

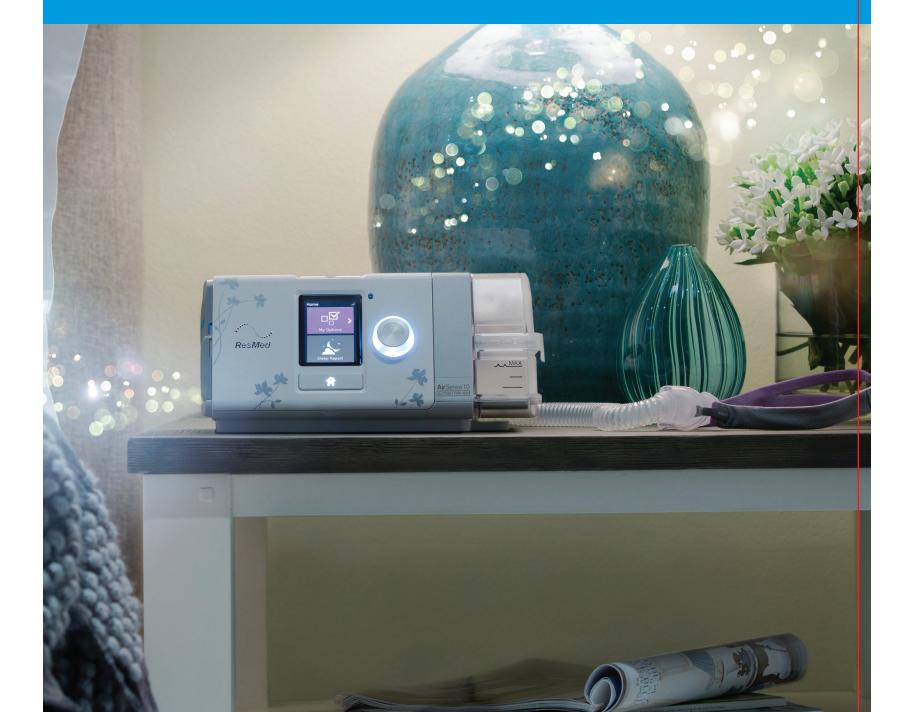
Sleep Lab Titration Guide



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Introduction





S9™ VPAP™ Tx Lab System

ResMed's award-winning sleep lab titration system is designed with the patient's comfort in mind. A truly all-in-one lab system, the S9 VPAPTx delivers comfortable therapy and caters to all patient types, allowing them to fall asleep and stay asleep, so your titrations are an overnight success.

The S9 VPAPTx provides continuous positive airway pressure (CPAP) and bilevel therapy. The S9 VPAPTx is a component of the S9 VPAPTx Lab System. The S9 VPAPTx Lab System provides remote PC control of a positive airway pressure therapy device (therapy device) capable of delivering multiple therapy modes. The system comprises:

EasyCare Tx software

- On-screen remote control of the therapy device
- Highly customized for the clinical environment to help manage a wide range of patients from one system
- Creates summary reports and prescriptions

Tx Link

- Provides connectivity between the software and
- Seamlessly integrates with all existing major polysomnography (PSG) systems, relaying real-time signals measured by the therapy device directly to the PSG equipment

S9 VPAP Tx therapy device

- Built on the award-winning S9 platform small, sleek, silent
- Makes treating a wide range of patients possible with adult and pediatric therapy titration applications
- Uses Climate Control, ResMed's most advanced humidification technology, to maximize patient comfort and minimize overall titration pressure

Delivering Efficient, Consistent Results

Patient comfort features

Climate Control humidification technology intelligently adapts to environmental conditions and delivers optimal temperature and humidity right to the mask via ClimateLine™ tubing. Our Climate Control technology simplifies titration while reducing rainout and dryness issues, which can lead to an average increase in usage of 30 minutes.1

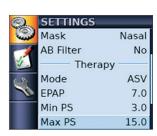
Whisper-quiet operation minimizes therapy disruptions as one of the quietest home therapy devices on the market and is available in our all-in-one lab titration device (26dBA).

Sleep lab efficiency features

ResMed's S9 VPAPTx makes patient therapy acceptance simple with all of its essential and advanced modes.

Intuitive and easily customizable software

reduces training time and allows navigation and control of all settings at the bedside and control room. Technicians can manage multiple patients across a spectrum of disorders in the same night allowing technicians to be more effective.



ResMed's Special Mask Fitting Feature displays real-time leak when fitting the mask at the bedside and ensures the selected mask has a proper seal before starting titration.

The color LCD provides quick access to therapy settings for easy device navigation at the patient's bedside.

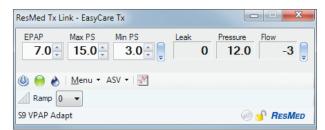
Guided mode transitions eliminate sudden changes in pressure and enable a smooth transition from one mode or pressure to another.

Customizable default settings enable customization of therapy settings in accordance with your lab protocols.

Customized prescription and detailed settings reports

capture all changes made to therapy pressures and settings during the night and can be easily generated and edited. With final mask and device settings incorporated into the script, study turnaround times can be minimized.

True leak reporting automatically displays accurate mask leak data, eliminating the need to reference charts to calculate appropriate leak values.



EasyCare Tx software has a user-friendly toolbar that allows remote control of a therapy device while displaying current therapy settings.

1 Wimms AJ, Richards GN, Benjafield et al. Adherence comparison of a new CPAP system in sleep disordered breathing. Sleep 2011

ResMed Therapy Modes and Algorithms, Specifications

The S9 VPAPTx gives you access to all of ResMed's advanced titration modes to provide complete care across the full range of sleep disorders.

ResMed technologies such as iVAPS™ and ASVAuto combine with innovative features like TiControl™ to make it easy and efficient to achieve comfortable, quality patient care.

Adult and pediatric therapy titration applications (CPAP, S, ST, T and PAC modes) are indicated for patients weighing more than 30 lb (13 kg), allowing sleep labs to provide titration for a wider range of patients. All other modes are indicated for patients weighing more than 66 lb (30 kg).

Technical Specifications

Pressure Ranges

CPAP

4-20 cm H2O (EPR 0-3)

AutoSet™

APAP 4-20 cm H2O (EPR 0-3)

Bilevel (S, S/T, T, PAC)

EPAP 3-25 cm H2O, IPAP 4-30 cm H2O

EPAP 4-25 cm H2O, IPAP 4-25 cm H2O

ASV and ASVAuto

EPAP 4-15 cm H2O,

Pressure Support 0-20 cm H2O

iVAPS

EPAP 3-25 cm H2O,

Pressure Support 0–27 cm H2O

Two-layered, powder-bonded, polyester

non-woven fiber

Altitude Compensation

Automatic

Electrical Requirements

100-240 V

DC Power

Direct connect cord

EasyCare Tx Software

Minimum Hardware and **Software Requirements**

- PC (Mac not supported)
- Pentium 1 GHz CPU
- 1 GB RAM
- 1024 x 768 display resolution
- 10/100 Mbps Ethernet Port
- Microsoft Windows Vista.
- Windows XP ≥ SP2 or Windows 2007
- Microsoft .NET Framework 2.0
- Cat5 cable or available network port between patient room and control room

S9 VPAP Tx Accessories

H5i™ Cleanable Tub	36800
H5i Standard Tub	36803
ClimateLine™	36995
ClimateLine MAX Oxy	36996
Filter (1 Pack)	36850
Filter (2 Pack)	36851
Filter (12 pack)	36852
Filter (50 pack)	36853

