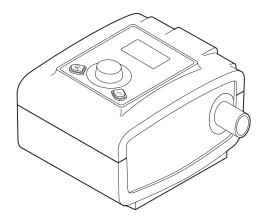


BiPAP AVAPS Provider Manual



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

Note: If required by the physician, ensure that an alternative means of ventilation is available in the event of a system failure.

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

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

Intended Use

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

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

Table of Contents

Intended Use	
Accessing the Provider Mode Screens	3
Navigating the Provider Mode Menu	3
Setup Screen	4
Updating Software Using the SD Card	9
Therapy Features	11
Ramp	11
Bi-Flex Comfort Feature	11
AVAPS	12
Rise Time	13
Digital Auto-Trak Sensitivity	14
Clear Patient Data for Multiple Users	16
Cleaning for Multiple Users	17
Heated Humidifier Performance Confirmation	17
Adding Supplemental Oxygen	18
Supplemental Oxygen Concentrations	
Verifying the Pressure	
Verifying the Alarms	22
Patient Disconnect Alarm Test	22
Apnea Alarm Test	22
Low Minute Ventilation Alarm Test	22
Loss of Power Alarm Test	23
Specifications	23

Accessing the Provider Mode Screens

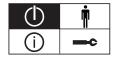
There are two levels of access:

- Provider Mode
- User Mode

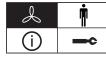
Note: Refer to the User Manual for device details about User Mode.

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

- Supply power to the device: Plug the socket end of the AC power cord into the power supply, and then plug the pronged end of the AC power cord into an electrical outlet 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" or the cicon.







Icon View - Blower Off

Text View

Icon View - Blower On

- 3. Once "Setup" or the •• icon 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 to indicate that you are now in provider mode and can access the provider mode settings.

Note: You will remain in provider mode until you exit the Setup screen using the "Back" selection, or until a screen time-out occurs after one minute.

Navigating the Provider Mode Menu

To navigate the provider mode menu:

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" or the — icon, you will exit provider mode and go back to the previous screen.

Setup Screen (—c)

From the Provider screen, highlight "Setup" or the cion and press the wheel. The following Setup screen will appear. Once you've entered provider mode, the Setup screen below appears. The screen will only display a few lines at a time. As you rotate the Wheel to toggle over different options, the screen slides up and down accordingly.

Note: The menu options will vary depending on what therapy mode you are in.

Note: If the text is too long to completely fit on the screen, it will scroll horizontally across the screen when highlighted.

	←	
	○ PAP	S/T
	CPAP	12
	AVAPS	~
	V _{TF}	500
	IPAP 🛣	25
	IPAP 💌	10
	IPAP	20
	EPAP	5
	BPM	10
	T,	2.0
	FLEX	~
	FLEX	2
	1	~
	~ <u>~</u> •	3
	J_	10
	=	
	•	4
	№ 3555	<u>0</u>
	№	4
	NI	3
ľ	SYSTEM ONE	<u>1</u>
	i i i i i i i i i i i i i i i i i i i	3
	~# 5	<u>ı</u>
	#₩# 	-
	Nº	15
		<u>ı</u>
		X1
		60
	\square \wedge	10
	↓MinVent ⚠	2.0
	↓ ∨ _π Δ	<u>1</u>
	,	-
		<u>1</u>
		English
	hPa cmH ₂ O	cmH_2O
	= 0	Leak
	// ¥	×
	//⊕ ≏	×
	//⊕ ∬ //⊖	
	"	<u>1</u>
		^
$\overline{\mathbf{v}}$	•	
	Icon Viow	

