RESMED

S8 Series II S8 AutoSet™ II S8 Elite™ II

POSITIVE AIRWAY PRESSURE DEVICES

User Guide

English Rx Only

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Contents

Indications for Use
S8 AutoSet II
S8 Elite II
Contraindications
Adverse Effects 1
Parts of the S8 Series II system
Masks
Humidifiers 2
Setting up the S8 Series II
Connecting the Device
Selecting the Mask Type
Using the Mask-fitting Feature Starting Treatment
Stopping Treatment
Changing the Settings on your S8 II Device
The Standard Menu 5
The Detailed Menu
Messages on the S8 Series II LCD
Using the Data Card to Collect Data
Copy Data onto the Data Card
Cleaning and Maintenance
Daily 10
Weekly 10
Monthly 11
Replacing the Air Filter
Servicing
Frequently Asked Questions
Troubleshooting
Technical Specifications
Limited Warranty

Indications for Use

S8 AutoSet II

The S8 AutoSet II self-adjusting sleep apnea system is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients. The S8 AutoSet II self-adjusting sleep apnea system has two treatment modes: AutoSet and fixed-pressure CPAP. The S8 AutoSet II system is intended for home and hospital use.

S8 Elite II

The S8 Elite II continuous positive airway pressure (CPAP) system is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients.

The S8 Elite II CPAP system is intended for home and hospital use.

Contraindications

Your S8 Series II is not a life-support device and may stop operating during power failure or certain fault conditions. It should not be used by patients who are dependent on continuous therapy.

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.

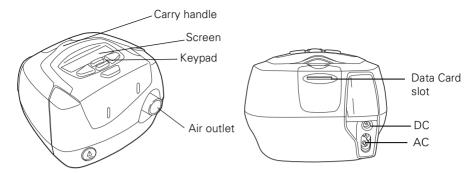
The following side effects may arise during the course of therapy with the CPAP device:

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

Parts of the S8 Series II system

Your S8 Series II device comprises:

- S8 Series II device
- Power cord
- Carry bag
- 2 m air tubing.



Accessories available:

- · Integrated humidifier
- Front cap
- 3 m air tubing
- DC-12 converter
- · ResMed Tubing Wrap.

Masks

A list of masks (and their settings) compatible with these devices can be found on **www.resmed.com**, on the **Products** page under **Service and Support**.

Humidifiers

A list of humidifiers compatible with ResMed devices can be found on **www.resmed.com**, on the **Products** page under **Service and Support**.

Setting up the S8 Series II



WARNING

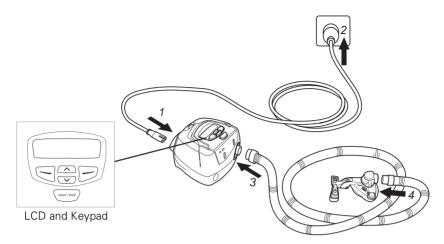
- Make sure the power cord and plug are in good condition and the equipment is not damaged.
- Only ResMed air tubing should be used with the device. A different type of air tubing may alter the pressure you actually receive and reduce the effectiveness of your treatment.
- Blocking the hose and/or air inlet of the device while in operation could lead to overheating of the device.



CAUTION

- Be careful to place the device where it cannot be bumped, and where no one will 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.
- · Make sure the area around the device is dry and clean.

Connecting the Device



Selecting the Mask Type

To ensure your device functions as intended with your selected mask, you need to select the mask type that you are using.

- 1 With the RAMP or SETTLING screen displayed, press . (In CPAP mode, the standby screen displays RAMP. In AutoSet mode (S8 AutoSet II only) the standby screen displays SETTLING.)
- 2 Press vuntil MASK is displayed.
- **3** Press to change the setting.
- **4** Press or until you see the setting that you require.
- **5** Press to apply.

Using the Mask-fitting Feature

You can use the S8 Series II mask-fitting feature to help you fit your mask properly. This feature delivers air pressure for a three-minute period, prior to starting treatment, during which you can check and adjust your mask fit to minimize leaks.

Note: Make sure that the mask setting on the MASK screen is the same as the mask you are using.

