

# RESMED

# AMERICA'S HEALTHCARE AT HOME

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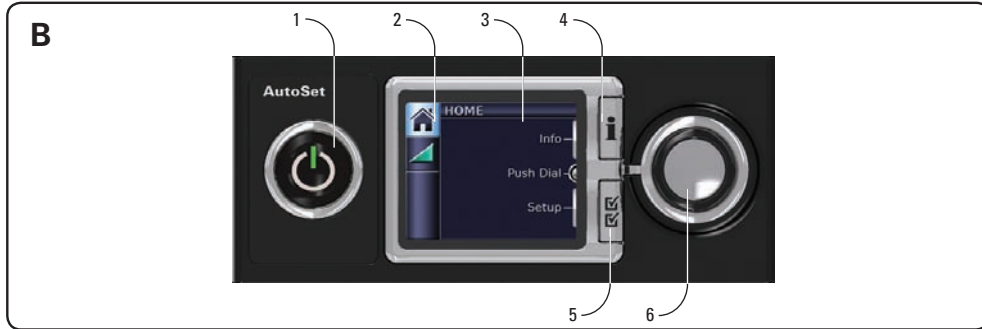
## S9™ Series

## AutoSet™ & Elite™

POSITIVE AIRWAY PRESSURE DEVICES

### User Guide

English • Deutsch • Français • Italiano • Español • Português • Nederlands • Ελληνικά • Polski • Magyar • Русский • Türkçe • Česky • Slovensky



**Manufacturer:** ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia. **Distributed by:** ResMed Corp 9001 Spectrum Center Boulevard San Diego CA 92123 USA.

**CE REP** ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK. See [www.resmed.com](http://www.resmed.com) for other ResMed locations worldwide.  
S9: Protected by one or more patents: AU 691200, AU 697652, AU 702820, AU 709279, AU 724589, AU 730944, AU 736723, AU 750095, AU 750761, AU 779327, AU 2007252223, CN 200780001837.6, EP 0651971, EP 0661071, EP 0920845, EP 0927538, EP 0934723, EP 1028869, EP 1126893, EP 1144036, EP 1502818, EP 2032857, JP 3580776, JP 3778797, JP 4647786, NZ 5045495, NZ 570415, NZ 573921, NZ 577485, US 5704345, US 57138675, US 6240921, US 6368393, US 6367474, US 6425395, US 6502572, US 6591834, US 6675797, US 6745768, US 6817361, US 6898498, US 7040317, US 7100608, US 7537010, US 7866944. Other patents pending. Protected by design registrations: AU 329025, AU 330142, AU 331272, AU 332891, AU 333658, CN 200830346524.1, CN 200830346526.0, CN 200830346525.6, CN 201030215797.X, EU 1067417, JP 1377401, JP 1377402, JP 1377403, JP 1415251, JP 1415252, NZ 411762, NZ 413090, NZ 413091, US D629891, US D629892, US D635232, US D635244, US D635245, US D635654, US D638536, US D638537, US D638933. Others pending. S9, S9 AutoSet, S9 Elite, ClimateLine, SlimLine and SmartStart are trademarks of ResMed Ltd. S9, AutoSet, ClimateLine, SlimLine and SmartStart are registered in U.S. Patent and Trademark Office.

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### **S9 AutoSet indications for use**

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

### **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.

### **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.

### **Masks and humidifiers**

Recommended masks and humidifiers are available on [www.resmed.com](http://www.resmed.com) on the Products page under Service & Support. For information on using your mask or humidifier, refer to the manual supplied with your mask or humidifier.

## Setup

Refer to illustration A.

1. Connect the DC plug of the power supply unit to the rear of the S9.
2. Connect the power cord to the power supply unit.
3. Plug the other end of the power cord into the power outlet.
4. Connect one end of the air tubing firmly onto the air outlet.
5. Connect the assembled mask system to the free end of the air tubing.

## Control panel

Refer to illustration B.





The control panel of your S9 devices includes the following items:

1. Start/Stop button: Starts or stops treatment
2. Home menu
3. LCD screen
4. Info menu: Allows you to view your sleep statistics
5. Setup menu: Allows you to make changes to settings
6. Push dial: Turning the dial allows you to scroll through the menu and change settings. Pushing the dial allows you to enter into a menu and confirm your choice.