Back Mode S/T CPAP 12 AVAPS 0n Tidal Volume 500 IPAP Max 25 IPAP Min 10 IPAP 20 EPAP 5 BPM 10 T, 2.0 Flex Lock 0n Bi-Flex 2 Rise Time Lock 0n Rise Time 10 Ramp Start Pressure 4 Heated Tube Humidification 0ff Humidity Level 4 Tube Temperature 3 System One Humidification 0n Humidifier 3 Tubing Type 15 System One Resistance Lock 0n System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm 0n Backlight 0n Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode 0n	scro	ll horizontally across	the s
CPAP 12 AVAPS 0 Tidal Volume 500 IPAP Max 25 IPAP Min 10 IPAP 20 EPAP 5 BPM 10 T ₁ 2.0 Flex Lock 0 Bi-Flex 2 Rise Time Lock 0 Rise Time 3 Ramp Time 10 Ramp Start Pressure 4 Heated Tube Humidification 0 Humidity Level 4 Tube Temperature 3 System One Humidification 0 Tubing Type Lock 0 Tubing Type Lock 0 System One Resistance Lock 0 System One Resistance Lock 0 System One Resistance 2 Low Tidal Volume Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm 0 Backlight 0 Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode 0		Back	
AVAPS on Tidal Volume 500 IPAP Max 25 IPAP Min 10 IPAP 20 EPAP 5 BPM 10 T, 2.0 Flex Lock on Rise Time Lock on Rise Time 3 Ramp Time 10 Ramp Start Pressure 4 Heated Tube Humidification off Humidity Level 4 Tube Temperature 3 System One Humidification on Tubing Type Lock on Tubing Type Lock on System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		Mode	S/T
Tidal Volume 500 IPAP Max 25 IPAP Min 10 IPAP 20 EPAP 5 BPM 10 T _i 2.0 Flex Lock on Bi-Flex 2 Rise Time Lock on Rise Time 3 Ramp Time 10 Ramp Start Pressure 4 Heated Tube Humidification off Humidity Level 4 Tube Temperature 3 System One Humidification on Humidificy Level 4 Tube Temperature 3 Tubing Type 15 System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		CPAP	12
IPAP Max 25 IPAP Min 10 IPAP 20 EPAP 5 BPM 10 T ₁ 2.0 Flex Lock on Bi-Flex 2 Rise Time Lock on Rise Time 3 Ramp Time 10 Ramp Start Pressure 4 Heated Tube Humidification off Humidity Level 4 Tube Temperature 3 System One Humidification on Humidifier 3 Tubing Type 15 System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		AVAPS	
IPAP Min			
IPAP 20		-	
EPAP 5			
BPM			
Tiles 2.0			
Flex Lock			
Bi-Flex 2			
Rise Time Lock Rise Time R			
Rise Time			
Ramp Time 10 Ramp Start Pressure 4 Heated Tube Humidification off Humidity Level 4 Tube Temperature 3 System One Humidification on Humidifier 15 System One Resistance Lock on System One Resistance Lock on System One Resistance Lock on System One Resistance Display Leak Reset Therapy Hrs no Resset Blower Hrs no Provider Mode 11 10 10 10 11 12 13 14 15 15 15 15 15 15 15 15 15 15 15 15 15			
Ramp Start Pressure 4 Heated Tube Humidification off Humidity Level 4 Tube Temperature 3 System One Humidification on Tubing Type Lock on Tubing Type Lock on System One Resistance Under the System One Resistance Incompared to the System One Incompared to the System One Incompared to the System One Incompared to the Incompared to Incompared to the I			-
Heated Tube Humidification off Humidity Level 4 Tube Temperature 3 System One Humidification on Humidifier 0 Humidity Level 4 Tube Temperature 3 System One Humidification on Tubing Type Lock 0 Tubing Type Lock 0 Tubing Type Lock 0 System One Resistance Lock 0 System One Resistance Lock 0 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm 0 Backlight 0 Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode 0			
System One Humidification on Tubing Type Lock on Tubing Type Lock on System One Resistance Lock on System One Resistance Lock Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on			
System One Humidification on Humidifier 3 Tubing Type Lock on Tubing Type Lock on System One Resistance Lock on System One Resistance Lock On Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on			
System One Humidification on Humidifier 3 Tubing Type Lock on Tubing Type Lock on System One Resistance Lock on System One Resistance Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		ŕ	
Humidifier 3 Tubing Type Lock on Tubing Type Lock on Tubing Type 15 System One Resistance Lock on System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on			
Tubing Type Lock Tubing Type 15 System One Resistance Lock on System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no	ţt	,	
Tubing Type 15 System One Resistance Lock on System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no	Se	Humidifier	3
System One Resistance Lock on System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		Tubing Type Lock	on
System One Resistance X1 Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no		Tubing Type	15
Patient Disconnect 60 Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no		System One Resistance Lock	on
Apnea Alarm 10 Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no		System One Resistance	X1
Low Min Vent Alarm 2.0 Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		Patient Disconnect	60
Low Tidal Volume Alarm on Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		Apnea Alarm	10
Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		Low Min Vent Alarm	2.0
Backlight on Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		Low Tidal Volume Alarm	on
Language English hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on			
hPa/cmH ₂ O cmH ₂ O Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		•	
Setup Parameter Display Leak Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on			-
Reset Therapy Hrs no Reset Blower Hrs no Provider Mode on		-	-
Reset Blower Hrs no Provider Mode on			
Provider Mode on		.,	
		Clear Patient Data	no
Back	V		

