



S8 AutoSet™ II System

Clinical Guide

English

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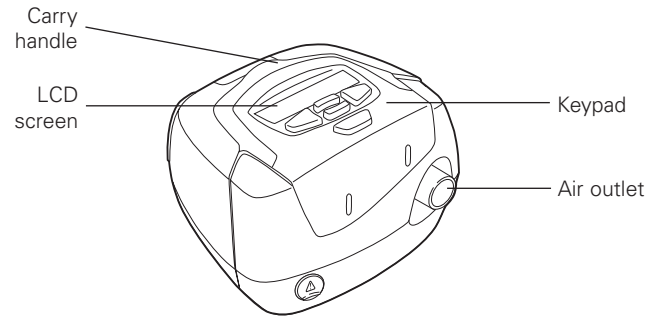
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S8 AutoSet™ II System

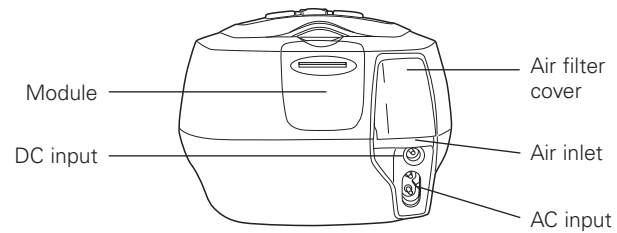
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ILLUSTRATIONS

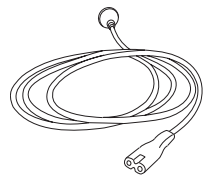
A SYSTEM COMPONENTS



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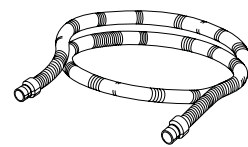
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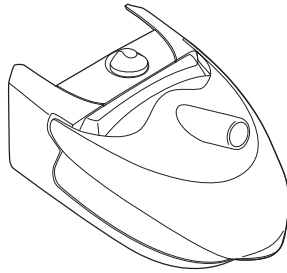


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6' 6" (2 m)

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B INTEGRATED HUMIDIFIER



HumidAire 3i™

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C OTHER ACCESSORIES



1



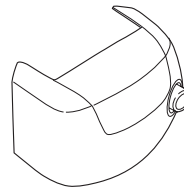
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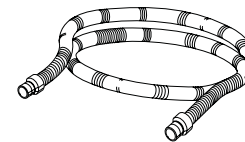
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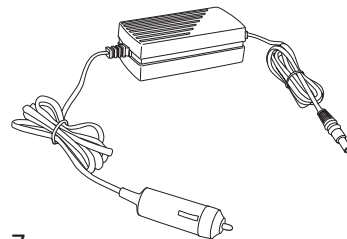


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9' 10" (3 m)



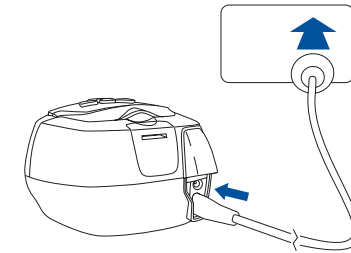
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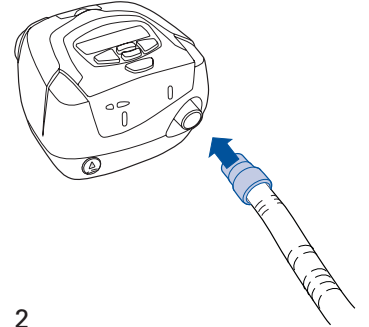
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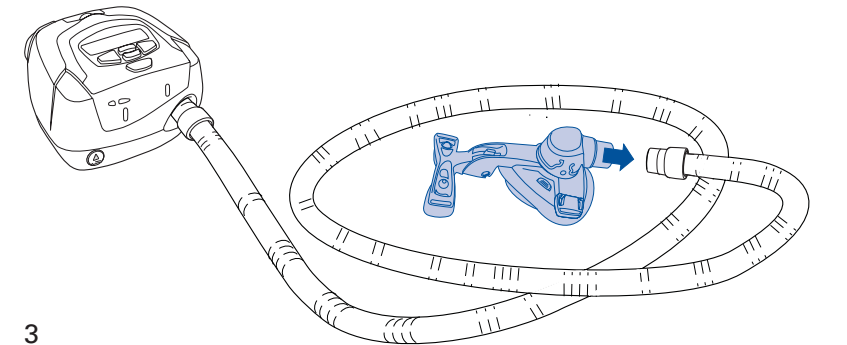
D SETTING UP THE S8™



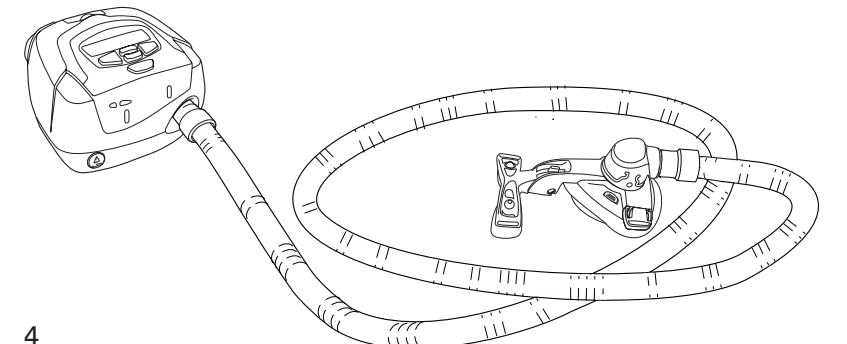
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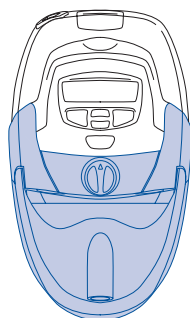


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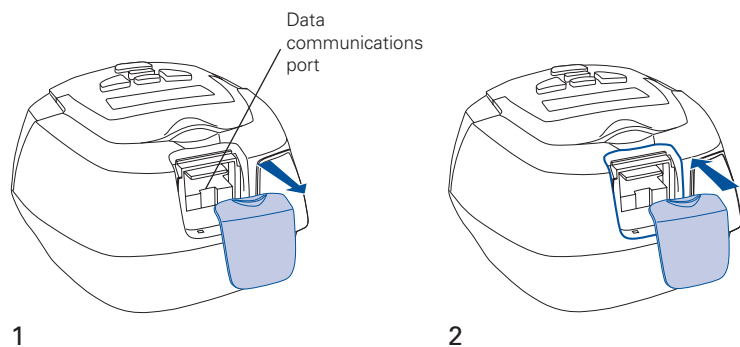
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E**HUMIDAIRE 3i AND S8**

HumidAire 3i

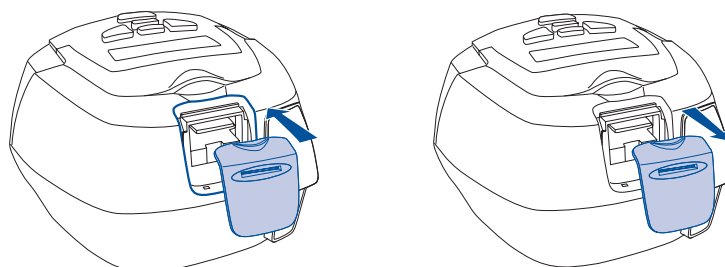
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F**BLANK MODULE**

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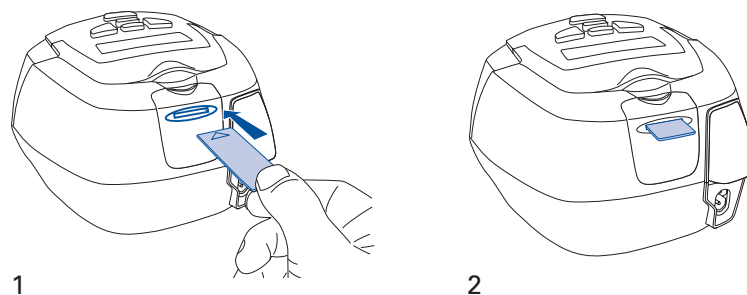
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G**DATA CARD MODULE**

1

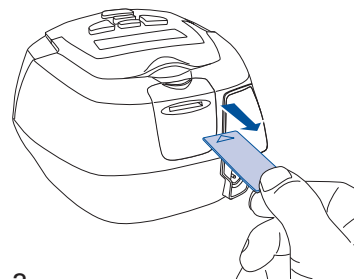
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H**USING THE DATA CARD**

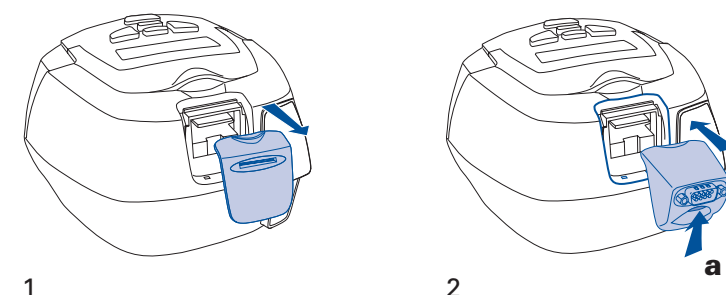
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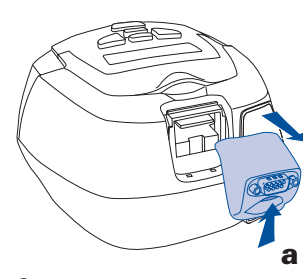
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I**USING AN ADAPTER**

1

2



3

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Note: Some products not available in all regions

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Introduction

The ResMed S8 AutoSet™ II system is designed to provide continuous positive airway pressure (CPAP) therapy to adult patients with obstructive sleep apnea (OSA). Patients with OSA experience recurrent obstruction of their upper airway (apneas) due to relaxation of the tongue and soft palate while they sleep. Common symptoms are associated with poor sleep quality and may include excessive daytime sleepiness and tiredness, as well as diminished concentration and memory loss.

The S8 AutoSet II device has two therapeutic modes. When set to AutoSet mode, the device self-adjusts the pressure delivered according to the state of the patient's airway. In CPAP mode, the device delivers a fixed treatment pressure. In both modes, pressure delivered is within the range 4 to 20 cm H₂O.

Data storage and processing capabilities of the S8 AutoSet II system facilitate patient management. The system provides summary data for a variety of time intervals, which can be viewed via the LCD menus. The patient's usage hours, treatment pressure, mask leak, apnea + hypopnea index (AHI), apnea index (AI), and hypopnea index (HI) are displayed in the Results section of the clinical menu. At your discretion, the patient may view mask fit, treatment pressure, and usage hours for the last session. This patient feature is called Smart Data™.

You can download the data stored in the S8 AutoSet II and review it in a PC-based software program. You can download the data directly, via cable. You can also access the data remotely, using a ResScan™ Data Card. A patient's therapy and reminder settings can also be updated using the software. Patient data can be accessed and S8™ device settings updated either via direct cable connection to the S8 AutoSet II or remotely, via a Data Card.

User/Owner Responsibility

The user or owner of this system shall have sole responsibility and liability for any injury to persons or damage to property resulting from:

- operation which is not in accordance with the operating instructions supplied
- maintenance or modifications carried out unless in accordance with authorized instructions and by authorized persons.

Please read this manual carefully before use.

This manual contains special terms and icons that appear in the margins to draw your attention to specific and important information.

- Warning alerts you to possible injury.
- Caution explains special measures for the safe and effective use of the device.
- Note is an informative or helpful note.

Medical Information

Indications for Use

The S8 AutoSet II self-adjusting sleep apnea system is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients. The S8 AutoSet II self-adjusting sleep apnea system has two treatment modes: AutoSet and fixed-pressure CPAP.

The S8 AutoSet II system is intended for home and hospital use.



CAUTION

In the US, Federal law restricts this device to sale by or on the order of a physician.

Contraindications

The S8 AutoSet II is not a life support device and may stop operating with power failure or certain fault conditions. It should not be used by patients who are dependent on continuous therapy.