- 1 Fit your mask as described in the mask user instructions.
- **2** With the RAMP or SETTLING screens displayed, hold down (START/STOP) for at least three seconds until air pressure delivery starts.

Your device will ramp to the mask-fit pressure and will remain at this pressure for three minutes.

The following displays on the LCD screen indicating that the mask-fitting feature is operating, where: ***** is an excellent fit;****- is a very good fit; ***- is a good fit; while **--, *--- and ---- each require you to adjust your mask.



3 Adjust your mask, mask cushion and headgear until you have a secure and comfortable fit.

After three minutes, the pressure reverts to the set pressure and treatment will begin. If you do not wish to wait three minutes, hold down start from for at least three seconds to start treatment immediately.

If you press (START/STOP) for less than three seconds, the unit will return to standby mode (the RAMP or SETTLING screen).

Starting Treatment

- 1 Make sure the power is on. The product name is displayed briefly on the screen, then the standby screen displays RAMP (or SETTLING). Press or to increase or decrease the ramping (or settling) period.
- **2** Fit mask, lie down and arrange the air tubing so that it is free to move if you turn in your sleep.



CAUTION

Do not leave long lengths of air tubing around the top of your bed. They could twist around your head or neck while you are sleeping.

- 3 To start treatment, press start for start delivering therapy automatically using SmartStart™, your device will start when you breathe into your mask.
- **4** Fit your mask as described in the mask user instructions.



WARNING

A mask should not be used unless the S8 Series II device is powered and operating properly.

When treatment begins, if ramp is set, the pressure increases from a low pressure to the prescribed treatment pressure over the set period. Ramping is designed to help you adjust to an increase in pressure gradually, and enhance your comfort.

Stopping Treatment

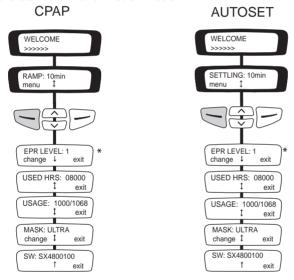
To stop treatment at any time, remove your mask and press (stant/stop). If your clinician has enabled SmartStart, simply remove your mask and treatment will end.

Changing the Settings on your S8 II Device

You can change settings (such as Ramp Time, EPR Level) on the S8 II by using the keypad and LCD. When the device is in standby mode you can display a series of screens (a menu) on the LCD screen in order to view and change the settings for a particular function.

The Standard Menu

Your clinician will have enabled the menu on your S8 Series II device. The picture shows the standard menu in each mode.



* Only displayed if access set by clinician.

Note: The AutoSet menu is available on the S8 AutoSet II only.

To enter the standard menu from the standby (RAMP or SETTLING) screen, press

You can use this menu to change the:

• Expiratory Pressure Relief (EPR) settings

Your clinician may have set up your device to deliver EPR. This can be used to help ease any discomfort you may experience when breathing out during treatment. There are four settings: OFF (no EPR); 1 (lowest EPR); 2; and 3 (highest EPR). The EPR LEVEL screen only appears if your clinician has enabled access to the EPR settings.

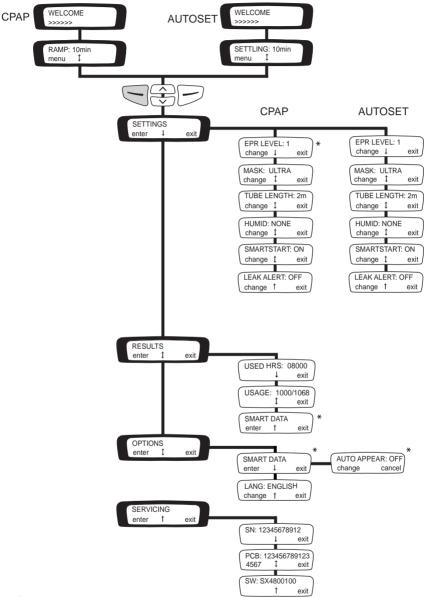
To change the EPR level, select . Press or until you see the setting that you require.

• Mask type – see page 3.

You can also view the total number of hours of treatment (USED HRS); the number of sessions that the S8 Series II device was used in a usage period (USAGE); and the current software version (SW).