Icon View

Text View

The sections below describe the settings on the Setup screen.

Therapy Settings

- **Mode** (○ PAP) Choose the therapy mode setting (CPAP, S, S/T, T, or PC). The default setting is S/T.
- **CPAP** (**CPAP**) If CPAP is the therapy mode, you can set the CPAP setting in 1.0 increments. The default setting is 10.
- **AVAPS** (**AVAPS**) You can enable or disable AVAPS when in S, S/T, T, or PC mode by selecting "on" or "off". The default setting is off.

Note: AVAPS cannot be enabled if Bi-Flex is turned on. Additionally, the IPAP setting is disabled when AVAPS is enabled.

- **Tidal Volume** (V_{TE}) When AVAPS is enabled, you can set the target tidal volume from 200-1500 ml in 10 ml increments. The default setting is 200.
- **IPAP Max** (IPAP ▲) When AVAPS is enabled, you can set the IPAP Max setting in 1.0 increments. The default setting is 12.
- **IPAP Min** (IPAP **▼**) When AVAPS is enabled, you can set the IPAP Min setting in 1.0 increments. The default setting is 12.
- **IPAP** (**IPAP**) When AVAPS is not enabled, you can set the IPAP setting in 1.0 increments. The default setting is 12.
- **EPAP** (**EPAP**) In any mode except CPAP, you can set the EPAP setting in 1.0 increments. The default setting is 4.

Warning: High EPAP pressures can cause patient discomfort. Carefully evaluate the patient if you set the EPAP level above 15.

- **BPM (BPM)** If you are in S/T or PC mode, you can set the Breaths Per Minute setting from 0-30 in 1.0 BPM increments. If you are in T mode, the minimum BPM setting is 4. The default is 10.
- **T**_i If you are in S/T, T, or PC mode, you can set the Inspiratory Time setting from 0.5 to 3 seconds in 0.1 increments. The default setting is 1.0.

Comfort Settings

• Flex Lock (FLEX a) - When in S mode, you can allow the user to adjust the Bi-Flex setting by selecting "off", or you can lock the Bi-Flex setting so the user cannot adjust it by selecting "on".

• **Bi-Flex (FLEX)** - When in S mode, you can enable or disable the Bi-Flex setting by selecting Off, 1, 2, or 3. This setting allows you to adjust the level of air pressure relief that the patient feels when exhaling during therapy. The default setting is Off.

Note: Bi-Flex only displays if AVAPS is disabled.

Note: If you did not lock the Bi-Flex setting, the user can only adjust the setting from 1-3. They cannot disable Bi-Flex.

Note: Bi-Flex is available up to 25 cmH₂O in S mode.

Note: The patient also has access to the Bi-Flex setting if it is enabled and unlocked.

