

AutoSet[™] & Elite[™]

POSITIVE AIRWAY PRESSURE DEVICES

H5i™

HEATED HUMIDIFIER

Clinical Guide

English





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Welcome

Thank you for choosing the S9 AutoSet, S9 Elite or H5i. Before operating these devices, please read the entire Clinical and Information Guides.

S9 AutoSet indications for use

The S9 AutoSet self-adjusting system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). The S9 AutoSet self-adjusting system is intended for home and hospital use.

S9 Elite indications for use

The S9 Elite CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). The S9 Elite CPAP system is intended for home and hospital use.

S9 contraindications

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.

S9 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 these devices:

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

H5i indications for use

The H5i is indicated for the humidification of the air delivered from a CPAP device. The H5i is for use only as recommended by a physician. The H5i is intended for single patient re-use in the home environment and re-use in a hospital/institutional environment.

H5i contraindications

The H5i is contraindicated for use with patients whose upper (supraglottic) airway has been bypassed.



S9 at a glance

The S9 system comprises the following elements:

- S9 device
- SlimLine air tubing
- 90W power supply unit
- S9 travel bag
- SD card
- S9 SD card protective folder.

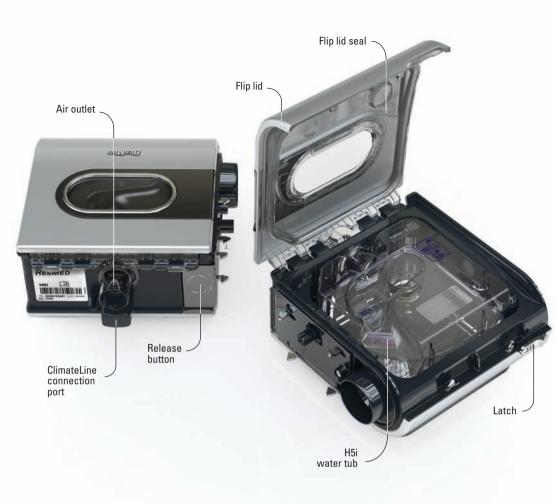
Optional components include:

- H5i heated humidifier
- Standard air tubing
- S9 USB Adapter
- S9 Oximeter Adapter.

Traveling with the S9

Patients when traveling may chose to leave behind their H5i and take their S9 device only. If this is the case, ensure they pack the SlimLine or Standard air tubing in their travel bag, as the ClimateLine heated air tubing is not designed to connect directly to the S9 device.

ResMed confirms that the S9 AutoSet and S9 Elite meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160F) for all phases of air travel.



H5i at a glance

The H5i system comprises the following elements:

- H5i heated humidifier
- H5i water tub
- ClimateLine heated air tubing (if sold as a Climate Control Kit).

Optional components include:

• ClimateLine heated air tubing.

Traveling with the H5i

When moving or traveling with your H5i:

- Ensure that the water tub is empty.
- Disconnect the H5i from the S9 by pressing the release button.

Operating information

The following table describes the operating modes available on the S9 AutoSet and S9 Elite.

Mode	S9 Elite	S9 AutoSet
CPAP mode		
A fixed pressure is delivered with optional Expiratory Pressure Relief (EPR). EPR can help ease any discomfort that your patient experiences when breathing out during treatment.	\checkmark	\checkmark
AutoSet mode The AutoSet algorithm automatically adjusts pressure in response to inspiratory flow limitation, snore and apnea. AutoSet mode offers optional EPR. You can set the minimum and maximum allowable treatment pressures.	-	✓

EPR technology

Designed to make therapy more comfortable, EPR maintains optimal treatment for the patient during inhalation and reduces the delivered mask pressure during exhalation. You can select EPR in either CPAP or AutoSet mode.

EPR checklist

- ✓ You can set EPR to Off, Ramp Only, Full Time.
- ✓ You can select an EPR Level of Patient (configurable by the patient), Off, 1, 2, or 3 cm H₂O.
- ✓ In CPAP mode you can set the EPR Inhale to Med or Fast.
- ✓ When EPR is enabled, the delivered pressure will not drop below a minimum pressure of 4 cm H_2O , regardless of the settings.

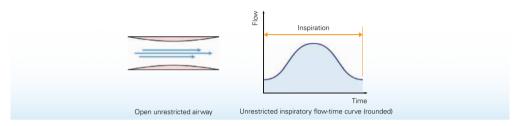
AutoSet technology

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

The device analyzes the state of your 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.

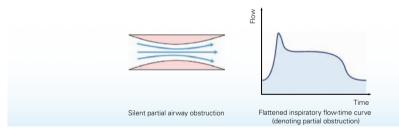
Normal airway

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.



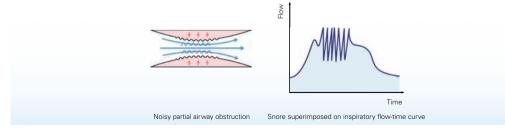
Flow limitation

As the upper airway begins to collapse, the shape of the inspiratory flow-time curve changes. The S9 recognises and treats traditional as well as less common flow-limited breath wave forms.



Snore

Snoring is sound generated by vibrations of the walls of the upper airway. It is often preceded by flow limitation or a partial obstruction of the airway.



