ResMed

# Lumis™ series

VPAP ST-A


## User guide

English | 简体中文

# Welcome

The Lumis™ 150 VPAP ST-A is a bilevel positive airway pressure device.

## ⚠ WARNING

- **Read this entire guide before using the device.**
- **Use the device according to the intended use provided in this guide.**
- **The advice provided by your prescribing doctor should be followed ahead of the information provided in this guide.**

## Indications for use

### Lumis 150 VPAP ST-A

The Lumis 150 ST-A device is indicated to provide non-invasive ventilation for patients weighing more than 13 kg or more than 30 kg in iVAPS mode with respiratory insufficiency or obstructive sleep apnea (OSA). It is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

### 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, or throat
- nosebleed
- bloating
- ear or sinus discomfort
- eye irritation
- skin rashes.

## At a glance

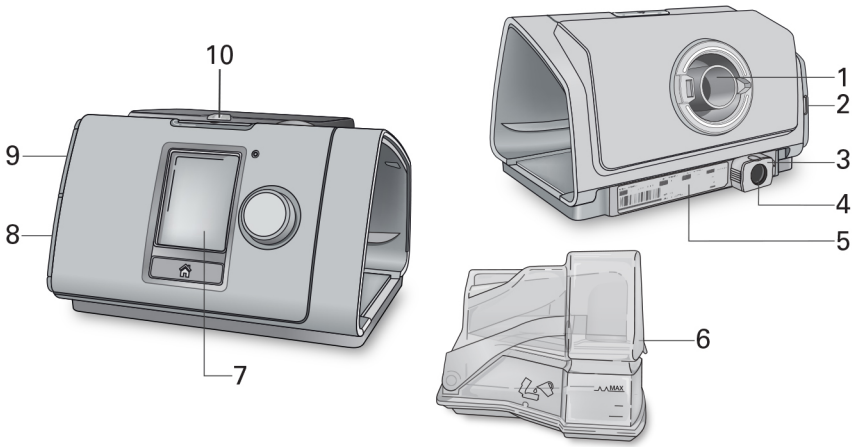
The Lumis includes the following:

- Device
- HumidAir™ humidifier (if supplied)
- Air tubing
- Power supply unit
- Travel bag
- SD card (already inserted).

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

- Air tubing (heated and non-heated): ClimateLineAir™, ClimateLineAir Oxy, SlimLine™, Standard
- HumidAir humidifier
- Side cover for use without the humidifier
- Filter: Hypoallergenic filter, standard filter
- Air10™ DC/DC converter (12V/24V)
- SD card reader
- Air10 oximeter adapter
- Air10 USB adapter
- Power Station II
- Air10 tubing elbow.

## About your device




1 Air outlet
2 Air filter cover
3 Retention clip
4 Power inlet
5 Serial number and device number
6 HumidAir humidifier
7 Screen
8 Adapter cover
9 SD card cover
10 LED alarm indicator

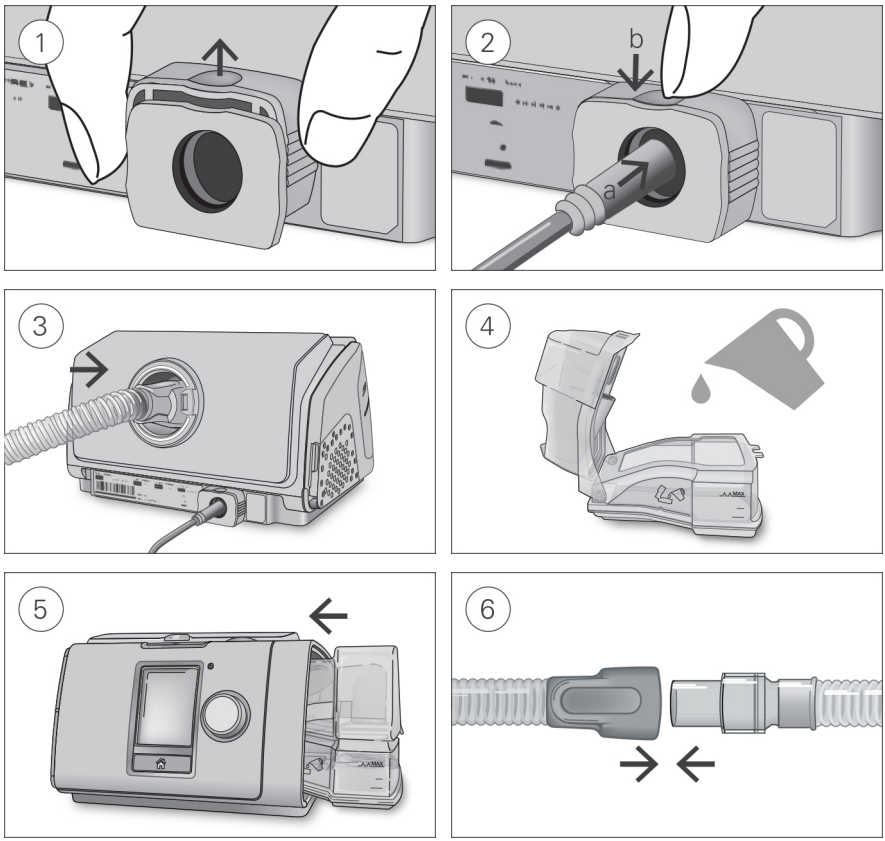
## About the control panel

| | |
|---|---|
| Start/Stop button | Press to start/stop therapy.<br>Press and hold for three seconds to enter power save mode. |
| Dial | Turn to navigate the menu and press to select an option.<br>Turn to adjust a selected option and press to save your change. |
| Home button | Press to return to the Home screen. |

Different icons may be displayed on the screen at different times including:

- Ramp Time
- Humidity
- Humidifier warming
- Humidifier cooling
- Alarm muted
- Wireless signal strength (green)
- Wireless transfer not enabled (gray)
- No wireless connection
- Airplane Mode

## Setup




## ⚠ CAUTION

Do not overfill the humidifier as water may enter the device and air tubing.

1. With the device on a stable level surface, grip the retention clip on the back of the device and pull up to open. Note: The retention clip is shown in the open position.
2. (a) Plug the power connector into the device power inlet then (b) push down the retention clip to secure in place. Connect one end of the power cord into the power supply unit and the other end into the power outlet.
3. Connect the air tubing firmly to the air outlet located on the rear of the device.
4. Open the humidifier and fill it with water up to the maximum water level mark. Do not fill the humidifier with hot water.
5. Close the humidifier 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.

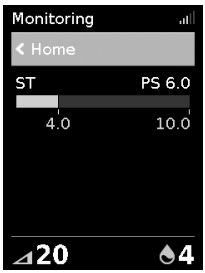
Recommended masks are available on www.resmed.com.

**Note:** Ensure the device is placed so that the LED alarm indicator is clearly visible.

## Starting therapy

1. Fit your mask.
2. Press Start/Stop or breathe normally if SmartStart™ is enabled.

You will know that therapy is on when the **Monitoring** screen is displayed.




The pressure bar shows the inspiratory and expiratory pressures in green. The green bar will expand and contract as you breathe in and out.

The screen will go black automatically after a short period of time. You can press Home or the dial to turn it back on. If power is interrupted during therapy, the device will automatically restart therapy when power is restored.

The Lumis device has a light sensor that adjusts the screen brightness based on the light in the room.

## Stopping therapy

1. Remove your mask.
2. Press Start/Stop or if SmartStart is enabled, therapy will stop automatically after a few seconds.

**Note:** If Confirm Stop is enabled, a message is displayed asking if you want to stop therapy. Turn the dial to select **Yes** and then press the dial to stop therapy.

Once therapy has stopped, the **Sleep Report** gives you a summary of your therapy session.


**Usage hours**–Indicates the number of hours of therapy you received last session.

**Mask Seal**–Indicates how well your mask sealed:

Good mask seal.

Needs adjusting, see Mask Fit.

**Humidifier**–Indicates if your humidifier is working properly:

Humidifier working.

Humidifier might be faulty, contact your care provider.

If set by your care provider, you will also see:

**Events per hour**–Indicates the number of apneas and hypopneas experienced per hour.

**More Info**–Turn the dial to scroll down to view more detailed usage data.

## Power save mode

Your Lumis device records your therapy data. In order to allow it to transmit the data to your care provider, you should not unplug the device. However, you can put it into power save mode to save electricity.

To enter power save mode:

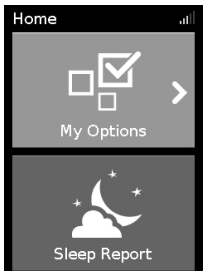
- Press and hold Start/Stop for three seconds.
  The screen goes black.

To exit power save mode:

- Press Start/Stop once.
  The **Home** screen is displayed.

# My Options

Your Lumis device has been set up for your needs by your care provider, but you may find you want to make small adjustments to make your therapy more comfortable.



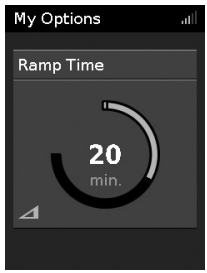


Highlight **My Options** and press the dial to see your current settings. From here, you can personalize your options.

## Ramp Time

Designed to make the beginning of therapy more comfortable, Ramp Time is the period during which the pressure increases from a low start pressure to the prescribed treatment pressure.

You can set your Ramp Time to Off or between 5 to 45 minutes.


To adjust Ramp Time:

1. In **My Options**, turn the dial to highlight **Ramp Time** and then press the dial.
2. Turn the dial to adjust the ramp time to your preferred setting and press the dial to save the change.

## Ramp Down

Ramp Down is intended to make stopping therapy more comfortable by reducing your pressure over a fixed 15 minute period. This option will only be available to you via your care provider.


**To enable Ramp Down:**

1. In **My Options**, turn the dial to highlight **Ramp Down** and then press the dial.
2. Turn the dial to select **On** and then press the dial to save the change.

**To start Ramp Down:**

1. Press the Start/Stop button.

**Note:** If Confirm Stop is enabled, a message is displayed asking if you want to start Ramp Down. Turn the dial to select **Yes** and then press the dial to start Ramp Down.

The Ramp Down icon  and time remaining will be displayed at the bottom left of the screen.

Once Ramp Down is complete, the device will continue to run at low pressure. To stop therapy at any time, press Start/Stop.

## 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 adjust the Humidity Level:**

1. In **My Options**, turn the dial to highlight **Humidity Level** and then press the dial.
2. Turn the dial to adjust the humidity level and press the dial to save the change.

If you continue to get a dry nose or mouth, or moisture in your mask, consider using ClimateLineAir heated air tubing. ClimateLineAir together with Climate Control delivers more comfortable therapy.

## Mask Fit

Mask Fit is designed to help you assess and identify possible air leaks around your mask.


To check Mask Fit:

1. Fit the mask as described in the mask user guide.
2. In **My Options**, turn the dial to highlight **Run Mask Fit** and then press the dial.
   The device starts blowing air.
3. Adjust the mask, mask cushion and headgear until you get a **Good** result.

To stop Mask Fit, press the dial or Start/Stop. If you are unable to get a good mask seal, talk to your care provider.