- Rise Time Lock () You can allow the user to adjust the Rise Time setting by selecting "off", or you can lock the Rise Time setting so the user cannot adjust it by selecting "on".
- **Rise Time** () You can adjust the Rise Time from 1-6. Rise time is the time it takes for the device to change from EPAP to IPAP. This allows you to adjust the rise time so you can find the most comfortable setting for the patient. The default setting is 1.

Note: If you did not lock the Rise Time setting, the user can adjust the setting from 1-6.

- Ramp Time () You can adjust the ramp time from 0 (off) 45 minutes in 5-minute increments. The default setting is 0.
- Ramp Start Pressure ()—I Ramp is enabled, you can adjust the Ramp Start Pressure from 4 to the CPAP or EPAP setting (depending on your therapy mode) in increments of 1. The default is 4. The user can also adjust this setting.
- **Heated Tube Humidification** (This setting will only display if you are using the heated tube. You can enable (1) or disable (0) this feature.
- **Humidity Level** (\(\sum_{\text{inj}}\)) This setting will only display if you are using the heated tube. 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. 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, 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 (1) or disable (0) 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.

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

• **Humidifier** (\$\text{\text{\$

Note: The Humidifier option is only available if the Heated Tubing is removed or has been disabled. **Note:** When not using Heated Tubing, the control wheel can also be used to change this setting.

• **Tubing Type Lock** () - You can lock the Tubing Type setting for either the 22 mm or the 15 mm tubing. "1" turns the lock "on" and "0" turns the lock "off".

Note: If locked, the patient will still see this setting with a "lock" icon next to it, but they will not be able to change it. **Note:** This will not prevent the user from using Heated Tubing at a later date.

• **Tubing Type** () - You can select the correct size diameter tubing that you are using with the device. Choose either "22" for the Philips Respironics 22 mm tubing, or "15" for the optional Philips Respironics 15 mm tubing. When using Heated Tubing, the device will automatically change this setting to the appropriate tubing type (15H).

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

• System One Resistance Lock (← □) - This enables you to lock the "System One" resistance control setting if you do not want the patient to change it. "1" turns the lock "on" and "0" turns the lock "off".

Note: If you lock this setting, the patient will see a "lock" icon next to the setting.

• 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 the System One Resistance Lock is off.

Alarm Settings

- Patient Disconnect Alarm () You can enable or disable the Patient Disconnect alarm by choosing 0, 15, or 60 seconds. The alarm will sound when a large, continuous air leak is detected in the circuit for more than the specified alarm setting. The default is 0.

- Low MinVent Alarm (↓ MinVent ⚠) You can enable or disable the Low Minute

 Ventilation alarm by choosing 0 (off) to 99 lpm in 1.0 increments. The alarm will sound

 when the calculated minute ventilation is less than or equal to the specified setting. The

 default is 0 (off).
- Low Tidal Volume Alarm ($\downarrow v_{TE}$ \bigwedge) When AVAPS is enabled, you can enable or disable the Low Tidal Volume alarm by choosing 0 (off) or 1 (on). If enabled, the alarm will sound when the measured patient pressure has reached the IPAP max setting and the estimated exhaled tidal volume is less than or equal to 90% of the target tidal volume. The default is 0 (off).

System Settings

- **Backlight** () You can turn the button backlights "on" or "off" with this setting.
- Language () This feature allows you to choose which language to display on the interface when in "Text mode". You can also turn off (0) text mode which means the device will display the "Icon Mode" on the interface.

