



ResMed

AirSense™ 11

AUTOSET

CPAP

ELITE



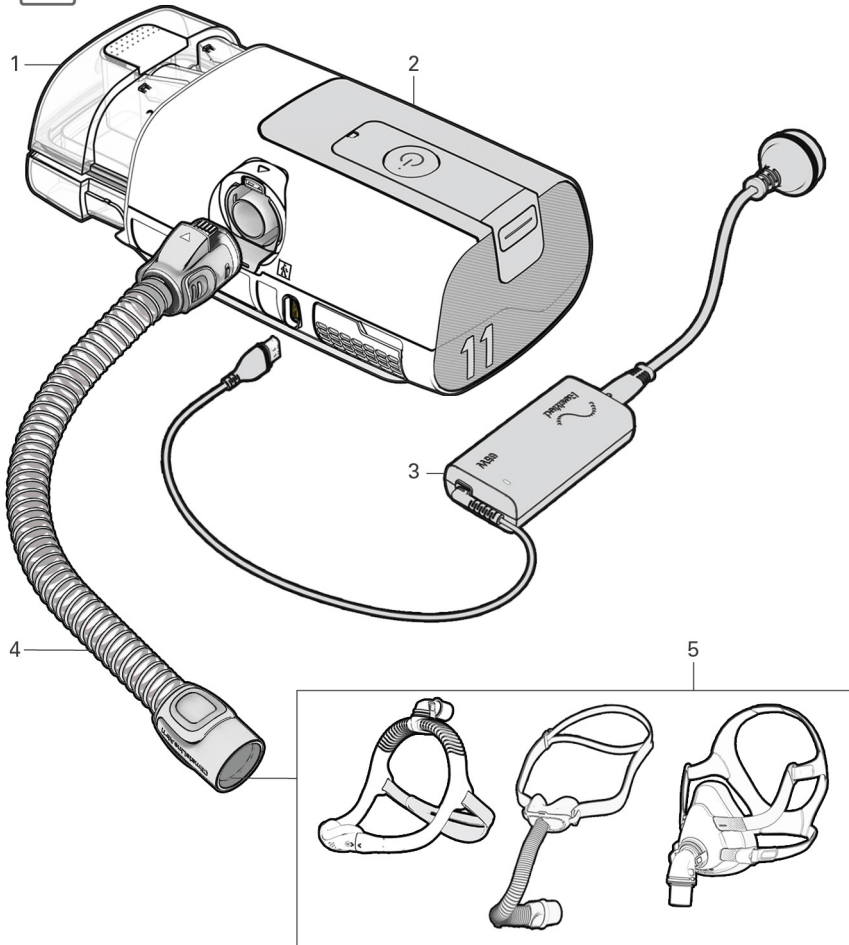
User guide

English | Français | Español | Português

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Quick setup view



Components

1. HumidAir™ 11 tub
2. AirSense™ 11 device
3. Power supply unit
4. ClimateLineAir™ 11 tubing
5. Mask

Welcome

The AirSense 11 AutoSet™ (including AutoSet for Her) device is ResMed's premium auto-adjusting pressure device. The AirSense 11 Elite and the AirSense 11 CPAP are ResMed's Continuous Positive Airway Pressure (CPAP) devices.

WARNING

- Read this entire guide before using the device.
- This device is not suitable for ventilator-dependent patients.

CAUTION

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

Indications for use

AirSense 11 AutoSet (including AutoSet for Her)

The AirSense 11 self-adjusting system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg), including female patients with mild to moderate OSA in AutoSet for Her mode. The AirSense 11 self-adjusting system is intended for home and hospital use.

AirSense 11 CPAP (including Elite)

The AirSense 11 CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg). The AirSense 11 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 or pneumomediastinum
- pathologically low blood pressure, particularly if associated with intravascular volume depletion
- dehydration
- cerebrospinal fluid leak, recent cranial surgery, or trauma.