## Navigating the menus

Refer to illustration C.

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.
3. Turn  until you see the setting that you require.
4. Press  to confirm your choice. The screen returns to blue.

## Getting started

1. Make sure the power is connected.
2. Adjust the ramp time if required.
3. Fit your mask as described in your mask user guide.
4. To start therapy, simply breathe into the mask and/or press .
5. Lie down and arrange the air tubing so that it is free to move if you turn in your sleep.
6. To stop treatment at any time, remove your mask and/or press .

**Note:** If your clinician has enabled SmartStart your device will start automatically when you breathe into the mask and stop automatically when you remove the mask.

## Cleaning and maintenance

### Daily:

Remove the air tubing by pulling on the finger grips on the cuff. Hang it in a clean, dry place until next use.

### 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 with a damp cloth and mild detergent.
2. Check the air filter for holes and blockage by dirt or dust.

### 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 air filter.
3. Insert a new ResMed air filter ensuring that it is sitting flat in the air filter cover.
4. Replace the air filter cover.

## Troubleshooting

If there is a problem, try the following suggestions. If the problem cannot be solved, contact your equipment supplier or ResMed. Do not attempt to open these devices.

### Problem/Possible cause

### Solution

#### No display

Power is not connected.

Ensure the power cable is connected and the power outlet (if available) is on.

The DC plug is partially inserted into the back of the device.

Fully insert the DC plug.

#### Insufficient air delivered from the device

Ramp time is in use.

Wait for air pressure to build up or change ramp time.

Air filter is dirty.

Replace air filter.

Air tubing is not connected properly.

Check air tubing.

**Problem/Possible cause**

Air tubing is blocked, pinched or punctured.  
Mask and headgear are not positioned correctly.  
Incorrect air tubing selected.

**Solution**

Unblock or free the air tubing. Check the air tubing for punctures.  
Adjust position of mask and headgear.  
If you are using the SlimLine or Standard air tubing ensure that you have the correct air tubing selected via the menu.

**Device does not start when you breathe into the mask**

Breath is not deep enough to trigger SmartStart/Stop.

Take a deep breath in and out through the mask.

There is excessive leak.

Adjust position of mask and headgear.  
Air tubing not connected properly. Connect firmly at both ends.

SmartStart/Stop is disabled.

Enable SmartStart/Stop.

**Device does not stop when you remove your mask**

SmartStart/Stop is disabled.

Enable SmartStart/Stop.

**SmartStart/Stop is enabled but the device does not stop automatically when you remove your mask**

Incompatible mask system being used.  
The patient is using a nasal pillows mask with a set pressure less than 7 cm H<sub>2</sub>O.

Only use equipment recommended by ResMed.  
Disable SmartStart/Stop.

**Pressure rises inappropriately**

Talking, coughing or breathing in an unusual manner.

Avoid talking with a nasal mask on, and breathe as normally as possible.

Mask cushion is buzzing against the skin.

Adjust the headgear.

**Displays error message: High temperature fault, refer to user manual**

Device has been left in a hot environment.

Allow to cool before re-use. Disconnect the power cord and then reconnect it to restart the device.

Air filter is blocked.

Replace your air filter. Disconnect the power cord and then reconnect it to restart the device.

**Problem/Possible cause****Solution**

Air tubing is blocked.

Check your air tubing and remove any blockages.  
Disconnect the power cord and then reconnect it to restart the device.

Humidifier setting is too high, resulting in accumulation of water in the air tubing.

Turn the humidifier setting down and empty the water from the air tubing.

**Displays error message: Check ResMed 30/90W Power Supply Unit and fully insert the connector**

The DC plug is partially inserted into the back of the device or inserted too slowly.

Fully insert the DC plug.

A non-ResMed power supply unit is connected to the device.

Remove the power supply unit and replace with a ResMed power supply unit.

The power supply unit is being covered by bedding.

Make sure that the power supply unit is free from bedding, clothes or other objects that could cover it.