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

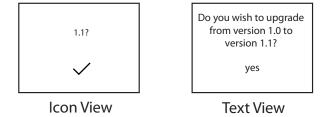
- **hPa/cmH2O** (hPa or "cmH₂O") You can select the units of pressure that are displayed on-screen. Choose "hPa" or "cmH₂O".
- **Setup Parameter Display** () You can select which measured parameters will display on the Monitor Pressure screen. Choose from Leak, RR (Respiratory Rate), Min vent, or Vte. See the Measured Parameter section in the User Manual for more information.
- **Reset Therapy Hours** (✓ 🛣) Resets the Therapy Hours back to the default of 0 hours. This setting is only available to the Provider.
- **Reset Blower Hours (**// () You can select "yes" if you want to reset the blower hours (e.g., to track device usage between patients), or "no" if you do not want to reset the blower hours.
- Provider Mode (n) You can choose "on" or "off" to enable or disable provider mode. Selecting "on" will put the device in provider mode (and the device will not automatically return to user mode when the screen times out or you select the Back option). Selecting "off" keeps the device in user mode.
- Clear Patient Data ($\mathscr{M} \cong$) You can choose to clear the patient data stored in internal memory by setting the Clear Patient Data menu to "yes". If "no" is selected, the confirmation screen is removed, and patient data is not erased from memory or the SD Card.

Updating Software Using the SD Card

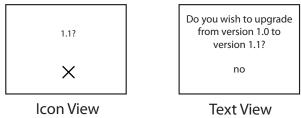
You can update the device software using the SD Card. The software update must be done when the therapy is off.

Note: The screens may vary slightly from the examples shown here (e.g., software version may be different than screens shown here.)

1. Insert an SD Card with the new software version into the device. One of the following screens appears on the display (depending if the Language parameter is set to a specific language or lcon):



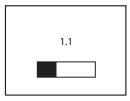
- 2. Press the Wheel to select "yes" or the ✓ displayed to start the software upgrade.
- 3. Rotate the Wheel to display "no" or X, as shown below, and press the Wheel to cancel the software upgrade.



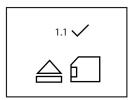
4. If there was a problem with the software on the SD Card before the upgrade process begins, the following informational alert is displayed:



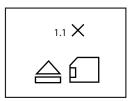
5. While the software upgrade is in progress, the following screen appears on the display. The progress bar will fill as the software upgrade process completes.



6. 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.



7. 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 Philips Respironics Customer Service department at 1-724-387-4000 or 1-800-345-6443.



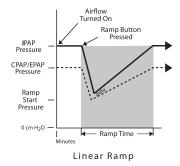
Therapy Features

The device provides the following therapy features. These features are enabled or disabled only in provider mode.

Note: Refer to the User Manual for detailed information about the device therapy modes.

Ramp

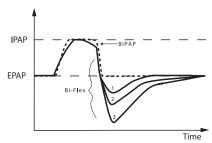
If enabled, the device is equipped with a linear ramp function. The Ramp feature will reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so patients can fall asleep more comfortably. The figure below illustrates how the ramp function works. See the section on AVAPS for information on how the Ramp feature works with the AVAPS feature.



* The delta is defined as the lesser of 2cmH₂O and the difference between IPAP and EPAP pressure settings.

Bi-Flex Comfort Feature

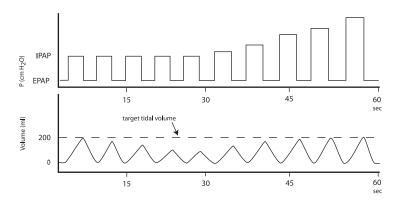
If enabled, the device provides a comfort feature called Bi-Flex in S mode only. The Bi-Flex attribute adjusts therapy by inserting a small amount of pressure relief during the latter stages of inspiration and during active exhalation (the beginning part of exhalation). In the following diagram, the bold lines represent Bi-Flex in comparison to the dashed line representing normal BiPAP 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.



AVAPS

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

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



Activation of the Ramp feature when using the AVAPS feature will reduce the current IPAP to the IPAP Min level and reduce the pressure support capability over the ramp duration. The pressure support will ramp from the IPAP Min setting to the IPAP Max setting. The delivered IPAP will be adjusted as required by the AVAPS algorithm, but may be limited by the ramp function.