The Detailed Menu

Your clinician may have enabled a detailed menu on your S8 Series II device. The picture shows the detailed menu in each mode.



^{*} Only displayed if access set by clinician.

Note: The AutoSet menu is available on the S8 AutoSet II only. To enter the detailed menu from the standby (RAMP or SETTLING) screen, press The SETTINGS menu screen is displayed.



Settings Menu Select on the Settings menu to access the options in this menu. You can use the Settings menu to change the: • Expiratory Pressure Relief (EPR) settings – see page 6. • Mask type – see page 3. Tube length Scroll to TUBE LENGTH and select . Press or until you see the setting that you require. Front cap You can set up your device to use the front cap accessory. Scroll to HUMID and select . Press \(\simeq \) or \(\sqrt{ until you see the setting that you require.} SmartStart settings SmartStart enables your device to start automatically when you breathe into the mask. Scroll to SMARTSTART and select Press \(\sqrt{ or } \sqrt{ or OFF.} \) · Leak alert settings

Leak alert indicates when a high mask leak is present.

Scroll to LEAK ALERT and select .

Press or to change the option to ON or OFF.

Results Menu

Select on the Results menu to access the options in this menu.

You can use the Results menu to view the total number of hours of treatment (USED HRS) and the number of sessions that the S8 AutoSet II was used in a usage period (USAGE).

Note: Your clinician may have customized your device to display Smart Data. Contact your clinician for further details about Smart Data.

Options Menu

Select on the Options menu to access the options in this menu.

You can use the Options menu to change the **language** setting. Scroll to LANG and select . Press or until you see the setting that you require.

Servicing Menu

Select on the Servicing menu to access the options in this menu.

You can use the Servicing menu to view the device system information.

Messages on the S8 Series II LCD

Your clinician may have set your S8 Series II device to remind you about important events, such as when to replace your mask, when to insert your Data Card (if your device is Data Card enabled) and so on.

The reminder message is displayed on the LCD and is visible if the device is not delivering therapy. The backlight on the LCD flashes when a message is displayed. Your clinician can set any of the following reminders on your LCD:

Message	Description	Action
INSERT CARD	May appear if your device is Data Card enabled.	Insert your Data Card and follow any instructions that your clinician has given you. When you have done this, the message will disappear from the LCD. Pressing (Ok) will also remove the message.
REPLACE MASK	May appear when your mask is due for replacement.	Press (Ok) to remove the message from your LCD, and replace your mask with a new one.
CALL PROVIDER	May appear as a reminder to contact your clinician, eg, to discuss how your therapy is going.	Press (Ok) to remove the message from your LCD, and contact your clinician.
REPLACE FILTER	May appear as a reminder to replace the air filter on your device.	Press (Ok) to remove the message from your LCD, and replace the air filter.
SERVICE DUE	May appear as a reminder to return your device for service.	Press (Ok) to remove the message from your LCD, and contact your clinician.

Using the Data Card to Collect Data

If your clinician needs to review your treatment, they will ask you to use the Data Card to copy data from your S8 Series II, and to return the card to them. The Data Card will be provided in a protective folder.

Data that is copied to a Data Card is still stored and available on the S8 Series II device.

Copy Data onto the Data Card

- 1 Switch on the S8 Series II and wait until you see the standby (Ramp) screen.
- 2 Hold the Data Card with the arrow facing up and insert it into the Data Card slot until it stops. Data copying starts automatically.
 The "Card Inserted Please Wait" message is displayed on the S8 Series II LCD while data is being copied. Copying takes approximately five seconds.

The "Copy Complete Remove Card" message is displayed on the LCD when copying has finished.

- **3** Remove the Data Card by gripping the end of the Data Card and pulling it out.
- **4** Store the Data Card in its protective folder when not in use.
- **5** Return the card in its protective folder to your clinician using a postal envelope.

Using the Data Card to Update Settings

If your clinician has provided a Data Card with new device settings:

1 With the device in standby (Ramp) mode, insert the Data Card into the Data Card slot. Updating will start automatically.

The "Card Inserted Please Wait" message is displayed on the LCD while updating is in progress. Updating takes approximately five seconds.

