

RESMED

**S9™ Series
AutoSet™ & Elite™**
POSITIVE AIRWAY PRESSURE DEVICES

User Guide

English



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 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:

Disconnect the air tubing and 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.
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.
Air tubing is blocked, pinched or punctured.	Unblock or free the air tubing. Check the air tubing for punctures.
Mask and headgear are not positioned correctly.	Adjust position of mask and headgear.
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.
Note: SmartStart/Stop is not available if you are using a Full Face Mask.	
Device does not stop when you remove your mask	
SmartStart/Stop is not enabled.	Enable SmartStart/Stop.
Note: SmartStart/Stop is not available if you are using a Full Face Mask.	
SmartStart/Stop is enabled but the CPAP device does not stop automatically when you remove your mask	
Incompatible mask system being used.	Only use equipment recommended by ResMed.
The patient is using a nasal pillows mask with a set pressure less than 7 cm H ₂ O.	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.

Problem/Possible cause

Solution

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.

The device or air inlet is being covered by bedding.

Make sure that the device is free from bedding, clothes or other objects that could cover the device or block the air inlet. 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.

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 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.

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.

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, 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 ₂ O
Maximum single fault steady state pressure	30 cm H ₂ O
Pressure measurement tolerance	±0.5 cm H ₂ 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 ISO 17510-1:2007
Sound power level	34 dBA with uncertainty of 2 dBA as measured according to ISO 17510-1:2007
Nominal dimensions (L x W x H)	153 mm x 140 mm x 86 mm
Weight	810 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, 1.83 m, 15 mm inner diameter
Standard air tubing	Flexible plastic, 2 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 www.resmed.com , 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.
- 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 RoHS;  Lot number;

 Part 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.

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">Mask systems (including mask frame, cushion, headgear and tubing) – excluding single-use devicesAccessories – excluding single-use devicesFlex-type finger pulse sensorsHumidifier water tubs	90 days
<ul style="list-style-type: none">Batteries for use in ResMed internal and external battery systems	6 months
<ul style="list-style-type: none">Clip-type finger pulse sensorsCPAP and bilevel device data modulesOximeters and CPAP and bilevel device oximeter adaptersHumidifiers and humidifier cleanable water tubsTitration control devices	1 year
<ul style="list-style-type: none">CPAP, bilevel and ventilation devices (including external power supply units)Battery accessoriesPortable diagnostic/screening devices	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.
- 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 connectors¹) 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 failure² 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 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.
- If the oxygen has been left on, turn off the device, then wait one hour before turning on the device again.
- 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.

CAUTIONS

- Be careful not to place your device where it can be bumped or where someone is likely to trip over the power cord.

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.

- 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.

Deutsch

S9 AutoSet Indikationen

Das S9 AutoSet ist ein selbstregulierendes Therapiesystem für die Behandlung von OSA (obstruktiver Schlafapnoe) bei Patienten mit einem Gewicht von über 30 kg. Das selbstregulierende S9 AutoSet System ist für die Verwendung zu Hause und im Krankenhaus vorgesehen.

S9 Elite Indikationen

Das S9 Elite CPAP System ist für die Behandlung von OSA (obstruktiver Schlafapnoe) bei Patienten mit einem Gewicht von über 30 kg vorgesehen. Das S9 Elite CPAP System ist für die Verwendung zu Hause und im Krankenhaus vorgesehen.

Kontraindikationen

Die Behandlung mit positivem Atemwegsdruck kann bei einigen Patienten mit den folgenden Erkrankungen kontraindiziert sein:

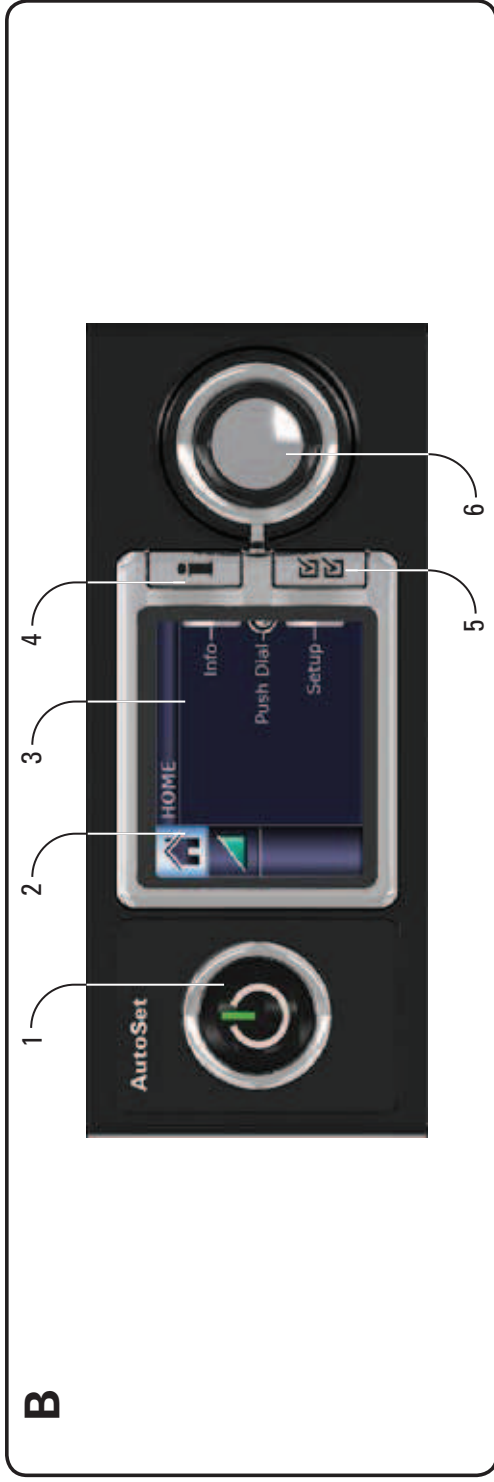
- schwere bullöse Lungenerkrankung
- Pneumothorax
- pathologisch niedriger Blutdruck
- Dehydrierung
- Liquorausfluss, kürzliche Schädeloperation oder Traumata.

Nebenwirkungen

Bei ungewöhnlichen Schmerzen in der Brust, starken Kopfschmerzen oder verstärkter Atemlosigkeit ist der behandelnde Arzt zu kontaktieren. Bei einer akuten Infektion der oberen Atemwege muss die Behandlung u. U. einstweilig eingestellt werden.

Folgende Nebenwirkungen können bei der Behandlung mit dem Gerät auftreten:

- Trockenheit von Nase, Mund oder Hals
- Nasenbluten
- Völlegefühl
- Ohren- oder Nasennebenhöhlenbeschwerden
- Augenreizungen
- Hautausschläge.



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. ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK. See www.resmed.com for other ResMed locations worldwide.

S9: Protected by patents: AU 691200, AU 697652, AU 702820, AU 709279, AU 724589, AU 730844, AU 736723, AU 750095, AU 750761, AU 764761, AU 779327, EP 0651971, EP 0661071, EP 0920845, EP 0927538, EP 0934723, EP 1028769, 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. S9 is a trademark of ResMed Ltd and is registered in U.S. Patent and Trademark Office.

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

© 2009 ResMed Ltd. 368147-Eng/1 09 10

