over a 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.
- **Periodic Breathing** - During any given night, the device recognizes the percentage of time the patient was experiencing period breathing. This screen displays the average of these individual nightly values of periodic breathing over a 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.
- **90% EPAP** - During any given night, the device recognizes the 90% Pressure achieved by the autoSV Algorithm. 90% Pressure 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 H₂O, and 1 hour was spent above 11 cm H₂O, then the 90% Pressure would be 11 cm H₂O. This screen displays the average of these individual nightly values of 90% Pressure over a 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.
- **Average PS** - This screen displays the average of the Pressure Support values over a 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.
- **Reset data** - This screen allows you to erase all 7 and 30 day averages, compliance data, therapy hours and patient information on the device. Make sure that “Reset data” is highlighted on the info screen. Press and hold both the control wheel and the ramp button  for at least 5 seconds. The device will beep once signifying that the data has been reset.
Note: Machine hours are not erased.
- **Machine hours** - This screen displays the amount of time that the machine has been active over the life of the device.
Note: Therapy hours and blower hours can be reset for new patients. Machine hours are not erased.

Bi-Flex Comfort Feature

The device consists of a special comfort feature called Bi-Flex. When Flex type is set to 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). In the diagram, the bold lines represent Bi-Flex in comparison to the dashed line representing normal Bi-level therapy. 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.

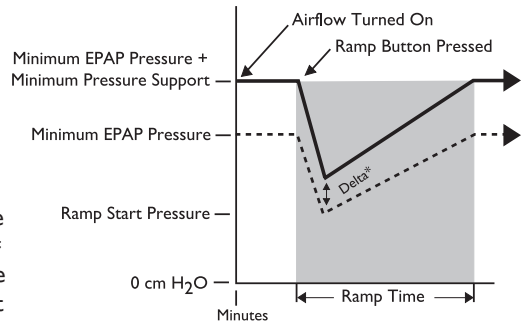


Ramp

The device is equipped with a linear ramp feature that allows patients to reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so they can fall asleep more comfortably. The diagram illustrates how the ramp feature works.

Note: Pressing the Ramp button provides pressure relief by lowering the device output pressures to the EPAP = Ramp Start pressure setting and IPAP = Ramp Start pressure setting + *delta (Min Pressure Support) and ramping to EPAP = Minimum EPAP pressure and IPAP = Minimum EPAP pressure + Min Pressure Support. If patient events are detected during the ramp, the Auto titrating EPAP algorithm will treat the events, and then continue the ramp at the same ramp rate. Due to the pressure increase during the ramp, the ramp duration may be reduced if the device detects and responds to patient events during the ramp.

Note: If Ramp Time is set to zero or if the Ramp Start Pressure is equal to the Minimum EPAP pressure setting, pressing the Ramp key shall provide pressure relief by lowering the EPAP pressure to the Minimum EPAP pressure and restarting the Auto titrating EPAP algorithm.



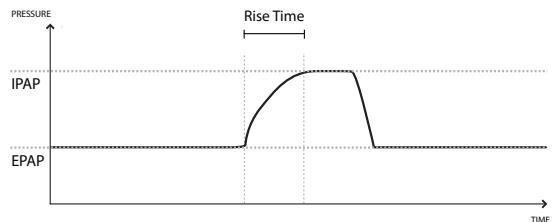
* Delta is defined as the Min Pressure Support setting.

Rise Time Comfort Feature

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.

Adjust the rise time to find the most comfortable setting for the patient. A setting of 0 is the fastest rise time while 3 is the slowest.

Note: Rise time cannot be adjusted when Bi-Flex is enabled. Rise Time during Bi-Flex is 300 msec.



Digital Auto-Trak Sensitivity

An important characteristic of the device is its ability to recognize and compensate for unintentional leaks in the system and to automatically adjust its trigger and cycle algorithms to maintain optimum performance in the presence of leaks. This feature is known as Digital Auto-Trak Sensitivity. The following sections examine this function in detail by describing the leak tolerance function and sensitivity.