Mode of ventilation	What it does	Treats patients with	Pressure capabilities
CPAP (continuous positive airway pressure)	Fixed pressure delivered with optional	OSA	4–20 cm H ₂ O
	expiratory pressure relief (EPR)	Patients weighing more than 30 lb (13 kg)	
AutoSet for Her/APAP	Automatically adjusts pressure in response to flow limitation, snore and obstructive apneas along with an increased sensitivity to each flow-limited breath, providing a more comfortable therapy for women. Increases sensitivity to each flow-limited breath, providing a more comfortable therapy for women	OSA Female patients with mild to moderate OSA weighing more than weighing more than 66 lb (30 kg)	4–20 cm H ₂ O
AutoSet/APAP (automatic positive airway pressure)	Automatically adjusts pressure in response to flow limitation, snore and obstructive apneas	OSA Patients weighing more than 66 lb (30 kg)	4-20 cm H ₂ 0
VAuto	Automatically adjusts pressure in response to flow limitation, snore and obstructive apneas; Pressure Support (PS) is fixed throughout the night and can be set by the clinician	OSA, non-compliant OSA Patients weighing more than 66 lb (30 kg)	4 – $25~\mathrm{cm}~\mathrm{H}_2\mathrm{O}$
ASV (adaptive servo-ventilation)	Targets the patient's minute ventilation, continually learning the patient's breathing pattern and instantly responding to any changes	Central or mixed apneas, complex sleep apnea, Periodic Breathing (PB) Patients weighing more than 66 lb (30 kg)	4 – $25~\mathrm{cm}~\mathrm{H}_2\mathrm{O}$
ASVAuto	Provides an ASV algorithm plus expiratory positive airway pressure (EPAP) that automatically responds on the patient's next breath to flow limitation, snore and obstructive sleep apneas	Central or mixed apneas, complex sleep apnea, Periodic Breathing (PB) Patients weighing more than 66 lb (30 kg)	$4-25~\mathrm{cm}~\mathrm{H_2O}$
S (Spontaneous)	Senses when the patient is inhaling and exhaling, and supplies appropriate pressures accordingly. Both treatment pressures are preset: inspiration (IPAP) and expiration (EPAP)	Non-compliant OSA and COPD Patients weighing more than 30 lb (13 kg)	3 – $30~\mathrm{cm}~\mathrm{H}_2\mathrm{O}$
ST (Spontaneous/Timed)	Augments any breaths initiated by the patient, but also supplies additional breaths if the breath rate falls below the clinician's set "backup" respiratory rate	COPD, NMD, OHS and other respiratory conditions Patients weighing more than 30 lb (13 kg)	3 – $30~\mathrm{cm}~\mathrm{H}_2\mathrm{O}$
T (Timed)	Supplies a clinician-set respiratory rate and inspiratory/expiratory time, regardless of patient effort	COPD, NMD, OHS and other respiratory conditions Patients weighing more than 30 lb (13 kg)	3–30 cm H ₂ O
iVAPS (intelligent Volume-Assured Pressure Support)	Maintains a preset target alveolar minute ventilation by monitoring delivered ventilation, adjusting the pressure support and automatically providing an intelligent backup breath	COPD, NMD, OHS and other respiratory conditions Patients weighing more than 66 lb (30 kg)	3–30 cm H ₂ O
PAC (Pressure Assist Control, also known as Pressure Control)	The inspiration time is preset in the PAC mode; there is no spontaneous/flow cycling. Inspiration can be triggered by the patient when respiratory rate is above a preset value, or delivered at a set time at the backup rate	NMD, pediatric patients Patients weighing more than 30 lb (13 kg)	3–30 cm H ₂ O

Votes	

Getting Started

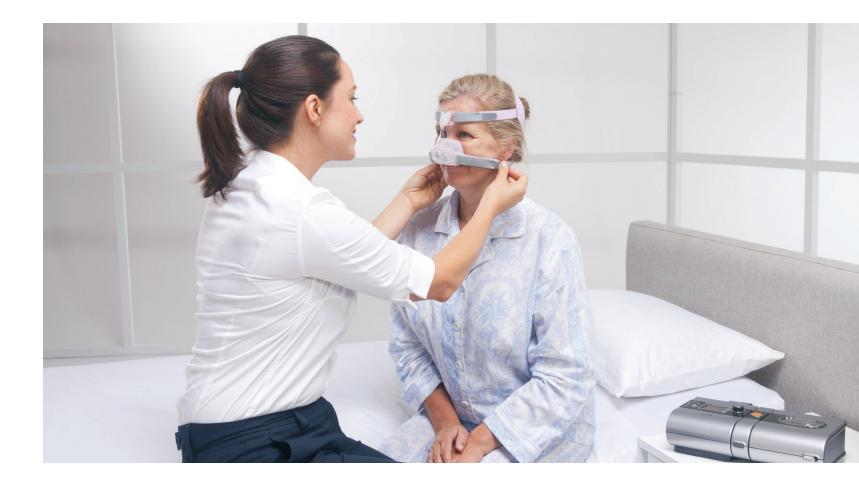


S9 VPAP™ Tx Control Panel



	Кеу	Function
	Start/Stop button	Starts or stops treatment. Power Save mode – hold for three seconds.
i	Info menu button	Allows you to view the device service information or to exit from the menu.
R	Setup menu button	Allows you to make changes to settings or to exit from the menu.
	Push dial	Turning the dial allows you to scroll through the menu and change settings. Pushing the dial allows you to enter into a menu and confirm your choice.
	Alarm mute button	Press once to mute alarms. Press a second time to un-mute. If the problem is still present, the alarm will sound again after two minutes.
	LCD screen	Displays the menus, treatment screens and reminders.
	LCD screen backlight	When treatment is being delivered, the backlight (including the Start/Stop button) automatically turns off after 30 seconds, otherwise it turns off after three minutes.
	Alarm LED	Yellow LED – flashes during an alarm.
	Therapy LED	Blue LED – always on during therapy (if enabled in the Options menu).

At the bedside



Setting Up the S9 VPAP Tx

- 1 Align the H5i with the S9 VPAPTx and push them together until they click into place.
- 2 Connect the DC plug of the power supply unit to the rear of the S9 VPAPTx.
- 3 Connect the power cord to the power supply unit.
- 4 Plug the USB Module into the Module/ Adaptor port at the rear of the S9 VPAPTx.
- 5 Connect the S9 VPAP Tx to the Tx Link via the USB serial cable.
- 6 Plug the other end of the power cord into the power outlet.
- Connect one end of the air tubing firmly onto the air outlet.
- 8 Connect the assembled mask system to the free end of air tubing.



Filling the H5i Water Tub

The S9 VPAPTx is compatible with the integrated H5i heated humidifier. For further information on using this humidifier refer to the H5i user guide.



Slide the silver latch on the front of the device and lift open the flip lid. Remove the water tub



Through the center hole, fill the water tub with room temperature (do not use hot or cold) distilled water up to the max water level mark (380 mL).

Filling water tub while still in humidifier may damage unit. Overfilling the water tub may result in water splashing through the tubing.

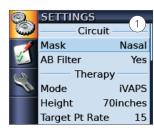


Return the water tub to the H5i.

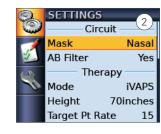


Close the flip lid, ensuring that it clicks into place.

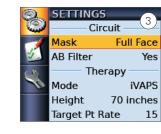
Navigating the Menus



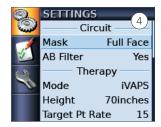
Turn the push dial until the parameter you require is displayed in blue.



Press the push dial. The selection is highlighted in orange.



Turn the push dial until you see the setting that you require.



Press the push dial to confirm your choice. The screen returns to blue.

Mask Type and Tube Type Settings

Use the following settings below for each mask type:

Mask type	Settings
Full Face	Full Face
Pillows	Pillows
Nasal	Nasal (for Ultra Mirage mask, use 'Nasal Ultra')
Pediatric	Pediatric

- For more information on assembling the mask, see the mask user guide.
- For a complete list of recommended masks and their settings go to www.resmed.com on the Support page under Masks. If you do not have Internet access, please contact your ResMed representative.

The S9 VPAP Tx is compatible with the following air tubing:

Air Tubing	Specifications	Settings
ClimateLine	Heated Length: 6'6" (2 m) Inner diameter: 0.6" (15 mm)	Automatically detected
ClimateLine MAX Oxy	Heated Length: 6'3" (1.9 m) Inner diameter: 0.75" (19 mm)	Automatically detected
ClimateLine MAX	Heated Length: 6'3" (1.9 m) Inner diameter: 0.75" (19 mm)	Automatically detected
SlimLine	Length: 6' (1.8 m) Inner diameter: 0.6" (15 mm)	If using the SlimLine, Standard or 3 m air tubing, adjust the tube setting via the Setup menu.
Standard	Length: 6'6" (2 m) Inner diameter: 0.75" (19 mm)	If using the SlimLine, Standard or 3 m air tubing, adjust the tube setting via the Setup menu.
3 m	Length: 9'10" (3 m) Inner diameter: 0.75" (19 mm)	If using the SlimLine, Standard or 3 m air tubing, adjust the tube setting via the Setup menu.