**Displays error message: Tube blocked, please check your tube**

Air tubing is blocked.

Check your air tubing and remove any blockages.

**Displays error message: High leak, please check system setup and all connections**

There is excessive leak.

Adjust position of mask and headgear.  
Air tubing is not connected properly. Connect firmly at both ends.

**The following message is displayed on the LCD after you try to update settings or copy data to the SD card: Card error, please remove SD card and contact service provider**

SD card is not inserted correctly.

Ensure that the SD card is inserted correctly.

You may have removed the SD card before settings were copied to the CPAP device.

Reinsert the SD card and wait for the home screen or the **Settings updated successfully, press any key** message to appear on the LCD.

**Note:** *This message only appears once. If you re-insert the SD card after you have updated your settings, the message will not be re-displayed.*

**Problem/Possible cause****Solution**

The following message is NOT displayed on the LCD after you try to update the settings using the SD card: Settings updated successfully, press any key

The settings were not updated.

Contact your clinician/service provider immediately.

**SD card**

An SD card has been supplied to gather therapy data from your S9 device and provide settings updates from your clinician. When instructed to do so, disconnect the S9 device from the power outlet, remove your SD card, insert it in the protective folder and send it to your clinician. For more information on removing and inserting your card refer to the S9 SD Card Protective Folder provided with your device. Please retain the S9 SD Card Protective Folder for future use.

**Technical specifications**

Operating pressure range	4 to 20 cm H <sub>2</sub> O
Maximum single fault steady state pressure	30 cm H <sub>2</sub> O
Pressure measurement tolerance	±0.5 cm H <sub>2</sub> O ± 4% of the measured reading
Flow measurement tolerance	±6 L/min or 10% of reading, whichever is greater
DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871:	
Sound pressure level	24 dBA as measured according to ISO 17510-1:2002 26 dBA with uncertainty of 2 dBA as measured according to EN ISO 17510-1:2009
Sound power level	34 dBA with uncertainty of 2 dBA as measured according to EN ISO 17510-1:2009
Nominal dimensions (L x W x H)	153 mm x 140 mm x 86 mm
Weight	835 g
90W power supply unit	Input range 100–240V, 50–60Hz, Nominal for aircraft use 110V, 400Hz Typical power consumption 70W (80VA) Maximum power consumption 110W (120VA)
30W power supply unit	Input range 100–240V, 50–60Hz, Nominal for aircraft use 110V, 400Hz Typical power consumption 20W (30VA) Maximum power consumption 36W (75VA)

Operating temperature	+5°C to +35°C
Operating humidity	10–95% non-condensing
Operating altitude	Sea level to 2,591 m
Storage and transport temperature	-20°C to +60°C
Storage and transport humidity	10–95% non-condensing
Housing construction	Flame retardant engineering thermoplastic
Supplemental oxygen	Recommended maximum supplemental oxygen flow: 4 L/min
Hypoallergenic air filter	Non-woven acrylic and polypropylene fibers with polypropylene carrier
Standard air filter	Polyester fiber
SlimLine™ air tubing	Flexible plastic, 1.8 m, 15 mm inner diameter
Standard air tubing	Flexible plastic, 2 m, 19 mm inner diameter
ClimateLine™ heated air tubing	Flexible plastic and electrical components, 2 m, 15 mm inner diameter
ClimateLine <sup>MAX</sup> ™ heated air tubing	Flexible plastic and electrical components, 1.9 m, 19 mm inner diameter
Air outlet	The 22 mm conical air outlet complies with ISO 5356-1
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 <a href="http://www.resmed.com">www.resmed.com</a> , on the Products page under Service and Support. Click on the PDF file for your language.
Aircraft use	Medical-Portable Electronic Devices (M-PED) that meet the Federal Aviation Administration (FAA) requirements of RTCA/DO-160F can be used during all phases of air travel without further testing or approval by the airline operator. ResMed confirms that the S9 meets RTCA/DO-160F requirements.
IEC 60601-1 classification	Class II (double insulation), Type BF






















## Notes:

- The manufacturer reserves the right to change these specifications without notice.
- The temperature and relative humidity settings displayed for ClimateLine or ClimateLine<sup>MAX</sup> are not measured values.
- Check with your clinician/service provider before using the SlimLine air tubing with devices other than the S9.