Adverse effects

You should report unusual chest pain, severe headache, or increased breathlessness to your 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 device:

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

Software functionality and device data

This ResMed device is a smart device and includes software functionalities which allow it to be connected to the cloud so that users and their care providers can access data about therapy remotely, receive regular upgrades to the device and much more. Check out <https://myair.resmed.com/> to learn about ResMed's patient coaching application, myAir™.

Software License

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Over-the-Air Download of Software Updates. If the device is connected to the cloud, then the ResMed Software on the device will automatically and periodically download updates and upgrades to the ResMed Software on the device. Such downloads may be done by various means including, but not limited to, using Bluetooth® wireless technology, WiFi and/or cellular networks and combinations of various wireless technologies and services. Such updates to the ResMed Software might include, without limitation, bug fixes, error corrections, security patches, and new versions and releases of the ResMed Software that may include changes to existing features or functions and/or the addition of new features and functions.

Use of Device Data

When you use this device it gathers and records data about your use and, if your device connectivity is enabled, the device sends certain data to ResMed via the cloud to enable ResMed to deliver various benefits to you and your care provider(s). Additionally, some of that data may be used by ResMed (1) to comply with its legal obligations; these legal obligations include collection and analysis of device data for medical device post market surveillance and vigilance, and compliance with these legal obligations includes assessing if ResMed is required to implement actions to improve device safety, usability and performance, and (2) to perform health-related research, study and/or evaluation for specific scientific and medico-economic purposes. ResMed will only use your device data in compliance with applicable laws and regulations in your country or region (for example the GDPR (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data), the MDR (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices)) in the European Union, and, as applicable, HIPAA (the Health Insurance Portability and Accountability Act of 1996) in the USA). Depending on the data protection or privacy laws of your country or region your device data may constitute your personal data. If so, ResMed has the obligation to inform you about your rights and freedoms for our use of your personal data. You can find more details related to our use of your data, your rights to access, rectify, erase, restrict or object at <https://www.resmed.com/myprivacy/>.

At a glance

WARNING

Use only recommended ResMed masks and accessories or other vented masks as recommended by the prescribing doctor with this device. Using these components allows normal breathing and prevents potential asphyxiation.

The AirSense 11 system includes the following:

- Device
- HumidAir 11 Standard tub
- HumidAir 11 Cleanable tub
- ClimateLineAir 11 heated tubing or SlimLine™ tubing
- Air 11™ Power supply unit: 65W AC adaptor
- Travel bag
- SD card (not available in all devices).

Contact your care provider for a range of spares and accessories available for use with the device including:

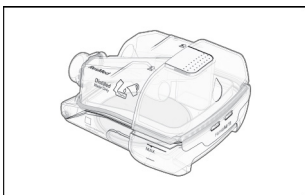
- Air tubing (ClimateLineAir 11 and SlimLine)
- HumidAir 11 Standard tub (Single patient re-use - cannot be reprocessed)
- HumidAir 11 Cleanable tub (Multi patient re-use - can be reprocessed)
- Side cover which allows use without the humidifier tub
- Air11 Filter - standard
- Air11 Filter - hypoallergenic
- Air11 DC/DC converter
- SD card
- SD card cover

Notes:

- The AirSense 11 device is compatible with ResMed masks. For a complete list, see the Mask/Device compatibility list on ResMed.com/downloads/devices.
- The HumidAir 11 Standard tub and the HumidAir 11 Cleanable tub are the only water tubs used with the AirSense 11 device.
- The ClimateLineAir 11 is the only heated tubing that is compatible with the AirSense 11 device.