Note: The ClimateLine, ClimateLine MAX and ClimateLine MAX Oxy are designed only for use with the H5i.

Mask Fit

Mask Fit is designed to help fit the mask properly to the patient. The Mask Fit feature delivers CPAP pressure for a three-minute period, prior to starting treatment. During this time, the mask can be adjusted to minimize leaks.

To use Mask Fit:

- Fit the mask as described in the mask user guide.
- Press the push dial for at least three seconds.
 One of the MASK FIT screens is displayed (as shown on the right).
- If necessary, adjust the mask, mask cushion and headgear until there is a secure and comfortable fit.
 After three minutes, the pressure reverts to the set pressure and treatment will begin. You can end Mask Fit at any time by pressing the push dial.







Viewing the Treatment Screens

Depending on how the system has been configured and what mode has been selected, you will see one of the following screens (shown in iVAPS mode below) when the device is running:



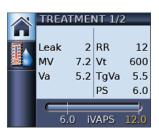
H5i humidifier



- H5i humidifier
- ClimateLine/ClimateLine MAX
- Climate Control Auto



- H5i humidifier
- ClimateLine/ClimateLine MAX
- Climate Control Manual



Therapy data

To toggle between the treatment screens, press the push dial from your HOME screen.



Treatment with device trigger (Timed) and cycle (Timed, Ti Max or Ti Min) breath indicators

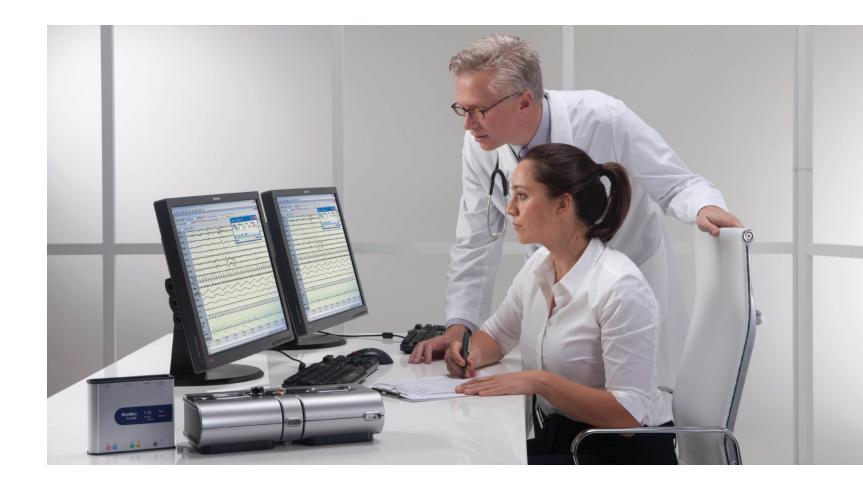


Treatment with spontaneous trigger and cycled breaths

Pressure bar:

In bilevel modes, the pressure bar is marked with fixed vertical lines indicating the expiratory and inspiratory pressures. In CPAP and AutoSet modes, only a set pressure is shown.

In the Control Room



Starting a Session

Before you start titrating a patient, you need to start EasyCare Tx and then start a titration session.

To start a titration session:

1. Double-click the EasyCare Tx icon on the Desktop. The EasyCare Tx toolbar is displayed and the default Tx Link is automatically connected. (If the Tx Link is not automatically connected, connect to a Tx Link.)



- 2. Configure Mask and Humidifier Settings.
- 3. Click the *Therapy Start/Stop* icon. Titration begins and the therapy indicator turns green.

Note: The Therapy ON/OFF indicator turns green during therapy and gray when therapy is off.

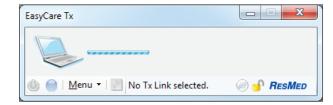
Manual Connection to a Tx Link

Connecting to a Tx Link

If you do not specify a default Tx Link in User Preferences, the following window is displayed every time you launch EasyCare Tx. From this window you can connect to any Tx Link on the network.

To connect to Tx Link:

- 1. From the Menu drop-down, click Connect. The Select Device window is displayed.
- 2. Select the required Tx Link from the Connect To drop-down list.
- 3. Click OK. A window indicating that EasyCare Tx is establishing a connection with Tx Link is displayed. Within a few seconds, EasyCare Tx will connect to the Tx Link.



Connectivity issues

You may experience connectivity issues in the following circumstances:

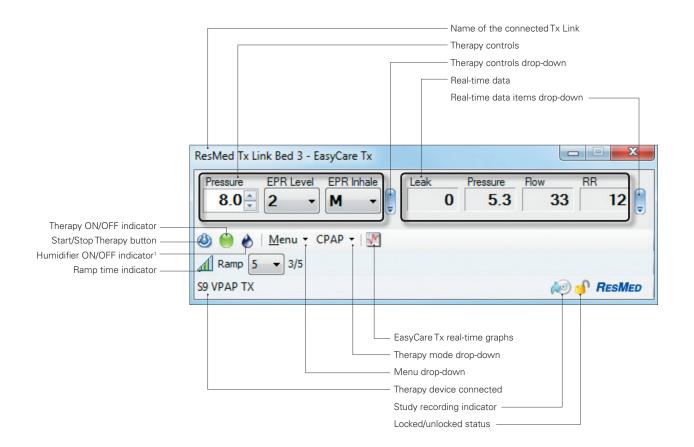
- EasyCare Tx is unable to connect to the Tx Link;
- EasyCare Tx loses connectivity with the Tx Link;
- Tx Link is unable to connect to the therapy device; or
- Tx Link loses connectivity with the therapy device.

In such instances, a window indicating the connectivity status is displayed and this helps you to take the appropriate action to restore connectivity. For instructions on resolving these issues, refer to troubleshooting in the S9 VPAPTx Clinical Manual.

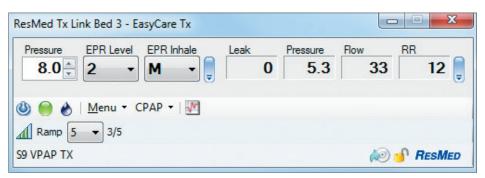
24 hour support is available at (888) 288 6738.

EasyCare Tx Toolbar Overview

EasyCare Tx is designed as a user-friendly toolbar and allows remote control of a therapy device while displaying current therapy settings.



Toolbar shown without callouts for clarity.



¹ The Humidifier icon is only displayed if the connected therapy device has a humidifier that can be remotely controlled.

Configurations and Settings

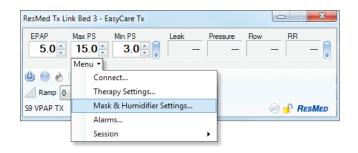
Configuring circuit settings

Before starting therapy, select the mask type used by the patient and review the humidifier settings.

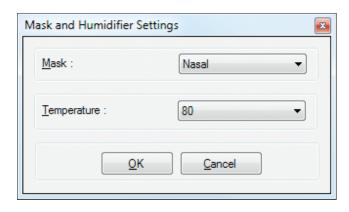
- Mask Settings: Mask Settings can be specified either at the bedside from the therapy device, or remotely using EasyCare Tx.
- Humidifier Settings: EasyCare Tx automatically provides humidifier controls relevant to the therapy device and H5i humidifier connected. Refer to the clinical guides provided with the therapy device and humidifier.

To configure circuit settings:

1. From the *Menu* drop-down, click *Mask* and Humidifier Settings. The Mask and Humidifier Settings window is displayed.



- 2. Select the required mask type from the Mask drop-down list.
- 3. Select the desired humidifier option from the Humidifier drop-down list, or the desired temperature setting from the Temperature drop-down list.
- 4. Click OK. The mask and humidifier settings are applied to EasyCare Tx.



Adjusting therapy settings

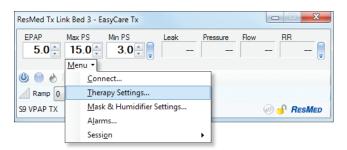
Therapy settings can be controlled in two ways:

- By adjusting individual parameters displayed on the toolbar
- Using the Therapy Settings window

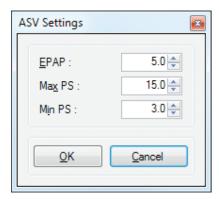
When adjusting individual parameters displayed on the toolbar, the changes are applied instantly. If a confirmation is not sent from the therapy device within two seconds, the parameter will revert to the original value. Alternatively, using the Therapy Settings window, changes are made to one or more parameters related to a therapy. To ensure the therapy setting changes have been accepted select the OK button.