Positive airway pressure therapy may be contraindicated in some patients with the following pre-existing conditions:

- severe bullous lung disease
- pneumothorax
- pathologically low blood pressure
- dehydration
- cerebrospinal fluid leak, recent cranial surgery, or trauma.

Warnings

- The entire manual should be read before using the S8 AutoSet II.
- Advice contained in this manual should not supersede instructions given by the prescribing physician.
- A patient should not connect a device to the data communication port unless instructed to do so by their health care provider or physician. Only ResMed products are designed to be connected to the data communication port. Connecting other devices could result in injury, or damage to the S8 AutoSet II device.

- The S8 AutoSet II should be used with masks (and connectors*) recommended by ResMed, or by a physician or respiratory therapist. A mask should not be used unless the S8 AutoSet II device is turned on and operating properly. The vent hole or holes associated with the mask should never be blocked.

Explanation: The S8 AutoSet II is intended to be used with special masks (or connectors*) which have vent holes to allow continuous flow of air out of the mask.

When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP devices.

- In the event of power failure or machine malfunction, remove the mask.
- The S8 AutoSet II can be set to deliver pressures up to 20 cm H₂O. In the unlikely event of certain fault conditions, pressures up to 30 cm H₂O are possible.
- If oxygen is used with this device, the oxygen flow must be turned off when the device is not operating. If oxygen has been left on while the device is not operating, disconnect the oxygen and wait 30 minutes before turning on the device.

Explanation: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the air delivery tubing may accumulate within the CPAP machine enclosure and create a risk of fire. This applies to most types of CPAP machines.

- Oxygen supports combustion. Oxygen should not be used while you are smoking or in the presence of an open flame.
- Always ensure airflow is being generated by the device before the oxygen supply is turned on.
- Always turn the oxygen supply off before stopping the airflow from the device.

Note: *At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on where the oxygen is introduced, the pressure settings, patient breathing pattern, and leak rate.*

- Do not use the S8 AutoSet II if there are obvious external defects or unexplained changes in performance.
- Do not open the S8 AutoSet II case. There are no user serviceable parts inside. Repairs and internal servicing should only be performed by an authorized service agent.
- Explosion hazard—do not use in the vicinity of flammable anesthetics.

* Ports may be incorporated in the mask or in connectors that are near the mask.

Cautions

- At low pressures, the flow through the exhalation ports of your mask may not clear all exhaled gas from the tubing. Some rebreathing may occur.
- The air flow for breathing produced by this device can be as much as 11°F (6°C) higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 90°F (32°C).

Note: *The above are general warnings and cautions. Specific warnings, cautions, and notes appear with the relevant instructions in the manual.*

Adverse Effects

Patients should report unusual chest pain, severe headache, or increased breathlessness to their prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.

The following side effects may arise during the course of therapy with the S8 device:

- drying of the nose, mouth, or throat
- nosebleed
- bloating
- ear or sinus discomfort
- eye irritation
- skin rashes
- chest discomfort.

The S8 AutoSet II System

A complete S8 AutoSet II system comprises the following elements:

- S8 AutoSet II self-adjusting flow generator
- Mask
- Humidifier
- Data management products
- Accessories.

S8 AutoSet II

The components of the S8 AutoSet II device are shown in the illustration sheet at the front of this manual:

- Front view (**A-1**)
- Rear view (**A-2**)
- Power cord (**A-3**)
- Travel bag (**A-4**).
- 6'6" (2 m) air tubing (**A-5**).

Masks

Patients will also need a **ResMed mask system** (supplied separately).

The ResMed mask systems that are recommended for use with the S8 AutoSet II are:

Nasal Masks

- Mirage Vista™ Nasal Mask
- Ultra Mirage™ Nasal Mask
- Mirage™ Nasal Mask
- Mirage Activa™ Nasal Mask
- Silent Papillon™
- Papillon™.

Nasal Pillows Systems

- Mirage Swift™ Nasal Pillows System
- Mirage Swift™ II Nasal Pillows System.

Full Face Masks

- Mirage™ Full Face Mask
- Mirage™ Full Face Mask Series 2
- Mirage Liberty™ Full Face Mask
- Mirage Quattro™ Full Face Mask
- Ultra Mirage™ Full Face Mask
- ResMed Hospital Full Face Mask.

Note: *Not all masks are available in all regions.*



WARNING

For optimal product performance and data recording, ResMed mask systems should be used with the S8 AutoSet II. Please refer to “Warnings” on page 3.

Humidifiers

The S8 AutoSet II is compatible for use with the HumidAire 3i™ integrated heated humidifier.

See “Using Humidifiers” on page 16.

Data Management Products

The S8 AutoSet II will have either a ResScan™ Data Card module or a “blank” module attached.

The following data management products may be purchased separately.

- ResScan Data Card (**C-1**)
- ResScan Data Card module (**C-2**)
- Serial adapter (**C-3**)
- USB adapter (**C-4**) and cable
- ResMed PC software.

Note: *Ensure that at least one module or adapter is connected to the S8 AutoSet II at all times.*

Accessories

The other accessories shown on the illustration sheet may also be purchased separately.

- Front cap (not available in all regions) (**C-5**)
- Air tubing 9’10” (3 m) (**C-6**)
- DC-12 converter (**C-7**)
- Blank module (**C-8**).

Note: *ResMed regularly releases new products. Please check our website at www.resmed.com.*

Operating Information

Principles of Operation

The S8 AutoSet II system is designed for clinical use and home treatment of adult patients with obstructive sleep apnea (OSA). The system has two therapy modes for treating OSA: **CPAP** mode and **AutoSet** mode.

CPAP mode

In CPAP mode, the S8 AutoSet II device provides fixed-positive-pressure room air via tubing to the mask worn by your patient. The continuous air stream “splints” open the upper airway, preventing airway collapse.

The S8 AutoSet II delivers pressure within the range 4 to 20 cm H₂O, depending on the patency of the upper airway. To make the beginning of treatment more comfortable, you may set a ramp so the pressure starts low and gradually increases to full treatment pressure over the ramp time.

AutoSet mode

The treatment pressure required by your patient may vary through the night, and from night to night, due to changes in sleep state, body position, and airway resistance. In AutoSet mode S8 AutoSet II provides only that amount of pressure required to maintain upper airway patency.

You can set the minimum and maximum allowable treatment pressures. The device analyzes the state of the patient’s upper airway on a breath-by-breath basis, and delivers pressure within the allowed range according to the degree of obstruction. The AutoSet algorithm adjusts treatment pressure as a function of three parameters: inspiratory flow limitation, snore, and apnea.

The flow sensor, located in the S8 AutoSet II device, enables detection of inspiratory flow limitation and apneas. The pressure sensor, also located in the device, enables measurement of pressure and snore.

Inspiratory flow limitation indicates silent partial obstruction. When your patient is breathing normally, the inspiratory flow measured by the device as a function of time shows a typically rounded curve for each breath.

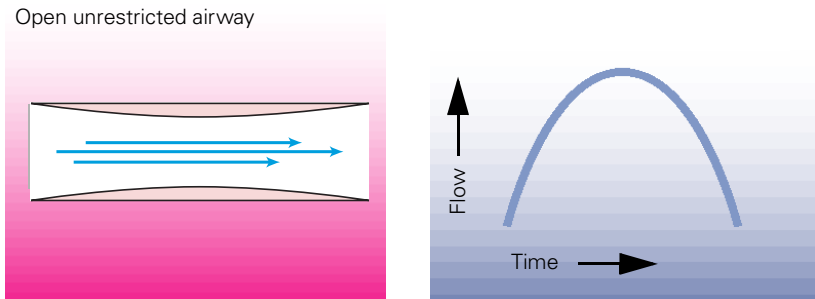


Figure 1: Inspiratory flow-time curve for an unrestricted airway

As the upper airway begins to collapse, the shape of the inspiratory flow-time curve changes and the central section flattens.

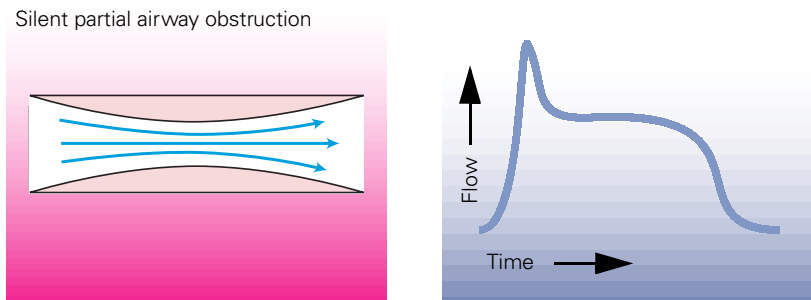


Figure 2: Inspiratory flow-time curve for a partially obstructed airway

The AutoSet algorithm analyzes the shape of the central part of the curve for each breath. If the inspiratory flow-time curve falls below a certain threshold, the pressure is increased.

Inspiratory flow limitation, or partial airway closure, usually precedes snoring and obstruction. Detection of this flow limitation enables the device to increase the pressure *before* obstruction occurs, making treatment pre-emptive. If no further flow limitation is detected, therapy is reduced towards the minimum pressure with a 20-minute time constant.

Flattening is a measure of silent inspiratory airflow limitation. Flow limitation with loud snoring is handled by the snore detector. When a patient **snores**, sound is generated and the inspiratory flow/time curve is distorted by the frequency of the sound.

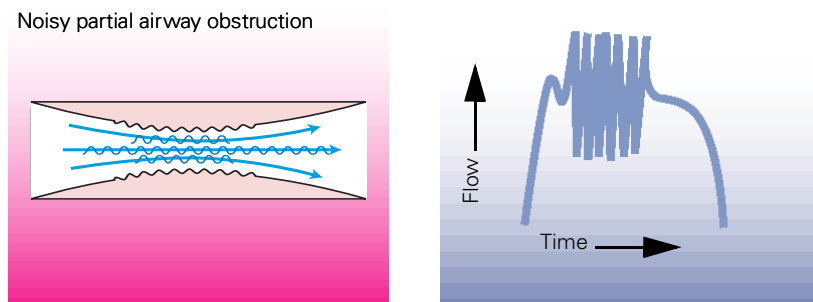


Figure 3: Inspiratory flow-time curve affected by snore

The AutoSet algorithm assigns an arbitrary value between 0.0 and 2.0 to the average amplitude of the snoring detected for the past 5 breaths. A value of 1.0 is equivalent to approximately 75 dBA measured 10 cm from the nares. Treatment pressure increases by up to 0.2 cm H₂O per second (proportional to

the severity of the snore) for snore above 0.2 snore units. When snore is less than 0.2 snore units, therapy is reduced towards the minimum pressure with a 20-minute time constant.

An **apnea** is defined as a greater than 75% decrease in ventilation. The AutoSet algorithm scores an apnea if the 2-second moving average ventilation drops below 25% of the recent time average (time constant 100 seconds) for at least 10 consecutive seconds. Treatment pressure increases based on the duration of the apnea. The pressure will not rise above 10 cm H₂O when an apnea is detected, to prevent an inappropriate response to central apneas. Initial pressure increases are rapid, but the rate of increase diminishes as the pressure approaches 10 cm H₂O. When no further apneas are detected, therapy is reduced towards the minimum pressure with a 20-minute time constant.

A **hypopnea** is defined as a 50 to 75% drop in ventilation. A hypopnea is scored if the 8-second moving average ventilation drops below 50%, but not below 25%, of the recent average for 10 consecutive seconds. In order to avoid falsely responding to central hypopneas, the AutoSet algorithm does not respond to hypopneas but rather to the associated snore or flow limitation.