Leak Tolerance

A microprocessor monitors the total flow of the patient circuit and calculates patient flow values.

Leak Estimation: Average and Parabolic

The device uses two leak estimation algorithms. A conservation of mass algorithm is used to compute the average leak for a given pressure support relationship. This average leak is used when large leak variations are present in the system. Average leak is a high estimate during EPAP pressure and a low estimate during IPAP pressure.

A better leak estimate, enabled by the digital system, is the parabolic leak algorithm. Parabolic leak is proportional to the square of the patient pressure; therefore, the leak estimate is correlated to the changing patient pressure. Both algorithms include unintentional circuit leak and are averaged over several breaths.

Patient Flow

The total circuit flow is comprised of the circuit leak and the patient flow. The calculated patient flow is the total flow minus the circuit leak. Patient flow is a primary input into the triggering and cycling mechanisms.

Sensitivity

An essential feature of the device's triggering function is its ability to effectively sense spontaneous breathing efforts, which causes the ventilator to trigger to IPAP and cycle to EPAP. Because no preset sensitivity threshold can assure patient and machine synchrony with changing breathing efforts and circuit leaks, the device continuously tracks patient breathing patterns and automatically adjusts sensitivity thresholds to ensure optimum sensitivity as breathing patterns change or as circuit leaks change. The algorithm used to ensure optimum sensitivity is the Volume Trigger.

Volume Trigger (EPAP to IPAP)

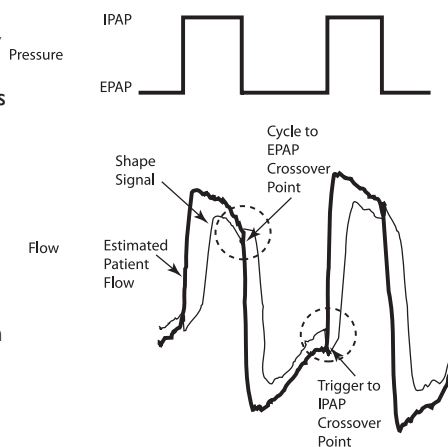
The volume trigger is the method used to trigger IPAP during spontaneous breathing. The volume trigger threshold is 6 ml of accumulated patient inspiratory volume. When patient effort generates inspiratory flow causing 6 ml of volume, IPAP is triggered.

Shape Trigger/Shape Cycle (EPAP to IPAP) (IPAP to EPAP)

The shape trigger/cycle is another method used to trigger IPAP and/or cycle from IPAP to EPAP during spontaneous breathing. This method continuously tracks patient inspiratory and expiratory flow and adjusts the spontaneous trigger and cycle thresholds for optimum sensitivity. The shape signal appears as a shadow image of the patient's actual flow. The shape signal functions as a sensitivity threshold at either inspiration or expiration. When the patient's flow rate crosses the shape signal the device changes pressure levels. The following figure illustrates how the shape signal is superimposed onto the actual waveform to trigger and cycle off IPAP.

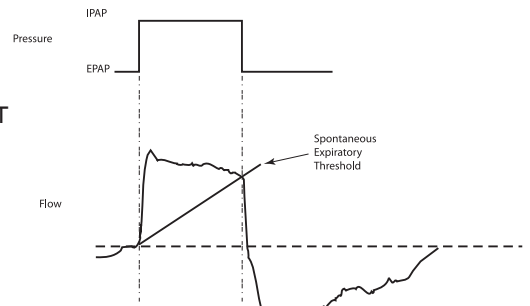
The shape signal is created by offsetting the signal from the actual patient flow by 15 LPM and delaying it for a 300 msec period. This intentional delay causes the shape signal to be slightly behind the patient's flow rate. A sudden change in patient flow will cross the shape signal, causing the pressure level to change.

Tracking the patient's flow pattern with the Shape Signal provides a sensitive mechanism to trigger to IPAP or cycle to EPAP in response to changing breathing patterns and circuit leaks.