To configure circuit settings:

1. From the Menu drop-down, select Therapy Settings. The current therapy settings window is displayed.



- 2. Change the appropriate therapy settings as required.
- 3. Click OK. The updated therapy settings are applied to EasyCare Tx.

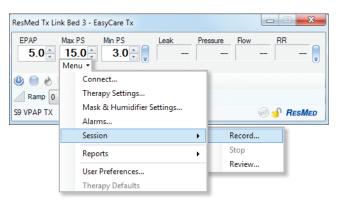


Detailed Settings Report

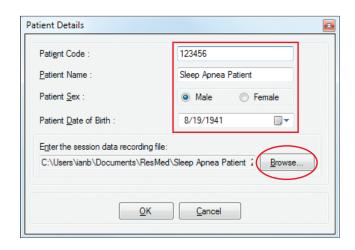
The Detailed Settings Report is an easy and efficient way to capture and display all pressure, mode and settings changes made during a session.

1. Record the session prior to starting therapy

a. From the Menu drop-down, select Session > Record



b. Populate the patient details in the pop-up window and click Browse to pull up the "Save Session Data" dialog box



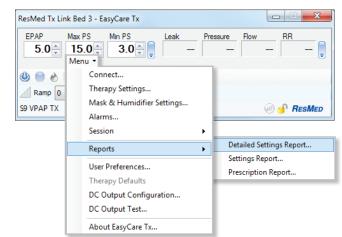
c. Choose a location to save the file, enter the file name and click Save

Note: EasyCare Tx will remember and load the previous location selected by the user as default.

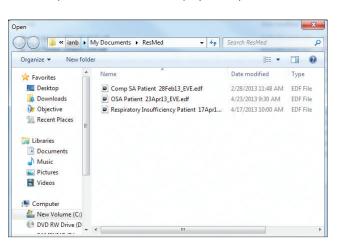
d. Click *OK* to begin recording. To stop the recording, select Session > Stop from the Menu drop-down

2. Run and print the Detailed Settings Report

a. From the Menu drop-down, select Reports > Detailed Settings Report



- b. Click Browse and select the saved patient file
- c. Click Open, and click OK to display the report

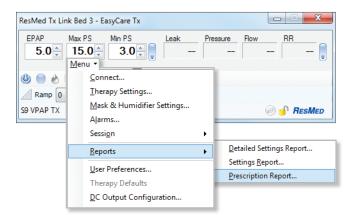


d. Click the *Print* icon to print the report

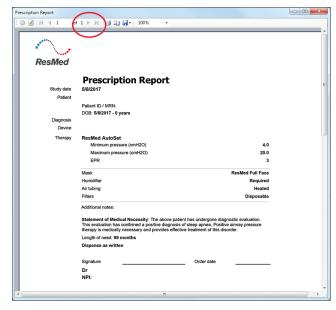


Running and Printing a Prescription Report

1. From the *Menu* drop-down, select *Reports > Prescription* Report. This will open a separate window for the report.



2. Use the print, or save, report button at the top of the screen. Follow standard procedures for your computer.



Obstructive Sleep Apnea (OSA)



CPAP/APAP

ResMed's AirSense™ 10 CPAP include Elite and AirSense 10 AutoSet and AutoSet for Her devices are recommended for patients suffering from obstructive sleep apnea (OSA).

The devices come with a variety of customizable comfort features to help patients get the quality sleep they deserve and are equipped with a range of technologies that help provide effective, tailored therapy for patients, including:

- Clinically proven algorithms
- Advanced event detection
- Comfort enhancing features



AutoSet Algorithm

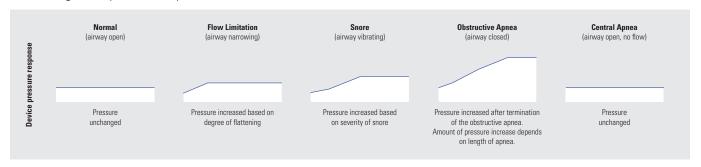
ResMed's AutoSet algorithm is one of the most clinically published in the field of sleep-disordered breathing (SDB). Numerous clinical studies¹⁻³ support the clinical outcomes of the AutoSet algorithm – citing the therapy, compliance and quality-of-life benefits associated with using AutoSet devices.

• Recognizes multiple shapes of flow limitation

• Qualifies hypopneas (hypopneas without flow limitation are not scored as they typically do not result in oxygen desaturation or arousal)

• Responds to flow limitation, snoring and obstructive apneas

AutoSet algorithm pressure responses4



How it works:

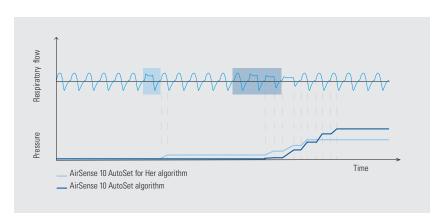
1 Massie CA et al. Comparison between automatic and fixed positive airway pressure therapy in the home. Am J Respir Crit Care Med 2003:167:20-23.

AutoSet for Her algorithm

The AutoSet for Her algorithm is based on ResMed's proven AutoSet algorithm, but is uniquely tailored to the breathing patterns of female OSA patients. It's the only device cleared by the FDA for use in women specifically with sleep apnea.

How it works:

- The maximum pressure increase per breath is capped at 0.5 cm H₂O, and pressure decline is slower to deliver gentler pressure changes
- Responds to women's flow limitation based on a single-breath index
- Helps prevent persistent events with a minimum floor pressure that adjusts according to the frequency of apneas and hypopneas
- Above 12 cm H₂O, response to snore and flow limitation is prioritized



Expiratory Pressure Relief (EPR) and Easy-Breathe

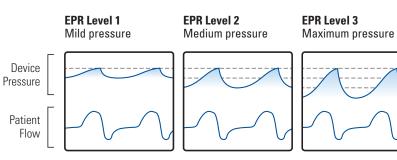
EPR is designed to maintain optimal treatment for the patient during inhalation and reduce the delivered mask pressure during exhalation in the CPAP or AutoSet mode or AutoSet for Her. The desired result of EPR is to decrease the pressure the patient must breathe out against, making the overall therapy more comfortable.

How it works:

EPR provides three comfort settings. Each comfort setting correlates to an exact drop in pressure relief:

- EPR Level 1: Mild reduction (1 cm H₂O)
- EPR Level 2: Medium reduction (2 cm H₂O)
- EPR Level 3: Maximum reduction (3 cm H₂O)

When EPR is turned on, our Easy-Breathe technology will provide enhanced comfort by delivering a smoother, more natural pressure and predictable levels of pressure relief.

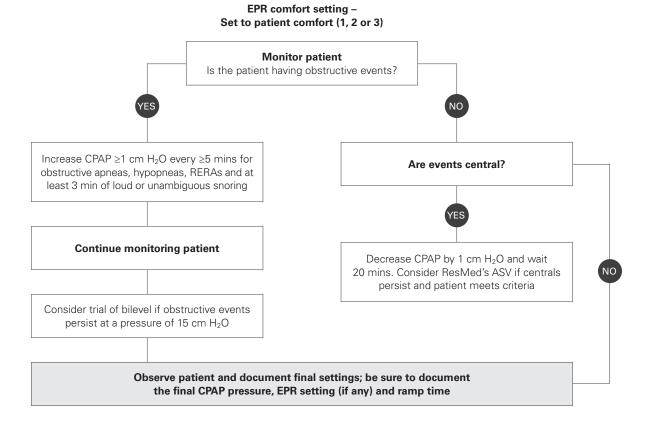


² Netzel T et al. APAP device technology and correlation with patient compliance. Somnologie 2014:18(2):113-120.

³ Armistead JP et al. Study of an auto-adjusting CPAP algorithm for the treatment of obstructive sleep apnoea. Am J Respir Crit Care Med 2009;179:A3570.

⁴ The AutoSet algorithm gradually increases pressure during inspiration on breaths with preceding flow limitation, snore or obstructive apnea

CPAP Titration protocol



Things to consider

For accurate results:

• Ensure the mask is fitted properly and leak is minimized. Additionally, verify that the mask setting is the mask type used. For example, if you are using a full face mask, be sure you select full face mask.