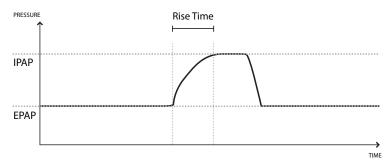
Use of the ramp may impact pressure support delivery and the ability of the unit to achieve target tidal volumes.

Note: Low Tidal Volume alarms will not be active during ramp periods.

Rise Time

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

Note: When Bi-Flex is enabled, Rise Time is fixed at 3.



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.

A. 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.

B. 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 while operating in the S, S/T, PC, and T modes 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 algorithms used to ensure optimum sensitivity are the Volume Trigger, Shape Signal, and the Spontaneous Expiratory Threshold (SET).

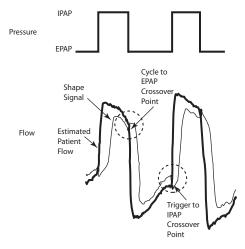
Volume Trigger (EPAP to IPAP)

The volume trigger is one method used to trigger IPAP during spontaneous breathing in the S, S/T, and PC modes. 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 in the S, S/T, and PC modes. 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.

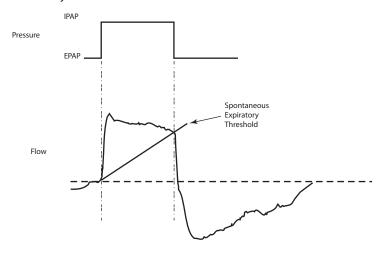
The shape signal is created by offsetting the signal from the actual patient flow by 15 lpm and delaying it for a 300 msec period. This intentional delay causes the shape signal to be slightly behind the patient's flow rate. A sudden change in patient flow will cross the shape signal, causing the pressure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

A second method used to cycle off IPAP during spontaneous breathing in the S, S/T, and PC modes is called Spontaneous Expiratory Threshold (SET). The SET rises in proportion to the inspiratory flow rate on each breath. When the Spontaneous Expiratory Threshold (SET) and actual patient flow value are equal, the device 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 in the S, S/T, and PC modes. 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.

Clear Patient Data for Multiple Users

If you are using the device on multiple users, you must use the "Clear Patient Data" option available through the Setup screen. Refer to the "Setup Screen" section of the User Manual for additional information.

Cleaning for Multiple Users



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

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.

Note: Additional cleaning details may be found in the User Manual.

Heated Humidifier Performance Confirmation

Humidifier preheat mode can be used to determine if the System One Heated Humidifier is working properly. The following steps should be followed if there is a desire to confirm the performance of the System One Heated Humidifier.



Marning: It is important to follow the exact steps below when performing this test in order to ensure no injury. Read all steps first before performing this test.



(All warning: Do not place your hand directly on the heater plate at any time during this test as it could result in a burn.

- 1. Disconnect the patient tubing (if attached) and remove the water tank.
- While the therapy device is not running, place your hand above the heater plate (without 2. touching it) to assess the temperature of the heater plate when off for later comparison.
- 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" or the \bigcirc icon, 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.

- 4. Allow the device to run in preheat mode for 30 seconds.
- 5. Place your hand above the heater plate (without touching it) to confirm an increase in heater plate temperature.
- 6. Press the control wheel while "Therapy" or the ① icon is highlighted on the Home screen to enter therapy and end preheat mode.
- 7. Press and hold the control wheel again to turn off therapy.

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:

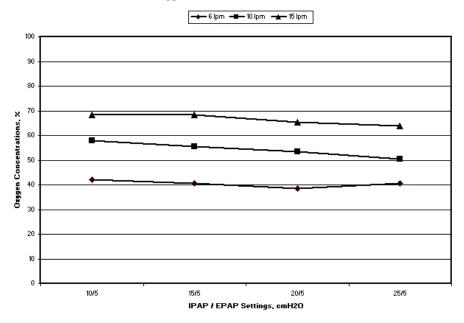
- Pressure settings
- Patient Tidal Volume
- Peak Inspiratory Flow
- I:E Ratio
- Respiratory rate
- Circuit leak rate
- Oxygen flow rate

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.