Apnea

The enhanced AutoSet algorithm detects both obstructive and central apneas. If an apnea occurs, the device responds appropriately.

Obstructive apnea

An obstructive apnea is when the upper airway becomes severely limited or completely obstructed. AutoSet generally prevents obstructive apneas from occurring by responding to flow limitation and snoring. If an obstructive apnea occurs, the device will respond by increasing pressure.

Flow	
	Absence of flow (for at least 10 sec)
	Time
Complete airway obstruction	Inspiratory flow-time curve

Central apnea

During a central apnea, the airway will remain open, but there is no flow. When a central apnea is detected, the device responds appropriately by not increasing pressure.

Open unrestricted airway Inspiratory flow-time curve	Flow	Absence of flow (for at least 10 sec)
	Open unrestricted airway	Inspiratory flow-time curve

New to the S9 platform

Climate Control

S9 devices, when used in conjunction with the H5i and ClimateLine heated air tubing, offer a feature called Climate Control.

Climate Control enables the automatic delivery of a constant value of absolute humidity to the patient's upper airway while protecting against rainout and allowing patients to select the air temperature that offers the most comfort for them.

Rainout protection

Rainout refers to the water or condensation that collects in the patient's tubing or mask. Rainout is a common side effect of using a humidifier due to the humidified air cooling as it travels down the tubing and into the mask. Rainout occurs when relative humidity, which is a measure of the air's capacity to hold water vapour, exceeds 100%.

Climate Control protects the patient from rainout by maintaining a target relative humidity of 80% as well as maintaining the temperature of the air delivered to the patient without compromising the amount of absolute humidity delivered.

Automatic constant humidity delivery

For each temperature setting, the Climate Control system delivers a constant amount of water vapour, or absolute humidity, to the patient's upper airway. The following table shows the target absolute humidity value that will be delivered to the mask for a selection of temperature settings.

Temperature delivered to the mask	Target absolute humidity at the mask, Body Temperature Pressure Saturated (BTPS)
60°F (16°C)	10 mg/L
68°F (20°C)	12 mg/L
75°F (24°C)	16 mg/L
80°F (27°C)	19 mg/L
86°F (30°C)	22 mg/L

Automatic constant temperature delivery

The temperature sensor located at the mask end of the ClimateLine heated air tube enables the system to automatically control the temperature of the air delivered to the patient. This ensures the temperature of the air delivered to the patient does not fall below the set minimum temperature, therefore maximizing breathing comfort for the patient.

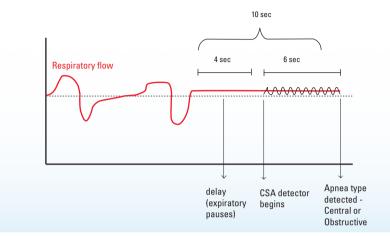
Automatic adjustment

The H5i and ClimateLine heated tubing are controlled by the Climate Control algorithm to deliver constant humidity and temperature outputs. The system adjusts automatically to changes in:

- ambient room temperature and humidity values
- flow due to pressure changes from the AutoSet algorithm or mask or mouth leak.

Central sleep apnea

The S9 Series detects both obstructive and central sleep apneas (CSA). CSA detection uses the Forced Oscillation Technique (FOT) to determine the state of the patient's airway during an apnea. When an apnea has been detected, small oscillations in pressure (1 cm H_2O peak-to-peak at 4 Hz) are added to the current device pressure. The CSA algorithm uses the resulting flow and pressure (determined at the mask) to measure the airway patency.



Sleep quality

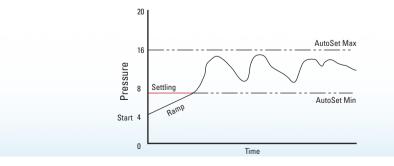
Designed to promote compliance, the Sleep Quality indicator allows the patient to actively engage in their own therapy by identifying leak, usage and AHI information. This information can be set to:

- Usage—where only usage hours are displayed
- On-where usage, leak and AHI information are displayed.

Ramp

Designed to make the beginning of treatment more comfortable, ramp is available in both CPAP and AutoSet modes.

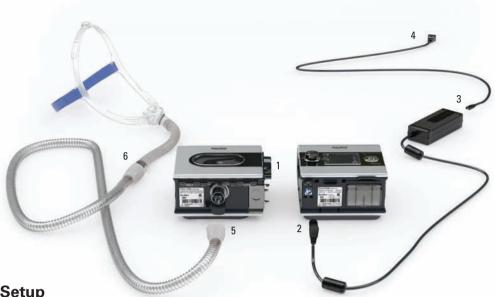
Ramp time defines the period during which the pressure gradually increases from a lower more comfortable start pressure to the minimum AutoSet pressure before the auto-adjusting algorithm commences. In previous products in the AutoSet range, settling was the period where the device was at a minimum AutoSet pressure until the auto-adjusting algorithm commenced.



Data management

Designed to make data more easily available, the S9 SD card gives clinicians greater insight to patient therapy by making high resolution flow and detailed data available on every device. The amount of data stored on the SD card varies compared to the data stored on the device.