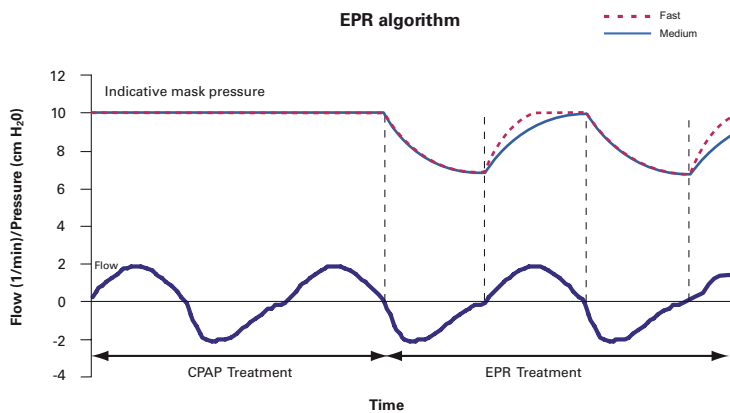
Expiratory Pressure Relief (EPR)

In either CPAP or AutoSet mode you can select expiratory pressure relief (EPR). EPR is designed to maintain optimal treatment for the patient during inhalation and reduce the delivered mask pressure during exhalation. The desired result of EPR is to decrease the pressure the patient must breathe out against, making the overall therapy more comfortable.

The features of EPR are:

- EPR is disabled automatically in the event of an apnea.
- EPR resumes automatically when the apnea event has passed.
- You can select an EPR pressure drop of OFF, 1, 2, or 3 cm H₂O.
- You can set EPR to be off, delivered only during ramping (CPAP mode) or settling (AutoSet mode), or delivered throughout therapy.
- Pressure drop is limited, to avoid sub-optimal treatment (maximum drop is 3 cm H₂O).
- When EPR is enabled, the delivered pressure will not drop below a minimum pressure of 4 cm H₂O, regardless of the settings.
- Either the clinician alone, or both the clinician and the patient can access the EPR level. You can enable or disable patient access to the EPR level setting.

The graph illustrates the performance of the S8 Elite II with the EPR inhalation settings.



System Setup

- 1 Place the S8 AutoSet II on a table near the head of the patient's bed.



CAUTION

Be careful to place the device where it cannot be bumped, and where no one will trip over the power cord.

Note: The S8 AutoSet II device may be placed on the floor beside or underneath the patient's bed. Ensure that the area is free from dust and clear of bedding, clothes, or any other objects that could block the air inlet.

- 2 Connect the AC power cord or ResMed DC-12 converter (not supplied) to the corresponding socket on the rear of the S8 AutoSet II (**D-1**). Plug the other end of the power cord or converter cable into the appropriate power outlet.



WARNING

- Make sure the power cord and plug or adapter cable are in good condition and the equipment is not damaged.
- In the clinical environment any personal computer that is used with your CPAP system must be at least 5' (1.5 m) away from, or at least 8' (2.5 m) above, the patient. It must also comply with the relevant test standard. For personal computers the international standard is IEC 60950 or equivalent.

- 3 Connect one end of the air tubing firmly onto the air outlet of the device (**D-2**) and the other end to the mask system (**D-3**).

When the S8 AutoSet II device is powered up, the Welcome screen is displayed, followed by the standby (RAMP or SETTLING) screen.

The S8 AutoSet II system is now ready for use (**D-4**).

Note: The S8 AutoSet II uses an internal pressure sensor, and therefore does not require calibration by a clinician or patient.

SmartStart™

If you enable the SmartStart™ function, the patient's device will start automatically when they breathe into their mask, and will stop automatically when they take the mask off. This means that the patient does not have to press the **Start/Stop** key to begin or end treatment. See "Clinical Menu" on page 21. for details about enabling SmartStart.

Note: A patient must not use SmartStart if they are using a mask with an anti-asphyxia valve, such as the Mirage Full Face Mask.

Delivering Therapy



WARNING

A mask should not be used unless the S8 AutoSet II is turned on and operating properly.

- 1 Ensure the patient settings are correct.

Instruct the patient to lie down in bed, arrange the air tubing, and put on the mask as in steps 1 and 2 in the section “Using the Mask Fitting Feature” on page 15.



WARNING

- Do not leave long lengths of air tubing around the top of the bed; they may twist around the patient's head or neck while they are sleeping.
- Blocking the air inlet or tubing while in operation could lead to overheating of the device.

- 2 Start therapy in one of two ways:

- If SmartStart is enabled, instruct the patient to breathe out strongly into the mask. The S8 AutoSet II device will start automatically.
- If SmartStart is not enabled, press the **Start/Stop** button to start the airflow. Air will begin flowing slowly and will build up to full operating pressure in about 15 to 25 seconds.

After starting therapy, the treatment pressure is displayed on the LCD.

Note: *The S8 AutoSet II measures pressure and compensates for air tubing and mask characteristics. The LCD shows the intended delivery pressure. If necessary, you can use a water manometer to take a more accurate reading.*

If the patient has difficulty falling asleep with full pressure, select a ramp (**CPAP** mode) or settling time (**AutoSet** mode). The airflow will start very gently while they fall asleep. In CPAP mode, the pressure slowly increases to full operating pressure over the selected ramp time. In AutoSet mode, the pressure remains at Minimum Pressure throughout the settling time.

- 3 Instruct the patient to put on the mask according to the mask user instructions.
- 4 Adjust the mask and headgear to achieve optimal fit.
- 5 At the end of the ramp/settling period, the LCD will display the word “CPAP” or “AUTOSET”.
- 6 Stop therapy in one of two ways:
 - Remove the mask, and press the **Start/Stop** button to stop airflow.
 - If SmartStart/Stop is enabled, simply remove the mask and treatment will stop automatically.

Using the Mask Fitting Feature

The S8 AutoSet II mask-fit feature delivers air pressure for a three-minute period before therapy begins for adjusting mask fit to minimize leak. It is particularly useful for patients receiving **AutoSet** mode therapy at home. It allows them to assess mask fit at typical treatment pressure at the start of the night, when pressure delivered is normally quite low.

The S8 AutoSet II system should be set up beside the patient’s bed with the air tubing and mask system connected. (See “System Setup” on page 13.)

- 1 Instruct the patient to lie down in bed. If desired, place the tubing over the top of the headboard to reduce drag on the mask.



WARNING

Do not leave long lengths of air tubing around the top of the bed; they may twist around the patient’s head or neck while sleeping.

- 2 Instruct the patient to put the mask on according to the mask user instructions.
- 3 Hold down the **Start/Stop** key on the control panel (see Figure 4, S8 AutoSet II Keypad and LCD, on page 17) for at least 3 seconds until pressure delivery starts and the following screen appears:



Note: When the device is in AutoSet mode, the mask-fit pressure is the 95th centile pressure of the previous treatment session, or 10 cm H₂O, whichever is greater. Note that 95th centile pressure is the pressure that has been exceeded for only 5% of the night. When the device is in CPAP mode, the mask-fit pressure is the set treatment pressure, or 10 cm H₂O, whichever is greater.

- 4 Adjust the mask, cushion and headgear to achieve optimal fit.

Table 1: Star ratings for the mask-fit and patient Smart Data features

Star rating	Indicative Leak Measure	
	(L/s)	(L/min)
* * * * * (Excellent)	0.00–0.18	0.0–10.8
* * * * _ (Very good)	0.19–0.26	10.9–15.6
* * * _ _ (Good)	0.27–0.34	15.7–20.4
* * _ _ _ (Adjust mask)	0.35–0.41	20.5–24.6
* _ _ _ _ (Adjust mask)	0.42–0.49	24.7–29.9
_ _ _ _ _ (Adjust mask)	≥ 0.50	≥ 30

Note: While using the mask-fit feature, the star rating values are indicative of the instantaneous leak calculated over the last 10 seconds.

Smart Data (designed for the patient) also uses a star rating for mask fit. The Smart Data star rating values correspond to 70th centile mask leak for the last session. A five-star rating is displayed, for example, if the leak rate was less than 0.10 L/s for 70% of the session.

- 5** After three minutes, the pressure will revert to the set pressure, and treatment will begin.
- If you do not wish to wait three minutes, **hold down** the **Start/Stop** key for three seconds and treatment will begin immediately.
 - If you **press** the **Start/Stop** key briefly (ie, for less than three seconds), the device will return to standby mode (the RAMP or SETTLING screen is displayed).

Using Humidifiers

Please refer to the illustration in section **E** of the illustration sheet, and your HumidAire 3i manual.

The HumidAire 3i humidifier attaches to the front of the S8 AutoSet II to provide heated humidification. No other accessories are required for its use.

Notes:

- a. Make sure the water chamber of the HumidAire 3i is empty before you attach or detach the humidifier.
- b. Remove the connector plug on the S8 AutoSet II before you attach the HumidAire 3i. Reattach the connector plug firmly after you detach the humidifier.

Storing the HumidAire 3i

Store the HumidAire 3i in its pouch in the S8 AutoSet II travel bag when not in use.

Navigating the S8 AutoSet II Menus

S8 AutoSet II Keypad and LCD

The control panel of the S8 AutoSet II includes a keypad for navigating through the menus and delivering treatment.

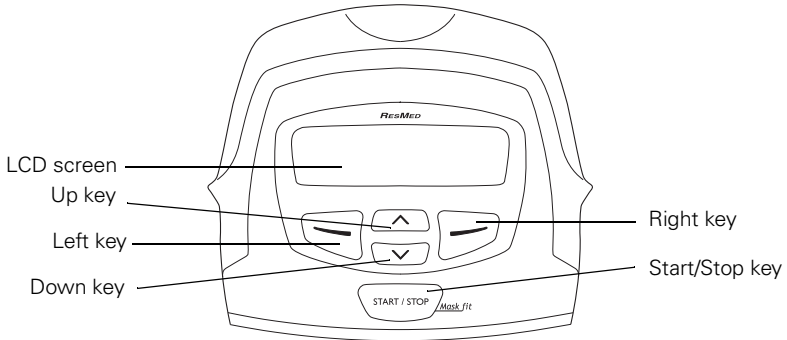

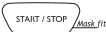






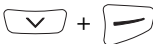
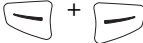
Figure 4: S8 AutoSet II Keypad and LCD

The LCD is used to display the menus and other data. The arrows and lowercase text on the bottom line of the LCD prompt the use of the keys within the menu. The keypad is used to navigate through the menus, access the mask-fit feature, and start/stop treatment. The functions of the keys and quick key combinations are listed in Table 2.

The LCD backlight turns off after two minutes of inactivity. It turns back on when you press a key.

Table 2: Keys on the front panel and their functions

Key	Function
LCD screen 	<ul style="list-style-type: none">• Displays S8 AutoSet II information including the menus and treatment screens.
Start/Stop 	<ul style="list-style-type: none">• Starts or stops treatment.• Extended hold for at least three seconds starts the mask-fit feature.
Up 	<ul style="list-style-type: none">• Navigates between items within the menu.• Allows you to increase settings options.
Down 	<ul style="list-style-type: none">• Navigates between items within the menu.• Allows you to decrease settings options.

Key	Function
Left 	<ul style="list-style-type: none"> Performs the function indicated by the guiding text displayed above it on the LCD (eg, change).
Right 	<ul style="list-style-type: none"> Performs the function indicated by the guiding text displayed above it on the LCD (eg, exit). Extended hold (for at least 3 seconds) returns you to the standby screen (if you are in the patient menu) or the CLINICAL MENU screen (if you are in the clinical menu). Returns you to the standby screen from the CLINICAL MENU screen.
Down + Right 	<ul style="list-style-type: none"> Extended hold (for at least 3 seconds) gives access to the clinical menu from the standby screen.
Left + Right 	<ul style="list-style-type: none"> Extended hold (for at least 3 seconds) gives quick access to the Quickview menu Settings section (for patients to view their device settings in read-only mode) and the Results section only. It does not allow further navigation (eg to other sections of the clinical menu). See Figure 10, Quickview menu screens, on page 25, and Figure 11, The clinical menu results series, on page 34.

When the S8 device is in standby mode all keys remain lit. During therapy, the keypad backlight turns off after two minutes of inactivity and the **Start/Stop** key dims.

S8 AutoSet II menus

The S8 AutoSet II LCD displays a variety of submenus, parameters, and data. Whether the machine is in standby mode or delivering therapy, you can view and change settings. When the S8 AutoSet II is first turned on, the Welcome screen appears while the device is performing self-checks.