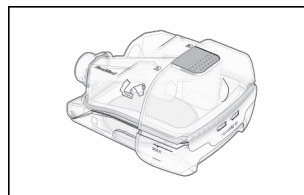
Humidifier tubs

HumidAir 11 Standard tub



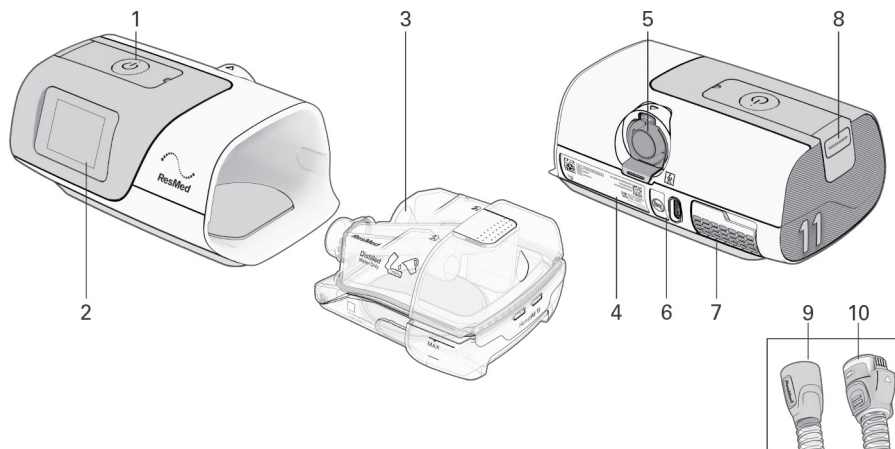
- single-patient use only
- cannot be reprocessed
- has a white thumb grip
- fill with distilled water only

HumidAir 11 Cleanable tub



- multi-patient use
- can be reprocessed
- has a grey thumb grip
- fill with drinking quality water (potable)

About your device



Description	Purpose
1 Start Therapy/ Standby button	Press to start/stop therapy. The LED indicator is green during standby mode, and white during therapy, Test Drive , and Mask Fit functions.
2 Display touch screen	Navigates between functions and displays information on the operating status of the device.
3 HumidAir 11 tub	Water tub that provides heated humidification.
4 Device label	Contains information relevant to the device.
5 Outlet connector	Connects the air tubing
6 Power inlet	Connects the power cord
7 Air inlet filter cover	Contains the air filter
8 SD card cover	Removable cover that protects the SD card slot. The LED indicator is blue when data is written to the SD card.
9 SlimLine tubing	Non-heated air tubing
10 ClimateLineAir 11 tubing	Heated air tubing

Notes:

- If the Start therapy/ Standby button has a flashing white light, a system error has occurred. Refer to the Troubleshooting section for more information.
- Use this device only as directed by your physician or healthcare provider.

Setting up your device

WARNING

Do not use any additives in the humidifier tub (eg, scented oils or perfumes). These may reduce humidification output and/or cause deterioration of the tub materials.

CAUTION

Use only ResMed parts (eg, air inlet filter, power supplies), masks and accessories with the machine. Non ResMed parts may reduce the effectiveness of the treatment, may result in excess carbon dioxide rebreathing and/or damage the machine. For compatibility information, refer to ResMed.com for more information.

When using the humidifier tub:

- Always place the device on a level surface, lower than your head, to prevent the mask and air tubing from filling with water.
- Do not overfill the humidifier tub as water may enter the device and air tubing.
- Do not fill the humidifier tub with hot water as this could lead to excessive air temperature at the mask. Ensure the water is cooled to room temperature before filling the humidifier tub.
- Do not place the device on its side while the humidifier is attached as water might get into the device and reduce motor life.

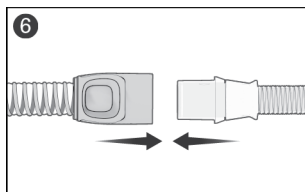
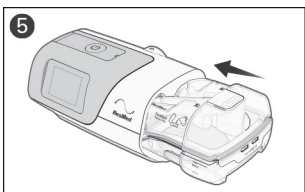
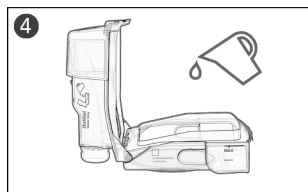
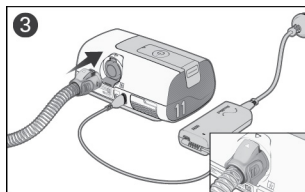
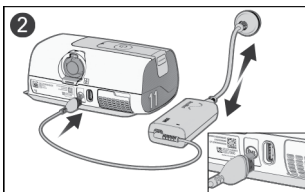
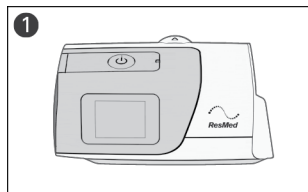
When setting up the AirSense 11 system:

- Do not place the power supply where it can be bumped, stepped on, or where someone is likely to trip over the power cord.
- Do not block the air tubing and/or air inlet of the device while in operation as this could lead to overheating of the device.
- Keep the area around the device dry, clean and clear of anything (eg, clothes or bedding) that could block the air inlet or cover the power supply unit.
- Ensure the system is correctly set up. Incorrect system setup may result in incorrect mask pressure reading.

When using a mask:

- Use only vented masks recommended by ResMed or by the prescribing doctor with this device.
- Fitting the mask without the device blowing air can result in rebreathing of exhaled air.
- Make sure that the mask vent holes are kept clear and unblocked to maintain the flow of fresh air into the mask.

To set up the device:



1. Place the device on a stable level surface.
2. Connect the power cord into the power inlet at the rear of the device. Connect one end of the power cord into the AC adaptor and the other end into the power outlet. Ensure the device is set up and connected to power to enable settings to be applied wirelessly to the device if required.
3. Connect the air tubing firmly to the outlet connector at the rear of the device.
4. Open the humidifier tub and fill it with water.

Note: The humidifier tub must be removed from the device before adding water.

- If using the HumidAir 11 Standard water tub, use distilled water only
- If using the HumidAir 11 Cleanable water tub, use drinking quality water (potable).

Fill the water tub up to the maximum water level mark. The humidifier tub has a maximum capacity of 380 mL.

5. Close the humidifier tub and insert it into the side of the device.
 6. Connect the free end of the air tubing firmly onto the assembled mask.
- See the mask user guide for detailed information.

Recommended masks for use with this device are listed on ResMed.com.









Notes:

- Do not insert any USB cable into the AirSense 11 device or attempt to plug the AC adaptor into a USB device. This may cause damage to the AirSense 11 device or USB device.
- The electrical connector end of the heated air tubing is only compatible with the air outlet at the device end and should not be fitted to the mask.
- Do not use electrically conductive or anti-static air tubing.

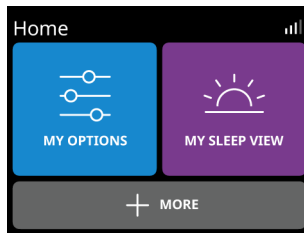
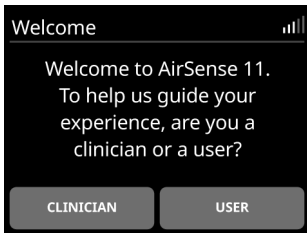
Navigating the touch screen

The AirSense 11 device operates via a display touch screen, which allows you to access, view and change therapy and device settings. You can also track your sleep health progress.

The status bar at the top of the screen may display icons at different times and may include:

Icon	Description	Purpose
	Home Screen	Return to the Home screen at any time.
	Humidifier fault	Detects fault in the humidifier. Therapy will run without heating.
	Humidifier warming	Water in the humidifier tub is pre-heating.
	Humidifier cooling	Water in the humidifier tub is cooling.
	Bluetooth connected	Device is successfully connected via Bluetooth wireless technology.
	Cellular signal strength	Indicates the strength of cellular connectivity.
	No cellular connection	Cellular coverage is not available.
	Airplane mode	Device is in airplane mode.

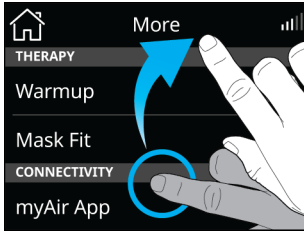
Initial Setup



From the **Welcome** screen, tap **USER** and follow the prompts.