Type of data	S9 device	SD Card
Compliance and therapy summary and statistic data (usage, AHI, pressure, and leak)	365 nights	365 nights
Detailed data	-	30 nights
High resolution flow data	-	7 nights



Setup

- 1. Align your H5i with your S9 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.
- 3. Connect the power cord to the power supply unit.
- 4. Plug the other end of the power cord into the power outlet.
- 5. Connect one end of the air tubing firmly onto the air outlet.
- 6. Connect the assembled mask system to the free end of air tubing.

Mask and tubing setup

- For more information on assembling the mask see the mask user guide.
- If your patient is using a full face mask ensure that the "Full Face" setting is selected. If your patient is using a nasal pillows mask ensure that the "Pillows" setting is selected. If your patient is using a nasal mask ensure that the "Nasal" setting is selected with the exception of the Ultra Mirage mask which should use the "Nasal Ultra" setting.
- For a complete list of recommended masks and their settings go to www.resmed.com on the Products page under Service & Support. If you do not have internet access, please contact your ResMed representative.
- The S9 device is compatible with the following tubing:

Tube	Specifications	Settings
SlimLine Length: Inner diameter:	6' (1.8 m) 0.6" (15 mm)	Default setting
Standard Length: Inner diameter:	6'6" (2 m) 0.75" (19 mm)	If using the standard tubing, adjust the tube setting in the Patient Setup or Clinical Setup menus.
ClimateLine Length: Inner diameter:	Heated 6'6" (2 m) 0.6" (15 mm)	Automatically detected

Filling the water tub

- 1. Slide the latch and lift open the flip lid.
- 2. Remove the water tub.
- 3. Fill the water tub (through the center hole) with distilled water up to the maximum water level mark (12.5 fl oz / 380 mL).
- 4. Return the water tub to the H5i.
- 5. Close the flip lid ensuring that it clicks into place.







Navigating the menus

In general, to navigate the menus:



1. Turn until the parameter you require is displayed in blue.



2. Press . The selection is highlighted in orange.



Turn ullet until you see the setting that you require.



 Press to confirm your choice. The screen returns to blue.

About the menus

There are three menus that are designed to help you to navigate to where you want to go. They are:

- 1. Home menu—for day to day adjustments.
- 2. Info menu—provides sleep quality information.
- 3. Setup menu—where settings can be adjusted.

Home menu

The Home menu shows you and your patient what features are currently activated, and the accessories that are connected to the device.



Clinical Setup menu.

Humidity Level—displayed when the H5i is connected.

Ramp—displayed when the Max Ramp function is activated in the



Climate Control—displayed when both the H5i and the ClimateLine heated air tube are connected and when Climate Control is activated in the Clinical Setup menu.



Humidity Level and **Heated Tube**—displayed when both the H5i and the ClimateLine heated air tube are connected and when Climate Control is set to Off in the Clinical Setup menu.

Changing settings via the Home menu

From the home menu, you can adjust or check the following features:



Ramp

Designed to make the beginning of treatment more comfortable for the patient, ramp time is the period during which the pressure increases from an initial pressure to the prescribed CPAP pressure or minimum AutoSet pressure.

Ramp is available in both AutoSet and CPAP modes.



Humidity level

The patient can adjust their humidity level at any time to find the setting that is most comfortable for them.



Climate Control

When the ClimateLine heated air tubing is connected and Climate Control is enabled, the patient can adjust the air temperature to find the setting that is most comfortable for them.

When set to Auto, Climate Control prevents rainout by maintaining 80% relative humidity in the delivered air. If Climate Control is set to Off, Humidity Level and Heated Tube temperature can be set independently.



Mask-fit

Designed to help patients fit the mask properly, the mask-fit feature delivers $10 \text{ cm H}_20 \text{ or set CPAP}$ pressure (whichever is greater) for a three-minute period, prior to starting treatment. During this time, the mask can be adjusted to minimize leaks.

To use mask-fit:

- 1. Fit the mask as described in the mask user guide.
- Press I for at least three seconds. One of the MASK FIT screens shown is displayed (as shown on the left).
- 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 .



Treatment screens

Depending on how the system has been configured, you will see one of the following screens when the device is running:



✓ H5i humidifier



 ✓ Standard S9 without optional accessories



- ✓ H5i humidifier
- ✓ ClimateLine heated air tube
- ✓ Climate Control Auto



 Oximetry data via oximeter adapter

Info menu

Designed to provide you with information about compliance, therapy and settings, the Info menu consists of: Standard Info menu; and Advanced Info menu.

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I	1	I	
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Standard Info menu

From the Standard Info menu, patients can check their sleep quality, sleep report and service information. When Sleep Quality is set to On (via Setup > Clinical Setup > Options), data on previous usage (up to 365 days of data), mask fit, and AHI can be viewed. For Sleep Report, only the period can be changed—other values are for display only.



Sleep Quality = On

Sleep Quality = Usage

Mask-fit indicates 'Good' if the 70th percentile leak is less than 24 L/min.



🛓 + 兰 🛛 Advanced Info menu

Hold for 3 sec

To access the Advanced Info menu, press and hold the Info and Setup buttons for three seconds. This provides patients with additional therapy settings and compliance information.

This screen provides the same options as shown on the Clinical Info menu on the following page.