Patient Menu

Depending on what menu type you have set in the clinical menu, the patient will see a standard or detailed menu.

Figure 5 summarizes the standard patient menu series.

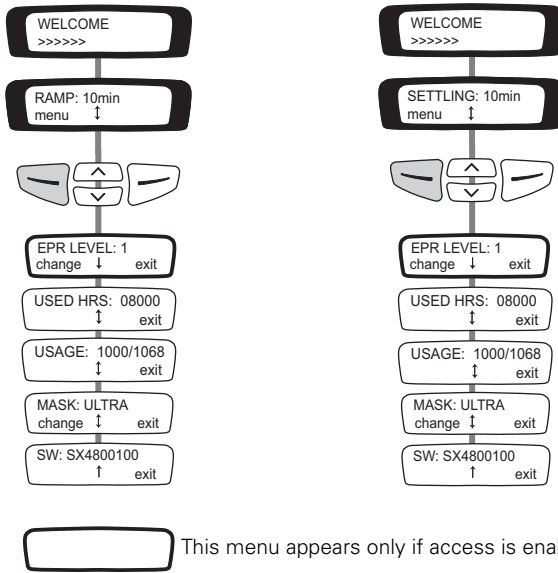
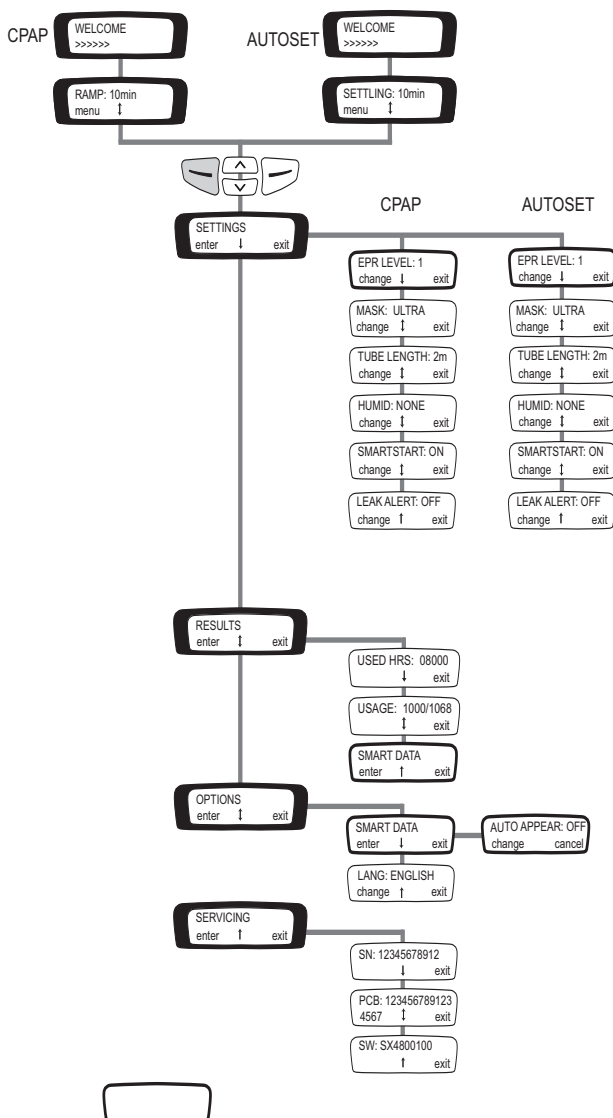


Figure 5: Standard patient menu series: CPAP and AutoSet modes

Figure 6 summarizes the detailed patient menu series. Either the **CPAP** (fixed CPAP) or **AUTOSET** (self-adjusting) menu series appears, according to the mode selected.



These menus appear only if access is enabled by a clinician.

Figure 6: Detailed patient menu series: CPAP and AutoSet modes

To navigate and make selections within the patient menu, use:

- the **Up/Down** keys to scroll through items within a level
- the **Left** key to enter a submenu and to apply an option choice
- the **Right** key to navigate out of a menu or submenu, and to exit without changing options.

Note: *The Results menu and Smart Data in the Options menu are displayed only if you have set one or more Smart Data options to ON in Clinical Menu, Options, Smart Data.*

Parameters in the standard and detailed patient menus are described in Table 3 on page 26. Those parameters that appear in one or both patient menus and the clinical menu are marked with an asterisk (*).

Clinical Menu

Access the clinical menu from the standby screen by holding down the **Right** and **Down** keys simultaneously for at least three seconds.

The flow charts in Figures 7–9 summarize the clinical menu series. For an expanded view of the Results section, see “The clinical menu results series” on page 34.

To navigate and make selections within the clinical menu, use:

- the **Up/Down** key to scroll through items within a level
- the **Left** key to enter a submenu and to apply an option choice
- the **Right** key to navigate out of a menu or submenu, and to exit without changing options.

Parameters in the clinical menu are described in Table 3, “Descriptions of parameters in the patient menu and the clinical menu,” on page 26.

EPR (expiratory pressure relief)

You can set the S8 AutoSet II to provide EPR (expiratory pressure relief). You may want to set EPR for patients who find it difficult to exhale against positive airway pressure. EPR provides a small reduction to therapy pressure during exhalation, reducing patient effort.

You can do any of the following:

- Specify when EPR will be applied. EPR can be switched off, set for use during ramp/settle only, or set for full-time use during therapy (including during the ramp/settle period.)
- Set EPR LEVEL. There are three levels of EPR available, each level corresponding to different levels of pressure relief. 1, 2 and 3 provide varying levels of EPR, with 3 providing the highest level.
- Set EPR INHALE (in CPAP mode only), which determines the rate of return to therapy pressure during inhalation. There are two inhalation rise levels: Medium and Fast.
- Set EPR ACCESS. If EPR ACCESS is ON, the patient can access EPR LEVEL from the patient menu.

Figure 7 shows the main menu screens. The Settings menu is expanded in Figure 8. The Options menu is expanded in Figure 9.

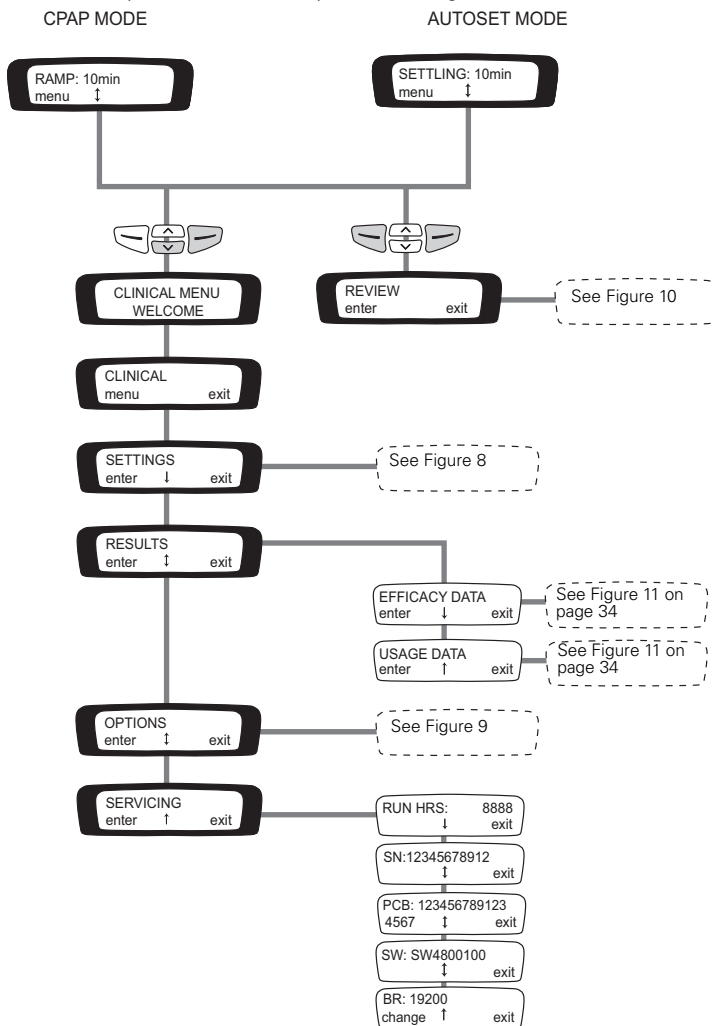


Figure 7: Clinical menu series: CPAP and AutoSet modes

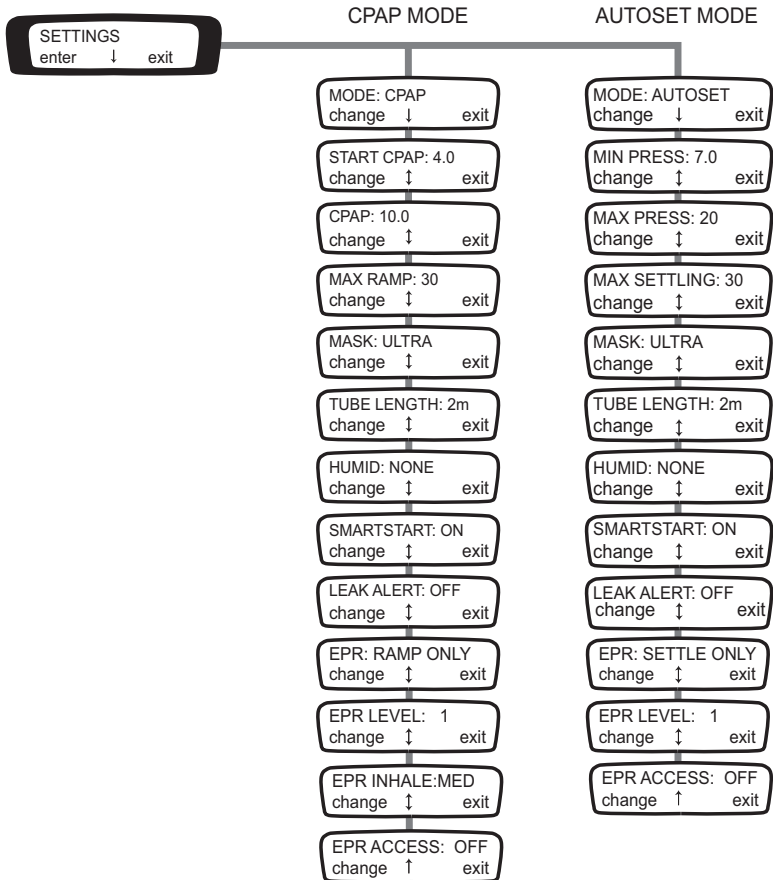


Figure 8: S8 Settings menu screens

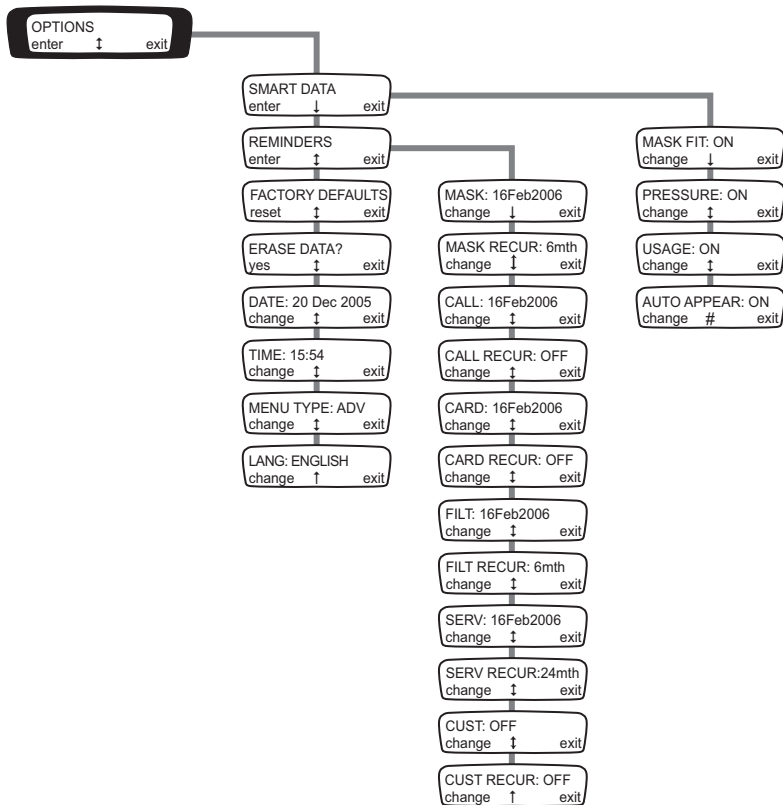


Figure 9: Options menu screens

QuickView

Note: QuickView is accessible by patients.