If you notice the patient is having central sleep apneas (CSA), look to see if the patient meets the definition of complex sleep apnea. If so, consider using ASV.

Consider using bilevel when:

- Patient is not tolerating high pressure settings1:
- Pulling at mask
- Experiencing arousals or microarousals
- Can't progress to REM sleep cycle
- Feels bloated or has a sensation of swallowing air
- Saying pressure is too high
- States it's difficult to exhale despite EPR feature
- Events persist at 15 cm H₂O²
- Women may need to be switched at a lower pressure due to their increased pressure sensitivity
- Patient has history of ventilatory insufficiency such as chronic obstructive pulmonary disease (COPD), restrictive lung disease, or obesity hypoventilation syndrome (OHS)¹
- More than 3 cm H₂O is required between IPAP and EPAP.²

¹ Gay P, Weaver T, Loube D, Iber C. Evaluation of positive airway pressure treatment for sleep related breathing in disorders in adults. Sleep 2006;29(3):381-401.

² Kushida CA, Chediak A, Berry RB, Brown LK, Gozal D, Iber C, Parthasarathy S, Quan SF, Rowley JA. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. J Clin Sleep Med 2008;4(2):157-171.

OSA (Non-Compliant)



S/VAuto

ResMed's AirCurve 10 S and AirCurve 10 VAuto devices are recommended for patients who may have a hard time acclimating to therapy. These patients often say it's difficult to breathe out against pressure or that they have a dry nose or mouth, and generally benefit from having greater pressure support.

The AirCurve 10 S is a fixed-pressure bilevel device designed to deliver effective, comfortable therapy for a wide range of patients, particularly non-compliant CPAP patients.

The AirCurve 10 VAuto is an auto-adjusting bilevel device that uses the comfort of both the proven AutoSet™ algorithm and Easy-Breathe waveform into its VAuto algorithm to treat obstructive sleep apnea (OSA) patients who need greater pressure support.



About the Technology

VAuto adjusts the baseline pressure to hold the airway open while maintaining a fixed pressure support.

For the VAuto algorithm, the Min EPAP and Max IPAP settings are used to set the lower and upper pressures delivered to the patient. A pressure support value is set according to what is most comfortable to the patient (a starting value of 4 cm H2O is commonly used). This is usually fixed for the night. The absolute IPAP and EPAP values are automatically adjusted by the algorithm, responding to snore, flow limitation and obstructive apneas. The difference between the inspiratory and expiratory pressure remains consistent throughout the night.

ResMed's bilevel technologies

AirCurve 10 devices give you the flexibility to fine-tune settings and accommodate various patient conditions.*

Both the S and VAuto modes contain the following technologies:

TiControl lets you set minimum and maximum time limits on either side of the patient's ideal spontaneous flow cycling, creating a window of opportunity for the patient to spontaneously cycle the breath and timely intervention during challenging conditions.

Adjustable trigger and cycle sensitivity settings can be used to optimize synchrony between the device and the patient's own respiratory efforts.





Trigger and cycle sensitivity



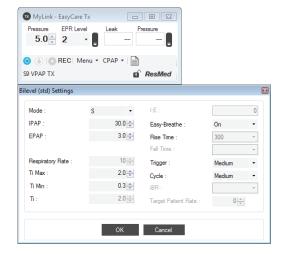
Vsync constantly monitors the flow so that if an unintentional mask leak occurs, the device can guickly compensate for the leak and maintain breathing synchrony.

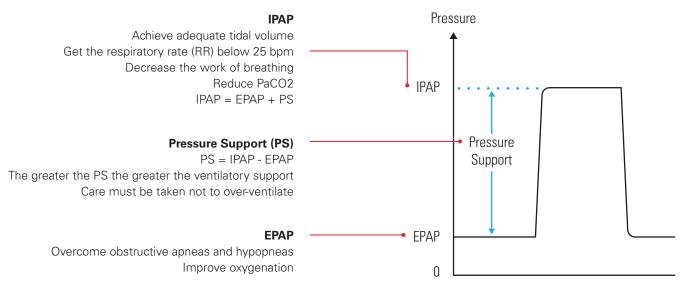
Easy-Breathe technology will provide enhanced comfort by delivering a smoother, more natural pressure and predictable levels of pressure relief.

What are the benefits of bilevel?**

Bilevel works to:

- Prevent nocturnal hypoventilation and hypoxia, which reduces cardiovascular consequences.
- Improve ventilation (gas exchange), which includes
- Reducing nocturnal CO₂ levels
- Increasing nocturnal O₂ levels
- Improving daytime blood gases
- Stabilize upper airway
- Rest respiratory muscles
- Decrease daytime sleepiness by correcting sleep architecture
- Reduces arousals due to SDB and associated sleep fragmentation

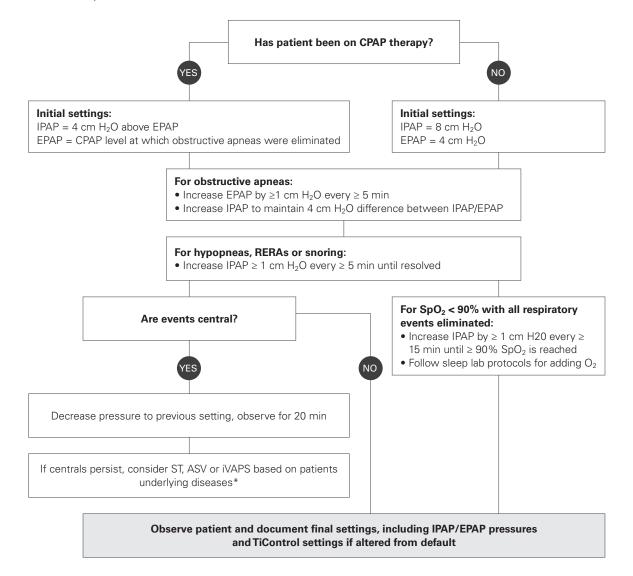




^{*}AirCurve 10 ASV does not include TiControl or trigger and cycle sensitivity.

^{**}Antonescu-Turcu A & Parthasarathy S. Respir Care 2010

S Titration protocol



Things to consider

For accurate results:

- Ensure the mask is fitted properly and leak is minimized.
 Additionally, verify that the mask setting is the mask type used. For example, if you are using a full face mask, be sure you select full face mask.
- A higher starting IPAP and EPAP may be selected for patients with an elevated BMI.

Addressing various conditions:

- If the patient is having central apneas look to see if the patient meets the definition of complex sleep apnea. If so, consider moving to ASV.
- If the patient presents with both nocturnal hypoventilation and central sleep apnea, consider moving to iVAPS.

^{*}See more detail under Addressing various conditions

Central Sleep Apnea (CSA)



Central Sleep Apnea (CSA)

Central Sleep Apnea (CSA) occurs when the patient's airway is open, but respiratory effort ceases due to a decrease in his or her ventilatory drive. CSA is a central nervous system disorder.

CSA can be caused by heart failure, a disease or injury to the brain, such as:

- stroke
- brain tumor
- viral brain infection
- chronic respiratory disease

Patients with CSA often don't snore, causing the condition to go unnoticed.

Mixed sleep apnea

Mixed sleep apnea occurs when the patient shows signs of both OSA (where the airway is obstructed) and CSA (where no effort is made to breathe).

Which patients is ASV suitable for?

This extensively studied therapy provides demonstrated results across the spectrum of central breathing disorders including:

- Periodic breathing, both normocapnic and hypocapnic
- Other forms of central and concomitant obstructive events¹ (mixed sleep apnea)
- Complex sleep apnea (CompSA)²

ResMed's ASV should also be considered for central sleep apnea (CSA) and ataxic breathing, which is sometimes seen in patients on opioids,3 and neurological patients.

ResMed ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.



What are the therapy goals of ASV?