- ✓ H5i humidifier
- ✓ ClimateLine heated air tube
- ✓ Climate Control Off

Setup menu

The Setup menu consists of:

- **Patient Setup menu**—allows the patient to optimize comfort settings as well as make changes to the mask or tube type.
- **Clinical Setup menu**—allows the clinician to set all parameters and options pertaining to the patient's therapy.



Patient Setup menu

Only settings relevant to the patient are displayed in the Patient Setup menu. Depending on how the device has been customized via the Clinical Setup menu, the following screens can be viewed:



EPR Level—displayed if set to PATIENT in the Clinical Setup menu.

Tube—only displayed if ClimateLine is not connected. If ClimateLine is attached, no setting is required.

Climate Ctrl—only displayed if ClimateLine is connected and also set to PATIENT in the Clinical Setup menu.

Mask—always available.

Mask Fit—always available.

SmartStart—only displayed if set to PATIENT in the Clinical Setup menu.

🖺 + 🥯 Clinical Setup menu

Hold for 3 sec

There are four screens available from the Clinical Setup menu:

- Settings—displays parameters directly affecting the patient's therapy.
- **Options**—displays parameters affecting the patient's comfort, therapy feedback and compliance reporting.
- Reminders—displays parameters for accessories requiring replacement.
- Configuration—displays general device setting and resetting options.

Clinical menus are identified by the yellow open lock shown in the top right corner.



0	CONFIGURA	TION 🚽
	Language	English
-	Restore Defa	ults ->
1	Erase Data ->	>
(m)	Press. Units	cmH2O
	Temp. Units	٩F
0.0	<- BACK	
1	<<- HOME	

Where further options exist on a screen, the blue scroll bar down the right of the screen (present on the first two screens above) indicates your position within these options.

Clinical Info menu (accessed from the Clinical Setup menu)



	SLEEP REP	ORT 🚽 🚽
-	Period	1 Month
	Days Used	22/27
	Days>4hrs	18/27
Q.,	Avg. Usage	6.0hrs
	Used hrs	132
3	Pressure	8.2
10	Leak	10 L/min

	VIEW SETTIN	IGS 🚽
-	Mode	AutoSet
	Max Pressure	12.0
<u> </u>	Min Pressure	8.0
<u>.</u>	Max Ramp	40min
0	Start Pressure	4.0
3	EPR	Off
10	EPR Level	1

24 Apr 09

6mth

24mth

12mth

05 Jun 09

06 Nov 09

Off

	SERVICE d
	SW SX1231234-12
	<- BACK
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i

Reminder menu

You can use the Reminder menu to alert a patient to specific events, such as when to replace their mask (shown below) or when to insert an SD card. When a reminder is due, a message is displayed on the LCD and remains while 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 will be displayed.

Patients can clear each message by pressing any key (except the Start/stop button).

You can access reminders from the Clinical Menu > Options. From the REMINDERS screen, scroll down to the submenus to set a number of different types of message.

For a list of each of the reminders available and their default settings, see the table on the next page.

Managing Climate Control

Designed to be ideal for most patients, Climate Control Auto enables the automatic delivery of a constant value of absolute humidity while protecting against rainout.

To allow for increased flexibility, Climate Control can be turned to Off in either the Patient Setup (when enabled) or the Clinical Setup menus. Setting Climate Control to Off disables the automatic control of humidity and allows the patient to set humidity and temperature levels independently. However, rainout protection is not provided when Climate Control is off.

Mode	Humidity		Temperature	
Ivioae	Setting range	Default settings	Setting range	Default settings
Climate Control – Auto		Climate	Control	
HOME Info- Push Dial- Setup-	Constant absolute humidity (depending on temperature setting)	_	Off,1 60°F–86°F (16°C–30°C)	80°F (27°C)
Climate Control – Off	Humidit			d tube
HOME Info- Push Dial- Setup-	Off–6.0 (0.5 increments)	3	Off, 60°F–86°F (16°C–30°C)	80°F (27°C)

¹When the temperature setting is set to Off the tube will not heat the air, nor will the humidifier heat the water to add humidity to the air.

Treatment screen and clinical setup menus

Parameter	Mo	odes	Default	Range	Description
	CPAP	AutoSet			
Treatment scre	en				
CPAP	\checkmark	\checkmark			Shows the set pressure.
AutoSet Min Max		~	$4 \text{ cm H}_2\text{O}$ 20 cm H $_2\text{O}$		Shows the treatment pressure.
Ramp	~	✓	-	-	Orange icon shows that device is ramping up.
Settings					
Mode		~	-	-	Sets the therapy mode depending on what modes are available on the device.
Set pressure (CPAP)	~		9 cm H ₂ O	$4-20 \text{ cm H}_2\text{O},$ 0.2 cm H $_2\text{O}$ increments	Sets the fixed treatment pressure.
Max pressure		~	$20 \text{ cm H}_2\text{O}$	Min–20 cm H_2O , 0.2 cm H_2O increments	Sets the upper limit of treatment pressure.
Min pressure		~	4 cm H ₂ O	4–Max cm H ₂ O, 0.2 cm H ₂ O increments	Sets the lower limit of treatment pressure.
Max ramp	~	~	45 minutes	Off–45 minutes, 5-minute increments	Limits the ramp times the patient may select.
Start pressure	~	~	4 cm H ₂ O	$4 \text{ cm H}_2\text{O},$ 0.2 cm H $_2\text{O}$ increments	Sets the pressure at the start of ramp, up to fixed treatment pressure (CPAP) or minimum treatment pressure (AutoSet mode).
EPR	~	~	Off	Off / Ramp Only / Full Time	Sets when EPR is to occur.
EPR level	~	~	Off	Off / 1 / 2 / 3 / Patient	Sets the EPR value.
Mask	~	~	Pillows	Pillows / Full Face / Nasal / Nasal (Ultra)	Selects the type of mask used by the patient.
Tube type	~	\checkmark	SlimLine	SlimLine / Standard	Selects the type of air tubing used by the patient.