## More options

There are some more options on your device which you can personalize.

| | |
|---|---|
| Mask | This option shows your mask type setting. If you use more than one type of mask, adjust this setting when switching between masks. |
| Run Warm Up | This option allows you to pre-heat the water before starting therapy, so that the air is not cold or dry at the beginning of therapy. |
| Ramp Down* | This option is intended to make stopping therapy more comfortable by reducing your pressure over a fixed 15 minute period. |
| Leak Alert* | When Leak Alert is enabled, the device beeps if the mask leaks too much air or if you remove the mask during therapy. |
| SmartStart* | When SmartStart is enabled, therapy starts automatically when you breathe into your mask. When you remove your mask, it stops automatically after few seconds. |

*When enabled by your care provider.

# Working with alarms

The device is fitted with an alarm feature that monitors your therapy and alerts you to changes that may affect your treatment.

When power is connected to the device, the yellow LED alarm indicator will flash and the alarm will sound to confirm that the alarm is working.


When an alarm is activated, the yellow LED alarm indicator will flash, the alarm will sound and a message will appear on the screen.

## Muting activated alarms


To mute the alarm:

1. Press the dial. A list of activated alarms will appear and the flashing alarm mute icon will be displayed in the top right corner of the screen. The alarm will be muted for 1 minute 50 seconds.
2. To return to the previous screen, highlight OK and press the dial.

Once the condition that activated the alarm is corrected, the alarm sound and flashing icon will stop.

If the condition that activated the alarm remains after 1 minute 50 seconds, the alarm will re-occur.

See the **Alarms troubleshooting** section for help with managing common alarm conditions.

## Multiple alarms


If multiple alarms are activated at the same time, the most recent alarm message will be displayed on the screen and any other activated alarms will be shown in the Alarms list.

## Viewing the alarms


To view the alarm list:

1. From the **Monitoring** screen, turn the dial clockwise until the last **Monitoring** screen is displayed.
2. To view the alarm details, highlight the alarm and press the dial.

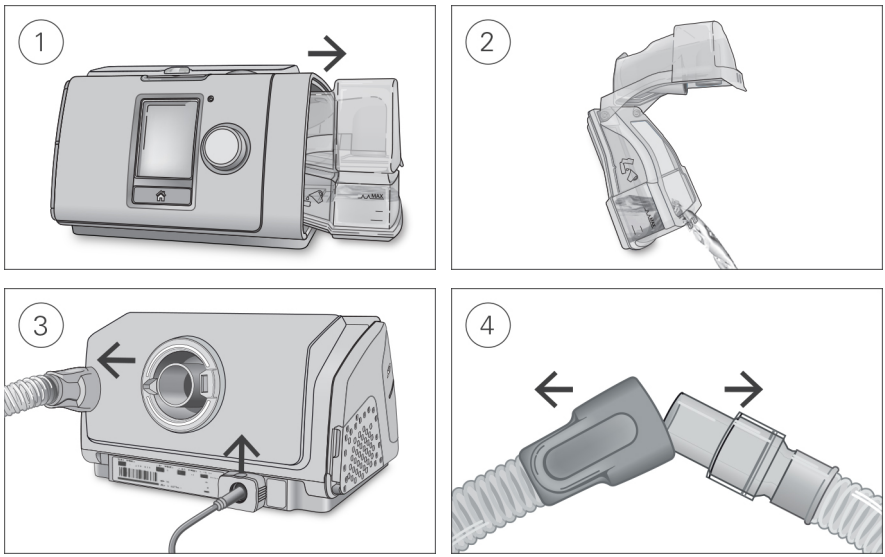
# Caring for your device

It is important that you regularly clean your Lumis device to make sure you receive optimal therapy. The following sections will help you with disassembling, cleaning, checking and reassembling your device.

## ⚠ WARNING

**Regularly clean your tubing assembly, humidifier and mask to receive optimal therapy and to prevent the growth of germs that can adversely affect your health.**

## Disassembling




1. Hold the humidifier at the top and bottom, press it gently and pull it away from the device.
2. Open the humidifier and discard any remaining water.
3. Hold the cuff of the air tubing and gently pull it away from the device.
   Grip the retention clip and pull up to release the power cord.
4. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart.

## Cleaning

You should clean the device weekly as described. Refer to the mask user guide for detailed instructions on cleaning your mask.

1. Wash the humidifier and air tubing in warm water using mild detergent.
2. Rinse the humidifier and air tubing thoroughly and allow to dry out of direct sunlight and/or heat.
3. Wipe the exterior of the device with a dry cloth.

Notes:

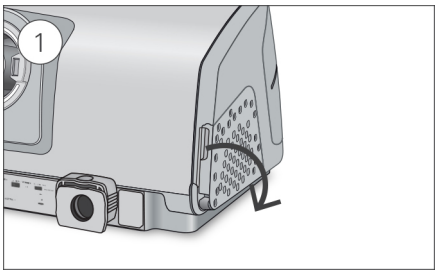
- Empty the humidifier daily and wipe it thoroughly with a clean, disposable cloth. Allow to dry out of direct sunlight and/or heat.
- The humidifier may be washed in a dishwasher on the delicate or glassware cycle (top shelf only). It should not be washed at temperatures higher than 65°C.
- Do not wash the air tubing in a dishwasher or washing machine.

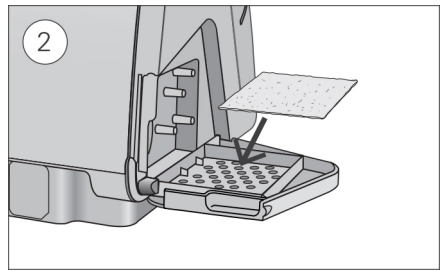
## Checking

You should regularly check the humidifier, air tubing and the air filter for any damage.

1. Check the humidifier:
   - 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 10 parts 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 at least every six months. Replace more often if there are any holes or blockages by dirt or dust.

**To replace the air filter:**




1. Open the air filter cover and remove the old air filter.
   The air filter is not washable or reusable.
2. Place a new air filter onto the air filter cover and then close it.
   Make sure the air filter is fitted at all times to prevent water and dust from entering the device.

## Reassembling

When the humidifier and air tubing are dry, you can reassemble the parts.

1. Connect the air tubing firmly to the air outlet located on the rear of the device.
2. Open the humidifier and fill it with room temperature water up to the maximum water level mark.
3. Close the humidifier and insert it into the side of the device.
4. Connect the free end of the air tubing firmly onto the assembled mask.

# Therapy data

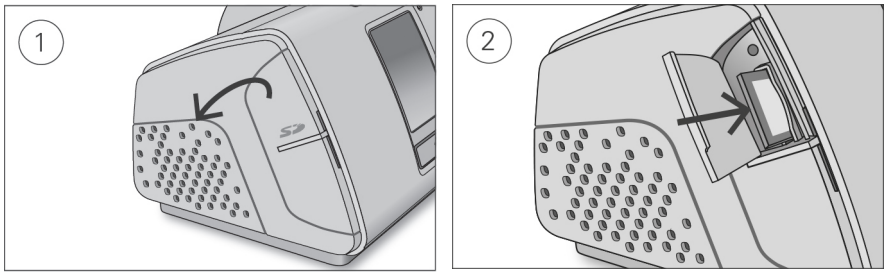
Your Lumis device records your therapy data for you and your care provider so they can view and make changes to your therapy if required. The data is recorded and can be uploaded from the SD card. The data may also be transferred wirelessly, if a wireless network is available.

## SD card

Your therapy data can be transferred to your care provider via the SD card. Your care provider may ask you to send the SD card by mail or to bring it in. When instructed by your care provider, remove the SD card.

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

To remove the SD card:




1. Open the SD card cover.
2. Push in the SD card to release it. Remove the SD card from the device.
   Place the SD card in the protective folder and send it back to your care provider.

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

**Note:** The SD card should not be used for any other purpose.

### Wireless Transmission

Your Lumis device is fitted with a cellular modem. Data from the device may be transmitted wirelessly after therapy has stopped. In order to ensure the data is sent promptly you should leave the device connected to mains power and make sure it is not in Airplane mode.

Notes:

- Therapy data might not be transmitted if you use the device outside of the country of purchase.
- Wireless communication depends on network availability.
- Devices with wireless communication might not be available in all regions.

## Traveling

You can take your Lumis device with you wherever you go. Just keep the following in mind:

- Use the travel bag provided to prevent damage to the device.
- Empty the humidifier and pack it separately in the travel bag.
- Make sure you have the appropriate power cord for the region you are traveling to. For information on purchasing, contact your care provider.
- If you are using an external battery, you should turn off the humidifier in order to maximize the life of your battery. Do this by turning the **Humidity Level** to Off.

### Traveling by plane

Your Lumis device may be taken on board as carry-on luggage. Medical devices do not count toward your carry-on luggage limit.

You can use your Lumis device on a plane as it meets the Federal Aviation Administration (FAA) requirements. Air travel compliance letters can be downloaded and printed from www.resmed.com.

When using the device on a plane:

- Make sure the humidifier is completely empty and inserted into your device. The device will not work without the humidifier inserted.
- Turn on **Airplane Mode.**



To turn on Airplane Mode:

1. In **My Options**, turn the dial to highlight **Airplane Mode** and then press the dial.
2. Turn the dial to select **On** and then press the dial to save the change.
   The Airplane Mode icon ✈ is displayed at the top right of the screen.

## ⚠ CAUTION

Do not use the device with water in the humidifier on a plane due to the risk of inhalation of water during turbulence.

# Troubleshooting

If you have any problems, have a look at the following troubleshooting topics. If you are not able to fix the problem, contact your care provider or ResMed. Do not try to open the device.

## General troubleshooting

| Problem/possible cause | Solution |
|---|---|
| **Air is leaking from around my mask** | |
| Mask may be fitted incorrectly. | Make sure your mask is fitted correctly. See your mask user guide for fitting instructions or use the Mask Fit function to check your mask fit and seal. |
| **I am getting a dry or blocked nose** | |
| Humidity level may be set too low. | Adjust the Humidity Level.<br>If you have ClimateLineAir heated air tubing, see the ClimateLineAir user guide. |
| **I am getting droplets of water on my nose, in the mask and air tubing** | |
| Humidity level may be set too high. | Adjust the Humidity Level.<br>If you have ClimateLineAir heated air tubing, see the ClimateLineAir user guide. |
| **My mouth is very dry and uncomfortable** | |
| Air may be escaping through your mouth. | Increase the Humidity Level.<br>You may need a chin strap to keep your mouth closed or a full face mask. |
| **Air pressure in my mask seems too high (it feels like I am getting too much air)** | |
| Ramp may be turned off. | Use the Ramp Time option. |

| Problem/possible cause | Solution |
|---|---|
| **Air pressure in my mask seems too low (it feels like I am not getting enough air)** | |
| Ramp may be in progress  . | Wait for air pressure to build up or turn Ramp Time off. |
| Ramp Down may be in progress  . | Press Start/Stop to stop therapy then press Start/Stop to restart and continue therapy. |
| Non-vented mask is used. | Only use a vented mask. |
| Mask vents might be blocked. | Check if you have sufficient venting. Unblock mask vents if necessary. |
| Expiratory pressure (EPAP) may be set too low. | Talk to your care provider about your settings. |
| **My screen is black** | |
| Backlight on the screen may have turned off. It turns off automatically after a short period of time. | Press Home or the dial to turn it back on. |
| Power may not be connected. | Connect the power supply and make sure the plug is fully inserted.<br>Note: The retention clip should be in the open position when inserting the plug. For instructions refer to the Setup section. |
| **I have stopped therapy, but the device is still blowing air** | |
| Device is cooling down. | Device blows a small amount of air in order to avoid condensation in the air tubing. It will stop automatically after 30 minutes. |
| **My humidifier is leaking** | |
| Humidifier may not be assembled correctly. | Check for damage and reassemble the humidifier correctly. |
| Humidifier may be damaged or cracked. | Contact your care provider for a replacement. |
| **Device data has not been transmitted wirelessly** | |
| Power may not be connected. | Connect the power supply and make sure the plug is fully inserted.<br>Note: The retention clip should be in the open position when inserting the plug. For instructions refer to the Setup section. |
| Wireless coverage may be poor. | Make sure that the device is placed where there is coverage (ie, on your bedside table, not in a drawer or on the floor). The Wireless signal strength icon  indicates good coverage when all bars are displayed, and poor coverage when fewer bars are displayed. |
| The No wireless connection icon  is displayed on the top right of the screen. no wireless network available. | Make sure that the device is placed where there is coverage (ie, on your bedside table, not in a drawer or on the floor). If instructed to do so, send the SD card to your care provider. The SD card also contains your therapy data. |
| Device may be in Airplane Mode. | Turn off Airplane Mode, see Traveling by plane. |

| Problem/possible cause | Solution |
|---|---|
| **Displays message: Read only card, please remove, unlock and re-insert SD card** | |
| SD card switch may be in the lock (read-only) position. | Move the switch on the SD Card from the lock position to the unlock position and then re-insert it. |