- The primary goal of ASV therapy is to stabilize ventilation, resulting in normalized PaCO2 levels to encourage stable breathing
- Improve sleep quality and minimize daytime sleepiness by reducing respiratory-related events
- Treat complex sleep apnea by automatically adapting to treat both obstructive and central events (in ASVAuto mode)

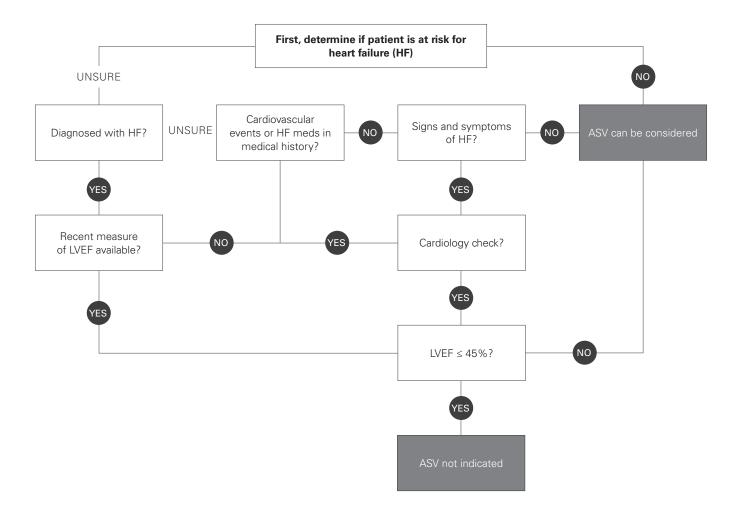
What does ASV target?

ResMed's ASV therapy continuously learns and adapts targets to reduce short-term oscillations in breathing, keeping ventilation stable. It is the only ASV therapy to target the patient's own recent minute ventilation (MV) and respiratory rate (RR), adapting to changing needs through various sleep stages.

ResMed's ASV therapy is contraindicated in patients with chronic, symptomatic heart failure (NYHA 2-4) with reduced left ventricular ejection fraction (LVEF ≤ 45%) and moderate to severe predominant central sleep apnea.

1 Allam JS et al. Efficacy of adaptive servo-ventilation in treatment of complex and central sleep appea syndromes. Chest 2007: 132(6):1839-46 2 Morgenthaler TI et al. Adaptive servo-ventilation versus noninvasive positive pressure ventilation for central, mixed, and complex sleep apnea syndromes. Sleep 2007;30(4):468-75 3 Javaheri S et al. Adaptive pressure support servo-ventilation: a novel treatment for sleep apnea associated with use of opioids. J Clin Sleep Med 2008;4(4):305-10

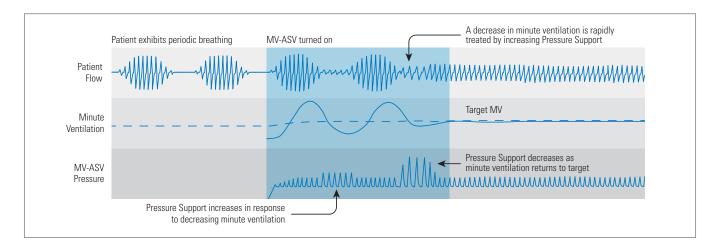
For patients with moderate to severe predominant central sleep apnea, use this flowchart to assess which patients should be considered for ASV therapy.¹



¹ Adapted from Aurora RN et al. Updated adaptive servo-ventilation recommendations for the 2012 AASM guideline: "The Treatment of Central Sleep Apnea Syndromes in Adults: Practice Parameters with an Evidence-Based Literature Review and Meta-Analyses", J Clin Sleep Med 2016;12(5):757-761.

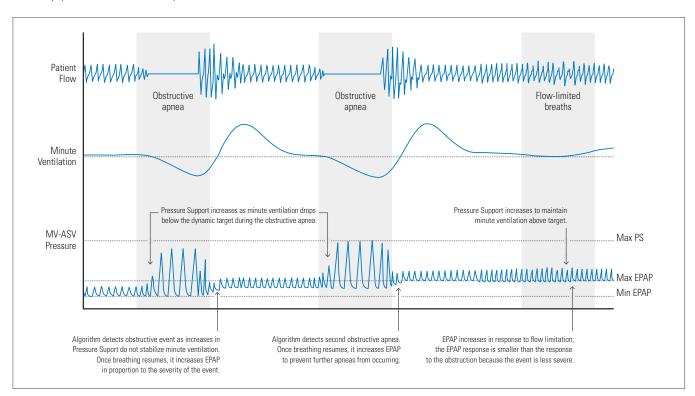
Stabilizing breathing with constant monitoring

Our ASV technology addresses the complications and unpredictable nature of central sleep apnea by providing responsive therapy. To treat central apneas and periodic breathing, the AirCurve 10 ASV constantly monitors the patient's breathing pattern and minute ventilation, and automatically adjusts pressure support to break the cycle of hyperventilation and central events that occur.

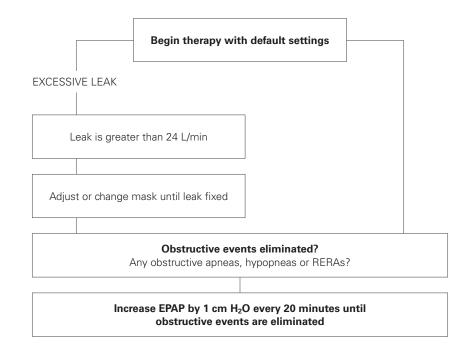


Responding rapidly for effective therapy

In ASVAuto mode, the AirCurve 10 ASV automatically adjusts pressure support and EPAP, stabilizing the upper airway to treat and help prevent obstructive apneas.



ASV Titration Protocol



The guidelines below can help to set up and treat patients with central breathing disorders using the standard ASV mode in ResMed's adaptive servo-ventilation (ASV) devices. This guidance is intended for in-lab titration and should not supercede direction by a physician. For more details on therapy settings and adjustments, please refer to the Clinical Guide for the specific therapy device.

ASV default settings Only three therapy parameters to set		
EPAP	5 cm H ₂ O	
Min PS	$3 \text{ cm H}_2\text{O}$	
Max PS	15 cm H₂O	
Ramp	OFF	

ASV Auto Protocol

ASVAuto mode includes automatically adjusting EPAP to respond to changes in upper airway stability throughout the night:

- Therapy settings should be left on default
- If EPAP reaches Max EPAP and upper airway obstruction (UAO) persists, progressively increase EPAP until UAO is eliminated
- The patient is feeling claustrophobic, increase the Min EPAP in steps of 1 cm H2O to provide comfort due to the higher mask vent flow

ASVAuto default settings Only four therapy parameters to set		
Min EPAP	4 cm H ₂ O	
Max EPAP	15 cm H ₂ O	
Min PS	3 cm H ₂ O	
Max PS	15 cm H ₂ O	
Ramp	OFF	

Things to consider

- ASV rapidly stabilizes breathing because it responds to:
- Central apneas stabilizing ventilation
- Obstructive events stabilizing the upper airway
- ASV's algorithm is not cleared or appropriate for the following patients:
- Chronic and profound hypoventilation
- Moderate to severe COPD
- Restrictive thoracic or neuromuscular disease
- ASV will likely under treat patients with the above conditions, and you should consider moving to iVAPS

Additional comfort settings

• Ramp: The ramp feature helps patients fall asleep more easily by delivering low pressure at the start of the therapy session and gradually increasing it to the prescribed level after a programmed amount of time.

Note: Consult the physician on the use of ramp if the patient is exhibiting any sleep onset events.

Notes

Respiratory Diseases



iVAPS Therapy

Which patients is iVAPS suitable for?

iVAPS is suitable for adults with respiratory insufficiency. It is ideal for patients whose condition is likely to change and is characterized by hypoventilation (day/night hypercapnia). Patient conditions may include:

- Neuromuscular disease and restrictive conditions iVAPS can maintain stable ventilation when respiratory effort fluctuates1
- Obesity hypoventilation Unlike standard Pressure Support therapy, iVAPS can compensate for changes in respiratory mechanics, such as during nocturnal changes in the patient's body position¹
- Chronic obstructive pulmonary disease iVAPS may reduce the risk of hyperinflation associated with increased respiratory rate and can compensate for changes in a patient's chronic airflow limitation¹

What are the therapy goals of iVAPS?

- Optimize therapy by delivering a clinician set ventilation target with the right pressure at the right time
- Enhance patient ventilator synchrony with an intelligent Backup Rate (iBR) to improve patient comfort
- Improve blood gases (and other respiratory parameters) as effectively as expertly titrated pressure support modes²
- Increase adherence to therapy³

What does iVAPS target?

iVAPS targets alveolar minute ventilation to deliver required ventilation at the alveoli, where gas exchange occurs. Unlike other volume-assurance modes, iVAPS maintains the alveolar target even when respiratory rate changes.