Parameter	Mo	odes	Default	Range	Description
	СРАР	AutoSet	-		
Options					
Climate Control	\checkmark	~	Auto	Auto / Off / Patient	Sets the type of Climate Control.
Sleep quality	\checkmark	\checkmark	Usage	On / Usage	Sets Sleep Quality to Usage or On.
SmartStart	~	~	Off	On / Off / Patient	Enables or disables the SmartStart feature.
EPR inhale	\checkmark		Med	Med / Fast	Sets the inhalation type.
Date	~	~	-	-	Sets the current date or time. If you set a new date or time that occurs in the past then an 'Invalid date/ time, data exists for this period'
Time	~	~	-	-	message is displayed. Before this change can be made, erase the compliance data – available under the Configuration menu.
Configuration					
Language	~	\checkmark	English	English / Français / Español / Português	Sets the display language.
Restore factory defaults	~	~	-	-	Resets machine default settings (except for language, date and time).
Erase data	~	~	-	-	Allows the clinician to erase all data stored in the unit and SD card (except for machine hours). Settings, date and time are not affected.
Temperature units	~	~	°F	°F/°C	Sets temperature units.
Advanced Info	menu	I			
Sleep quality	~	~	-	-	Displays information on last night's usage, mask fit and AHI data or usage only.
View settings	~	~	-	-	Displays Mode, Pressure, Ramp, EPR, Mask, Tube type, Climate Control, Sleep quality, and SmartStart settings.
Service					
SW	✓	~	-	-	Displays the current software version.

Parameter	Parameter Modes		Default Range	Description	
	CPAP	AutoSet			
Reminders					
Replace mask	√	~	6	Seven-day increments (starting from the current	A timed reminder to remind a patient when they need to replace their mask.
Replace water tub	~	~	6	set date) with a recurrence period of one to 24 months.	A timed reminder to remind a patient when they need to replace their water tub.
Replace tubing	~	~	6		A timed reminder to remind a patient when they need to replace their tubing.
Replace filter	~	~	6		A timed reminder to remind a patient when to replace the air filter.
Return SD card	~	~	Off		A timed reminder to remind a patient that they need to remove their SD card and return it to you, enabling you to establish compliance.
Service due	√	~	Off		A timed reminder to remind a patient when to return the device for service.
Customized messages (Custom 1, Custom 2)	~	~	Off		Customized reminders, eg, to return equipment or to phone a particular person or number. Custom reminder text can be up to 16 characters long, via PC application software. See your PC application manual for more information.

Delivering therapy

- 1. Make sure the power is connected.
- 2. Adjust the ramp time or humidification level if required.
- Instruct the patient to fit their mask as described in the mask user guide.
- 4. To start therapy, instruct the patient to breathe into the mask and/or press ().
- 5. Instruct the patient to lie down and arrange the air tubing so that it is free to move if they turn in their sleep.
- 6. To stop treatment at any time, instruct the patient to remove the mask and/or press .

In order to assist the heater plate in cooling, your S9 device will continue to blow air for up to an hour after treatment has stopped. However, you can unplug the device from the power outlet at any time and allow the heater plate to cool without air flow.

If you enable SmartStart, the patient's device will start automatically when the patient breathes into the mask and stop automatically when they remove their mask.

Once therapy has started the HUMIDITY LEVEL screen is displayed.

Data management

The SD card 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 values for the last week, the last month, the last three months, the last six months, and the last year. The device stores usage and summary data for up to 365 sessions.

SD card

The SD card allows S9 devices to capture data. The S9 Series comes with the SD card already inserted and ready to be used.

Compliance data is also stored on the device, so if the card is lost, the data is not. You can also create new treatment settings and transfer them to the patient's device via the SD card.



Removing the card

Instruct the patient to:



- 1. Push in the SD 2 card to release it.
- - Remove the card.



- N. A. A.
- 3. Insert the card into the protective folder.
- Send the protective folder back to you as instructed.

Inserting the card

- 1. Remove the card from the protective folder.
- 2. Push the card into the S9 device until it clicks.
- 3. The following message is briefly displayed: Reading SD card

Notes:

- For more information on removing and inserting the card refer to the S9 SD Card Protective Folder provided with the device.
- Ask the patient to retain the S9 SD Card Protective Folder for future use.

