

RESMED

S9 AutoSet™ / S9 AutoSet™ for Her / S9 Elite™ / S9 Escape™ / S9 Escape Auto™

POSITIVE AIRWAY PRESSURE DEVICES

H5i™ / H5i™ for Her

HEATED HUMIDIFIER

ClimateLine™ / ClimateLine^{MAX}™ / SlimLine™ / Standard

AIR TUBING

Information Guide

English

Please read the entire Information and Welcome Guides before using your device.



CAUTION

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

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 AutoSet for Her indications for use

The S9 AutoSet for Her 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 for Her 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 Escape Auto indications for use

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

S9 Escape indications for use

The S9 Escape CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). The S9 Escape 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 or bilevel 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 for Her indications for use

The H5i for Her is indicated for the humidification of the air delivered from a CPAP or bilevel device. The H5i is for use only as recommended by a physician. The H5i for Her 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.

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.
The S9 and H5i are not connected correctly.	Ensure that the S9 and H5i are securely attached.
Insufficient air delivered from the S9 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.
The H5i flip lid is not latched correctly.	Close the flip lid ensuring that it clicks into place.
The H5i flip lid seal is not fitted correctly.	Make sure the flip lid seal is facing the right way up and fitted securely.
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.

Problem/possible cause

SmartStart/Stop is disabled.

Note: *SmartStart/Stop is not available in S9 Escape and S9 Escape Auto.*

Solution

Enable SmartStart/Stop.

Device does not stop when you remove your mask

SmartStart/Stop is disabled.

Enable SmartStart/Stop.

Note: *SmartStart/Stop is not available in S9 Escape and S9 Escape Auto.*

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 H₂O.

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: Heated tube fault, replace tube

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.

There is a fault in your ClimateLine or ClimateLine^{MAX} air tubing.

Discontinue using your ClimateLine or ClimateLine^{MAX} air tubing and contact your clinician/service provider. Use Standard or SlimLine tubing in the interim.

Displays error message: Humidifier fault, replace humidifier

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.

There is a fault in your H5i heated humidifier.

Discontinue using your H5i and contact your clinician/service provider.

Refilling the humidifier with cold water while humidifier is still hot after therapy.

Allow the humidifier to cool before re-filling.

Problem/possible cause**Solution**

Filling the humidifier with ice cold water on a warm day or with hot water.

Use room temperature water.

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.

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 H5i flip lid is not latched correctly.

Close the flip lid ensuring that it clicks into place.

Displays error message: Please close H5i flip lid, attach tube and press any key

H5i flip lid is not closed.

Close the flip lid ensuring that it clicks into place.

Problem/possible cause**Solution**

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.

Water splashing on your face from the H5i

The water tub is overfilled.

Check that the water level is below the maximum water level mark.

Condensation is forming in the air tube and mask.

Turn the H5i or relative humidity setting down via the menu.

Leaking water tub

The water tub may be damaged or cracked.

Contact your service provider for a replacement.

The cleanable water tub is not assembled correctly.

Check for damage and reassemble the cleanable water tub correctly.

Air feels too warm/cold in the mask

The temperature of the ClimateLine or ClimateLine^{MAX} air tubing is set too high/low.

Turn up/down the heated tubing temperature via the menu.

General technical specifications

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 (40VA) Maximum power consumption 36W (75VA)
Operating temperature	41°F to 95°F (+5°C to +35°C) Note: <i>The air flow for breathing produced by this therapy device can be higher than the temperature of the room. Under extreme ambient temperature conditions (104°F / 40°C) the device remains safe.</i>
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. 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 Series meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160) for all phases of air travel.
IEC 60601-1 classification	Class II (double insulation), Type BF

S9 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)	6.0" x 5.5" x 3.4" (153 mm x 140 mm x 86 mm)
Weight	1.8 lb (835 g)
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
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	≤ 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 (standard water tub)	Docking station and unfilled water tub 1.52 lb (0.69 kg)
Weight (cleanable water tub)	Docking station and unfilled water tub 1.74 lb (0.79 kg)
Water capacity	To maximum fill line 380 mL
Docking station	Flame retardant engineering thermoplastic, aluminium

Cleanable water tub
Standard water tub

Injection molded plastic, stainless steel and silicone seal
Injection molded plastic, aluminium and thermoplastic elastomer

Air tubing technical specifications

ClimateLine heated air tubing

Flexible plastic and electrical components,
6'6" (2 m), 15 mm inner diameter

ClimateLine^{MAX} heated air tubing

Flexible plastic and electrical components,
6'3" (1.9 m), 19 mm inner diameter

SlimLine air tubing

Flexible plastic, 6' (1.8 m), 15 mm inner diameter

Standard air tubing

Flexible plastic, 6'6" (2 m), 19 mm inner diameter

Heated tubing 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 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 or H5i.

Humidifier performance

The following settings have been tested at 22°C ambient temperature:

CPAP mask pressure, cm H ₂ O	RH output %		Nominal system output AH ^a , BTPS ^b	
	Setting 3	Setting 6	Setting 3	Setting 6
4	90	100	10	18
10	95	100	11.5	21
20	95	100	11	18

a. AH - Absolute Humidity in mg/L.

b. BTPS - Body Temperature Pressure Saturated.

Symbols

The following symbols may appear on your S9, H5i, power supply unit, air tubing or packaging.

 Caution;  Read instructions before use;  Follow instructions for 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;  European Authorised Representative;  European RoHS;  Batch code;  Catalogue number;  Serial number;  Direct current;  Not for use on more than one patient;  Maximum water level;  Disinfectable up to 200°F (93°C);  Use distilled or deionized water only;  Lock/unlock;  Remove tub to fill; **Rx Only** Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician.);  Keep dry;  China pollution control logo 1;  China pollution control logo 2.

Servicing

The S9 and H5i devices are intended to provide safe and reliable operation when operated in accordance with the instructions provided by ResMed. ResMed recommends that the S9 and H5i be inspected and serviced by an authorized ResMed Service Center 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 Pty 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 - 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 - Humidifiers	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 organization that has not been expressly authorized by ResMed to perform such repairs and c) any damage or contamination due to cigarette, pipe, cigar or other smoke.

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 connectors¹) 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.
- Do not operate the H5i if it is not working properly or if any part of the device or H5i has been dropped or damaged.

CAUTIONS

- Do not open the device enclosure. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized 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.
- Ensure that the device is protected against water if used outdoors. Enclose the device in the S9 travel bag for transport.
- 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.
- Do not open the H5i enclosure. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized ResMed service agent.
- Do not overfill the water tub as water may enter the device and air tubing.
- Do not use any additives (eg, scented oils and perfumes). These may reduce the humidification output of the H5i and/or cause deterioration of the water tub materials.
- Take care when handling the H5i as the water/water tub may be hot. Allow 10 minutes for the heater plate and any excess water to cool.
- The H5i 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 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.
- If liquids are inadvertently spilled into or on the H5i, unplug the device from the power outlet. Disconnect the H5i from the device and allow it to drain and dry before re-using.

 **Manufacturer:** ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia.

See www.resmed.com for other ResMed locations worldwide.

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

S9, H5i, SlimLine, ClimateLine, SmartStart are trademarks of ResMed. S9 and SmartStart are registered in U.S. Patent and Trademark Office.

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