Spontaneous Expiratory Threshold (IPAP to EPAP)

The method used to cycle off IPAP during spontaneous breathing is called Spontaneous Expiratory Threshold (SET). The SET rises in proportion to the inspiratory flow rate on each breath. When the SET and the actual patient flow value are equal, the unit cycles to EPAP.



Maximum IPAP Time (IPAP to EPAP)

A maximum IPAP time of 3.0 seconds acts as a safety mechanism to limit the time spent at the IPAP level during spontaneous breathing. Once the time limit is reached, the device automatically cycles off IPAP to the EPAP level.

Flow Reversal (IPAP to EPAP)

As flow begins to decrease during IPAP, a flow reversal can occur due to a large leak around the mask or because the patient's mouth is open. When the device senses this flow reversal, the device automatically cycles to the EPAP level.

Cleaning for Multiple Patient Use (Home or Hospital)

WARNING: If you are using the device for multiple patients, a new bacteria filter shall be used each time the device is used on a different person.

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

1. Unplug the device before cleaning.
2. 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
3. Allow the device to dry completely before plugging in the power cord.

IMPORTANT: The device is not intended for high level disinfection.

Verifying the Pressure

WARNING: If the device fails to perform within the stated specifications, have the system serviced by a qualified Respiroics-approved service facility.

If part of your patient setup procedure is to verify actual pressure with a manometer, please use the following instructions to ensure that the device is functioning properly. You will need the following equipment to verify the pressure:

- Respiroics Pressure Calibration Kit

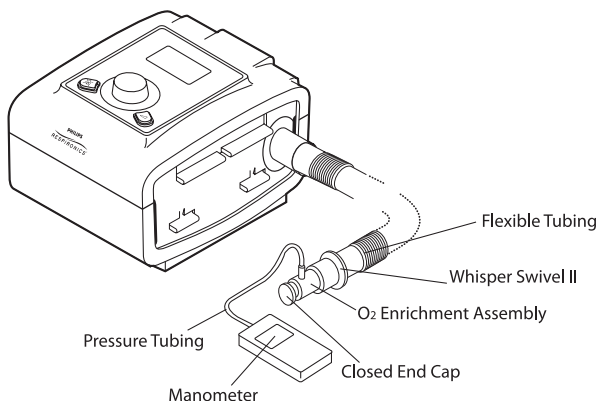
Kit Includes:

- Respiroics Whisper Swivel II
 - Respiroics O₂ Enrichment Final Assembly
 - Closed end cap
- Respiroics flexible tubing
 - Pressure tubing
 - Respiroics Digital Manometer or equivalent

Minimum Specifications:

- 0 - 25 cm H₂O (or better)
- ± 0.3 cm H₂O accuracy
- ± 0.1 cm H₂O resolution

- Foam filter



To verify the pressure, complete the following steps:

1. Install the foam filter into the back of the device.
2. With the device unplugged, connect the system as illustrated in the diagram.
3. Turn the manometer on. If it does not display a reading of zero, adjust the manometer to calibrate it. If the manometer has variable settings for devices, set it to cm H₂O.
4. Supply power to the device then place the device in provider mode.
5. Set the therapy parameters according to the patient specific data.
6. Set the device to the specific pressure value for the patient.
7. Verify that the pressure setting matches the pressure displayed on the manometer. If the pressure setting does not match the measured value for the device, contact Respiroics or an authorized service center to have the device serviced.

Note: Output pressures may vary at local altitude and barometric pressure. Because of these factors, devices may slightly vary in output pressure over the range of the altitude settings.

8. Set up the remaining parameters and exit provider mode. The unit is ready for patient use.

Verifying the Alarms

Use the test orifice from the “Verifying the Pressure” instructions and the patient’s prescription for the following tests.

Patient Disconnect Alarm Test

Note: The Patient Disconnect Alarm relies on a fixed relationship between the patient pressure settings and the open circuit flow of the patient circuit. You must verify that the Patient Disconnect Alarm operates properly with the prescribed patient pressures and circuit.

