ResMed

S9 AutoSet™ & S9 Elite™

POSITIVE AIRWAY PRESSURE DEVICES

Information Guide

English

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.

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. ***Note:*** *Replace the air filter every six months (or more often if necessary).*
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.
Incorrect air tubing selected.	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.

Problem/Possible cause	Solution
SmartStart/Stop is enabled but the 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_2O.	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.
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.

Problem/Possible cause	Solution
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.*
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.

Technical specifications

Operating pressure range	4 to 20 cm H_2O
Maximum single fault steady state pressure	30 cm H_2O
Pressure measurement tolerance	±0.5 cm H_2O ± 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 NOISE EMISSION VALUES in accordance with ISO 4871:1996	
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

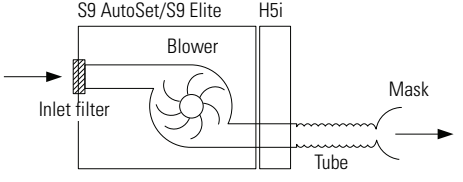
90W power supply unit	Input range 100–240V, 50–60Hz, Nominal for aircraft use 115V, 400Hz Typical power consumption 70W (80VA) Maximum power consumption 110W (120VA)
30W power supply unit	Input range 100–240V, 50–60Hz, Nominal for aircraft use 115V, 400Hz Typical power consumption 20W (30VA) Maximum power consumption 36W (75VA)
Operating temperature	+5°C to +35°C ***Note:*** *The air flow for breathing produced by this therapy device can be higher than the temperature of the room. Under extreme ambient temperature conditions (40°C) the device remains safe.*
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	Acrylic and polypropylene fibres in a polypropylene carrier
Standard air filter	Polyester non-woven fibre
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$^{MAX™}$ 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 5356-1:2004

Electromagnetic compatibility	Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial, and light industry environments. It is recommended that mobile communication devices are kept at least 1 m away from the device. 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/Elite meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160, section 21, category M) for all phases of air travel. This applies to frequencies up to 400Hz nominal.
IEC 60601-1 classification	Class II (double insulation), Type BF

Notes:

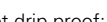
- *The manufacturer reserves the right to change these specifications without notice.*
- *The temperature and relative humidity settings displayed for ClimateLine or ClimateLine^{MAX} are not measured values.*
- *Check with your clinician/service provider before using the SlimLine air tubing with devices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

Pneumatic flow path



Symbols

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

 Caution;  Read instructions before use; IP21 Protection against insertion of fingers and against vertically dripping water; IP20 Not drip proof;  Type BF equipment;  Class II equipment;  Start/Stop;  Manufacturer; EC REP European Authorised Representative;  Keep Dry;  European RoHS; LOT Batch code; REF Catalogue number; SN 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
• Mask systems (including mask frame, cushion, headgear and tubing)—excluding single-use devices • Accessories—excluding single-use devices • Flex-type finger pulse sensors • Humidifier water tubs	90 days
• Batteries for use in ResMed internal and external battery systems	6 months
• Clip-type finger pulse sensors • CPAP and bilevel device data modules • Oximeters and CPAP and bilevel device oximeter adapters • Humidifiers and humidifier cleanable water tubs • Titration control devices	1 year
• CPAP, bilevel and ventilation devices (including external power supply units) • Battery accessories • Portable 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 the device.
- Use the device only as directed by your physician or healthcare provider.
- Use the device only for the intended use as described in this manual. Advice contained in this manual should not supersede instructions given by the prescribing physician.
- If you notice any unexplained changes in the performance of the 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 Center.
- Beware of electrocution. Do not immerse the device, humidifier, power supply or power cord in water. In the event of a spill, disconnect the device from the power supply and let the parts dry. Always unplug the device before cleaning and make sure that all parts are dry before plugging in the device.
- Explosion hazard—do not use in the vicinity of flammable anesthetics.
- 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.
- The device should only be used with masks (and connectors[1]) 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: The device 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 or bilevel devices.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame.

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

- Always ensure that the device is turned on and airflow generated before the oxygen supply is turned on. Always turn the oxygen supply off before the device is turned off, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- 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.
- Do not use electrically conductive or antistatic air tubings.
- Do not use the air tubing if there are any visible signs of damage.
- Only ResMed air tubing and accessories should be used with the device. A different type of air tubing or accessory may alter the pressure you actually receive, reducing the effectiveness of the treatment.
- Only use the ResMed 90W or 30W power supply unit. Use the 90W power supply unit to power the system comprising the device, H5i, air tubing, DC/DC converter and battery pack. The 30W power supply unit is designed to power the device only and recommended for traveling.
- Only ResMed products are designed to be connected to the module connector port. Connecting other devices could damage the device.
- Blocking the air tubing and/or air inlet of the device while in operation could lead to overheating of the device.

⚠ CAUTIONS

- Do not open the device enclosure. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorised ResMed service agent.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturising or antibacterial soaps or scented oils to clean the device, humidifier or air tubing. These solutions may cause damage and reduce the life of these products.
- Incorrect system setup may result in incorrect mask pressure reading. Ensure the system is correctly set up.
- Be careful not to place the device where it can be bumped or where someone is likely to trip over the power cord.
- Make sure the area around the device is dry and clean and clear of bedding, clothes or other objects that could block the air inlet or cover the power supply unit.
- The airflow for breathing produced by the device can be as much as 6ºC higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 35ºC.
- Ensure that the device is protected against water if used outdoors. Enclose the device in the S9 travel bag for transport.

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For patent information, see www.resmed.com/ip.

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