The "Settings Success Remove Card" message is displayed on the LCD if the settings were updated successfully.

Note: This message only appears once. If you re-insert the Data Card after you have updated your settings, this message is not displayed.

- 2 Remove the Data Card from the S8 Series II.
- **3** Store the Data Card in its protective folder when not in use.



WARNING

If your clinician has told you to use this Data Card to update the settings on your device and the "Settings Success" message does not appear, contact your clinician immediately.

Cleaning and Maintenance



WARNING

Beware of electric shock. Do not immerse the device or power cord in water. Always unplug the device before cleaning and make sure it is dry before reconnecting.



CAUTION

- Do not hang the air tubing in direct sunlight as it may harden over time and eventually crack.
 - · Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the air tubing or the device. These solutions may cause hardening and reduce the life of the product.

Daily

Disconnect the air tubing and hang it in a clean, dry place until next use.

Weekly

1 Remove the air tubing and wash it in warm water using mild detergent.

- 2 Rinse thoroughly, hang, and allow to dry.
- **3** Before next use, reassemble the mask and headgear.
- 4 Reconnect the air tubing.

Monthly

- Clean the exterior of the S8 Series II with a damp cloth and mild liquid soap.
- Check the air filter for holes and blockage by dirt. Replace it every six months, or more often in a dusty environment.

Replacing the Air Filter



CAUTION

- 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 onto the device. Ensure the air filter and air filter cover are fitted at all times.
- 1 Remove the air filter cover at the back of the device.



- 2 Remove and discard the old air filter.
- 3 Insert a new filter with the blue tinted side facing out from the device.
- 4 Replace the air filter cover.

Servicing

This product (S8 AutoSet II; S8 Elite II) should be inspected by an authorized ResMed service centre five years from the date of manufacture. Prior to this, the device is intended to provide safe and reliable operation provided that it is operated and maintained in accordance with the instructions provided by ResMed. Applicable ResMed warranty details are provided with the device at the time of original supply. Of course, as with all electrical devices, if any irregularity becomes apparent, you should exercise caution and have the device inspected by an authorized ResMed service centre.

If you feel that your device is not performing properly, see "Troubleshooting" on page 13.

Frequently Asked Questions

How will it feel when I am breathing with the S8 Series II?

When you first use your S8 Series II, you may feel uncomfortable breathing against the airflow. This is normal. You will continue to breathe normally while you sleep. The EPR setting may also improve comfort. Take time to adjust to this new sensation.

What do I do when I want to get up in the night?

If you need to get up during the night, remove your mask and stop therapy. Always remember to restart therapy and put your mask on when you return to bed.

What do I do if I feel air leaking out of the mask?

The S8 Series II delivers the most effective treatment when the mask is well fitted and comfortable. Treatment can be affected by leaks, so it is important to eliminate any leaks that may arise. For example, try repositioning the mask and adjusting the straps. If you are using a nasal mask, try to keep your mouth closed during treatment. Air leaks from your mouth can decrease the effectiveness of your treatment. If mouth leaks are a problem, a full face mask or chin strap may help. Contact your clinician or equipment supplier for further details.

If you are using a full face mask and you have problems trying to get a comfortable mask fit, contact your clinician or equipment supplier. You may benefit from a different size or style of mask.

Anything special I should do before putting the mask on?

Before wearing your mask, wash your face to remove excess facial oils. This will allow a better fit and prolong the life of the mask cushion. Do not use moisturizer when wearing a mask.

My mouth feels dry during treatment - what can I do?

You may experience dryness of the nose, mouth, and/or throat during the course of treatment, especially during winter. In many cases, a humidifier may resolve this discomfort. Contact your clinician for advice.

My nose is irritated during treatment – what can I do?

You may experience sneezing and/or a runny or blocked nose during the first few weeks of treatment. In many cases, nasal irritation can be resolved with a humidifier. Consult your clinician or equipment supplier for advice.

Can I travel with the S8 Series II?

Your S8 Series II has an internal power supply that enables it to operate in other countries. It will operate on power supplies of 100–240V and 50/60Hz. No special adjustment is necessary, but you will require an approved power cord for the region in which you are using the device.