## Alarms troubleshooting

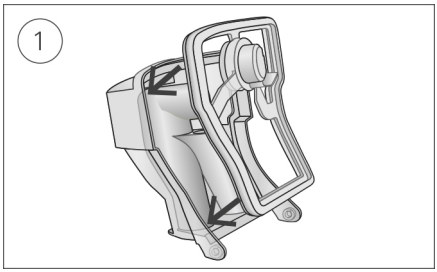
| Problem/possible cause | Solution |
|---|---|
| **Display disappears and an alarm is activated** | |
| Power failure. | Remove your mask until power is restored. |
| Power cord is disconnected or mains power has been turned off during therapy. | Ensure the power cord is connected and the mains power switch (if available) is on. |
| **Displays message: High leak detected, check your water tub, tub seal or side cover** | |
| Humidifier may not be inserted properly. | Make sure the humidifier is correctly inserted. |
| Humidifier seal may not be inserted properly. | Open the humidifier and make sure that the seal is correctly inserted. |
| **Displays message: High leak detected, connect your tubing** | |
| Air tubing may not be connected properly. | Make sure the air tubing is firmly connected at both ends. |
| Mask may be fitted incorrectly. | Make sure your mask is fitted correctly. See your mask user guide for fitting instructions or use the Mask Fit function to check your mask fit and seal. |
| **Displays message: Tubing blocked, check your tubing** | |
| Air tubing may be blocked. | Check the air tubing and remove any blockages. Press the dial to clear the message and then press Start/Stop to restart the device. |
| **Displays message: Leak detected, check your system setup and all connections** | |
| Mask may be fitted incorrectly. | Make sure your mask is fitted correctly. See your mask user guide for fitting instructions or use the Mask Fit function to check your mask fit and seal. |
| **Displays message: Low MV detected** | |
| Minute ventilation level has dropped below the pre-set alarm level. | Contact your care provider. |
| **Displays message: Apnea detected** | |
| The device detects an apnea that has exceeded the pre-set alarm. | Breath normally to disable the alarm.<br>If the problem persists contact your care provider. |

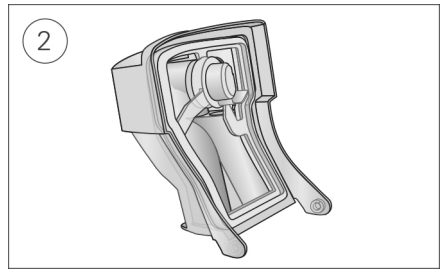
| Problem/possible cause | Solution |
|---|---|
| **Displays message: Low $SpO_2$ detected** | |
| $SpO_2$ has dropped below the pre-set alarm level. | Check the attachment of the sensor.<br><br>If the problem persists contact your care provider. |
| **Displays message: No $SpO_2$ data, check your oxi sensor attachment to module/finger** | |
| Oximeter sensor is not attached properly. | Ensure that the oximeter sensor is attached properly to the module and to your finger. |
| Oximeter sensor may be faulty. | If the message appears repeatedly, the oximeter sensor might be faulty. Replace the oximeter. |
| **Displays message: Non-vented mask detected, use vented mask or unblock your mask vents** | |
| Non-vented mask is used. | Only use a vented mask. |
| Mask vents might be blocked. | Check if you have sufficient venting. Unblock mask vents if necessary. |
| Expiratory pressure (EPAP) may be set too low. | Talk to your care provider about your settings. |
| **Displays message: System fault, refer to user guide, Error 004** | |
| Device may have been left in a hot environment. | Allow to cool before re-use. Disconnect the power supply and then reconnect it to restart the device. |
| Air filter may be blocked. | Check the air filter and replace it if there are any blockages. Disconnect the power supply and then reconnect it to restart the device. |
| Air tubing may be blocked. | Check the air tubing and remove any blockages. Press the dial to clear the message and then press Start/Stop to restart the device. |
| There may be water in the air tubing. | Empty the water from the air tubing. Disconnect the power supply and then reconnect it to restart the device. |
| **Displays message: System fault, refer to user guide, Error 022** | |
| Power cord may not be correctly inserted into the device. | Remove the power cord from the device and then re-insert it. Ensure that the power cord is fuly inserted into the device.<br><br>Note: the retention clip should be in the open position when inserting the plug. For instructions refer to the Setup section.<br><br>If the problem continues, contact your local ResMed dealer or ResMed office. Do not open the device. |
| **All other error messages, for example, System fault, refer to user guide, Error 0XX** | |
| An unrecoverable error has occurred on the device. | Contact your care provider. Do not open the device. |

## Reassembling parts

Some parts of your device are designed to easily come off in order to avoid damage to the parts or the device. You can easily reassemble them as described below.

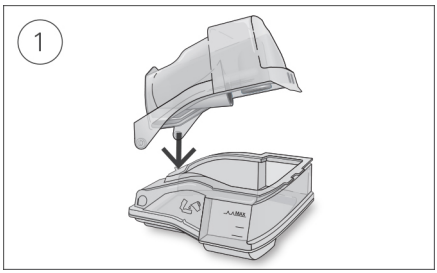
To insert the humidifier seal:




1. Place the seal into the lid.
2. Press down along all edges of the seal until it is firmly in place.

To reassemble the humidifier lid:





1. Insert one side of the lid into the pivot hole of the base.
2. Slide the other side down the ridge until it clicks into place.

## General warnings and cautions

### ⚠ WARNING

- Make sure that you arrange the air tubing so that it will not twist around the head or neck.
- 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.
- If you notice any unexplained changes in the performance of the device, if it is making unusual sounds, if the device or the power supply are dropped or mishandled, or if the enclosure is broken, discontinue use and contact your care provider or your ResMed Service Center.
- 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.
- Beware of electrocution. Do not immerse the device, power supply or power cord in water. If liquids are spilled into or onto the device, unplug the device and let the parts dry. Always unplug the device before cleaning and make sure that all parts are dry before plugging it back in.
- Supplemental oxygen must not be used while smoking or in the presence of an open flame.
- Always make sure 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 perform any maintenance tasks while the device is in operation.
- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.
- Regularly check the antibacterial filter for signs of moisture or other contaminants, particularly during nebulization or humidification. Failure to do so could result in increased breathing system resistance.
- The device has not been tested or certified for use in the vicinity of X-ray, CT or MRI equipment. Do not bring the device within 4 m of X-ray or CT equipment. Never bring the device into an MR environment.
- Therapy settings should not be changed remotely for patients in a hospital setting.

### ⚠ CAUTION

- Use only ResMed parts and accessories with the device. Non-ResMed parts may reduce the effectiveness of the treatment and/or damage the device.
- 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 the fresh air into the mask.
- Be careful not to place the device where it can be bumped or where someone is likely to trip over the power cord.
- Blocking the air tubing and/or air inlet of the device while in operation 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.

- Do not place the device on its side as water might get into the device.
- Incorrect system setup may result in incorrect mask pressure reading. Ensure the system is correctly set up.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the device, the humidifier or air tubing. These solutions may cause damage or affect the humidifier performance and reduce the life of the products.
- If you use the humidifier, always place the device on a level surface lower than your head to prevent the mask and air tubing from filling with water.
- Leave the humidifier to cool for ten minutes before handling to allow the water to cool and to make sure that the humidifier is not too hot to touch.
- Make sure that the humidifier is empty before transporting the device.

Note: The device 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.

# Technical specifications

Units are expressed in cm $H_2O$ and hPa. 1 cm $H_2O$ is equal to 0.98 hPa.

| 90W power supply unit | |
|---|---|
| AC input range: | 100–240V, 50–60Hz 1.0–1.5A, Class II<br>115V, 400Hz 1.5A, Class II (nominal for aircraft use) |
| DC output: | 24V ⎓ 3.75A |
| Typical power consumption: | 53W (57VA) |
| Peak power consumption: | 104W (108VA) |

| Environmental conditions | |
|---|---|
| Operating temperature: | +5°C to +35°C<br>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 to 95% relative humidity, non-condensing |
| Operating altitude: | Sea level to 8,500' (2,591 m); air pressure range 1013 hPa to 738 hPa |
| Storage and transport temperature: | -20°C to +60°C |
| Storage and transport humidity: | 5 to 95% relative humidity, non-condensing |

### Electromagnetic compatibility

The Lumis complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC 60601-1-2:2014, 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 this ResMed device can be found on www.resmed.com/downloads/devices

### Classification: IEC60601-1:2005+A1:2012

Class II (double insulation), Type BF, Ingress protection IP22.

| Sensors | |
|---|---|
| Pressure sensors: | Internally located at device outlet, analog gauge pressure type, -5 to +45 cm $H_2O$ (-5 to +45 hPa) |
| Flow sensor: | Internally located at device inlet, digital mass flow type, -70 to +180 L/min |

### Maximum single fault steady pressure

Device will shut down in the presence of a single fault if the steady state pressure exceeds:
30 cm $H_2O$ (30 hPa) for more than 6 sec or 40 cm $H_2O$ (40 hPa) for more than 1 sec.

### Sound

Pressure level measured according to ISO 80601-2-70:2015 (CPAP mode):

| | |
|---|---|
| SlimLine: | 25 dBA with uncertainty of 2 dBA |
| Standard: | 25 dBA with uncertainty of 2 dBA |
| SlimLine or Standard and humidification: | 27 dBA with uncertainty of 2 dBA |

Power level measured according to ISO 80601-2-70:2015 (CPAP mode):

| | |
|---|---|
| SlimLine: | 33 dBA with uncertainty of 2 dBA |
| Standard: | 33 dBA with uncertainty of 2 dBA |
| SlimLine or Standard and humidification: | 35 dBA with uncertainty of 2 dBA |

Declared dual-number noise emission values in accordance with ISO 4871:1996.