Analyzing the SD card data

To analyze the data, use a ResMed PC application to transfer data and settings between an S9 or an SD card and your personal computer. Refer to your PC application guide for more information about analyzing the information on returned SD cards.

Data storage

The amount of data stored on the SD card varies compared to the data stored on the device.

Type of data	S9 device	SD Card	Sampling rate
Compliance and therapy summary and statistic data (usage, AHI, pressure, and leak)	365 nights	365 nights	
Detailed data	-	30 nights	
AHI and AI (events/hr)			-
Apnea or hypopnea events (sec)			Aperiodic
Flow limitation (flat to round)			1/2 Hz
Flow (L/min)			25 Hz
Leak (L/sec)			1/2 Hz
Minute ventilation (L/min)			1/2 Hz
Pressure (cm H ₂ O)			1/2 Hz
Pulse rate (beats/min) ¹			1 Hz
Snore (quiet to loud)			1/2 Hz
Oxygen saturation (SpO ₂) (%) ¹			1 Hz
Usage (hr:min)			-
High resolution flow data	_	7 nights	

¹ Information only available via oximeter adapter.

Data transmission adapters

The following data transmission adapters are designed for use with S9 devices.

Device	Method	Description	Type of data transfered
	USB adapter	Allows the download of data directly from the device to the computer.	Summary therapy and compliance data
HEBANKO BOINER ANNO	Oximeter adapter	Enables collection of oximetry data from an oximeter for storing data on the SD card inserted into the device.	Oximetry data (oxygen saturation and pulse rate)

Note: For more information on setting up your S9 adapter refer to the relevant S9 adapter user guide.

Cleaning and maintenance

You should regularly carry out cleaning and maintenance as described in this section.

Daily

- 1. Disconnect the air tubing and hang it in a clean, dry place until next use.
- 2. Slide the H5i latch.
- 3. Lift open the flip lid and remove the water tub.
- 4. Wash the H5i water tub in warm water using a mild detergent.
- 5. Rinse thoroughly in clean water and allow it to dry away from direct sunlight.
- 6. Before next use, fill the water tub, return it to the H5i and close the flip lid.

Note: Do not open the H5i water tub. There are no user serviceable parts inside.



Weekly

- 1. Remove the air tubing from the S9 device and the mask.
- 2. Wash the air tubing in warm water using mild detergent.
- 3. Rinse thoroughly, hang, and allow to dry.
- 4. Before next use, reconnect the air tubing to the air outlet and mask.

Monthly

- 1. Wipe the exterior of the S9 and H5i with a damp cloth and mild detergent.
- 2. Check the air filter for holes and blockage by dirt or dust.
- 3. Peel the flip lid seal from the flip lid and wash it in warm water using a mild detergent.

Maintenance checklist

- ✓ Inspect the H5i water tub and flip lid seal for wear and deterioration.
- ✓ Replace the water tub if any component is leaking or has become cracked, cloudy or pitted.
- ✓ Replace the flip lid seal if cracked or torn.
- Clean white powder deposits in the water tub by using a solution of one part household vinegar to 10 parts water.

Replacing the air filter

Replace the air filter every six months (or more often if necessary).

- 1. Remove the air filter cover from the back of the S9 device.
- 2. Remove and discard the old filter.
- 3. Insert a new ResMed air filter ensuring that it is sitting flat in the air filter cover.



The following filters are available for use with S9 devices:

Filter	Efficiency
Standard (ASMB 160)	88% at 7 micron
Hypo-allergenic (Air Safety Electret100 – electrostatic filter)	89.8% at 0.5 micron, bacterial efficiency of 99.54%.

Antibacterial filters increase resistance in the air circuit and may affect triggering and cycling, accuracy of displayed and delivered pressure. ResMed recommends using a filter with a low impedance (eg, less than 2 cm H₂O at 60 L/min).

Technical specifications

General technical specification	s
90W power supply unit	Input range: 100–240V; 50–60Hz; 110V, 400Hz nominal for aircraft use; 70W (80VA) (typical power consumption); 110W (120VA) (maximum power consumption)
30W power supply unit	Input range: 100–240V; 50–60Hz; 110V, 400Hz nominal for aircraft use; 20W (30VA) (typical power consumption); 36W (75VA) (maximum power consumption)
Operating temperature	+41°F to +95°F (+5°C to +35°C)
Operating humidity	10-95% non-condensing
Operating altitude	Sea level to 8,500' (2,591 m)
Storage and transport temperature	-4°F to +140°F (-20°C to +60°C)
Storage and transport humidity	10–95% non-condensing
Electromagnetic compatibility	Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial, and light industry environments. Information regarding the electromagnetic emissions and immunity of these ResMed devices can be found on www.resmed.com, on the Products page under Service and Support. Click on the PDF file for
	your language.
Aircraft use	ResMed confirms that the S9 AutoSet and S9 Elite meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160F) for all phases of air travel. This applies to frequencies up to 400Hz nominal.
EC 60601-1 classification	Class II (double insulation), Type BF
Measuring and display devices	
Pressure sensor:	Internally located at device outlet, analog gauge pressure type, -5 to 45 cm $\rm H_{2}O$
Flow sensor:	Internally located at device inlet, digital mass flow type, -70 to 200 L/min