1. Set the Apnea Alarm setting to Off.
2. Set the Patient Disconnect Alarm setting to 15 seconds.
3. Exit to the Monitor Pressure screen. Remove the closed end cap. Verify that the Patient Disconnect alarm occurs in approximately 15 seconds.
4. Press the Alarm Silence/Indicator button to silence the alarm, and wait for one minute until the alarm sounds again.
5. Press the Wheel to clear the alarm.
6. Replace the closed end cap.
7. Set the Patient Disconnect alarm to Off.

Apnea Alarm Test

8. Set the Apnea Alarm setting to 10 seconds.
9. Exit to the Monitor Pressure screen. Verify that the Apnea alarm occurs in approximately 10 seconds.
10. Press the Wheel to clear the alarm.
11. Set the Apnea Alarm setting to Off.

Low Minute Ventilation Alarm Test

12. Connect the device to a test lung.
13. Observe the displayed Min Vent parameter.
14. Set the Low Minute Ventilation Alarm to a value greater than the displayed Min Vent parameter on the bottom of the Monitoring screen. Verify that the Low Minute Ventilation alarm occurs.
15. Press the Wheel to clear the alarm.
16. Set the Low Minute Ventilation Alarm setting to Off.

Loss of Power Alarm Test

17. While the device is providing therapy, remove the power connector and verify that Loss of Power alarm sounds.
18. Reconnect power and verify that the device resumes providing therapy.

Important: When testing is complete, and before patient use, adjust the device to the appropriate patient settings.

Adding Supplemental Oxygen

Please note the oxygen warnings listed in the User Manual when using supplemental oxygen.

The delivered oxygen concentration varies with changes in flow in the circuit. The following may have an impact on oxygen concentration:

- Pressure settings
- Patient Tidal Volume
- Peak Inspiratory Flow
- I:E Ratio
- Respiratory rate
- Circuit leak rate
- Oxygen flow rate

To add oxygen to the patient circuit, the oxygen supply must comply with the local regulations for medical oxygen. The oxygen flow into the patient circuit cannot exceed 15 LPM and the pressure cannot exceed 50 psi.

Specifications

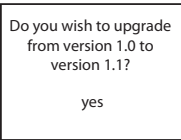
Spontaneous Breathing During Power Failure Conditions

Patient Flow (LPM)	Expiratory Resistance (cm H ₂ O) Passive Circuit	Inspiratory Resistance (cm H ₂ O) Passive Circuit
30	<1.0	<1.0
60	<2.8	<2.8

Updating Software Using the SD Card

You can update the device software using the SD Card. The software update must be done when the therapy is off.

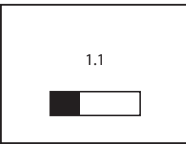
1. Insert an SD Card with the new software version into the device. The following screen appears on the display.



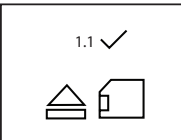
2. Press the Wheel to select “yes” to start the software upgrade. Rotate the Wheel to display “no” and press the Wheel to cancel the software upgrade.
3. If there was a problem with the software on the SD Card before the upgrade process begins, the following informational alert is displayed.



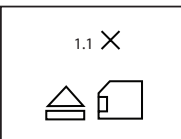
4. While the software upgrade is in progress, the following screen appears on the display. The progress bar will fill as the software upgrade process completes.



5. If the software update process was successful, the following screen appears on the display. Remove the SD Card from the device to restart the device and use the new software.



6. If the software update process was not successful after it was initiated, the following screen appears on the display. Remove the SD Card from the device. Reload the new software onto the SD Card or load the new software onto another SD Card and try again. If the problem persists, contact the customer service department at 1-800-345-6443 or 1-724-387-4000.



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.

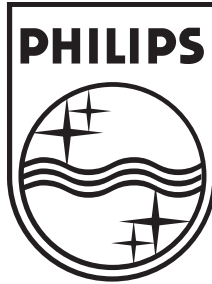
NOTE: U_T is the a.c. mains voltage prior to application of the test level.

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	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>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.</p> <p>b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p>			

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
<p>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.</p> <p>Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			



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