### Alarm volume settings

Low (nominal 54 dBA), Medium (nominal 60 dBA), High (nominal 73 dBA)

### Physical - device and humidifier

| | |
|---|---|
| Dimensions (H x W x D): | 116 mm x 255 mm x 150 mm |
| Air outlet (complies with ISO 5356-1:2004): | 22 mm |
| Weight (device and cleanable humidifier): | 1336 g |
| Housing construction: | Flame retardant engineering thermoplastic |
| Water capacity: | To maximum fill line 380 mL |
| Cleanable humidifier - material: | Injection molded plastic, stainless steel and silicone seal |

### Temperature

| | |
|---|---|
| Maximum heater plate: | 68°C |
| Cut-out: | (74°C |
| Maximum gas temperature: | ≤ 41°C |

### Air filter

| | |
|---|---|
| Standard: | Material: Polyester non woven fiber<br>Average arrestance: >75% for ~7 micron dust |
| Hypoallergenic: | Material: Acrylic and polypropylene fibers in a polypropylene carrier<br>Efficiency: >98% for ~7-8 micron dust; >80% for ~0.5 micron dust |

### Aircraft use

ResMed confirms that device meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160, section 21, category M) for all phases of air travel.

### Wireless module

| | |
|---|---|
| Technology used: | 3G 2G GSM |

It is recommended that the device is a minimum distance of 2 cm from the body during operation.

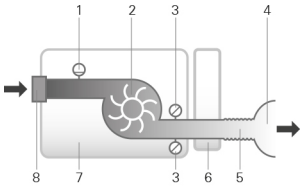
### Operating pressure range

| | |
|---|---|
| S, ST, T, PAC, iVAPS: | 2 to 30 cm $H_2O$ (2 to 30 hPa) |
| CPAP | 4 to 20 cm $H_2O$ (4 to 20 hPa) |

### Supplemental oxygen

| | |
|---|---|
| Maximum flow: | 15 L/min (S, ST, T, PAC, CPAP), 4 L/min (iVAPS) |

### Pneumatic flow path




1. Flow sensor
2. Blower
3. Pressure sensor
4. Mask
5. Air tubing
6. Humidifier
7. Device
8. Inlet filter

### Design life

| | |
|---|---|
| Device, power supply unit: | 5 years |
| Cleanable humidifier: | 2.5 years |
| Air tubing: | 6 months |

### General

The patient is an intended operator.

### Operator position

The device is designed to be operated within arm's length. An operator should position their line of sight within an angle of 30 degrees from a plane perpendicular to the screen.

### Humidifier performance

| Mask Pressure cm $H_2O$ (hPa) | Nominal RH output % | | Nominal system output AH[1], BTPS[2] | |
|---|---|---|---|---|
| | Setting 4 | Setting 8 | Setting 4 | Setting 8 |
| 3 | 85 | 100 | 6 | >10 |
| 4 | 85 | 100 | 6 | >10 |
| 10 | 85 | 100 | 6 | >10 |
| 20 | 85 | 90 | 6 | >10 |
| 25 | 85 | 90 | 6 | >10 |
| 30 | 85 | 90 | 6 | >10 |

[1] AH - Absolute Humidity in mg/L

[2] BTPS - Body Temperature Pressure Saturated

### Air tubing

| Air tubing | Material | Length | Inner diameter |
|---|---|---|---|
| ClimateLineAir | Flexible plastic and electrical components | 2 m | 15 mm |
| ClimateLineAir Oxy | Flexible plastic and electrical components | 1.9 m | 19 mm |
| SlimLine | Flexible plastic | 1.8 m | 15 mm |
| Standard | Flexible plastic | 2 m | 19 mm |
| 3 m | Flexible plastic | 3 m | 19 mm |

Heated air tubing temperature cut-out: ≤ 41°C

Notes:

- The manufacturer reserves the right to change these specifications without notice.
- 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 antistatic air tubing.
- The temperature and relative humidity settings displayed are not measured values.

## Displayed values

| Value | Range | Display resolution |
|---|---|---|
| Pressure sensor at air outlet: | | |
| Mask pressure | 2–30 cm $H_2O$ (2–30 hPa) | 0.1 cm $H_2O$ (0.1 hPa) |
| Flow derived values: | | |
| Leak | 0–120 L/min | 1 L/min |
| Tidal volume | 0–4000 mL | 1 mL |
| Respiratory rate | 0–50 BPM | 1 BPM |
| Minute ventilation | 0–30 L/min | 0.1 L/min |
| Ti | 0.1–4.0 sec | 0.1 sec |
| I:E ratio | 1:100–2:1 | 0.1 |

| Value | Accuracy[1] |
|---|---|
| Pressure measurement[1]: | |
| Mask pressure[2] | ±[0.5 cm $H_2O$ (0.5 hPa) + 4% of measured value] |
| Flow and flow derived values[1]: | |
| Flow | ±6 L/min or 10% of reading, whichever is greater, at 0 to 150 L/min positive flow |
| Leak[2] | ±12 L/min or 20% of reading, whichever is greater, 0 to 60 L/min |
| Tidal volume[2,3] | ±20% |
| Respiratory rate[2,3] | ±1.0 BPM |
| Minute ventilation[2,3] | ±20% |

[1] Results are expressed as STPD (Standard Temperature and Pressure, Dry). 101.3kPa at an operating temperature of 20°C, dry.

[2] Accuracy may be reduced by the presence of leaks, supplemental oxygen, tidal volumes <100 mL or minute ventilation <3 L/min.

[3] Measurement accuracy verified as per EN ISO 10651-6:2009 for Home Care Ventilatory Support Devices (Figure 101 and Table 101) using nominal ResMed mask vent flows.

## Measurement system uncertainties

In accordance with ISO 80601-2-70:2015 the measurement uncertainty of the manufacturer's test equipment is:

| | |
|---|---|
| For measures of flow | ± 1.5 L/min or ± 2.7% of reading (whichever is greater) |
| For measures of volume (< 100 mL) | ± 5 mL or 6% of reading (whichever is greater) |
| For measures of volume (≥ 100 mL) | ± 20 mL or 3% of reading (whichever is greater) |
| For measures of pressure | ± 0.15 cm $H_2O$ (0.15 hPa) |
| For measures of time | ± 10 ms |

## Pressure accuracy

**Maximum static pressure variation at 10 cm $H_2O$ (10 hPa) according to ISO 80601-2-70:2015**

| | Standard air tubing | SlimLine air tubing |
|---|---|---|
| Without humidification | ± 0.5 cm $H_2O$ (± 0.5 hPa) | ± 0.5 cm $H_2O$ (± 0.5 hPa) |
| With humidification | ± 0.5 cm $H_2O$ (± 0.5 hPa) | ± 0.5 cm $H_2O$ (± 0.5 hPa) |

**Maximum dynamic pressure variation according to ISO 80601-2-70:2015**

Device without humidification and Standard air tubing / Device with humidification and Standard air tubing

| Pressure [cm $H_2O$ (hPa)] | 10 BPM | 15 BPM | 20 BPM |
|---|---|---|---|
| 4 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 8 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 12 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 16 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 20 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 25 | 0.3 / 0.3 | 0.5 / 0.4 | 0.7 / 0.7 |

Device without humidification and SlimLine air tubing / Device with humidification and SlimLine air tubing

| Pressure [cm $H_2O$ (hPa)] | 10 BPM | 15 BPM | 20 BPM |
|---|---|---|---|
| 4 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 8 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 12 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 16 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 20 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 25 | 0.4 / 0.3 | 0.6 / 0.5 | 0.8 / 0.8 |

## Pressure accuracy - bilevel

Maximum dynamic pressure variation according to ISO 80601-2-70:2015.

Device without humidification and Standard air tubing / Device with humidification and Standard air tubing

| Breath rate | Inspiratory pressure (cm $H_2O$ [hPa]) (Means, Standard Deviations) | | | | | |
|---|---|---|---|---|---|---|
| | 6 | 10 | 16 | 21 | 25 | 30 |
| 10 BPM | -0.09, 0.01 / -0.22, 0.01 | -0.01, 0.07 / -0.22, 0.01 | 0.07, 0.05 / -0.24, 0.01 | -0.03, 0.09 / -0.29, 0.03 | 0.12, 0.01 / -0.26, 0.02 | 0.12, 0.01 / -0.14, 0.02 |
| 15 BPM | 0.02, 0.08 / -0.22, 0.01 | 0.12, 0.01 / -0.22, 0.01 | 0.15, 0.01 / -0.26, 0.01 | 0.15, 0.01 / -0.31, 0.02 | 0.16, 0.12 / -0.30, 0.02 | 0.20, 0.05 / -0.22, 0.02 |
| 20 BPM | 0.17, 0.01 / -0.23, 0.01 | 0.21, 0.01 / -0.28, 0.01 | 0.25, 0.01 / -0.34, 0.01 | 0.21, 0.17 / -0.38, 0.02 | 0.32, 0.02 / -0.40, 0.03 | 0.34, 0.02 / -0.34, 0.03 |
| Breath rate | Expiratory pressure (cm $H_2O$ [hPa]) (Means, Standard Deviations) | | | | | |
| | 2 | 6 | 12 | 17 | 21 | 25 |
| 10 BPM | -0.14, 0.01 / -0.27, 0.01 | -0.16, 0.01 / -0.29, 0.02 | -0.11, 0.10 / -0.34, 0.02 | -0.16, 0.05 / -0.33, 0.01 | -0.17, 0.05 / -0.33, 0.02 | 0.04, 0.17 / -0.21, 0.01 |
| 15 BPM | -0.16, 0.01 / -0.25, 0.01 | -0.20, 0.01 / -0.33, 0.02 | -0.20, 0.05 / -0.35, 0.01 | -0.21, 0.05 / -0.38, 0.02 | -0.23, 0.08 / -0.38, 0.02 | 0.04, 0.21 / -0.25, 0.01 |
| 20 BPM | -0.27, 0.01 / -0.37, 0.01 | -0.26, 0.02 / -0.34, 0.01 | -0.25, 0.01 / -0.38, 0.01 | -0.29, 0.01 / -0.43, 0.02 | -0.31, 0.01 / -0.45, 0.03 | -0.13, 0.23 / -0.31, 0.01 |

Device without humidification and SlimLine air tubing / Device with humidification and SlimLine air tubing

| Breath rate | Inspiratory pressure (cm $H_2O$ [hPa]) (Means, Standard Deviations) | | | | | |
|---|---|---|---|---|---|---|
| | 6 | 10 | 16 | 21 | 25 | 30 |
| 10 BPM | -0.26, 0.01 / -0.52, 0.01 | -0.25, 0.02 / -0.53, 0.02 | -0.24, 0.02 / -0.53, 0.01 | -0.25, 0.02 / -0.54, 0.02 | -0.20, 0.02 / -0.51, 0.02 | -0.07, 0.09 / -0.18, 0.02 |
| 15 BPM | -0.26, 0.01 / -0.51, 0.01 | -0.25, 0.01 / -0.54, 0.01 | -0.26, 0.01 / -0.56, 0.01 | -0.31, 0.03 / -0.58, 0.02 | -0.30, 0.05 / -0.60, 0.03 | 0.18, 0.08 / -0.25, 0.02 |
| 20 BPM | -0.25, 0.02 / -0.52, 0.01 | -0.29, 0.02 / -0.58, 0.01 | -0.34, 0.02 / -0.62, 0.01 | -0.36, 0.02 / -0.67, 0.02 | -0.36, 0.03 / -0.69, 0.02 | 0.36, 0.02 / -0.40, 0.02 |
| Breath rate | Expiratory pressure (cm $H_2O$ [hPa]) (Means, Standard Deviations) | | | | | |
| | 2 | 6 | 12 | 17 | 21 | 25 |
| 10 BPM | -0.28, 0.01 / -0.43, 0.01 | -0.30, 0.03 / -0.50, 0.01 | -0.30, 0.01 / -0.54, 0.01 | -0.33, 0.01 / -0.58, 0.01 | -0.34, 0.01 / -0.60, 0.02 | -0.27, 0.01 / -0.30, 0.01 |
| 15 BPM | -0.24, 0.02 / -0.37, 0.01 | -0.29, 0.02 / -0.47, 0.01 | -0.35, 0.01 / -0.55, 0.01 | -0.38, 0.01 / -0.62, 0.02 | -0.42, 0.02 / -0.66, 0.01 | -0.33, 0.01 / -0.36, 0.01 |
| 20 BPM | 0.05, 0.21 / -0.38, 0.01 | -0.31, 0.02 / -0.50, 0.02 | -0.37, 0.02 / -0.57, 0.02 | -0.43, 0.02 / -0.65, 0.02 | -0.48, 0.02 / -0.68, 0.02 | -0.43, 0.02 / -0.45, 0.01 |

Note: The table above is based on data that covers between 60.1 and 88.8% of the inspiratory phase and 66.1 and 93.4% of the expiratory phase durations. These data time slots start immediately after the initial transient overshoot/undershoot periods and end at the point that flow diminishes to an equivalent absolute value of its starting point, towards the end of the breath phases (this corresponds to the % ranges of values given immediately above).