S9 technical specifications	
Operating pressure range	4 to 20 cm H ₂ O
Maximum single fault steady	30 cm H ₂ O
state pressure	
Pressure measurement tolerance	$\pm 0.5 \text{ cm H}_2\text{O} \pm 4\%$ of the measured reading
Flow measurement tolerance	± 6 L/min or 10% of reading, whichever is greater, at 0 to 150 L/min positive flow
DECLARED DUAL-NUMBER NO	ISE EMISSION VALUES in accordance with ISO 4871:
Sound pressure level	
with SlimLine tube:	24 dBA as measured according to ISO 17510-1:2002
	26 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
with Standard tube:	24 dBA as measured according to ISO 17510-1:2002
	27 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
with either SlimLine tube or	27 dBA as measured according to ISO 17510-1:2002
Standard tube and H5i:	28 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
Sound power level	
with SlimLine tube:	34 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
with Standard tube:	35 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
with either SlimLine tube or Standard tube and H5i:	36 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
Nominal dimensions (L x W x H)	6.0" x 5.5" x 3.4" (153 mm x 140 mm x 86 mm)
Weight	1.8 lb (810 g)
Housing construction	Flame retardant engineering thermoplastic
Supplemental oxygen	Recommended maximum supplemental oxygen flow: 4 L/min
Air filter	
Standard:	Polyester non-woven fiber
Hypoallergenic:	Acrylic and polypropylene fibers in a polypropylene carrier
Air outlet	The 22 mm conical air outlet complies with ISO 5356-1
H5i technical specifications	
Maximum heater plate temperature	150°F (65°C)
Temperature cut-out	165°F (74°C)
Maximum gas temperature at mask	≤ 106°F (≤ 41°C)
Nominal dimensions (L x W x H)	Docking station and water tub: 6.0" x 5.7" x 3.4" (153 mm x 145 mm x 86 mm)
Weight (water tub)	Docking station and unfilled water tub 1.5 lb (0.67 kg)
Weight (cleanable water tub)	Docking station and unfilled water tub 1.7 lb (0.77 kg)
Water capacity	To maximum fill line 380 mL
Docking station	Flame retardant engineering thermoplastic, aluminium
Cleanable water tub	Injection molded plastic, stainless steel and silicone seal
Water tub	Injection molded plastic, aluminium and elastomer seal
	27

Air tubing technical specifications			
ClimateLine air tubing	Flexible plastic and electrical components, 6'6" (2 m), 0.6" (15 mm) inner diameter		
SlimLine air tubing	Flexible plastic, 6' (1.8 m), 0.6" (15 mm) inner diameter		
Standard air tubing	Flexible plastic, 6'6" (2 m), 0.75" (19 mm) inner diameter		
ClimateLine temperature cut-out	≤ 106°F (≤ 41°C)		

Notes:

- The manufacturer reserves the right to change these specifications without notice.
- The temperature and relative humidity settings displayed for Climate Control are not measured values.

Humidifier performance

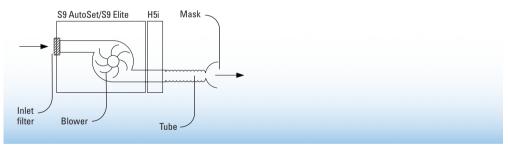
The following settings have been tested at 22°C, 40% RH ambient conditions:

CPAP mask	RH output %		Nominal system	output AH ¹ , BTPS ²
pressure cm H ₂ O	Setting 3	Setting 6	Setting 3	Setting 6
4	100	100	21	27
10	100	100	16	23
20	100	100	14	17

¹ AH- Absolute Humidity in mg/L.

² BTPS- Body Temperature Pressure Saturated.

Pneumatic flow path



Flow (maximum) at set pressures

The following are measured at the end of the specified tubing:

Pressure cm H ₂ O	S9 and Standard air tube L/min	S9 and SlimLine air tube L/min	S9, H5i and ClimateLine heated air tube L/min
4	191.1	179.1	115.75
8	176.5	165.2	117.51
12	164.5	152.3	118.28
16	150.1	138.8	117.32
20	136.8	127.3	95.53

Displayed values

Value	Range	Accuracy	Display resolution			
Pressure sensor at air outlet						
Pressure	4 to 20 cm H_2O	± 0.5 cm H ₂ O (\pm 4% of measured value)	0.1 cm H ₂ O			
Flow derived values ¹						
Leak	0–120 L/min	2	1 L/min			

1 2

Results may be inaccurate in the presence of leaks or supplemental oxygen. The displayed values are estimates. They are provided for trending purposes only.