About the Technology

iVAPS (intelligent Volume-Assured Pressure Support) is ResMed's unique volume-assurance mode that intelligently and automatically tailors therapy to patients' individual breathing needs. It is designed to target each patient's alveolar ventilation, and auto-adjusts to maintain that target and improve blood gases.

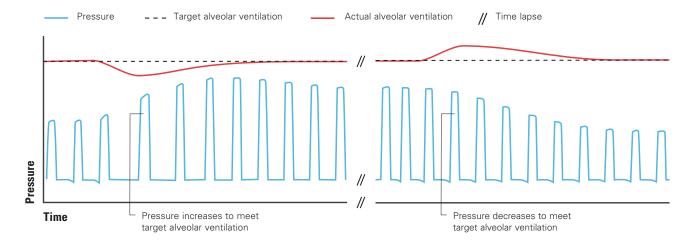
How it works:

- iVAPS can maintain stable ventilation when respiratory
- When compared to standard Pressure Support therapy, iVAPS can compensate for changes in respiratory mechanics, such as during nocturnal changes in the patient's body position
- iVAPS may reduce the risk of hyperinflation associated with increased respiratory rate, as compared to therapy targeting tidal volume

1 Ketheeswaran S et al. Non-invasive ventilation therapy: An overview of intelligent volume assured pressure support (iVAPS). [White paper]. ResMed Science Center, Sydney, Australia 2012 2 Ekkernkamp E et al. Impact of intelligent volume-assured pressure support on sleep quality in stable hypercapnic chronic obstructive pulmonary disease patients: A randomized crossover study. Respiration 2014;88(4):270-6 3 Kelly JL et al. Randomized trial of 'intelligent' autotitrating ventilation versus standard pressure support non-invasive ventilation: Impact on adherence and physiological outcomes. Respirology 2014;19:596-603

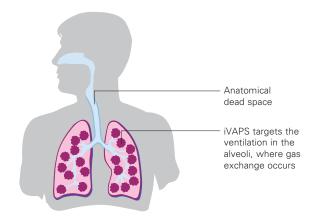
iVAPS: Auto-adjusting pressure support

iVAPS automatically adapts to the patient's changing needs by constantly monitoring their actual ventilation and respiratory rate in relation to their target ventilation and respiratory rate.

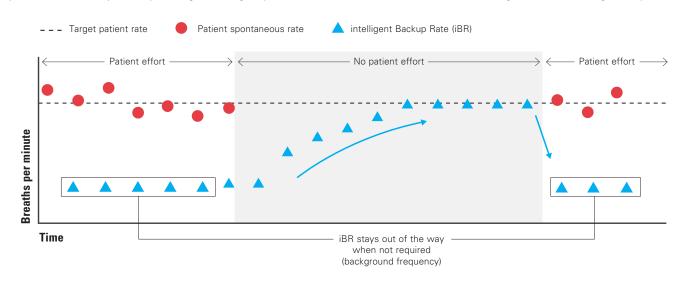


Targeting alveolar ventilation

Some ventilation modes target tidal volume without taking into account the anatomical dead space in the patient's airways. iVAPS targets alveolar ventilation, which best represents the useful portion of ventilation that reaches the alveoli. Because iVAPS takes into account both tidal volume and respiratory rate, you can better control the effect of respiratory rate variation on ventilatory support.



iBR, ResMed's intelligent Backup Rate, maximizes the patient's opportunity to spontaneously breathe before bringing the patient back up to target if backup breaths are required. iBR is set by entering the patient's resting respiratory rate, and if the patient fails to trigger the device, or falls two-thirds below the set respiratory rate, the iBR quickly normalizes synchrony, bringing the patient comfortably back up to target. A single spontaneous breath resets the iBR to the background until it is again required.



iVAPS Titration Protocol

Initial iVAPS settings:

- Set Patient Height (eg, 70 inches for 5'10")
- Set Target Pt Rate equivalent to patient's spontaneous respiratory rate (recommended no less than 15 bpm)
- Set Target Va such that Vt is equal to 6ml/kg IBW
- EPAP = $5 \text{ cm H}_2\text{O}$
- Min PS = 4 cm H₂O
- Max PS = 20 cm H₂O

Evaluate and titrate:

• Based on Target Pt Rate, Target Va, Vt, SpO₂ and CO₂ compared to baseline

For obstructive apneas:

• Increase EPAP by ≥ 1 cm H₂O every ≥ 5 min to eliminate obstructive apneas, hypopneas, snoring and flow limitation

For $SpO_2 < 90\%$ with all respiratory events eliminated:

• Increase Target Va by 0.3 every ≥ 5 min until desaturations are resolved

Evaluate if Target Pt Rate is adequate:

If central events persist, increase Target Pt Rate by 1–2 BPM every 20 min as needed

Things to consider

Adjust TiControls and Synchrony features if

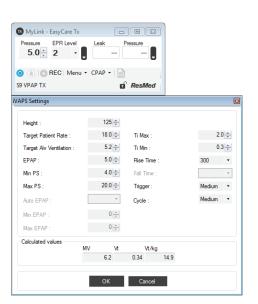
- Patient complains of pressure discomfort
- Chest wall movement is not in sync with mask pressure tracing
- Inspiratory efforts don't trigger the device

See details on TiControls and Synchrony features in the back.

Clinical Indications for iVAPS therapy

- Neuromuscular/restrictive disorders
- Obesity hypoventilation
- Patients weighing more than 66lbs (30kg)

Once a patient is fitted with an appropriate mask, select the appropriate mask setting.



Bilevel ST Titration Protocol

Initial settings:

- IPAP = 8 cm H₂O settings
- EPAP = $4 \text{ cm H}_2\text{O}$
- Set backup rate at 2–4 below resting respiratory rate

Evaluate and titrate:

• Based on VT, rate, SpO₂ and CO₂ compared to baseline

For obstructive apneas:

- Increase EPAP by ≥1 cm H₂O every ≥5 min
- Increase IPAP to maintain 4 cm H₂O difference between IPAP/EPAP

For residual snoring, hypopneas and/or O₂ desats:

• Increase IPAP ≥1 cm H₂O every ≥ 5 min until resolved

For $SpO_2 < 90\%$ with all respiratory events eliminated:

- Increase IPAP by > 1 cm H_2O every \geq 15 min until $SpO_2 > 90\%$ is reached
- Follow sleep lab protocol for adding O₂

Evaluate VT (tidal volume) if too small:

• Maintain EPAP raise IPAP by 1 cm H_2O every ≥ 15 min until $SpO_2 \geq 90\%$

Evaluate if backup rate is adequate:

• Increase backup rate by 1-2 BPM every 20 min as needed

Observe patient and document final pressure settings (IPAP/EPAP pressures, respiratory rate and TiControl settings) if altered from default

Clinical Indications for ST therapy

- Neuromuscular/restrictive disorders
- COPD
- Obesity hypoventilation

Continuously monitor sleep and blood gas parameters

Ensure patient's ventilation levels stay consistent with initial levels, including tidal volume (IPAP-EPAP) and patient respiratory rate versus device backup rate.

SpO₂, VT and backup rate should be reviewed/ monitored throughout the night.

Respiratory Diseases

It is common to see patients with chronic respiratory conditions in the sleep lab. ResMed has designed specific algorithms and modalities to address these more challenging ventilation scenarios, as well as an assortment of comfort and synchrony features to ensure your patient receives optimal ventilation that is customized specifically for them.

Obstructive Lung Disease (COPD, Emphysema)

Patients with obstructive lung disease have chronic airflow limitation. These patients have particular difficulty exhaling air. This can lead to air trapping and hyperinflation. Because these patients require longer exhalation, asynchrony can exist when using standard bilevel settings.

The recommended settings for a ResMed bilevel device provide a good baseline for to initiate therapy on an obstructive patient. The settings use a faster rise time to ensure that the lungs are filled quickly, and a high cycle **sensitivity** to provide an earlier cycle to exhalation. The rapid inhalation and prolonged exhalation will help to prevent auto-PEEP and preserve synchrony.