### Flow (maximum) at set pressures

The following are measured accordingly to ISO 80601-2-70:2015 at the end of the specified air tubing:

| Pressure cm $H_2O$ (hPa) | Lumis and Standard L/min | Lumis, humidification and Standard L/min | Lumis and SlimLine L/min | Lumis, humidification and ClimateLineAir L/min |
|---|---|---|---|---|
| 4 | 180 | 143 | 162 | 151 |
| 8 | 168 | 135 | 151 | 142 |
| 12 | 157 | 136 | 140 | 135 |
| 16 | 144 | 134 | 128 | 121 |
| 20 | 131 | 123 | 117 | 109 |
| 25 | 120 | 115 | 96 | 84 |

## Guidance and manufacturer's declaration electromagnetic emissions and immunity

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

The Lumis device has been designed to meet EMC standards. However, should you suspect that the device performance (eg, pressure or flow) is affected by other equipment, move the device away from the possible cause of interference.

### Guidance and manufacturer's declaration—electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment — guidance |
|---|---|---|
| RF emissions CISPR 11<br>GB 4824 | Group 1 | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11<br>GB 4824 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes. |
| Harmonic Emissions<br>IEC 61000-3-2<br>GB 17625.1 | Class A | |
| Voltage Fluctuations/Flicker Emissions<br>IEC 61000-3-3<br>GB 17625.2 | Complies | |

### Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

| Immunity test | IEC60601-1-2 test level | Compliance level | Electromagnetic environment — guidance |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2<br>GB/T 17626.2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |

| Immunity test | IEC60601-1-2 test level | Compliance level | Electromagnetic environment — guidance |
|---|---|---|---|
| Electrical fast transient/burst<br>IEC 61000-4-4<br>GB/T 17626.4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5<br>GB/T 17626.5 | ±1 kV differential mode<br>±2 kV common mode | ±1 kV differential mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11<br>GB/T 17626.11 | <5% Ut (>95% dip in Ut) for 0.5 cycle<br>40% Ut (60% dip in Ut) for 5 cycles<br>70% Ut (30% dip in Ut) for 25 cycles<br><5% Ut (>95% dip in Ut) for 5 sec | <5% Ut (>95% dip in Ut) for 0.5 cycle<br>40% Ut (60% dip in Ut) for 5 cycles<br>70% Ut (30% dip in Ut) for 25 cycles<br><5% Ut (>95% dip in Ut) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment.<br>If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8<br>GB/T 17626.8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF<br>IEC 61000-4-6<br>GB/T 17626.6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms<br>150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF<br>IEC 61000-4-3<br>GB/T 17626.3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m<br>80 MHz to 2.5 GHz | Recommended separation distance<br>$d = 1.2 \sqrt{P}$<br>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz<br>Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:  |

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes:

- Ut is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.

- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

### Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter (W) | Separation distance according to frequency of transmitter (m) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz<br>$d = 1.2 \sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.2 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Symbols

The following symbols may appear on the product or packaging.

Read instructions before use. Indicates a warning or caution. Follow instructions before use. Manufacturer. EC REP European Authorized Representative. LOT Batch code. REF Catalog number. SN Serial number. DN Device number. On / Off. Device weight. IP22 Protected against finger sized objects and against dripping water when tilted up to 15 degrees from specified orientation. Direct current. Type BF applied part. Class II equipment. Humidity limitation. Temperature limitation. Non-ionising radiation. **Rx Only** Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician). MAX Maximum water level. DISTILLED WATER ONLY Use distilled water only. Operating altitude. 70 kPa 106 kPa Atmospheric pressure limitation. Complies with RTCA DO-160 section 21, category M. MR unsafe (do not use in the vicinity of an MRI device). Contains no China environmental hazardous substances. 10 20 10/20 years of China environmental protection use period.

Hazardous substances

| Part name | Hazardous Substances | | | | | |
|---|---|---|---|---|---|---|
| | Lead (Pb) | Mercury (Hg) | Cadmium (Cd) | Hexavalent Chromium (Cr6) | Polybrominated biphenyls (PBB) | Polybrominated diphenyl ethers (PBDE) |
| Power Supply Unit 90W | X | O | O | O | O | O |

O: Indicates that the content of toxic and hazardous substances in all homogeneous materials of the part is below the contraction limit required as described in GB/T 26572-2011.

X: Indicates that the content of toxic and hazardous substance in at least one homogeneous material of part exceeds the concentration limit requirement as described in GB/T 26572-2011.

The Environmentally Friendly User Period (EFUP) for the **90W AC Adapter** is per the symbol shown here. Certain parts may have a different EFUP and will be marked as such. The EFUP is valid only when the product is operated under the conditions defined in the user guide.

The Environmentally Friendly User Period (EFUP) for the **Lumis device** is per the symbol shown here, unless otherwise marked. Certain parts may have a different EFUP and will be marked as such. The EFUP is valid only when the product is operated under the conditions defined in the user guide.

### Environmental information

This device 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 Lumis device is intended to provide safe and reliable operation when operated in accordance with the instructions provided by ResMed. ResMed recommends that the Lumis device be inspected and serviced by an authorized ResMed Service Centre if there is any sign of wear or concern with device function. Otherwise, service and inspection of the products generally should not be required during their design life.

## 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 | 90 days |
| • Accessories—excluding single-use devices | |

| Product | Warranty period |
| --- | --- |
| • Flex-type finger pulse sensors<br>• Humidifier water tubs | |
| • Batteries for use in ResMed internal and external battery systems | 6 months |
| • Clip-type finger pulse sensors<br>• CPAP and bilevel device data modules<br>• Oximeters and CPAP and bilevel device oximeter adapters<br>• Humidifier cleanable water tubs<br>• Titration control devices | 1 year |
| • CPAP, bilevel and ventilation devices (including external power supply units)<br>• Humidifiers<br>• Battery accessories<br>• 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 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.

## Further information

If you have any questions or require additional information on how to use the device, contact your care provider.

# 欢迎

Lumis™ 150 VPAP ST-A 是一种双水平气道正压。

## ⚠警告

- 使用装置前，请阅读此指南内所有内容。
- 根据本指南中提供的预期用途使用装置。
- 相比本指南中提供信息，由主治医生提供的建议应该优先服从。

# 使用指示

### Lumis 150 VPAP ST-A

Lumis 150 VPAP ST-A装置适用于为体重超过 13 kg（或在 iVAPS 模式下体重超 过 30 kg） 且患有呼吸功能不 全或阻塞性睡眠呼吸暂停（OSA）的患者提供无创通气。 它适合在家中和医院中使用。

增湿器用于在家中供一名患者使用，在医院/机构中可重复使用。

禁忌症

患有以下已有病症的患者，可能要禁用气道正压通气疗法:

- 严重肺大泡性疾病
- 气胸或纵隔气肿
- 病理性低血压，尤其是如果伴有血管内血容量耗竭
- 脱水
- 脑脊液外漏、近期开颅手术或外伤。

不良反应

若出现异常胸痛、严重头痛或呼吸困难程度增加，须告知您的经治医生。
出现急性上呼吸道感染时，可能需要暂时中止治疗。

以此装置实施治疗时，可能会出现以下副作用:

- 口鼻或喉咙干燥
- 鼻衄
- 腹胀
- 耳部或额窦不适
- 眼部刺激
- 皮疹。

# 简介

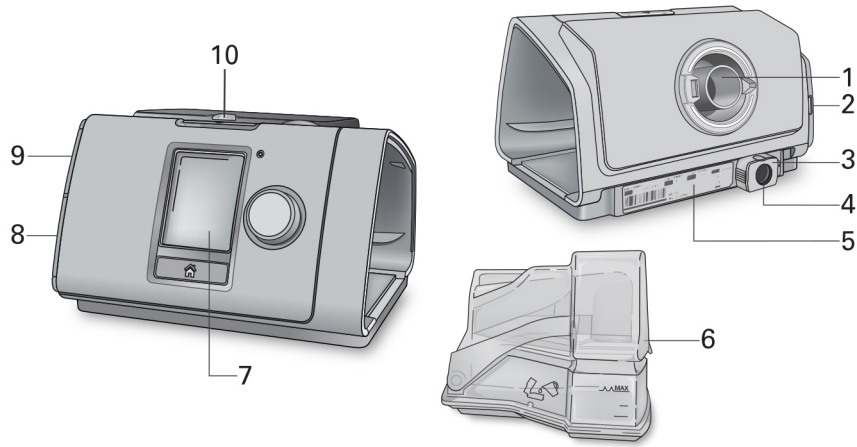
Lumis包括以下：

- 装置
- HumidAir™湿化器（如果提供的话）
- 空气管线
- 电源装置
- 旅行包
- SD卡（已经插入）。

联系您的保健服务提供商以了解一系列可用于装置的附件，包括：

- 空气管线（加热和未加热的）：ClimateLineAir™、ClimateLineAir Oxy, SlimLine™、标准
- HumidAir湿化器
- 不与湿化器配套使用的侧盖
- 过滤器： 低过敏原性过滤器、标准过滤器
- Air10™ DC/DC 转换器 (12V/24V)
- SD卡读卡器
- Air10 血氧仪适配器
- Air10 USB 适配器
- Power Station II
- Air10 管路弯头.