1. From the **Home** screen, you can access the following menus:
 - **MY OPTIONS**: View and adjust therapy settings (eg, Adjust Ramp time)
 - **MY SLEEP VIEW**: Track sleep health (check the number of hours used last night or mask status)
 - **MORE**: Access additional features such as Run Mask Fit or switch to Airplane mode.

Using the touch screen:



There are two actions to navigate through the touch screen:

Swipe: Swipe up or down the screen to view menu options.

Tap: Select a parameter setting to update. For other parameters (eg Pressure Relief, Airplane mode), tap the parameter to turn it on  or tap to turn it off .

Prescription settings

If you have received the device direct to your home, prescription settings may not have been applied to your device. Ensure a wireless connection has been established to enable your care provider to install the prescribed settings.

Personalizing your settings

The device can be set up for your needs by your care provider, but you may want to make adjustments to make your therapy more comfortable.

1. Tap **MY OPTIONS** from the **Home** screen.
2. Tap the parameter you wish to change.
3. Tap the preferred setting.

Tap **OK** to confirm the change or **CANCEL** to go back to the previous screen.

Additional features

There are some other features on your device which you can personalize.

Note: Not all functions are available in all regions. Functions vary based on therapy mode.

Menu	Function	Description
MY OPTIONS	Ramp Time	Period during which the pressure increases from a low start pressure to the prescribed treatment pressure. Ramp Time can be set to Off, 5 to 45 minutes (in 5-minute increments), or Auto.
	Pressure Relief*	When EPR (Expiratory Pressure Relief) is enabled, you may find it easier to breathe out. This setting can help you get used to therapy.
	SmartStart™*	When SmartStart is enabled, therapy starts automatically when you breathe into your mask.
	SmartStop*	When SmartStop is enabled, therapy stops automatically after a few seconds when you remove your mask.
MORE	Mask Fit	This function helps you assess and identify possible air leaks around your mask.

*Features enabled by your care provider.

Connecting your AirSense 11 device and smart device

myAir is a smartphone app that guides you through the setup process. This includes device setup videos, mask fitting videos, trying therapy using the Test Drive feature, and tracking your sleep health progress. The app is not required to operate the AirSense 11 device.

Before pairing the AirSense 11 device to a smartphone, ensure the app's latest version is installed on the smartphone. If not, download the app from the App Store® or on Google Play®. Pair the AirSense 11 device to your phone. To set up the app, go to the **MORE** menu.

1. Ensure your AirSense 11 device is set up correctly and plugged into a power source.
2. Launch the myAir app. Tap **Continue**.
3. Follow the prompts on the myAir app to complete the Bluetooth connection.
AirSense 11 is now connected to the app. The Bluetooth connection symbol appears on the status bar to confirm the connection between the AirSense 11 device and the smartphone.
4. Tap **Done**.

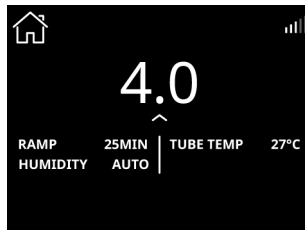
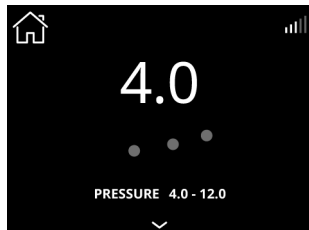
Starting/Stopping therapy

WARNING

The machine is not intended to be operated by persons (including children) with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.

To start therapy:

1. Fit your mask
2. Press the Start therapy/Standby button or breathe normally if SmartStart is enabled



Therapy will begin and the treatment screen is displayed. A dynamic pulse wave will appear during therapy.

To review your sleep progress, click on  to view more details

Notes:

- The screen will fade and then go black automatically after a short period of time. Tap the screen to turn it back on.
- If power is interrupted during therapy, the device will automatically restart therapy when power is restored.
- The device has a light sensor that adjusts the screen brightness based on the light in the room.