## Symbols which appear on these devices

The following symbols may appear on your S9, power supply unit, air tubing or packaging.

 Caution;  Read instructions before use;  Drip proof;  Not drip proof;  Type BF equipment;  Class II equipment;  Start/Stop;  Manufacturer;  European Authorised Representative;  European RoHS;  Batch Code;  Catalogue number;  Serial number;  Direct current;  Lock/unlock;  Remove tub to fill;  China pollution control logo 1;  China pollution control logo 2;  **Environmental information**

WEEE 2002/96/EC is a European Directive that requires the proper disposal of electrical and electronic equipment. These devices should be disposed of separately, not as unsorted municipal waste. To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment. If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your ResMed device please contact your ResMed office, local distributor or go to [www.resmed.com/environment](http://www.resmed.com/environment).

## Servicing

The S9 device is intended to provide safe and reliable operation when operated in accordance with the instructions provided by ResMed. ResMed recommends that the S9 be inspected and serviced by an authorised ResMed Service Centre if there is any sign of wear or concern with device function. Otherwise, service and inspection of the devices generally should not be required during the five year design life of the device.

## Limited warranty

ResMed Ltd (hereafter 'ResMed') warrants that your ResMed product shall be free from defects in material and workmanship from the date of purchase for the period specified below.

Product	Warranty period
<ul style="list-style-type: none"><li>• Mask systems (including mask frame, cushion, headgear and tubing) – excluding single-use devices</li><li>• Accessories – excluding single-use devices</li><li>• Flex-type finger pulse sensors</li><li>• Humidifier water tubs</li></ul>	90 days
<ul style="list-style-type: none"><li>• Batteries for use in ResMed internal and external battery systems</li><li>• Clip-type finger pulse sensors</li><li>• CPAP and bilevel device data modules</li><li>• Oximeters and CPAP and bilevel device oximeter adapters</li><li>• Humidifiers and humidifier cleanable water tubs</li><li>• Titration control devices</li></ul>	6 months 1 year
<ul style="list-style-type: none"><li>• CPAP, bilevel and ventilation devices (including external power supply units)</li><li>• Battery accessories</li><li>• Portable diagnostic/screening devices</li></ul>	2 years

This warranty is only available to the initial consumer. It is not transferable.

If the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components.

This limited warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organisation that has not been expressly authorised by ResMed to perform such repairs; c) any damage or contamination due to cigarette, pipe, cigar or other smoke; and d) any damage caused by water being spilled on or into an electronic device.

Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the

exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.



## **WARNINGS**

- Read the entire manual before using these devices.
- Use these devices only for their intended use as described in this manual.
- Use these devices only as directed by your physician or healthcare provider.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device or the power supply are dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact your ResMed Service Centre.
- Do not open the S9. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorised ResMed service agent.
- Beware of electrocution. Do not immerse the S9 device, power supply or power cord in water. Always unplug the device before cleaning and make sure it is dry before plugging it back in.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturising or antibacterial soaps or scented oils to clean the S9 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 anaesthetics.
- 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.
- 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<sup>1</sup>) recommended by ResMed, or by a physician or respiratory therapist. A mask should not be used unless the S9 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 suffocation. This applies to most models of CPAP devices.

- In the event of power failure<sup>2</sup> or machine malfunction, remove the mask.
- These S9 devices can be set to deliver pressures up to 20 cm H<sub>2</sub>O. In the unlikely event of certain fault conditions, pressures up to 30 cm H<sub>2</sub>O are possible.
- Oxygen flow must be turned off when the CPAP device is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame.
- If damage to the tubing results in air leaking, do not continue using the air tubing.
- Do not wash the air tubing in a washing machine or dishwasher.

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1. Ports may be incorporated into the mask or in connectors that are near the mask.  
 2. During partial (below rated minimum voltage) or total power failure, therapy pressures will not be delivered. When power is restored, operation will recommence with no change to settings.

## **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 6°C higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 32°C.