## 关于您的装置




1 空气输出口
2 空气过滤器盖
3 固定夹
4 电源线插口
5 序列号和装置号
6 HumidAir 增湿器
7 屏幕
8 适配器盖
9 SD 插卡盖
10 LED 报警指示灯

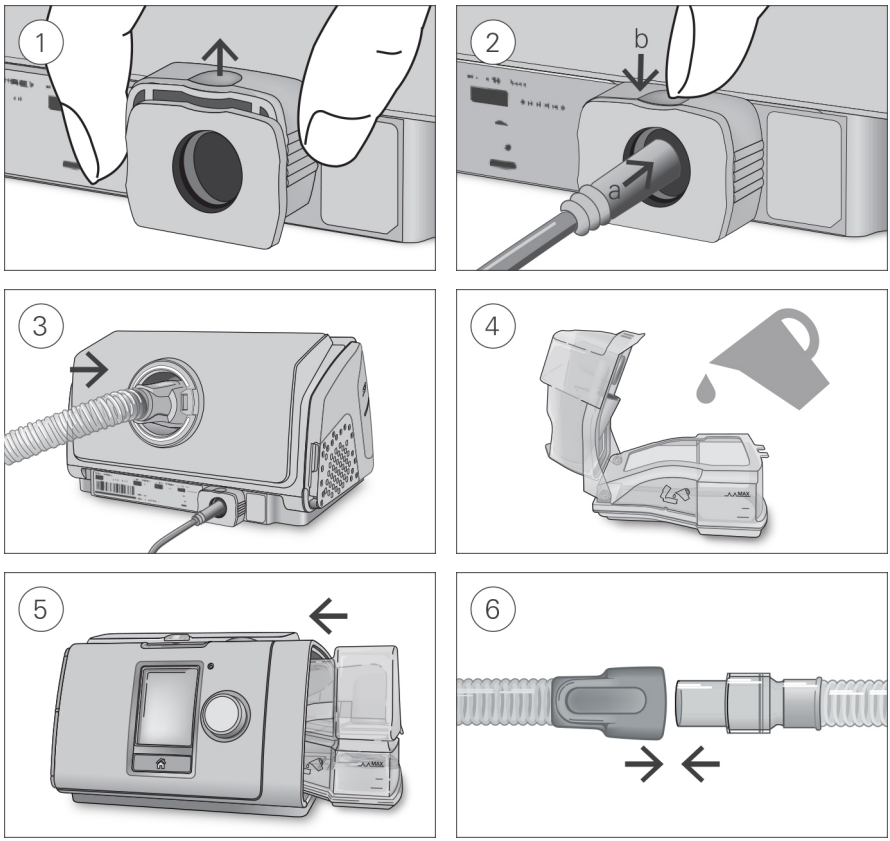
## 关于控制面板

| | | |
|---|---|---|
|  | 开始/停止按钮 | 按下以开始/停止治疗。<br>按下并按住3秒以进入省电模式。 |
|  | 微调器 | 找到导航菜单，按下以选择一个选项。<br>旋转以调节已选定的选项，然后按下以保存更改。 |
|  | 首页按钮 | 按下以返回到首页屏幕。 |

不同时间里屏幕上可能会显示不同的图标，包括：

| | | | |
|---|---|---|---|
|  | 升压时间 |  | 无线信号强度（绿色） |
|  | 湿度 |  | 未启用无线传输（灰色） |
|  | 增湿器加温 |  | 没有无线连接 |
|  | 增湿器冷却 |  | 飞机模式 |
|  | 报警静音 | | |

# 设置




## ⚠注意

不得在增湿器中添加过多的水，以免水进入装置和空气管线。

1. 将装置放在稳定、水平表面上，握住装置背面的固定夹，拉起以打开装置。 注意：固定夹显示在打开位置。
2. (a) 将电源插头插入装置的电源插口，然后 (b) 向下推固定夹以固定到位。连接电源线的一头到呼吸机电源接口，另一头至电源插座。
3. 将空气管线牢固地连接至位于设备后面的空气输出口。
4. 打开湿化器并将水添加到最大水位线标志处。不得将热水装入湿化器。
5. 关闭湿化器并将其插入设备的一侧。
6. 将空气管线的自由端牢固地连接到组装好的面罩。参阅面罩用户指南中的详细信息。

推荐的面罩可在 www.resmed.com 网站上找到。

注意： 确保装置放置的方式使 LED 报警指示灯可以清楚看见。

# 开始治疗

1. 佩戴您的面罩。
2. 如果已启用智能启动，按下开始/停止按钮或正常呼吸。

当监测屏幕显示时，您就会知道治疗正在进行。


压力栏用绿色显示吸气和呼气压力。 绿条会随着您吸气和呼气而扩大和缩小。

很短一段时间后会自动黑屏。 您可以按下首页或微调器将屏幕重新打开。
如果治疗期间电源中断，恢复供电时，装置将自动重新启动治疗。

Lumis 装置有一个光传感器，它会根据室内光线调节屏幕亮度。

# 停止治疗

1. 取下您的面罩。
2. 按下开始/停止按钮，或者如果已启用智能启动，治疗会在几秒钟后自动停止。

备注： 如果启用了确认停止，会显示一条消息，询问您是否要停止治疗。
旋转调节键以选择确认，然后按下调节键以停止治疗。

治疗停止后，睡眠报告给出一份您的治疗时段的总结。


使用时间–指示上一次接受治疗的小时数。

面罩密封–显示面罩的密封程度：

面罩密封良好。

需要调整，请参阅面罩试戴。

增湿器–指示您的增湿器正常工作。

增湿器正常工作。

增湿器可能会出现故障，联系您的保健服务提供商。

如果由您的保健服务提供商设置，您将也会看到：

每小时事件–指示每小时呼吸暂停和呼吸浅慢经历的次数。

更多信息–旋转微调器向下滚动来查看更多的使用时间数据细节。

## 省电模式

Lumis装置记录您的治疗数据。
为了使装置能够向您的保健服务提供商传输数据，切勿拔下装置的电源插头。
但您可以将装置置于省电模式以省电。

要进入省电模式：

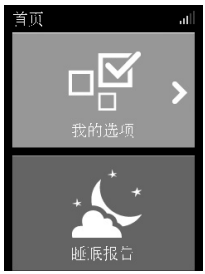
- 按下开始/停止按钮并按住三秒钟。
  屏幕变黑。

要退出省电模式：

- 按下开始/停止按钮一次。
  首页屏幕显示。

# 我的选项

您的Lumis装置应该已由您的保健服务提供商按您的需要设置完毕，但是您可能会发现您需要稍作调整以使您的治疗更加舒适。





加亮 我的选项并且按下微调器查看当前设定。
从这里，您可以对您的选项进行个性化设置。

## 延迟升压时间

延迟升压时间功能是为了治疗开始时感到更舒适而设计的，这期间是压力从低的开始压力至指定的治疗压力。

您可以将升压时间设定为关闭或5至45分钟之间。



调整延迟升压时间：

1. 在 我的选项界面，旋转微调器至升压时间变亮，然后按下微调器。
2. 旋转微调器将延迟升压时间调至您想要设定的值，然后按下微调器保存更改。

## 延迟降压

延迟降压旨在通过在固定的 15 分钟时间内降低压力而使停止治疗的过程更舒适。
该选项仅将通过您的保健服务提供商提供给您。


要启用延迟降压：

1. 在我的选项，旋转微调器至延迟降压变亮，然后按下微调器。
2. 旋转微调器选择开启，然后按下微调器保存更改。

要开始延迟降压：

1. 按下开始/停止按钮。

备注： 如果启用了确认停止，会显示一条消息，询问您是否要开始延迟降压。
旋转调节键以选择确认，然后按下调节键以开始延迟降压。

延迟降压图标 和剩下的时间将显示在屏幕的左下角。

延迟降压完成后，设备会继续在低压下运行。 要在任何时候停止治疗，按开始/停止按钮。

## 湿度水平

增湿器将空气湿化从而设计使治疗更加舒适。 如果您感到口鼻干燥，开大湿度。
如果您感到面罩内有任何湿气，关小湿度。

您可以将湿度水平设定为关闭或1和8之间，其中1为最低湿度设置，8是最高湿度设置。



调节湿度水平：

1. 在 我的选项界面，旋转微调器至湿度水平变亮，然后按下微调器。
2. 旋转微调器调节湿度水平，然后按下微调器保存更改。

如果仍然感觉到您的面罩干燥或潮湿，考虑使用ClimateLineAir加热空气管线。ClimateLineAir连同温度控制会给予更舒适的治疗。

## 面罩试戴

面罩试戴旨在帮助您评估并确定面罩周围是否可能漏气。


检查面罩试戴：

1. 按照面罩用户指南戴上面罩。
2. 在 我的选项界面，旋转微调器至运行面罩试戴变亮，然后按下微调器。装置开始输送气体。
3. 调整面罩、面罩护垫和头带，直到显示良好结果为止。

要停止面罩试戴，按下微调器或开始/停止按钮。
如果无法获得良好的面罩密封，请致电保健服务提供商。

## 更多选项

您的设备上还有更多可以个性化设定的选项。

| | |
|---|---|
| 面罩 | 该选项显示您的面罩类型的设置。<br>如果您使用一种以上类型的面罩，在面罩更换时，调节这一设置。 |
| 运行预热 | 该选项允许您在开始治疗前预热水槽，使治疗起始空气不冷或不干燥。 |
| 延迟降压* | 该选项旨在通过在固定的15 分钟时间内降低压力而使停止治疗的过程更舒适。 |
| 漏气警报* | 启用漏气警报后，治疗期间如果面罩漏气过多或者如果您取下面罩，设备会发出蜂鸣声。 |
| SmartStart（智能启动）* | 智能启动启动后，当您在面罩内呼气时，治疗会自动开始。<br>当您取下面罩后，它会在几秒钟后自动停止。 |

*在您的保健服务提供商启用了的情况下。

# 操作报警

装置配备一个报警功能，可监测您的治疗并提醒您可能影响您的治疗的变化。

当电源连接到装置时，黄色的 LED 报警指示灯会闪烁，报警会发出声响以确认报警正在工作。


当报警启动时，黄色的 LED 报警指示灯会闪烁，报警会发出声响并且会有一则消息出现在屏幕上。

## 使启动的报警静音


要使报警静音：

1. 按下微调器。会出现一份已启动报警的列表并且闪烁的报警静音图标 _ 会出现于屏幕的右上角。
   报警会静音 1 分钟 50。
2. 要回到上个屏幕，突出显示“确定”，然后按微调器。

一旦纠正了启动报警的情况，报警声和闪烁图标会停止。

如果启动报警的情况在 1分50秒后仍然存在，会重新发生报警。

如需要有关管理常见报警情况的协助，请参阅报警故障排除部分。

## 多个报警


如果多个报警同时启动，最新的报警消息会出现在屏幕上，任何其他启动的报警会显示在报警列表中。

## 查看报警


要查看报警列表：

1. 从监测画面，按顺时针方向转动微调器直到最后的监测 画面 显示。
2. 要查看报警详细信息，突出显示报警，然后按微调器。

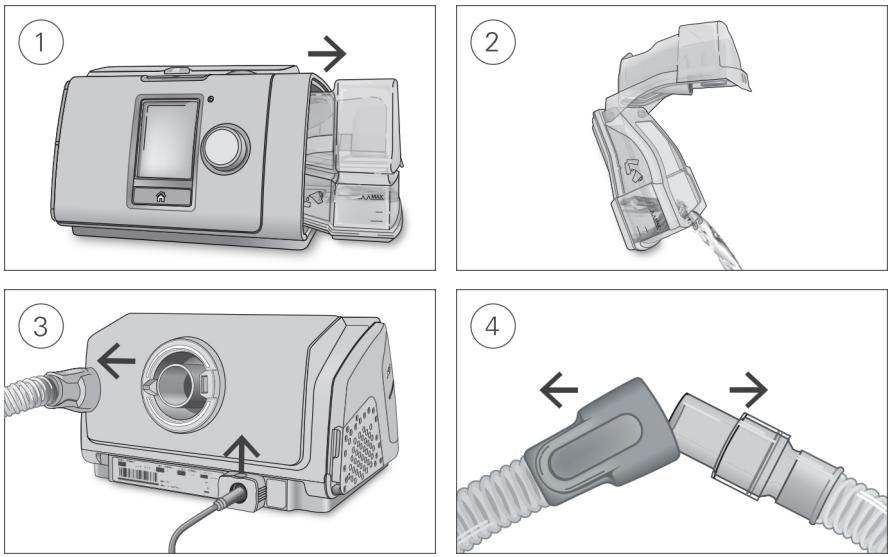
# 维护您的装置

定期清洁您的Lumis装置对确保您获得优化的治疗是十分重要的。
以下的部分将会帮助您拆卸、清洁、检查和重新组装您的装置。

## ⚠警告

定期清洁管路套组、增湿器和面罩，以获得最佳治疗，并防止细菌滋生，细菌滋生可能会对您的健康造成不良影响。

## 拆卸




1. 抓住湿化器的上部和底部，轻轻地按压并从呼吸机上拉出。
2. 打开湿化器并倒掉所有残余的水。
3. 抓住空气管线的接口并轻轻地将其从设备上拉开。
   抓住并拉起固定夹，以松开电源线。
4. 同时抓住空气管线的接口和面罩的转环，然后轻轻地拉开。