QuickView provides a quick, read-only way for a patient to access their device settings. This is useful if you cannot see the patient's device and you want them to provide details of their current settings and efficacy data remotely.

QuickView is accessed by holding down the **Right** and **Left** keys simultaneously for 3 seconds. The screens in Figure 10 are then available to the patient.

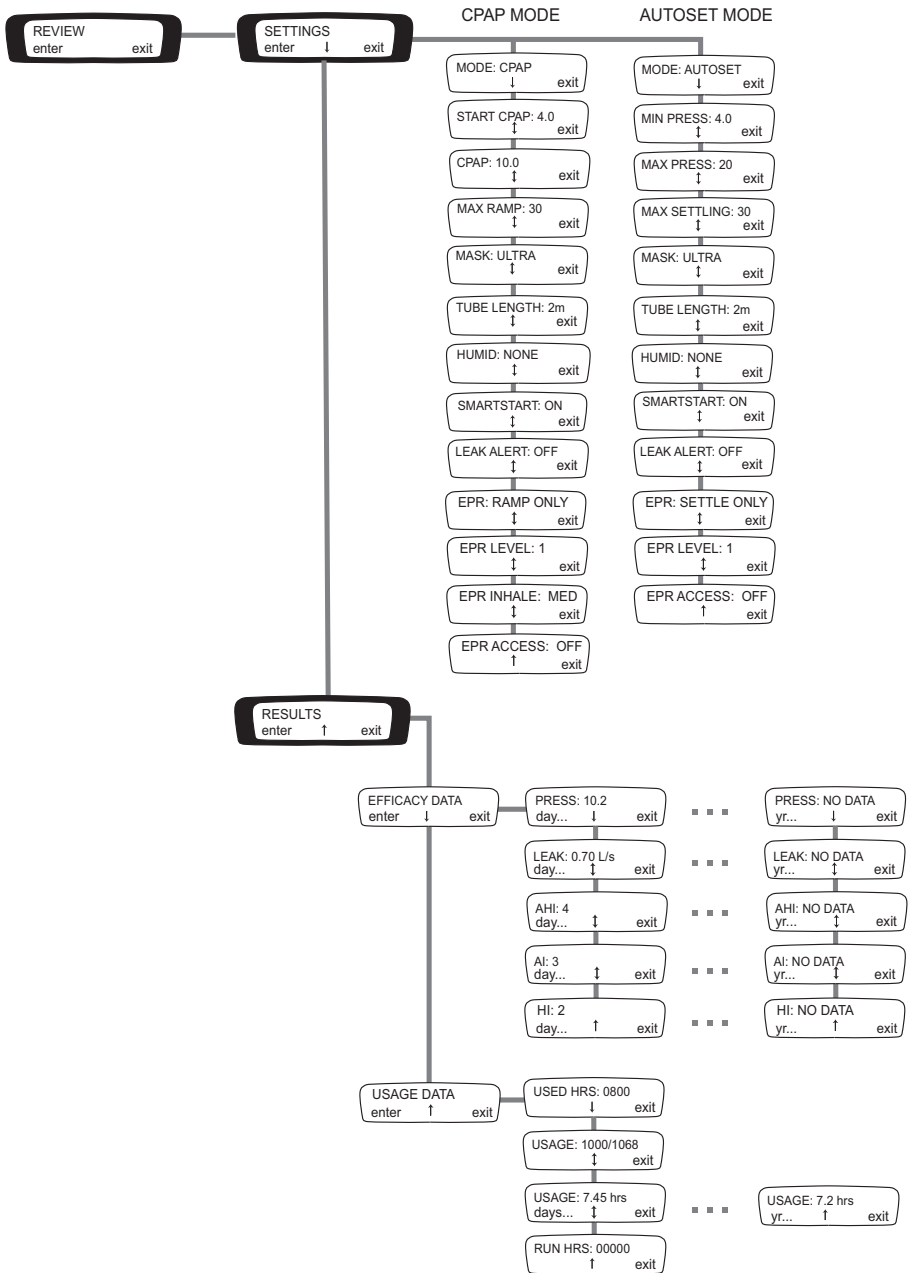


Figure 10: Quickview menu screens

Table 3: Descriptions of parameters in the patient menu and the clinical menu

Menu	Parameter	Description
	Ramp* (CPAP mode)	Sets the ramp time.
	Settling* (AutoSet mode)	Sets the time period the device waits (at Min Press) before beginning to adjust pressure according to the AutoSet algorithm.
	Used Hrs*†	Displays the total number of treatment hours. (View only.)
	Usage*†	The number of used sessions greater than 1 minute in length over the number of days elapsed since the first used day.
Settings	Mode	Sets CPAP (fixed CPAP pressure) or AutoSet (self-adjusting pressure).
	Start CPAP (CPAP mode)	Sets the pressure at the start of the ramp up to fixed treatment pressure.
	CPAP (CPAP mode)	Sets the fixed treatment pressure.
	Max Ramp (CPAP mode)	Limits the ramp times the patient may select.
	Min Press (AutoSet mode)	Sets the lower limit of treatment pressure.
	Max Press (AutoSet mode)	Sets the upper limit of treatment pressure.
	Max Settling (AutoSet mode)	Limits the settling times the patient may select.
	Mask*	Sets the mask type. <i>Note: when the mask type is MIR FULL, SmartStart/Stop is automatically disabled.</i>
	Humid*	Provides a setting option for a humidifier or front cap, if one is required. (Automatically detects the presence of a HumidAire 3i.)
	Tube Length*	Sets the length of the air tubing used.
	SmartStart*	Enables or disables the SmartStart/Stop feature; when enabled, the device will start automatically when the patient breathes into the mask, and stop automatically when the patient takes the mask off.

Menu	Parameter	Description
	Leak Alert*	Enables or disables the Leak Alert feature; when enabled, leaks > 0.7 L/s for > 20s result in an audible alert and a high leak message in the LCD. <i>Note: when Leak Alert is enabled, SmartStart/Stop is automatically disabled.</i>
	EPR	Sets expiratory pressure relief to occur all the time, during ramping only, or never.
	EPR Level*	Sets the expiratory pressure relief value. This screen is not displayed if EPR is set to OFF. <i>Note: EPR LEVEL only appears in the patient menu if you have set patient access to EPR.</i>
	EPR Access	Enables or disables patient view of, and ability to change, EPR level. This screen is not displayed if EPR is set to OFF.
	EPR Inhale*	Sets the rate at which pressure returns to therapy pressure during inhalation. <i>Note: EPR INHALE is only available in CPAP mode.</i>
Results	Efficacy Data	Displays pressure, leak, AHI (apnea + hypopnea index), AI (apnea index), and HI (hypopnea index) data for a range of time intervals. For details, see "Clinical Menu Results" on page 33.
	Usage Data	Displays usage data (including Run Hours) for a range of time intervals. For details, see "Clinical Menu Results" on page 33.
Options	Smart Data*	Allows the clinician to select which Smart Data screens, if any, are displayed in the patient menu. <i>Note: if you wish to make Smart Data available, set one or more of the options (Mask Fit, Pressure, or Usage) to ON. Set Auto Appear to ON so that the Smart Data screens are displayed in the morning if the patient resets the device.</i> In the patient menu, the Smart Data menu is displayed only if one or more of the options have been set to ON by the clinician. If AutoAppear is set to OFF, Smart Data is displayed in the Results menu only.
	Reminders	Enables you to schedule and/or create reminder messages for a patient, via a number of submenu screens. See "Setting Reminders" on page 29. You can also set individual reminders to recur at intervals from 1 to 24 months. See "Setting Reminder Recurrence" on page 30.

Menu	Parameter	Description
	Factory Defaults	Resets machine default settings (except for Language, Date, and Time).
	Erase Data?	Allows the clinician to erase all data stored in the device (except for Run Hours). Settings are not affected.
	Date	Sets the current date.
	Time	Sets the current time.
	Menu Type	Sets the menu that the patient will see: standard (STD) or detailed (ADV).
	Language*	Sets the display language.
Servicing	Run Hours*	Displays the total number of machine hours. (View only)
	SN*	Displays the device serial number. (View only)
	PCB*	Displays the printed circuit board number. (View only)
	SW*	Displays the current software version.
	BR	Sets the baud rate. This value is reset to 19200 every time the S8 AutoSet II is powered up.

* These parameters may appear in one or both patient menus and the clinical menu.

† More detailed data is available via your PC application.

Note: When Leak Alert is set to ON, SmartStart/Stop is automatically set to OFF. SmartStart/Stop cannot be used with Leak Alert because, if a high leak occurs, SmartStop may stop treatment before the Leak Alert signal is activated.

Settings for Mask Types

The following table shows the setting that should be selected for each mask type.

Settings	Mask
ULTRA	Ultra Mirage Nasal Mask
MIR FULL	Mirage Full Face Mask Mirage Full Face Mask Series 2 Mirage Liberty Full Face Mask Mirage Quattro Full Face Mask Ultra Mirage Full Face Mask ResMed Hospital Full Face Mask

Settings	Mask
ACTIVA	Mirage Activa Nasal Mask
SWIFT	Mirage Swift Nasal Pillows System Mirage Swift II Nasal Pillows System
MIRAGE	Mirage Nasal Mask
STANDARD	Mirage Vista Nasal Mask Papillon Silent Papillon

Setting Reminders

You can set a number of reminders to alert the patient to specific events; for example, when to replace their mask, when to insert a Data Card (if their device is Data Card enabled) and so on. You can also set special customized reminders. When a reminder is due, a message is displayed on the LCD and remains whenever the device is not delivering therapy. The backlight on the LCD flashes when a message is displayed.

If more than one reminder for a patient is scheduled for the same date, all scheduled reminders are displayed on that date. Patients can clear each message by pressing the **Left** key (or inserting a Data Card, in the case of the Data Card reminder).

You access reminders from Clinical Menu, Options (see Figure 8, S8 Settings menu screens, on page 23). From the REMINDERS screen, scroll down to the submenus to set a number of different types of message.

Replace mask

You can set a timed reminder to remind a patient when they need to replace their mask. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Call Provider

You can set a timed reminder for your patient to phone you at a certain time; for example, to discuss how their therapy is going. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Insert Card

If a patient's flow generator is Data Card enabled, you can set a timed reminder on the flow generator to remind them that they need to insert a Data Card to transfer patient data. This enables you to establish compliance. The patient should actually insert the Data Card in order to clear the message from the LCD. (They can also press the **Left** (Ok) key to remove the message.)

Replace filter

You can set a timed reminder to remind your patient when to replace the air filter. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Service Due

You can set a timed reminder to remind your patient when to return the device for service. The patient can press the **Left** (Ok) key to remove the message from the LCD.

Customized messages

You can also set reminders for other reasons; for example, to return equipment or to phone a particular person or number. You can make the custom reminder text up to 16 characters long, via PC application software. See your PC application manual for more information.

The following table shows the options and default settings for the types of reminders you can set.

Type of reminder	Reminder date*	Recurrence period
Replace mask (MASK)	7-day increments, starting from the current set date	1–24 months
Call provider (CALL)	7-day increments, starting from the current set date	1–24 months
Insert Card (CARD)	7-day increments, starting from the current set date	1–24 months
Change filter (FILT)	7-day increments, starting from the current set date	1–24 months
Service due (SERV)	7-day increments, starting from the current set date	1–24 months
Customised reminder (CUST)	7-day increments, starting from the current set date	1–24 months

* If you have used a PC application to set a reminder date, and you later change that date using the S8 AutoSet II Reminder screens, you can only change it in 7-day increments.