Recommended Settings	Obstructive Lung Disease
IPAP [cm H ₂ O]	13
EPAP [cm H ₂ 0]	5
Ti Max [sec] ¹	1.0
Ti Min [sec] ¹	0.3
Rise time [ms] ²	150
Trigger sensitivity	Medium
Cycle sensitivity	High
PS [cm H ₂ O]	8

Restrictive Lung Disease (Neuromuscular Disease, chest wall abnormality)

Patients with restrictive lung diseases have a difficult time maintaining the inhalation phase long enough to ensure adequate tidal volume and gas exchange. This can be caused by a physical restriction of the lungs or by neuromuscular weakness.

The suggested settings use a low cycle sensitivity and longer Ti Min. This creates a longer inhalation time to help increase tidal volume and gas exchange.

Recommended Settings	Restrictive Lung Disease
IPAP [cm H ₂ O]	11
EPAP [cm H ₂ 0]	5
Ti Max [sec] ¹	1.5
Ti Min [sec] ¹	0.8
Rise time [ms] ²	300
Trigger sensitivity	High
Cycle sensitivity	Low
PS [cm H ₂ 0]	6

Obesity Hypoventilation Syndrome (OHS)

Obesity hypoventilation patients often have reduced tidal volumes caused by the additional weight pressing down on the chest and abdomen. Additionally, these patients may also have obstructive sleep apnea (OSA) caused by excess tissue in the upper airway and a high body mass index (BMI).

The recommended settings use a higher EPAP pressure to keep the airway open and a higher IPAP to provide additional pressure support and ventilatory assistance.

Recommended Settings	Obesity Hypoventilation Syndrome
IPAP [cm H ₂ O]	15
EPAP [cm H ₂ 0]	7
Ti Max [sec] ¹	1.5
Ti Min [sec] ¹	0.8
Rise time [ms] ²	300
Trigger sensitivity	Medium
Cycle sensitivity	Medium
PS [cm H ₂ O]	8

Normal Lungs (Patients with normal lung dynamics—for example, spinal cord injury)

There are some patients with normal lung function that may still require ventilation support. Patients with a spinal cord injury can often fall in this group. They may have a restrictive defect, but their lungs are still able to function normally. Despite this, they may require ventilation assistance.

The settings below provide basic suggested settings for patients with normal lung mechanics.

Recommended Settings	Normal Lung Mechanics
IPAP [cm H ₂ O]	11
EPAP [cm H ₂ 0]	5
Ti Max [sec] ¹	2.0
Ti Min [sec] ¹	0.3
Rise time [ms] ²	300
Trigger sensitivity	Medium
Cycle sensitivity	Medium
PS [cm H ₂ O]	6

¹ Ti settings based on an observed respiratory rate of 20 bpm.

² The rise time miliseconds scale is approximate

¹ Ti settings based on an observed respiratory rate of 20 bpm.

² The rise time miliseconds scale is approximate

Additional comfort features and synchrony settings can help to customize therapy to meet each patient's unique needs. (Available in VAuto, S, iVAPs and ST.)*

Rise Time

Rise Time sets the time taken for the device to reach IPAP. The greater the rise time value, the longer it takes for pressure to increase from EPAP to IPAP.

Patients with a high ventilatory demand may prefer a shorter rise time, while patients who are slow breathers may prefer a longer rise time.

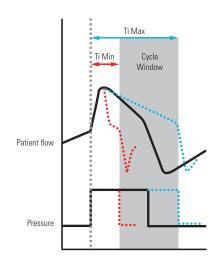
Note: A prolonged rise time inhibits fast pressurization, therefore, rise time should not be set longer than Ti Min or the patient's normal inspiratory time.

IPAP EPAP Breath cycle

TiControl for patient-device synchrony

TiControl allows you to manage your patient's inspiratory time according to their disease state. For challenging respiratory conditions, TiControl allows you to manage the time a patient spends in the inspiratory phase of their breath cycle.

Ti Max lets you set a maximum inspiratory time, to reduce the risk of intrinsic PEEP and missed patient effort. For example, Ti Max can be helpful for patients with obstructive disease, ensuring a limited time is spent in inspiration and allowing a longer time spent in the exhaling phase. Ti Min ensures adequate time for gas exchange without having to increase the pressure setting. Ti Min may be helpful for patients with restrictive lung disease.

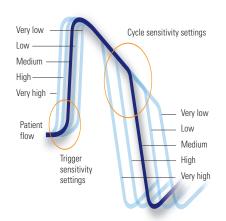


Trigger & Cycle Sensitivity Settings for better patient comfort

To achieve patient-ventilator synchronization, you can customize the beginning and end of each inspiration with ResMed's adjustable Trigger & Cycle technology.

Recognizing that each patient is different, ResMed provides five levels of Trigger & Cycle sensitivity to help you tailor and fine-tune triggering and cycling values to different patient conditions.

- The Trigger sensitivity setting helps care providers customize the sensitivity level of the device to better recognize patients with decreased inspiratory efforts.
- The Cycle sensitivity helps the care provider ensure appropriate breath termination for every patient, promoting patient-device synchrony.



When to adjust the trigger sensitivity threshold?

The Medium (default) setting will be ideal for most patients.

A Low (or Very Low) trigger sensitivity setting is recommended for the following conditions:

- Cardiogenic oscillations and subsequent auto-triggering
- Any time the patient complains that breaths are starting before inhaling you can decrease the trigger sensitivity to assist the patient in transitioning from EPAP to IPAP.

Recommend the High (or Very High) trigger sensitivity setting for the following conditions:

- Patients with very weak respiratory effort (eg, neuromuscular diseases)
- Any time the patient complains of not being able to initiate a breath. You can increase the triggers sensitivity to assist the patient in transitioning from EPAP to IPAP with greater ease.

When to adjust the cycle sensitivity threshold?

The Medium (default) setting will be ideal for most patients.

Recommend the High (or Very High) cycle sensitivity setting for the following:

- In situations where a shorter inspiratory time is desirable (eg, COPD), whereby a shorter inspiratory time is essential in order to preserve an adequate expiratory time. Ti Max can also be used to shorten inspiratory time
- Any time the patient complains that breaths are too long or finds it difficult to get the machine to cycle from IPAP to EPAP pressure, adjust the cycle sensitivity to help the patient easily transition from IPAP to EPAP.

Recommend the Low (or Very Low) cycle sensitivity setting for the following conditions:

- In situations where a longer inspiratory time is desirable (eg, neuromuscular diseases or patients with a very weak respiratory effort). Ti Min can also be used to lengthen inspiratory time
- Any time the patient complains that the device seems to switch from IPAP to EPAP too quickly or is cutting off their breath, adjust the cycle sensitivity to help the patient transitioning from IPAP to EPAP

Setting TiControl

Setting Ti Max and Ti Min using the respiratory rate table:

- 1. Instruct the patient to breathe normally while comfortably sitting or lying down.
- 2. Count the patient's respiratory rate (breaths/minute).
- 3. Considering the patient's respiratory disease, refer to the appropriate range of settings in the table below (restrictive, COPD or normal) to set Ti Max and Ti Min.
- 4. In the case of COPD or normal lungs, use the Ti Min default setting.

ResMed TiControl: Ti Min and Ti Max Calculation Guide Restrictive Normal Respiratory Ti Max Ti Max Ti Max Frequency (bpm) Ti Min 30 1.0 0.7 1.0 29 1.0 0.5 0.7 1.0 28 1.1 0.5 0.7 1.1

27	1.1	0.6	0.7	1.1
26	1.2	0.6	0.8	1.2
25	1.2	0.6	0.8	1.2
24	1.3	0.6	0.8	1.3
23	1.3	0.7	0.9	1.3
22	1.4	0.7	0.9	1.4
21	1.4	0.7	0.9	1.4
20	1.5	0.8	1.0	1.5
19	1.6	0.8	1.0	1.6
18	1.7	0.8	1.1	1.7
17	1.8	0.9	1.2	1.8
16	1.9	0.9	1.2	1.9

1.0

1.1

1.2

1.3

1.3

1.4

1.5

1.7

2.0

2.1

2.3

2.5

2.0

2.1

2.3

2.5

Note: COPD patients may benefit, but they may benefit from an increase in EPAP to compensate for auto PEEP or intrinsic PEEP. This should be evaluated first before considering the High trigger sensitivity setting.

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Votes