To stop therapy:

1. Remove your mask.
2. Press the Start therapy/Standby button or wait until the device stops if SmartStop is enabled.

About the heated tubing

The ClimateLineAir 11 is a heated breathing tube that delivers air to a compatible mask. When used with the device humidifier tub, ClimateLineAir 11 heated air tubing allows you to use the Climate Control feature.

Note: Not all types of air tubing are available in all regions.

Climate Control

Climate Control is designed to make therapy more comfortable by enabling constant temperature and maintaining humidity.

This feature:

- delivers comfortable humidity level and temperature during therapy
- maintains the set temperature and relative humidity during sleep to prevent dryness in the nose and mouth
- can be set to either **Auto** or **Manual**
- is only available when both the ClimateLineAir 11 and HumidAir 11 tub are attached.

Climate Control - Auto setting

Auto is the recommended and default setting. It is designed to make therapy as easy as possible so there is no need to change the temperature or humidity settings.

- Sets the tube temperature to Auto (80°F/27°C). If the air in the mask is too warm or too cold, you can adjust the tube temperature to anywhere from 60 to 86°F (16 to 30°C) or turn it off completely
- Adjusts the humidifier output to maintain a constant, comfortable humidity level of 85% relative humidity
- Protects against rainout (water droplets in the heated air tubing and mask).

Climate Control - Manual setting

Manual is designed to offer more flexibility and control over settings and offers the following:

- Temperature and humidity can be adjusted to find the most comfortable setting
- Temperature and humidity level can be set independently
- Rainout protection is not guaranteed. If rainout does occur, first try increasing the tube temperature
- If the air temperature becomes too warm and rainout continues, try decreasing the humidity.

Note: If Climate Control is set to **Manual**, the **Auto** Tube Temperature setting is not available.

Humidity Level

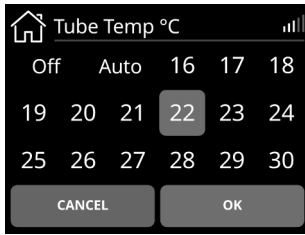
The humidifier moistens the air and is designed to make therapy more comfortable.

- If you are getting a dry nose or mouth, turn up the humidity
- If you are getting any moisture in your mask, turn down the humidity.
- You can set the **Humidity Level** to Off or between 1 and 8, where 1 is the lowest humidity setting, and 8 is the highest humidity setting.

To update the setting for **Tube Temperature**, **Climate Control**, or **Humidity Level**, tap **MY OPTIONS** from the **Home** screen, go down the list of options, and select the setting.

Note: Tube Temp **Auto** setting is only relevant when using the **Climate Control Auto** setting. If **Climate Control** is set to **Manual**, **Auto** set temperature is not a valid selection.

Tube Temperature



1. Tap **Tube Temp**.
2. Tap the preferred setting.
3. Tap **OK** to save the change.

Climate Control



1. Tap **Climate Control**.
2. Tap **Manual**.
3. Tap **OK** to save the change.

Humidity Level



1. Tap **Humidity Level**.
2. Tap the preferred setting.
3. Tap **OK** to save the change.

Note: The temperature and humidity settings are not measured values.

Therapy data

The AirSense 11 device records your therapy data for viewing and adjusting by your care provider if required. The data is transferred to your care provider in the following methods:

Wireless

The device is equipped with cellular communication that allows your sleep therapy data to be wirelessly transmitted to your care provider. It also allows for prescribed settings to be applied or updated.

Transfer of data will occur after therapy has stopped. Leave your device connected to the power outlet at all times and make sure it is not in Airplane Mode. Data will only be transferred if a wireless connection is available.

Within the wireless network, the availability and quality of the network may be affected by terrain, buildings, and the weather. Wireless communication depends on network availability. Coverage is not available everywhere and varies by service.

Notes:

- Cellular feature may not work/ therapy data might not be transmitted if you use it outside of the country or region of purchase.
- Devices with cellular communication might not be available in all regions.