Setting Reminder Recurrence

You can set each reminder to keep re-occurring at a specific time period, starting from the date set for the original reminder. You can set the recurrence time period from 1 month to 24 months. (Each month in the recurrence time period is equal to 30 days.)

You have to set a date for a specific reminder before its recurrence time period will take effect.

For example, if you set a REPLACE MASK reminder for 30 August 2008, the patient will see that reminder on 30 August 2008. If you have also set a MASK RECUR reminder for 6 months, the mask reminder will occur again 6 months (180 days) from the date the reminder is acknowledged by the patient. The mask reminder will continue to recur at 6-month intervals unless you change the recurrence period, or set the mask reminder to OFF.

You access reminder recurrences from Clinical Menu, Options (see Figure 9, Options menu screens, on page 24). From the REMINDERS screen, scroll down to the submenus to set recurrences for the different reminders.

Data Management Using the Menu

The S8 AutoSet II system may be used to monitor patient usage as well as treatment pressure, mask leak, and incidence of apneas and hypopneas. To assess the patient's progress, data for the last session may be compared to median values for the last week, the last month, the last six months, and the last year, as displayed in the Results menu. The device stores usage and summary data for up to 365 sessions.

Comprehensive patient data can be viewed either on the LCD or in a PC software application. Data and settings can be transferred between the S8 AutoSet II and the PC application via S8 data management products. See "S8 Data Management Products" on page 39.

Clinical Menu Results

A comprehensive set of data (usage data and efficacy data) is available in Clinical Menu, Results, as shown in Figure 11 on page 34.

To navigate within the Efficacy or Usage Data screens, use:

- the **Up/Down** key to scroll through items within a time series
- the **Left** key to navigate between time series.

The USED screen reports total hours the device has been used and the number of days the device was used compared to the total days since the hour meter was last reset.

Other statistics quoted include:

- usage
- pressure (95th centile value for mask-on time only)
- leak (95th centile value for mask-on time only)
- AHI: apnea + hypopnea index (calculated per session)
- AI: apnea index (calculated per session)
- HI: hypopnea index (calculated per session).

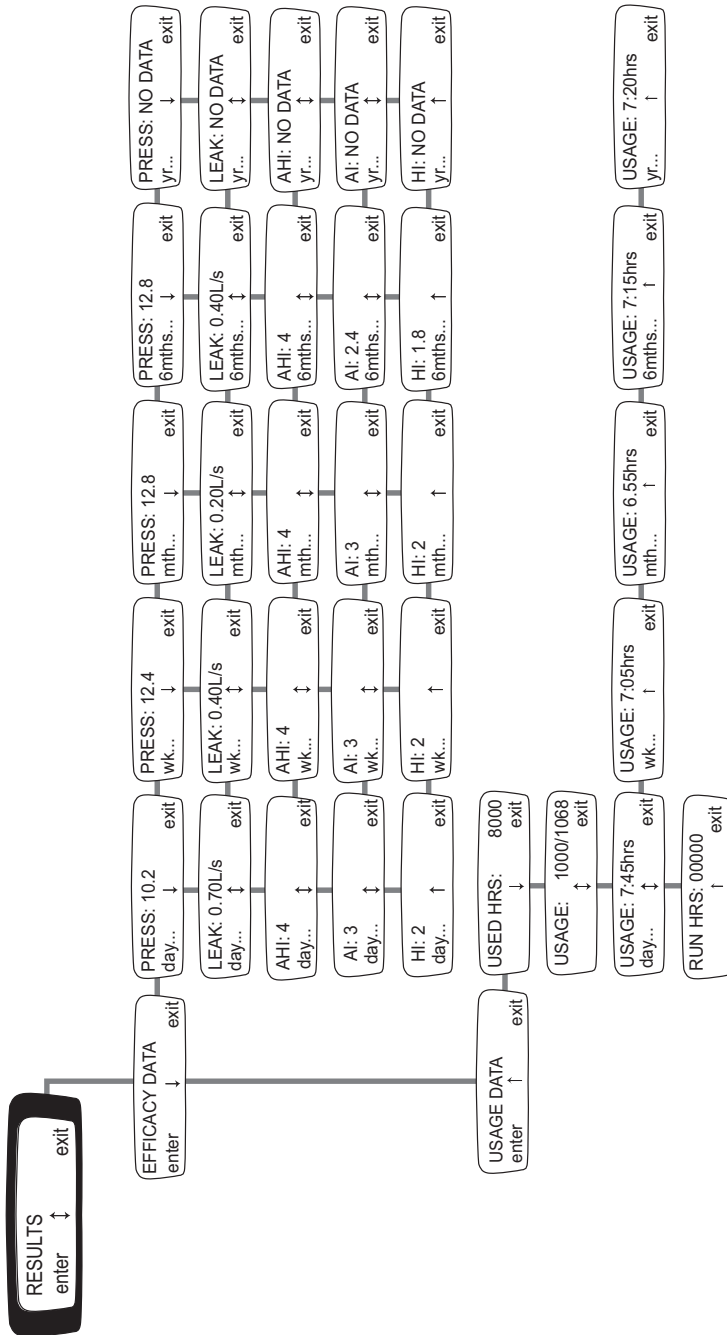


Figure 11: The clinical menu results series

Statistics are provided for five time intervals (last day, last week, last month, last six months, last year) so you can assess the significance of recent events. All statistics calculated for a range of dates are median values. The median is the middle value after the data have been sorted in order (50% of the values are smaller and 50% are larger). For example, Table 4 presents one week of 95th centile leak data (values in L/s). On day 7, the value 0.30 L/s would be displayed as the most recent day's leak value. In column 3 of the table, the seven leak values have been sorted in increasing order to calculate the median value.

Table 4: Sample calculation of median leak value

Day	95th centile leak (L/s)	Ordered data set (L/s)	Median value (L/s)
7	0.30	0.20	0.30
6	0.20	0.20	
5	1.00	0.30	
4	0.20	0.30	
3	0.30	0.30	
2	0.40	0.40	
1	0.30	1.00	

The median corresponds to the fourth value (0.30 L/s) in the ordered data set. The value 0.30 L/s would be displayed as the most recent week's leak value. If the data set had included an even number of days (eg a 30-day month), the median would be the average of the middle two values in the ordered data set.

Notes:

- a. *The median is a more robust measure than an average (or arithmetic mean) for a data set that has some extreme values. The average of the data in the above table is 0.39 L/s, reflecting the single session that had unusually high leak (1.00 L/s).*
- b. *You may make the Efficacy and Usage Data screens available to your patient by instructing them to press the Left and Right keys simultaneously. This does not give access to the other parts of the clinical menu.*

The Erase Data feature in Clinical Menu, Options enables you to remove all efficacy and usage data stored in the device (except Run Hours). Machine settings are not affected.

Interpreting Data in the Clinical Menu

Note: When assessing results, check the leak data first. Leak values greater than 0.4 L/s (24 L/min) affect the accuracy of other measurements.

Pressure

The pressure transducer located in the device measures treatment pressure; the average pressure is calculated and recorded each minute. The pressure reported in the Efficacy Data submenu (see Figure 11, The clinical menu results series, on page 34) for a single session is the 95th centile pressure for mask-on time, excluding periods when the leak has exceeded 0.4 L/s (24 L/min). For selected time intervals (last week, last month, last six months, or last year), the median of the daily 95th centile values is reported. Non-usage days are not included in calculations.

Leak

Leak is derived by analyzing inspiratory and expiratory airflows (via the flow sensor located in the device). Theoretically, inspiratory and expiratory volumes should be equal. A net airflow greater than the expected mask vent flow is equal to the leak. Generally, a leak rate of more than 0.4 L/s (24 L/min) is associated with patient discomfort, disturbed sleep, and reduced efficacy of treatment.

Notes:

- a. If the leak exceeded 0.4 L/s (24 L/min) for more than 30% of the previous session, the following message will appear on the LCD: *High leak in last session.*
- b. The Leak Alert feature, if enabled, will alert the patient when mask leak exceeds 0.7 L/s (42 L/min) for more than 20 seconds. When the leak exceeds this level, the autotitrating algorithm ceases to perform optimally.

The leak reported in the Efficacy Data submenu (see Figure 11, The clinical menu results series, on page 34) is the 95th centile value for mask-on time for each session, or the median 95th centile value for a selected time interval (last week, last month, last 6 months, or last year). Non-usage days are not included in calculations.

Apneas and hypopneas

For details of apnea and hypopnea scoring, see “AutoSet mode” on page 9. The AHI, AI, and HI reported in the Efficacy Data submenu are calculated values per usage hour per session, or median values for a selected time interval (last week, last month, last six months, or last year).

Smart Data in the Patient Menu

A Smart Data feature has been incorporated in the S8 AutoSet II device to increase patient involvement in their therapy. Display of Smart Data for the patient to review is at your discretion. Select some or all options for display in the patient menu from the Smart Data submenu in Clinical Menu, Options (see Figure 9, Options menu screens, on page 24). The following data can be made available, showing, for the most recent session:

- the star rating of the 70th centile mask fit
- 95th centile pressure
- total duration of session (usage).

Set the Mask Fit, Pressure or Usage options to ON to enable the patient to see any or all of this data.

If the Auto Appear option is set to OFF, the data will be displayed in the Results submenu of the patient menu only. If you (or the patient) set Auto Appear to ON, the data for the previous session will be displayed after the patient restarts the device.

Data for the current session are available for display up until noon, when a new session commences.

Note: *If none of the Smart Data options (Mask Fit, Pressure or Usage) has been set to ON in the clinical menu, the Results submenu is not displayed in the patient menu.*

Patients can use a Smart Data diary to monitor their therapy. You can download a PDF of the Smart Data diary for S8 AutoSet II from www.resmed.com.

S8 Data Management Products

Note: Do not remove data management products from the S8 AutoSet II while power is connected.

The S8 AutoSet II will have one of two modules fitted to the back:

- blank module
- Data Card module.

Serial and USB adapters are also available, for transferring data to a PC.

Using a Blank Module

The blank module is a protective cover on the S8 AutoSet II. At times, you may wish to remove or attach the module, for example to use an adapter.

To *remove* the blank module, pull it off the back of the S8 AutoSet II to show the data communications port (**F-1**).

To *attach* the blank module, push the blank module onto the data communications port, until the module clicks into place (**F-2**).

Note: To protect the data communications port, always ensure there is a module attached to the back of the device.

Using the ResScan Data Card Module

The ResScan Data Card module is a convenient way of gaining remote access to the data stored in the S8 AutoSet II, and of updating the settings in the S8 AutoSet II. The Data Card module is for home and hospital use. This module uses the ResScan Data Card for data collection and transmission.

Note: Patient compliance data stored in the S8 AutoSet II remains unchanged when copied to the Data Card.

If a patient has an S8 AutoSet II with a Data Card module attached, they can use a Data Card to retrieve data or update settings that are stored in the S8 AutoSet II.

If a patient has an S8 AutoSet II with a blank module attached, and they need to use a Data Card, you can order a Data Card starter pack from ResMed. This pack contains a Data Card module and Data Card.

1. Remove the blank module from the S8 AutoSet II (**F-1**).
2. Attach the Data Card module to the S8 AutoSet II (**G-1**).
3. Follow the instructions for inserting the Data Card (page 41).

Patient Management of the Data Card

Before issuing the Data Card, make sure that it has been labeled with the patient's ID is correctly addressed. Refer to "Using the Mailback Envelope" on page 41 for more details.

Check that the patient knows:

- why they are being issued with a Data Card
- when and how they must use the Data Card
- how to insert the Data Card
- how to remove the Data Card
- how to return the Data Card
- where to look for information (the "Troubleshooting" section of the User's Manual for their S8 device) if the data transfer does not work as expected.