Pressure accuracy

Maximum static pressure variation at 10 cm H_2^0 according to ISO 17510-1:2007:						
Without humidifier (SlimLine tube)						
With H5i humidifier (SlimLine tube)	10.12 cm H_2O to 10.15 cm H_2O					
Maximum dynamic pressure variation according to ISO 17510-1:2007:						
Pressure (cm H ₂ O)	10 BPM	15 BPM	20 BPM			
	S9 and SlimLine tube $without$ H5i / S9 and SlimLine tube $with$ H5i					
4	0.39 / 0.30	0.38 / 0.33	0.40 / 0.36			
8	0.27 / 0.27	0.37 / 0.29	0.42 / 0.41			
12	0.26 / 0.28	0.34 / 0.35	0.38 / 0.44			
16	0.30 / 0.31	0.33 / 0.33	0.44 / 0.54			
20	0.28 / 0.29	0.33 / 0.35	0.47 / 0.58			

Warnings and cautions

⚠ GENERAL WARNINGS

- Read the entire manual before using these devices.
- In the US, Federal law restricts these devices to sale by or on the order of a physician.
- Use these devices only for their intended use as described in this manual.
- Do not open the S9 or H5i. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized ResMed service agent.
- Beware of electrocution. Do not immerse the S9 device, H5i docking station, power supply or power cord in water. Always unplug these devices before cleaning and make sure they are dry before plugging them back in.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the S9, H5i or air tubing. These solutions may cause damage and reduce the life of these products.
- Follow all precautions when using supplemental oxygen.
- Explosion hazard—do not use in the vicinity of flammable anesthetics.
- Only use the ResMed 90W or 30W power supply units.
- Make sure the power cord and plug are in good condition and the equipment is not damaged.
- Keep the power cord away from hot surfaces.
- Do not drop or insert any object into any tubing or opening.
- Do not leave long lengths of air tubing around the top of your bed. It could twist around your head or neck while you are sleeping.

[▲] S9 WARNINGS

- Advice contained in this manual should not supersede instructions given by the prescribing physician.
- Do not use your S9 if there are obvious external defects or unexplained changes in performance.
- Only ResMed air tubing and accessories should be used with these devices. A different type of air tubing or accessory may alter the pressure you actually receive, reducing the effectiveness of your treatment.
- Blocking the air tubing and/or air inlet of the S9 device while in operation could lead to overheating of the device.
- If your clinician has told you to use the SD card to update the settings on your device and the "Settings updated successfully" message does not appear, contact your clinician immediately.
- A patient should not connect a device to the module connector port unless instructed to do so by their health care provider or physician. Only ResMed products are designed to be connected to the module connector port. Connecting other devices could result in injury, or damage to the S9 device.
- These S9 devices should only be used with masks (and connectors) recommended by ResMed, or by a physician or respiratory therapist. A mask should not be used unless the device is turned on. Once the mask is fitted, ensure that the device is blowing air. The vent hole or holes associated with the mask should never be blocked.
- Explanation: Your S9 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 sufficient. This applies to most models of CPAP devices.
- In the event of power failure or machine malfunction, remove the mask.
- These S9 devices 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.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame.
- Oxygen flow must be turned off when the S9 device is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.

riangle s9 cautions

- Be careful not to place your device where it can be bumped or where someone is likely to trip over the power cord.
- If you put the device on the floor, make sure the area is free from dust and clear of bedding, clothes or other objects that could block the air inlet or cover the power supply unit.
- Make sure the area around the device is dry and clean.
- Do not hang the air tubing in direct sunlight as it may harden over time and eventually crack.
- 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. Ensure the air filter and air filter cover are fitted at all times.
- 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 airflow for breathing produced by these devices 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).

🗥 H5i WARNINGS

- The H5i is designed only for use with specific ResMed devices. Do not use the H5i with any other CPAP device.
- Do not operate the H5i if it is not working properly or if any part of the CPAP device or H5i has been dropped or damaged.
- The H5i should only be used with tubing or accessories recommended by ResMed. Connection of
 other delivery tubes or accessories could result in injury, or damage to the device.
- Water must be prevented from entering your CPAP device.
- Do not overfill the water tub as water may enter the device and air tubing.
- Take care when handling your H5i as the water/water tub may be hot. Allow 10 minutes for the heater plate and any excess water to cool.
- The H5i docking station should only be connected or disconnected when the water tub is empty.
- Make sure that the water tub is empty before transporting the H5i.
- Do not operate the H5i on an aircraft as water may enter the CPAP device and air tubing during turbulence.
- Always place the H5i on a level surface below the level of the user to prevent the mask and tubing from filling with water.
- The H5i should be used with caution for users who are unable to remove the mask for themselves.
- If liquids are inadvertently spilled into or on the H5i docking station, unplug the device from the power outlet. Disconnect the docking station from the CPAP device and allow the docking station to drain and dry before re-using.

🗥 AIR TUBING WARNINGS

- If damage to the air tubing results in air leaking, stop using the air tubing.
- Do not wash the air tubing in a washing machine or dishwasher.
- Avoid covering the ClimateLine air tubing with materials such as sheets or blankets.
- The ClimateLine is designed only for use with the H5i.
- ClimateLine is not compatible with supplemental oxygen.



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EP 1126893, EP 1144036, EP 1502618, JP 3580776, JP 3778797, NZ 504595, US 5199424, US 5245995, US 5522382,

US 5704345, US 6029665, US 6138675, US 6240921, US 6363933, US 6367474, US 6425395, US 6502572, US 6591834,

US 6675797, US 6745768, US 6817361, US 6988498, US 7040317, US 7100608, US 7320320, US 7537010.

Other patents pending. Design registrations pending.

H5i: Protected by AU 2002233025, CN ZL02804936.5, HK 1065483, NZ 527088, US 6935337. Other patents pending. Designs pending.

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