## 清洁

如前所述您应该每周都清洁装置。 参阅面罩用户指南关于清洁您面罩的细节信息。

1. 用含有柔和洗涤剂的温水清洗增湿器和空气管线。
2. 彻底冲洗增湿器和空气管线，自然晾干，避免阳光直射/或高温。
3. 用干布擦拭装置外部。

备注：

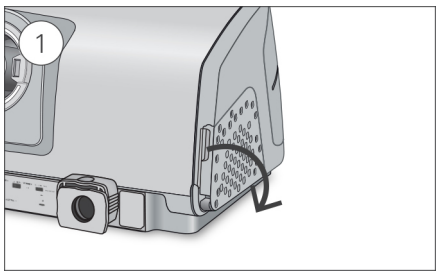
- 每天排空增湿器，并用一次性使用的洁净的布彻底擦试。 自然晾干，避免阳光直射和/或高温。
- 增湿器可以在洗碗机中以轻柔或用于玻璃器皿的周期清洗（仅适用于顶架）。
  清洗温度不应高于65°C。
- 不得在洗碗机或洗衣机中清洗空气管线。

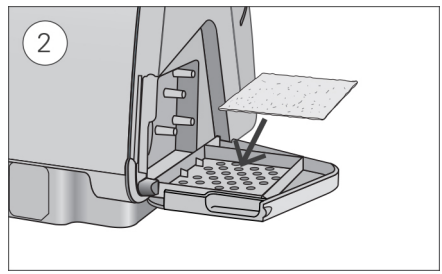
## 检查

您需要定期检查增湿器、空气管线和空气过滤器是否有任何损坏。

1. 检查增湿器：
   - 若出现漏水或裂纹、混浊或凹痕，请更换。
   - 如果密封条出现裂纹或撕裂，请更换。
   - 用一份食醋兑10 份水的溶液去除任何白色水垢。
2. 检查空气管线，若有任何破洞、撕裂或裂纹，请更换。
3. 至少每6个月检查并更换一次空气过滤器。 如果有破洞或因污垢、灰尘造成的堵塞，请更经常更换。

更换空气过滤器：




1. 打开空气过滤器盖并取下旧的空气过滤器。
   空气过滤器不可清洗，也不可重复使用。
2. 将新的空气过滤器放在空气过滤器盖上，然后关上它。
   确保空气过滤器一直安装以防止水和灰尘进入装置。

## 重新组装

增湿器和空气管线干燥后，就可以重新组装部件。

1. 将空气管线牢固地连接至位于装置后面的空气输出口。
2. 打开增湿器，将室温下的蒸馏水装至最高水位线标志处。
3. 关闭增湿器并将其插入到装置的一侧。
4. 将空气管线的自由端牢固地连接到组装好的面罩系统。

# 治疗数据

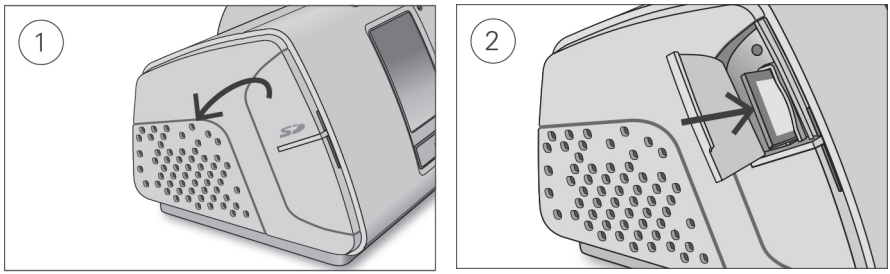
Lumis 装置为您和您的保健服务提供商记录您的治疗数据，以便他们需要时查看并且对您的治疗做出变动。数据被记录，然后通过无线或者是SD插卡传输给您的保健服务提供商。

## SD插卡

您的治疗数据可通过SD插卡传输给您的保健服务提供商。您的保健服务提供商可能会要求您将 SD 插卡寄过去或者带过去。当得到保健服务提供商的指示后，取下SD插卡。

SD指示灯闪烁时不得从装置中取出SD 插卡，因为此时正在向卡内写入数据。

取下SD插卡：




1. 打开SD 插卡盖。
2. 推入SD 插卡将其释放。 从装置上取出SD 插卡。
   将SD 插卡放在保护套中，然后将它寄回给您的保健服务提供商。

欲了解更多关于SD插卡的信息，请参阅装置附带SD插卡保护套信息。

备注： SD 插卡不应用于任何其他目的。

数据管理和治疗依从性

您的Lumis装置配有一个蜂窝调制解调器。治疗结束后，装置的数据可以无线传输。为了确保数据传输及时，您应将装置保持连接到电源，并确保它不处于飞机模式。

备注：

- 若您是在购买国家或地区境外使用该装置，可能无法传输治疗数据。
- 无线通讯取决于网络的可得性。
- 具备无线通讯功能的装置可能并非在所有国家或地区均有销售。

# 旅行

无论去哪您可以随身携带您的Lumis装置。 只需牢记以下几点：

- 使用提供的旅行包防止装置损坏。
- 排空增湿器并将其单独装入旅行包。
- 确保您有适合您所要旅行区域的电源线。 有关购买信息，请联系您的保健服务提供商。
- 如果您使用的是外接电池，您应该关闭增湿器以使电池的寿命最大化。
  通过关闭湿度水平来关闭增湿器。

## 乘飞机旅行

您的Lumis装置可以作为随身行李带上飞机。医疗装置不计入您的随身行李限额。

您可以在飞机上使用您的Lumis装置，因为他符合联邦航空管理局（FAA）的要求。
飞机旅行依从性的信件可以从www.resmed.com网站上下载打印。

在飞机上使用本装置时：

- 确保增湿器已完全排空，并插入到您的装置中。 未插入增湿器的情况下该装置将不会工作。
- 打开飞行模式。



要打开飞行模式：

1. 在我的选项界面，旋转微调器以亮显飞行模式，然后按下微调器。
2. 旋转微调器以选择开启，然后按下微调器保存更改。
   飞行模式图标 ✈ 显示在屏幕右上角。

## ⚠注意

增湿器中有水时，不得在飞机上使用该装置，因为在晃动中有吸入水的危险。

# 故障排除

如果您有任何问题，可以查阅下列故障排除专题。如果您不能解决问题，请联系您的医疗服务提供方或是ResMed。不得试图打开装置。

## 常见故障排除

| 问题/可能的原因 | 解决方案 |
|---|---|
| 空气从我的面罩周围泄漏出来。 | |
| 面罩可能未佩戴好。 | 请确认面罩已佩戴好。<br>请参阅面罩的用户指南了解佩戴的说明，或使用面罩试戴功能来检查面罩适配和密封是否良好。 |
| 我的鼻子干燥或不通。 | |
| 湿度水平可能设置的太低。 | 调节湿度水平。<br>如果您有ClimateLineAir加热的呼吸管，参阅ClimateLineAir用户指南。 |
| 我的鼻子、面罩和空气管线内有水滴。 | |
| 湿度水平可能设置的太高了。 | 调节湿度水平。<br>如果您有ClimateLineAir加热的呼吸管，参阅ClimateLineAir用户指南。 |
| 我的口腔干燥不适。 | |
| 空气可能从您的口中溢出。 | 增加湿度水平。<br>您或许需要一个下巴托来保持您的嘴巴关闭或者是一个全脸面罩。 |
| 我面罩内的空气压力似乎太高了（感觉我吸入了太多的空气） | |
| 延迟升压可能关闭了。 | 使用延迟升压时间选项。 |

| 问题/可能的原因 | 解决方案 |
| --- | --- |
| 我面罩内的空气压力似乎太低了（感觉我没有吸入足够的空气） | |
| 升压可能正在进行  。 | 请等候空气压力上升或关闭升压时间。 |
| 延迟降压可能正在进行  。 | 按开始/停止按钮停止治疗，然后按开始/停止按钮重新启动并继续治疗。 |
| 使用了无排气孔面罩。 | 仅可使用有排气孔面罩。 |
| 面罩排气孔可能堵住。 | 检查您是否有足够的排气。 如有必要，疏通面罩排气孔。 |
| 呼气压力（呼气压 (EPAP)）可能设置太低。 | 将您的设定告诉保健服务提供商。 |
| 黑屏了。 | |
| 屏幕上的背景灯可能关闭了。<br>一个短暂的时间之后，它会自动关闭。 | 按下首页或者微调器将它重新打开。 |
| 电源可能没有连接。 | 连接电源并且确保插头插入完全。<br>注意：插入插头时，固定夹应位于打开位置。<br>如需详细说明，请参阅设定部分。 |
| 我已经停止治疗，但是装置仍然在输送气体。 | |
| 装置正在冷却。 | 为了避免空气管线里的凝结，装置会吹少量的空气。30分钟之后它会自动停止工作。 |
| 我的增湿器漏气 | |
| 增湿器可能未组装好。 | 检查增湿器是否有损坏，然后重新组装好。 |
| 增湿器可能有损坏或裂纹。 | 与您的保健服务提供商联系更换事宜。 |
| 我的治疗数据还没有传送给保健服务提供商。 | |
| 电源可能没有连接。 | 连接电源并且确保插头插入完全。<br>注意：插入插头时，固定夹应位于打开位置。<br>如需详细说明，请参阅设定部分。 |
| 无线覆盖范围可能不佳。 | 确保装置放在有无线覆盖的地方（即放在您的床头桌上，而不是放在抽屉里或地面上）。<br>无线信号强度图标 <br>显示所有竖条时，表示无线覆盖范围良好；未显示所有竖条时，表示无线覆盖范围不佳。 |
| 屏幕右上角显示没有无线连接图标  <br>没有可用的无线网络。 | 确保装置放在有无线覆盖的地方（即放在您的床头桌上，而不是放在抽屉里或地面上）。<br>如果系统提示您这样做，将SD 插卡寄给您的保健服务提供商。 SD 插卡也包含您的治疗数据。 |

| 问题/可能的原因 | 解决方案 |
| --- | --- |
| 装置可能在飞行模式下。 | 关闭飞行模式，请参阅乘飞机旅行。 |
| 显示消息： 只读卡，请移除，开启并重新插入 SD 卡 | |
| SD 插卡开关可能在锁定（只读）位置。 | 将SD插卡上的开关从锁定位置 移动到解锁位置，然后重新插入。 |