Labeling the Data Card

- We strongly advise that you write the patient's identification details on the Data Card to prevent any mix-up of patient data. A space is provided on the Data Card for this purpose.
- Each Data Card is reusable. If you are issuing an existing Data Card to a new patient, make sure that the card is labeled with the new patient's ID. Use the space provided on the Data Card label when issuing a new card.

Notes:

- a. When reusing a Data Card, make sure that you use a label that does not cover more than the ID area on the Data Card, and is not more than 0.078" (0.2 mm) thick. If the label is larger than this, the patient may not be able to insert the Data Card into the Data Card module on their flow generator.*
- b. If you reuse a Data Card that already has a label on it, remove the old label before attaching a new one.*

Supplying the Data Card

You can monitor a patient's treatment with the Data Card and mailback envelope supplied with their device. The patient can return the card to you when they have copied their data onto it.

Ensure that the patient knows that they must remove their Data Card from the device when they have finished copying data to it. Leaving the Data Card in the device during therapy will not result in additional data being copied to the card. If a patient needs to copy additional data to the Data Card, they will need to insert the card again.

Notes:

- a. The Data Card should be stored in its mailback envelope when not in use.*
- b. Use a postal envelope to mail the mailback envelope and its contents to the patient.*

Using the Mailback Envelope

The Data Card slots into the mailback envelope to keep it safe while in transit or storage.

Figure 12 shows the inside of the mailback envelope.

Dear patient, please follow the directions as marked below.

Cher/Chère patient(e), veuillez suivre les instructions ci-dessous.
 Estimado paciente, tenga a bien seguir las instrucciones que se indican a continuación.
 Caro paciente, siga as instruções abaixo indicadas.

COPY DATA / COPIEZ LES DONNEES / COPIADO DE DATOS / COPIAR DADOS

1. **CARD INSERTED** / Carte insérée / Tarjeta insertada / Cartão inserido

2. **COPY COMPLETE** / Copie terminée / Copia completa / Cópia completada

3. **Return by mail** / Retournez la carte par courrier / Devolver por correo / Devolve o cartão por correio

4. **Return by person** / Retournez la carte personnellement / Devolver en persona / Devolve o cartão pessoalmente

5. **Keep the card** / Gardez la carte / Conservar la tarjeta / Fique com o cartão

UPDATE SETTINGS / METTEZ LES REGLAGES A JOUR / ACTUALIZACIÓN DE LA CONFIGURACIÓN / ATUALIZAR PARÂMETROS

1. **SETTINGS SUCCESS** / Paramètres réussis / Configuración correcta / Parâmetros bem-sucedidos

! If messages differ, see your manual. Use Data Card as per above before returning.

Si les messages affichés sont différents, référez-vous à votre manuel. Utilisez la carte de données conformément aux instructions ci-dessus avant de la retourner.
 Si los mensajes son distintos, consulte el manual. Antes de devolverla, utilice la tarjeta tal como se indica.
 Se as mensagens forem diferentes, consulte o seu manual. Use o cartão de dados tal como é descrito acima antes de o devolver.

Figure 12: Data Card mailback envelope

Use the mailback envelope for transporting and storing the Data Card. You can write your name and address details on the front of the mailback envelope to assist the patient in mailing it back to you. Use a postal envelope to mail the mailback envelope and its contents to the patient.

Inserting the Data Card

To insert the Data Card, the patient needs to:

1. Ensure the S8 AutoSet II is switched on and displaying the standby (RAMP or SETTLING) screen.
2. Insert the Data Card into the slot in the Data Card module (H-1). Continue inserting the Data Card smoothly until it stops moving (H-2) and messages start appearing on the LCD.

Removing the Data Card

To remove the Data Card, the patient needs to:

1. Grip the end of the Data Card and pull it out (H-3).

2. Place the Data Card in the mailback envelope supplied.

Transmitting Data with the Data Card

Copying Data onto a Data Card

If you want a patient to give you their data, you need to tell them how to copy data onto their Data Card.

Instruct the patient to carry out the following steps to copy data onto a Data Card:

1. With the device in standby (RAMP or SETTling) mode, insert the Data Card into the slot on the Data Card module. Copying of data will start automatically.
2. The "Card Inserted Please Wait" message is displayed on the LCD while data is copied to the Data Card. Copying takes up to 30 seconds.
3. The "Copy Complete Remove Card" message is displayed on the LCD.
4. No additional data is copied onto the card once the "Copy Complete Remove Card" message is displayed, even if the card is left in the device. If mailing the Data Card and mailback envelope, put them in a postal envelope to send to the clinician.

This information is also supplied in the patient's User Guide.

Updating Settings on a Flow Generator

You can create new treatment settings and transfer them to a Data Card via a ResMed PC application. A patient can then use the Data Card to update the settings in their S8 AutoSet II. If you mail the Data Card to the patient, send it in the mailback envelope. If you need the Data Card sent back to you for verification, use a postal envelope to mail the mailback envelope and its contents to the patient.

Instruct the patient to carry out the following steps to update settings on their S8 AutoSet II:

1. With the device in standby (RAMP or SETTling) mode, insert the Data Card into the slot on the Data Card module. Updating will start automatically.
2. The "Card Inserted Please Wait" message will appear on the LCD while updating is in progress. Updating takes up to 30 seconds.
3. The "Settings Success Remove Card" message is displayed on the LCD, if the settings were updated successfully.

Note: *This message only appears once. If you re-insert the Data Card after you have updated your settings, this message is not displayed.*

4. Remove the Data Card from the device.

This information is also supplied in the patient's User's Manual.

When you create a Data Card with therapy settings you can store the serial number of the device on the Data Card. This prevents the settings from being applied to the wrong device. Refer to your PC application manual for more details.

Compliance and efficacy data are always stored in the S8 AutoSet II. If a Data Card is lost or damaged in transit, data stored in the S8 device can be recopied onto a Data Card.



WARNING

Advise the patient to contact you immediately if they are using the Data Card to update the settings on their device and the “Settings Success” message does not appear.

Analyzing the Data Card

Use a ResMed PC application to transfer data and settings between an S8 AutoSet II or a Data Card and your personal computer. Refer to the user guide for your PC application for more information about analyzing the information on returned Data Cards.

S8 Adapters

S8 adapters are designed for use with the ResMed S8 series of devices, to transfer data between the device and a personal computer.

Two adapters are available:

- Serial adapter, which uses a standard serial cable
- USB adapter (supplied with a USB cable).



WARNING

- Only use S8 adapters as specified in this manual.
- S8 adapters are specifically designed for use with ResMed S8 devices.

Attach the S8 serial or USB adapter to a ResMed S8 device to create a serial or USB port. You can then connect a cable that enables transfer of data between the device and a personal computer.



CAUTION

If a cable is not attached when an S8 adapter is attached to an S8 device, either attach the adapter’s protective cover, or remove the adapter and replace it with a blank or Data Card module. This is to prevent damage to the S8 adapter.

Attaching an S8 adapter

Notes:

- a. Ensure that a module or an adapter is attached to the S8 device at all times.*
- b. Remove the existing module from the S8 device if a serial or USB adapter is required.*
- c. The device should be turned off when removing a module and attaching an adapter.*

To attach an S8 adapter to an S8 device:

1. Unplug the device from the wall.
2. Remove the module currently attached to the S8 device (**I-1**).

3. Press and hold down the button on the adapter (**I-2 a**), while pushing it onto the device.
4. Connect one end of the cable to the adapter, and the other end to the computer.

Removing an S8 adapter

Note: *The device should be turned off when removing an adapter and attaching a module.*

To remove the S8 adapter:

1. Press and hold down the button on the adapter (**I-3 a**), while pulling it off the S8 device.
2. Attach another module to the S8 device according to the instructions for that module.

See the manual for your PC application for information about downloading data to your computer.

Cleaning and Maintenance

You should regularly carry out the cleaning and maintenance described in this section. Refer to your mask manual for detailed instructions.

Daily Cleaning

Mask

Clean the mask according to the instructions supplied with the mask.

Air tubing

Disconnect the air tubing from the S8 AutoSet II (and humidifier, if used) and hang the tubing and mask in a clean, dry place until next use.

Humidifier

If you are using a humidifier, clean it according to the instructions in the humidifier user's manual.

Weekly Cleaning

1. Remove the air tubing from the S8 AutoSet II *and* the mask.
2. Wash the air tubing in warm water using mild detergent. Rinse thoroughly, hang, and allow to dry.
3. Before next use, assemble the mask and headgear according to the user instructions.
4. Reconnect the air tubing to the air outlet and mask.

Periodic Cleaning

1. Clean the exterior of the S8 AutoSet II with a damp cloth and mild liquid soap.
2. Check the air filter for blockage or holes (see "Replacing the Air Filter" on page 46).



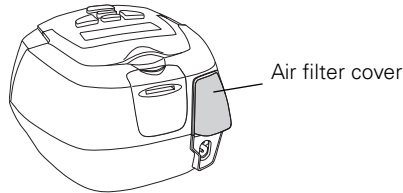
WARNING

- Beware of electric shock. Do not immerse the unit or power cord in water. Always unplug the unit before cleaning and be sure it is dry before plugging back in.
- The mask system and air tubing are subject to normal wear and tear. Inspect them regularly for damage.

Replacing the Air Filter

To replace the air filter:

1. Remove the air filter cover at the back of the S8 AutoSet II.



2. Remove and discard the old air filter.
3. Insert a new filter with the blue tinted side facing out from the device.
4. Replace the air filter cover.

Inspect the air filter every month to check if it is blocked by dirt or contains holes. With normal use of an S8 AutoSet II, the air filter needs to be replaced every six months (or more often if your device is in a dusty environment).

WARNING



- Do not wash the air filter. The air filter is not washable or reusable.
- The air filter cover protects the device in the event of accidental liquid spillage onto the device. Ensure the air filter and air filter cover are fitted at all times.

Servicing

CAUTION



- Do not attempt to open the S8 AutoSet II case. There are no user serviceable parts inside.
- Inspection and repair should only be performed by an authorized agent. Under no circumstances should you attempt to service or repair the flow generator yourself.

This product (S8 AutoSet II) should be inspected by an authorized ResMed service center 5 years from the date of manufacture. Prior to this, the device is intended to provide safe and reliable operation provided that it is operated and maintained in accordance with the instructions provided by ResMed. Applicable ResMed warranty details are provided with the device at the time of original supply. Of course, as with all electrical devices, if any irregularity becomes apparent, you should exercise caution and have the device inspected by an authorized ResMed service center.

If you feel that your flow generator is not performing properly, see "Troubleshooting" on page 49.

Frequently Asked Questions

Can patients use the S8 AutoSet II with a humidifier?

Yes. Patients may experience dryness of the nose, mouth and/or throat during the course of treatment, especially during winter. In many cases, a humidifier may resolve this discomfort. The S8 AutoSet II can be used with the HumidAire 3i to form an integrated device.

What is EPR?

EPR is designed to help patients who experience discomfort when breathing out against the therapy pressure. If you set EPR, there are three levels available (1–3 cm H₂O) and two inhalation levels available (Medium and Fast). You can set EPR so that it is available either during ramping/settling only, or throughout therapy. Use the EPR ACCESS menu setting to give the patient access to EPR level.

How can I obtain data or make data available to a patient?

Both the clinician and the patient can view data on the S8 AutoSet II LCD screen. You can also use a Data Card to obtain patient data and update patient settings data remotely. You can use an S8 adapter and cable to transfer data directly between an S8 AutoSet II and a PC application.

How long does the patient have to leave the Data Card in the S8 AutoSet II to collect data?

The Data Card can be inserted at any time. Data in the S8 AutoSet II will be transferred to the Data Card within 30 seconds.

How much data can I obtain from the S8 AutoSet II?

The S8 AutoSet II stores up to 365 days of summary data and up to five nights of detailed data (up to 500 events per session). The Data Card stores up to 180 days of summary data and up to four nights of detailed data (up to 200 events per session).

Can I set reminders for my patients?