Your S8 Series II device automatically adjusts to changes in altitude up to 8500' (2591 m).

Please consult the medical services department of your carrier if you intend to use your S8 Series II on an aircraft. The S8 Series II complies with US FCC Part 15, Class B requirements.

Note: Do not use your S8 Series II while the aircraft is taking off or landing.

Can I use my S8 Series II if mains (AC) power is not available?

A DC-12 converter is available to connect the S8 Series II to a 12V or 24V DC power source. Contact your clinician for details.

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 the device.

Problem/Possible Cause Solution

No display

Power is not connected Ensure the power cable is connected and the power

switch (if available) is on

Insufficient air delivered from S8 Series II device

Ramp or settling time is in use. Wait for air pressure to build up or change ramp or

settling time.

Air filter is dirty. Replace air filter.

Air tubing is kinked or Straighten or replace tubing.

punctured.

Air tubing not connected Check air tubing.

properly.

Mask and headgear not Adjust position of mask and headgear.

positioned correctly.

Cap(s) missing from access Replace cap(s).

port on mask.

Pressure required for See your clinician to adjust the pressure.

treatment may have changed.

Device does not start when you breathe into the mask although your clinician has enabled SmartStart

Power cord not connected Connect power cord firmly at both ends.

properly.

Power outlet may be faulty. Try another power outlet. Contact your clinician.

Leak Alert has been enabled by your clinician; SmartStart automatically disabled.

Use of a ResMed Full Face SmartStart does not work with a full-face mask as the mask anti-asphyxia valve will not allow sufficiently high

pressure on exhalation.

Breath not deep enough to Take a deep breath in and out through the mask.

trigger SmartStart. Excessive leak Adjust position of mask and headgear.

Replace caps if missing from ports on mask.

Air tubing may not be connected properly. Connect firmly

at both ends

Air tubing may be kinked or punctured. Straighten or

replace.

Problem/Possible Cause

Solution

Displays error message: SYSTEM ERRXXXX Call Service! or EXXXX (where XXXX defines an error)

Component failure. Record error number and call service.

Displays error message: Check tube!! Key if done

Air tubing is loose or blocked. Check that the air tubing is connected securely to your

mask and the air outlet to the front of the S8 Series II. When you have checked the air tubing, press the Start/ Stop key to restart the device. If this does not clear the

message, disconnect the power cord and then

reconnect it to restart the device.

The following message is displayed on the LCD after you try to update settings or copy data to the Data Card: Card Error Remove Card

Data Card is not inserted

correctly.

Check that the patient is inserting the Data Card into the Data Card module with the arrow facing up, while the S8

Escape II is switched on and not delivering therapy

(standby mode).

The Data Card is only partly

inserted.

Ensure that the Data Card is inserted into the Data Card

slot as far as it will go.

You may have removed the Data Card before settings were copied to the

S8 Escape II.

Reinsert the Data Card and wait for the **Settings Success Remove Card** message to appear on the

LCD.

The card is not a ResScan Data

Card.

Only use a ResScan Data Card.

The following message is displayed on the LCD after you try to update settings or copy data to the Data Card: Settings Error Remove Card

There is a data error on the Data Card.

Contact your clinician immediately.

The following message is NOT displayed on the LCD after you try to update the settings using the Data Card: Settings Success Remove Card

The settings were not

Contact your clinician immediately.

updated.

The following message is displayed on the LCD after you try to update settings or copy data to the Data Card: Settings Invalid Remove Card

The identification details on the Data Card do not match the identification details on your device.

Contact your clinician immediately.

Technical Specifications

Operating pressure range 4 to 20 cm H₂O

Dimensions (H x W x D) 4.6" x 6.5" x 5.7" (112 mm x 164 mm x 145 mm)

Weight 3.1 lb (1.4 kg)

Operating Temperature +41°F to +95°F (+5°C to +36°C)

Power Supply

• Input range for S8 Series II with HumidAire 3i: 100–240V, 50/60Hz; 110V, 400Hz; 2.5A <140VA (110W) (maximum power consumption).

Instantaneous peak power consumption <340VA.