SD card

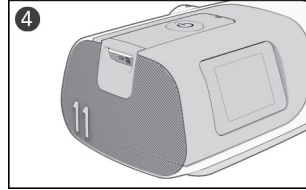
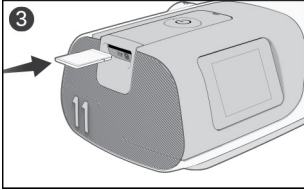
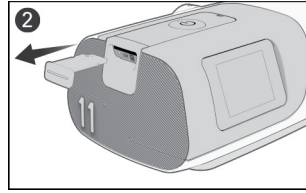
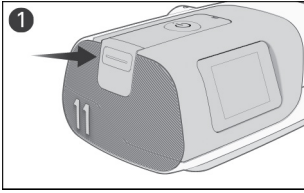
Your sleep therapy data may be transferred to your care provider via SD Card (if provided). Your care provider may ask you to send the SD card by mail or to bring it in. Only remove the SD card when instructed by your care provider.

To use the SD card to record your sleep data, remove the SD card cover.

Do not remove the SD card from the device when the SD light is flashing, because data is being written to the card.

Note: The SD card should not be used for any other purpose as it may corrupt therapy data stored on the card.

To remove the SD card cover and insert SD card:



1. Push the SD card cover.
2. Remove the SD card cover and keep the SD card cover in a safe place.
3. Insert the SD card.
4. Push in the SD card until it clicks in place.

To remove the SD card:

1. Push in the SD card to release it.
2. Place the SD card in the protective folder and follow your care provider's instructions.

For more information on the SD card, refer to the SD card protective folder provided with your device.

Cleaning and caring for the device

WARNING

- Beware of electrocution:
 - Do not immerse the device, AC Adaptor or power cord in water.
 - Do not connect to power while the device is wet. Make sure that all parts are dry before plugging it in.
 - If liquids are spilled into or onto the device, unplug the device and let the parts dry.
- Always unplug the device before cleaning and ensure that all parts are dry before plugging it back in.
- Do not perform any maintenance tasks (eg, cleaning, changing the air filter) while the device is in operation.
- Clean the device and its components according to the schedules shown in this guide, to maintain the quality of the device and to prevent the growth of germs that can adversely affect your health.
- Regularly inspect power cords, cables, and power supply for damage or signs of wear. Discontinue use and replace if damaged.
- Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized ResMed service agent.

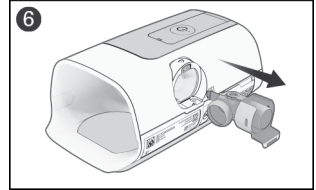
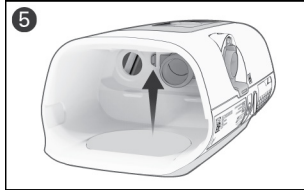
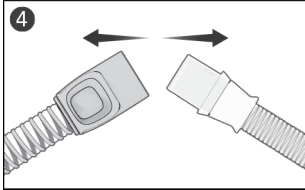
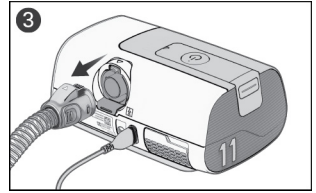
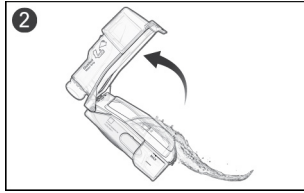
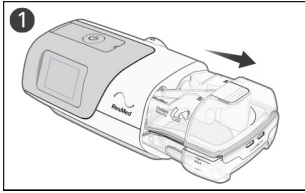
CAUTION

- Do not use bleach, chlorine, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the device, the humidifier tub or air tubing. These solutions may cause damage or affect the humidifier performance and reduce the life of the products. Exposure to smoke, including cigarette, cigar or pipe smoke, as well as ozone or other gases, may damage the device. Damage caused by any of the foregoing, will not be covered by ResMed's limited warranty.
- Leave the humidifier tub to cool for at least ten minutes after turning off the humidifier or until the cool down mode is complete before handling the humidifier tub.
- Only clean, maintain and/or reprocess the device and components according to the instructions shown in this guide.