You can set a series of reminders, to let patients know when to replace their mask or air filter, when to get their device serviced, when to use a Data Card or when to contact you. You can use a PC application to customize specific reminders.

Can patients travel with the S8 AutoSet II?

International use

The S8 AutoSet II flow generator has an internal power supply that enables it to operate in other countries. It will operate on power supplies of 100–240 V and 50/60 Hz. No special adjustment is necessary, but patients will require an approved power cord for the region in which they are using the device.

Use on an aircraft

The S8 AutoSet II complies with US FCC Part 15, Class B requirements if no external data cables are used. Patients should consult the medical services department of their carrier if they intend to use their S8 AutoSet II on an aircraft.

Note: Patients should not use their S8 AutoSet II while the aircraft is taking off or landing.

Can patients use the S8 AutoSet II if mains (AC) power is not available?

There is a DC input socket at the rear of the S8 AutoSet II. A ResMed DC-12 converter must be used to connect the S8 AutoSet II to a 12 V or 24 V DC power source. The DC-12 converter is available separately from ResMed dealers.



WARNING

The device should not be connected to both AC and DC power sources simultaneously.

Troubleshooting



CAUTION

If the problem cannot be solved, contact your equipment supplier or ResMed. Do not attempt to open the S8 AutoSet II case. There are no user serviceable parts inside. Repairs and internal servicing should only be performed by an authorized service agent.

Problem	Possible Cause	Solution
<i>No display.</i>	Power is not connected.	Ensure the power cable is connected and the power switch (if available) is on.
<i>Treatment pressure seems low.</i>	Ramp time or settling time is in use.	Wait for air pressure to build up.
	Air filter is dirty.	Replace air filter.
	Air tubing is kinked or punctured.	Straighten or replace tubing.
	Air tubing is not connected properly.	Check air tubing.
	Mask and headgear are not positioned correctly.	Adjust position of mask and headgear.
	Caps are missing from access port on mask.	Replace caps.
	Therapy has been changed from CPAP to AutoSet mode.	Explain that lower pressure is delivered in AutoSet mode as the algorithm adjusts pressure according to measured inspiratory flow limitation, snore, and apneas. For further details, see "Principles of Operation" on page 9.

Problem	Possible Cause	Solution
<i>Device does not start when the patient breathes into the mask.</i>	Power cord is not connected properly.	Connect power cord firmly at both ends.
	Power outlet may be faulty.	Try another power outlet.
	SmartStart not on.	Enable SmartStart.
	Leak Alert has been enabled; SmartStart has automatically been disabled.	Disable Leak Alert to enable SmartStart.
	Breath is not deep enough to trigger SmartStart.	Advise patient to take a deep breath in and out through the mask.
	The patient is using a full-face mask.	SmartStart does not work with a full-face mask as the anti-asphyxia valve will not allow sufficiently high pressure on exhalation.
	There is excessive leak.	Adjust position of mask and headgear. Caps may be missing from ports on mask. Replace them. Air tubing not connected properly. Connect firmly at both ends. Air tubing kinked or punctured. Straighten or replace.
<i>Device does not stop when the patient removes their mask.</i>	SmartStart/Stop is not enabled.	Enable SmartStart/Stop.
<i>SmartStart is enabled but the flow generator does not stop automatically when the patient removes their mask.</i>	Incompatible mask system being used.	Use only equipment as recommended by ResMed.

Problem	Possible Cause	Solution
<i>Pressure rises inappropriately (in AutoSet mode).</i>	Talking, coughing, voluntarily breath-holding (eg, while rolling over in bed), or intentionally breathing in an unusual manner while using the nasal mask.	Avoid talking with a nasal mask on, and breathe as normally as possible.
	Mask cushion is buzzing against the skin (may be interpreted as snore).	Adjust the headgear.
	Cushion seated incorrectly causing excessive leak.	Adjust headgear or re-fit cushion.
	Air tubing is kinked or punctured causing excessive leak.	Straighten or replace air tubing.
<i>Date or time in data files is wrong.</i>	Date or time on device is wrong.	Correct the current time and date on the device.
<i>Displays error message:</i> Check tube!! Key if done	The air tubing is loose or blocked.	Check that the air tubing is connected securely to your mask and the air outlet on the front of the S8 AutoSet II. When you have checked the air tubing, press the Start/Stop key to restart the device. If this does not clear the message, disconnect the power cord and then reconnect it to restart the device.
<i>Displays error message:</i> SYSTEM ERRnnnn Call service!	Component failure.	Record error number and contact the ResMed service center.
<i>Displays error message:</i> High leak in last session.	Your patient has experienced leak levels of greater than 0.4 L/s (24 L/min) for more than 30% of the previous session.	Check air tubing connections and mask fit.

Problem	Possible Cause	Solution
<p><i>Displays error message:</i> HIGH LEAK!!! Adjust mask.</p>	<p>Your patient has experienced leak levels of greater than 0.7 L/s (42 L/min) for more than 20 seconds.</p>	<p>Check air tubing connections and mask fit.</p>
<p><i>Display error message:</i> Exxxx (where xxxx defines an error)</p>	<p>Component failure.</p>	<p>Return the S8 AutoSet II for servicing.</p>
<p><i>The Data Card is returned without the expected patient data.</i></p>	<p>Data Card was not inserted correctly.</p>	<p>Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8 AutoSet II is powered and not delivering therapy (in standby mode).</p>
	<p>Data Card was only partly inserted.</p>	<p>Check that the patient is inserting the Data Card as far as it will go into the slot on the Data Card module.</p>
	<p>The card is not a ResScan Data Card.</p>	<p>Check that the card used is a ResScan Data Card.</p>
<p><i>The following message is displayed on the LCD after the patient inserts a Data Card:</i> Card Error Remove Card</p>	<p>Data Card is not inserted correctly.</p>	<p>Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8 AutoSet II is switched on and not delivering therapy (standby mode).</p>
	<p>The card is not a ResScan Data Card.</p>	<p>Check that the card used is a ResScan Data Card.</p>
	<p>Data Card has been removed before the Copy Complete Remove Card message was displayed.</p>	<p>Advise the patient to reinsert the Data Card and wait for the Copy Complete Remove Card message to appear on the LCD.</p>

Problem	Possible Cause	Solution
	<p>If this message occurs repeatedly even when the Data Card is inserted correctly, there may be a physical card fault on the Data Card.</p>	<p>Issue a new Data Card to the patient.</p>
<p><i>The following message is displayed on the LCD after the patient tries to update the settings using the Data Card:</i> Settings Invalid Remove Card</p>	<p>The identification details on the Data Card do not match the identification details on the device the patient is trying to update.</p>	<p>Check that the identification details on the Data Card are correct. (See the clinician's manual for your PC application for instructions.)</p>
<p><i>The following message is displayed on the LCD after the patient tries to update the settings using the Data Card:</i> Settings Error Remove Card</p>	<p>There is an unrecoverable data error on the Data Card.</p>	<p>Use the appropriate PC application to reprogram the settings on a new Data Card and issue it to the patient.</p>

Problem	Possible Cause	Solution
<p><i>The following message is NOT displayed on the LCD after the patient tries to update the settings using the Data Card:</i></p> <p>Settings Success Remove Card</p>	<p>The settings were not updated.</p>	<p>The message only appears the first time a Data Card is inserted into a device to update settings. The patient may have missed seeing the message. To check whether the settings have actually been applied:</p> <ul style="list-style-type: none"> • Ask the patient whether the therapy they are receiving feels different. • Check the settings data written on the Data Card from the S8 AutoSet II to see if they are correct (refer to your PC application clinician’s manual for more information). If the settings data on the Data Card matches the intended settings the device has been programmed successfully.

If the patient doesn’t feel any difference in therapy and/or the settings are not correct, you need to consider the following possible causes:

<p>Data Card given to patient did not contain settings because the patient received the wrong card.</p>	<p>Use the appropriate PC application to reprogram the Data Card with the settings, and reissue it to the patient.</p>
<p>The Data Card was removed before settings were copied to the S8 AutoSet II.</p>	<p>Check that the patient does not remove the Data Card before the Settings Success Remove Card message appears on the LCD.</p>

Problem	Possible Cause	Solution
	Data Card given to patient did not contain settings because programming of settings did not complete.	Use the appropriate PC application to reprogram the Data Card with the settings, making sure that programming completes. Reissue the card to the patient.
	Data Card was not inserted correctly.	Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8 AutoSet II is switched on and not delivering therapy (standby mode).
	Data Card was only partly inserted.	Check that the patient is inserting the Data Card as far as it will go into the slot on the Data Card module.
	The card is not a ResScan Data Card.	Check that the card used is a ResScan Data Card.

System Specifications

S8 AutoSet II (without Accessories)

Performance

Operating pressure range: 4 to 20 cm H₂O

Dimensions (H x W x D): 4.4" x 6.5" x 5.7" (112 mm x 164 mm x 145 mm)

Weight: 3.1 lb (1.4 kg)

Power Supply

- Input range for S8 AutoSet II with HumidAire 3i: 100–240 V, 50/60 Hz; 110 V, 400 Hz; 2.5 A <140 VA (110 W) (maximum power consumption). Instantaneous peak power consumption <340 VA.
- Refer to the DC-12 converter instructions for DC ratings. Only use the ResMed DC-12 converter for DC input.

Actual power consumption will vary, depending on factors such as the use of accessories, height above sea level, and ambient temperature. Power consumption values for typical treatment conditions (using a breathing machine set to 0.5 L and 15 breaths/min with 6'6" [2 m] air tubing and an Ultra Mirage mask) are given in the following table.

Device	Pressure (cm H ₂ O)	Power (VA)	Power (W)
S8 AutoSet II	5	18	7.6
	10	23	11.6
	15	30	15.9
	20	39	20.7

Power outlet for HumidAire 3i

Outlet range: 100–240 V, 50/60 Hz; 110 V, 400 Hz; 2.0 A

Air Filter: Two-layered, powder-bonded, polyester non-woven fiber

Air Tubing: Flexible plastic, 6'6" (2 m)

Air Outlet: The 22 mm conical air outlet complies with EN 1281-1

IEC 60601-1 Classifications: Class II (double insulation), Type CF

Noise Level

S8 AutoSet II—CPAP mode, 10 cm H₂O set pressure^a

Measured total A-weighted sound pressure level (dB re 20 µPa)	24 dBA
--	--------

Uncertainty (dB re 20 µPa)	2 dBA
----------------------------	-------

Measured values are determined according to the noise test procedure given in ISO 17510.

Note: *The sum of a measured noise emission value and its associated uncertainty represents an upper boundary of the range of values that is likely to occur in measurements.*

a. Declared dual number noise emission values in accordance with ISO 4871.

Accessories

Data Card

Dimensions (L x W x D): 2.56" x 0.87" x 0.03" (65.04 mm x 22.15 mm x 0.85 mm)

Data Card Module

Dimensions (H x W x D): 1.95" x 1.66" x 0.47" (49.7 mm x 42.2 mm x 12 mm)

S8 Serial and USB Adapters

Dimensions (H x W x D): 1.64" x 1.67" x 1.57" (41.8 mm x 42.8 mm x 40 mm)

All Devices (where applicable)

Housing Construction: Flame retardant engineering thermoplastic

Environmental Conditions

Operating Temperature: +41°F to +97°F (+5°C to +36°C)

Operating Humidity: 10%–95% non-condensing

Storage and Transport Temperature: -4°F to +140°F (-20°C to +60°C)

Storage and Transport Humidity: 10%–95% non-condensing

Operating Altitude: Sea level to 8500' (2591 m)

Electromagnetic Compatibility

The electromagnetic compatibility tables for this ResMed device can be found on www.resmed.com, on the **Products** page under **Service and Support**. Click on the PDF file for your device.

Note: *The manufacturer reserves the right to change these specifications without notice.*

Symbols which appear on the device

S8 AutoSet II



Attention, consult accompanying documents



Type CF equipment



Class II equipment



IPX1

Drip proof



Dangerous voltage



Start/Stop and mask-fit

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