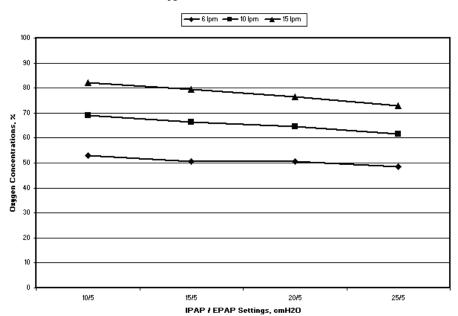
Supplemental Oxygen Concentrations

The following figures illustrate the potential range of oxygen concentration available to the patient at a given tidal volume, supplemental oxygen flow, and pressure setting. The figures represent bench test results without inadvertent mask leaks when oxygen is administered at the ventilator outlet. Substantial leaks around the mask may reduce the expected oxygen concentration delivered to below the levels shown in these figures. This guideline may be used as a starting point for initiating oxygen therapy. Oxygen flow should be gradually adjusted until the patient's oxygen needs are adequately met.

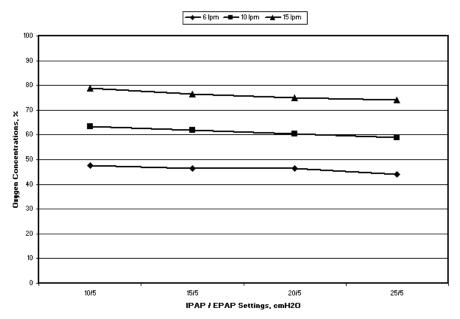
Oxygen Concentrations 300 ml Tidal Volume



Oxygen Concentrations 600 ml Tidal Volume



Oxygen Concentrations 1000 ml Tidal Volume



Verifying the Pressure

 $oldsymbol{A}$ Warning: If the device fails to perform within the stated specifications, have the system serviced by a qualified Philips Respironics-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:

Philips Respironics Pressure Calibration Kit includes:

- Philips Respironics Whisper Swivel II
- Philips Respironics O₂ Enrichment Final Assembly
- Closed end cap
- Philips Respironics flexible tubing
- Pressure tubing

Philips Respironics Digital Manometer or equivalent

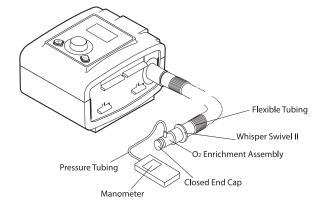
Minimum Specifications:

- 0 30 cm H₂O (or better)
- ±0.3 cm H₂O accuracy
- ±0.1 cm H₂O resolution
- Foam filter

Note: The device automatically compensates for pressure drops associated with a 6-foot (1.83 m) smooth bore tube. Additional pressure drops will occur when restrictive elements such as a bacteria filter or Pass-over humidifier are added to the patient circuit. Always use a manometer to verify patient mask pressure.

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 Philips Respironics or an authorized service center to have the device serviced.
- 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

- 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.
- Set the Patient Disconnect alarm to Off.

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.

Apnea Alarm Test

- 1. Set the Apnea Alarm setting to 10 seconds.
- 2. Exit to the Monitor Pressure screen. Verify that the Apnea alarm occurs in approximately 10 seconds.
- 3. Press the Wheel to clear the alarm.
- 4. Set the Apnea Alarm setting to Off.

Low Minute Ventilation Alarm Test

- 1. Connect the device to a test lung.
- 2. Observe the displayed Min Vent parameter.
- 3. 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.
- Press the Wheel to clear the alarm.
- 5. Set the Low Minute Ventilation Alarm setting to Off.

Loss of Power Alarm Test

- 1. While the device is providing therapy, remove the power connector and verify that Loss of Power alarm sounds.
- 2. 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.

Specifications

Note: Refer to the User Manual for complete device specifications.



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



REF 1105885

1105909 R00 JJB 01/01/2013