The following sections will help you with:

- Disassembling
- Cleaning
- Checking
- Reassembling.

Disassembling



1. Hold the humidifier tub at the top and bottom, press it gently and pull it away from the device.
Note: take care when handling the humidifier tub as the humidifier tub may be hot. Allow 10 minutes for the heater plate and any excess water to cool.
2. Open the humidifier tub and discard any remaining water.
3. Pinch the cuff of the air tubing, and gently pull it away from the device.
4. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart.
5. Locate the outlet connector on the inside of the device and release it by pressing the clip firmly.
6. Remove the outlet connector by pulling it out through the outlet connector socket at the rear of the device.

Cleaning

The following instructions are for home cleaning. Instructions for reprocessing devices intended for multi-patient re-use can be found in the clinical guide.

You should clean the device, humidifier tub, air tubing, and outlet connector as described. For cleaning your mask, refer to the mask user guide for detailed instructions.

Daily:

1. Empty the humidifier tub and wipe it thoroughly with a clean disposable cloth. Allow it to dry out of direct sunlight.
2. Refill the humidifier tub.
 - If using the HumidAir 11 Standard water tub, use distilled water only
 - If using the HumidAir 11 Cleanable water tub, use drinking quality water (potable).

Weekly:

1. Wash the components as described:
 - Air tubing - in warm water using a mild dishwashing liquid.
 - Humidifier tub - in warm water using a mild dishwashing liquid OR in a solution with a ratio of 1 part vinegar and 9 parts water at room temperature.
 - Outlet connector - in warm water using a mild dishwashing liquid OR in a solution with a ratio of 1 part vinegar and 9 parts water at room temperature.
 - Components should not be washed in temperatures higher than 131°F (55°C).
2. Rinse each component thoroughly in water.
3. Allow to dry out of direct sunlight or heat
4. Wipe the exterior of the device with a dry cloth.

Notes:

- The humidifier tub and outlet connector may be washed in a dishwasher.
- Do not wash the air tubing in a dishwasher or washing machine.
- The air filter is not washable or reusable.

Checking

⚠ WARNING

- Discontinue use and contact your care provider or ResMed Service Center if any of the following occur:
 - device does not perform as usual
 - device is making unusual sounds
 - device is damaged
- If using a bacterial/viral filter, regularly check it for signs of moisture or other contaminants, particularly during nebulization or humidification. Failure to do so could result in increased breathing resistance or affect the delivery of the therapeutic pressure.

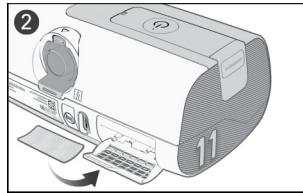
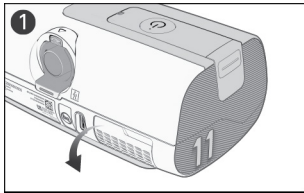
⚠ CAUTION

If any visible deterioration of a system component is apparent (cracking, discoloration, tears etc.), the component should be discarded and replaced.

Regularly check the humidifier tub, air tubing, and air filter for any damage.

1. Check the humidifier tub:
 - Replace it if it is leaking or has become cracked, cloudy, or pitted.
 - Replace it if the seal is cracked or torn.
 - Remove any white powder deposits using a solution of one-part household vinegar to 9 parts water. Rinse with clean water.
2. Check the air tubing and replace it if there are any holes, tears, or cracks.
3. Check the air filter and replace it every six months. Replace it more often if there are any holes or blockages by dirt or dust.

Replacing the air filter



1. Open the air filter cover and remove the old air filter.
2. Place a new air filter onto the air filter cover and then close the cover. Make sure the air filter and air filter cover are fitted at all times to prevent water and dust from entering the device.

Note: The air filter is not washable or reusable.