• Refer to the DC-12 converter instructions for DC ratings. Only use the ResMed DC-12 converter for DC input.

Typical power consumption at 20 cm H₂O is 39VA or 20.7W.

Operating Humidity

Storage and Transport Temperature 10%-95% non-condensing -5°F to -140°F (-20°C to +60°C)

Storage and Transport Humidity 10%-95% non-condensing

Operating Altitude

Sea level to 8500' (2591 m)

Electromagnetic Compatibility

Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments. The electromagnetic compatibility tables for 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 device.

Air Filter Two-layered, powder-bonded, polyester non-woven fibre

Air Tubing Flexible plastic, 6' 6" (2 m)

Air Outlet The 22 mm conical air outlet complies with EN 1281-1

IEC 60601-1 Classifications Class II (double insulation), Type CF

Supplemental Oxygen Recommended maximum supplemental oxygen flow: 4 L/min

Housing Construction Flame retardant engineering thermoplastic

Noise Level Radiated sound pressure is measured at <24±2 dBA at 10 cm H₂O and

3'3.36" (1 m) according to ISO17510-1

The manufacturer reserves the right to change these specifications without notice.

Symbols which appear on the device

⚠ Attention, consult accompanying documents; Drip proof; Type CF equipment;

Dangerous voltage; Class II equipment; (START/STOP) Start/Stop.



GENERAL WARNINGS AND CAUTIONS

A warning alerts you to possible injury.

- Read the entire guide before using the S8 Series II device.
- The advice in this guide should not supersede instructions given by the prescribing physician.
- A patient should not connect a device to the data communication port unless instructed to do so by their health care provider or physician. Only ResMed products are designed to be connected to the data communication port. Connecting other devices could result in injury, or damage to the S8 Series II device.
- The S8 Series II device should be used with masks (and connectors)* recommended by ResMed, or by a physician or respiratory therapist. A mask should not be used unless the S8 Series II device is turned on and operating properly. The vent hole or holes associated with the mask should never be blocked.

Explanation: The S8 Series II 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 devices.

- In the event of power failure or machine malfunction, remove the mask.
- The S8 Series II device 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.
- If oxygen is used with this device, the oxygen flow must be turned off when the device is not operating. If oxygen has been left on, turn off the device, then wait 30 minutes before turning on the device.

Explanation: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the air delivery tubing may accumulate within the CPAP machine enclosure and create a risk of fire. This applies to most types of CPAP machines.

- Oxygen supports combustion. Oxygen should not be used while you are smoking or in the presence of an open flame.
- Always ensure airflow is being generated by the device before the oxygen supply is turned on.
- Always turn the oxygen supply off before stopping the airflow from the device
 Note: At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration
 varies, depending on where the oxygen is introduced, the pressure settings, patient
 breathing pattern, mask selection and leak rate.
- Explosion hazard do not use in the vicinity of flammable anesthetics.
- Do not open the S8 Series II case. There are no user serviceable parts inside.
 Repairs and internal servicing should only be performed by an authorized service agent.

^{*} Ports may be incorporated into the mask or in connectors that are near the mask.

A caution explains special measures for the safe and effective use of the device.

- 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 this device 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).
- When using DC power, always use a ResMed DC-12 converter. (The DC-12 converter is available as an optional accessory. It is not supplied with all models.)
 The device should not be connected to both AC and DC power sources simultaneously.

Note: The above are general warnings and cautions. Specific warnings, cautions, and notes appear with the relevant instructions in this User Guide.

Limited Warranty

ResMed warrants that your ResMed product shall be free from defects in material and workmanship for the period specified below from the date of purchase by the initial consumer. This warranty is not transferable.

Product	Warranty Period
ResMed humidifiers, ResControl™, ResLink™, ResTraxx™	1 Year
ResMed flow generators	2 Years
Accessories, mask systems (including mask frame, cushion, headgear and tubing). Excludes single-use devices.	90 Days

Note: Some models are not available in all regions.

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;
- c) any damage or contamination due to cigarette, pipe, cigar or other smoke;
- d) any damage caused by water being spilled on or into a flow generator.

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 is in lieu of all other express 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 occurred as a result of 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

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