## 报警故障排除

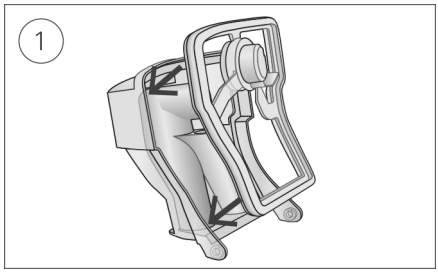
| 问题/可能的原因 | 解决方案 |
| --- | --- |
| 显示会消失且会有一个报警启动 | |
| 电源故障。 | 移除您的面罩直到供电恢复。 |
| 电源线断开连接或干线电源在治疗期间已被关闭。 | 确保电源线连接且干线电源开关（如有）处于开启位置。 |
| 显示消息： 检测到大量漏气，请检查储水盒密封垫或侧盖 | |
| 增湿器可能未插好。 | 确保增湿器已插好。 |
| 增湿器密封条可能未插好。 | 打开增湿器，确保密封条已插好。 |
| 显示消息： 检测到大量漏气，请检查管路是否连接妥当 | |
| 空气管线可能连接不当。 | 确认空气管线两端都已牢固连接。 |
| 面罩可能未佩戴好。 | 请确认面罩已佩戴好。<br>请参阅面罩的用户指南了解佩戴的说明，或使用面罩试戴功能来检查面罩适配和密封是否良好。 |
| 显示消息： 管路阻塞，请检查管路 | |
| 空气管线可能阻塞。 | 检查空气管线，去除所有的阻塞。<br>按下微调器清除该消息，然后按下开始/停止按钮以重新启动装置。 |
| 显示消息： 检测到漏气，请检查系统设定与所有连接点 | |
| 面罩可能未佩戴好。 | 请确认面罩已佩戴好。<br>请参阅面罩的用户指南了解佩戴的说明，或使用面罩试戴功能来检查面罩适配和密封是否良好。 |
| 显示消息：检测到低 MV | |
| 分钟通气量水平已经降到低于预设置的报警水平。 | 请联系您的代理商。 |
| 显示消息：检测到呼吸暂停 | |
| 装置检测到某个已超出预设置报警的呼吸暂停。 | 正常呼吸以禁用报警。<br>如果问题持续存在，请联系您的代理商。 |

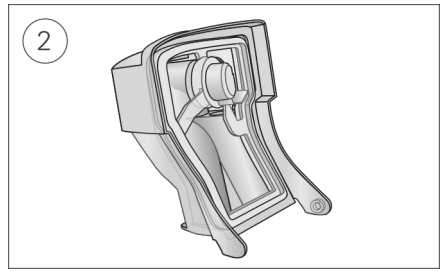
| 问题/可能的原因 | 解决方案 |
| --- | --- |
| 显示消息：检测到低脉氧饱和度。 | |
| 脉氧饱和度已降到低于预设置的报警水平。 | 检查传感器的连接情况。<br>如果问题持续存在，请联系您的代理商。 |
| 显示消息： 无 $SpO_2$ 数据，检查血氧仪传感器是否安装在模块/手指 | |
| 血氧仪传感器未正确连接。 | 确保血氧仪传感器妥善连接到模块和您的手指。 |
| 血氧仪传感器可能故障。 | 如果消息重复出现，血氧仪传感器可能故障。 更换血氧仪。 |
| 显示消息： 检测到无排气孔面罩，使用排气孔面罩或解锁面罩排气 | |
| 使用了无排气孔面罩。 | 仅可使用有排气孔面罩。 |
| 面罩排气孔可能堵住。 | 检查您是否有足够的排气。 如有必要，疏通面罩排气孔。 |
| 呼气压力（呼气压 (EPAP)）可能设置太低。 | 将您的设定告诉保健服务提供商。 |
| 显示消息： 系统故障，请参阅用户指南中的错误项 004 | |
| 设备可能被置于过热环境。 | 待其冷却后再使用。 断开电源，然后重新连接以便重启设备。 |
| 空气过滤器可能阻塞。 | 检查空气过滤器，如有阻塞则将其更换。<br>断开电源，然后重新连接以便重启设备。 |
| 空气管线可能阻塞。 | 检查空气管线，去除所有的阻塞。<br>按下微调器清除该消息，然后按下开始/停止按钮以重新启动装置。 |
| 空气管线中可能有水。 | 将水从空气管线中去除。 断开电源，然后重新连接以便重启设备。 |
| 显示消息： 系统故障，请参阅用户指南中的错误项 022 | |
| 电源线可能未正确插入装置。 | 从装置拔出电源线，然后重新插入。 确保电源线完全插入装置。<br>注意：插入插头时，固定夹应位于打开位置。<br>如需详细说明，请参阅设定部分。<br>如果问题仍旧持续，请联系您当地的 ResMed 经销商或 ResMed 办事处。 不得打开装置。 |
| 所有其他错误消息（例如系统故障），请参阅用户指南中的错误项0XX | |
| 装置上出现了一个无法恢复的错误。 | 请联系您的保健服务提供商。 不得打开装置。 |

## 重新组装部件

为了避免部件或装置的损坏，装置的一些部件被设计为容易脱离。
您可以根据以下描述很容易的重新组装他们。

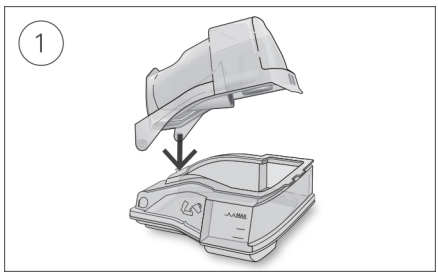
要插入增湿器密封条：

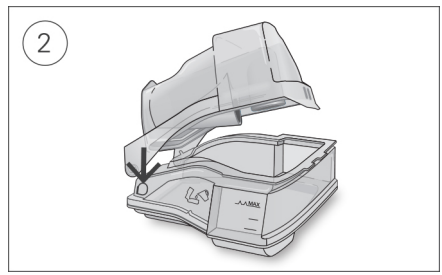



1. 将密封条放入盖内。
2. 向下按压密封条的各边缘，直至其牢固到位。

要重新组装增湿器盖：




1. 将水槽盖的一边插入到底座的轴心孔内。
2. 沿边缘向下滑动另一边直至卡入到位。

# 一般性警告和注意事项

## ⚠警告

- 确保已整理好空气管线，使其不会缠绕在头或颈部周围。
- 确保电源线和插头处于良好状态，且设备无任何损坏。
- 确保电源线远离过热表面。
- 如果您发现本装置的性能发生任何无法解释的变化、装置发出异常的声音、装置或电源坠落或操作不当、或者外壳损坏，请停止使用并与您的保健服务提供商或者ResMed服务中心联系。
- 不得打开或修改装置。 装置内没有用户可维修的部件。
  仅应由ResMed授权的维修商实施修理和维修。
- 小心触电。 不得将此装置、电源或电源线浸泡在水中。
  如果有液体流到装置里边或者表面，拔出电源插头，使该部件晾干。
  在清洗前务必拔出电源插头，并在插回电源插头前确保所有部件是干燥的。
- 吸烟或者存在明火时，切勿使用补充性供氧。
- 在开启供氧之前务必确保本装置已开启并已产生气流。
  在关闭装置之前务必关闭供氧，使未使用的氧气不在装置外壳内积累，造成火灾危险。
- 不得在装置工作期间执行任何保养任务。
- 在与其他设备毗邻或堆叠时，不应使用本装置。
  如果必须毗邻或堆叠使用，应观察装置运行情况，确保其在当前配置中运行正常。
- 除了指定用于装置的附件以外，不推荐使用其他附件。
  这些附件可能会增加辐射或降低本装置的抗干扰性。
- 定期检查细菌过滤器是否有水分或其他污染物的迹象，特别是在雾化或湿化过程中。否则可能导致呼吸系统阻力增加。
- 装置没有经过测试和认证的X射线，CT或MRI设备附近使用。不要将装置放在距离 X 光或 CT 设备的 4 米)内。切勿将装置带入磁共振环境中。
- 不应远程更改医院设置中的患者的治疗设置。

## ⚠注意

- 仅使用与装置一起的ResMed部件与附件。 非ResMed部件将会减少治疗的有效性和/或损坏装置。
- 仅使用由ResMed或者主治医生推荐的排气孔面罩与该装置。
  装置没有鼓气时面罩试戴会导致呼出的空气被再次吸入。
  确保面罩排气孔洞畅通无阻以便维持进入面罩的新鲜空气流量。
- 放置装置时要小心，不要放置在会使其受到碰撞或使人跩到电源线的地方。
- 装置正在运行时，如果阻塞空气管线和/或空气输入口，会导致装置过热。
- 确保装置周围区域的干燥清洁，无可能阻塞空气输入口或覆盖电源装置的任何物体（例如衣服或被褥）。
- 切勿把装置放置在旁，因为水可能会进入装置。
- 系统设定不正确可能会导致面罩压力读数不正确。 确保系统设定正确。
- 不得使用漂白剂、氯、酒精或芳香类溶液、湿润或抗菌肥皂或香味精油来清洁装置、增湿器或空气管线。 这些溶液可能会损坏或影响增湿器的性能，缩短产品使用寿命。
- 使用增湿器时，始终将装置放在低于头部的平面上，以免水进入面罩和空气管线。
- 在处理前，让增湿器冷却十分钟，使水冷却，以确保增湿器不会因为过热而难以触摸。
- 运输装置之前，确保增湿器已排空。

备注：
该装置并非意在由身体、感官或心智能力下降的人员（包括儿童）在没有负责患者安全的人员的充分监督下进行操作。

# 技术规格

单位均为cm $H_2O$和hPa。 1 cm $H_2O$等于0.98 hPa。

**90W**电源装置

| | |
|---|---|
| 交流电输入范围： | 100-240V, 50-60Hz 1.0-1.5A，II类<br>115V，400Hz 1.5A，II类（在飞机上使用时的标称值） |
| 直流电输出： | 24V ⎓ 3.75A |
| 典型功耗： | 53W（57VA） |
| 最大耗能： | 104W（108VA） |

环境条件

| | |
|---|---|
| 工作温度： | +5°C至+35°C<br>备注：<br>该治疗装置所产生供患者呼吸的气流温度可能会比室温高。在极端的环境温度条件下（40°C），装置仍可保持安全。 |
| 工作湿度： | 10%至95%相对湿度，非冷凝 |
| 工作海拔高度: | 海平面至 2,591 公尺，空气压力范围为1013 hPa至738 hPa。 |
| 存放和运输温度： | -20°C至+60°C |
| 存放和运输湿度： | 5%至95%相对湿度，非冷凝 |

电磁兼容性

Lumis符合IEC 60601-1-2:2014标准的所有适用电磁兼容性(EMC)要求，适用于民用、商用和轻工业环境。
建议将移动通信装置与本装置保持至少1m的距离。
有关该ResMed装置电磁辐射和抗干扰性方面的信息，请参阅www.resmed.com/downloads/devices。

分类：**IEC60601-1:2005+A1:2012**

II级（双重绝缘），BF型，IP22防护等级。

传感器

| | |
|---|---|
| 压力传感器： | 位于装置出口内，模拟压力型，-5 至 +45 cm $H_2O$ (-5 至 + 45 hPa) |
| 流量传感器： | 位于装置入口内，数字质量流量型，-70 至 +180 升/分 |

最大单一故障稳定状态压力

如果超过稳定状态压力，装置会在存在一个单一故障时关机。
30 cm $H_2O$ (30 hPa)持续超过6秒或40 cm $H_2O$ (40 hPa)持续超过1秒。

声音

压力水平根据ISO 80601-2-70:2015 (CPAP 模式)测量：

| | |
|---|---|
| Slimline: | 25 dBA，正负2 dBA |
| 标准： | 25 dBA，正负2 dBA |
| SlimLine或标准和湿化： | 27 dBA，正负2 dBA |

功率级根据ISO 80601-2-70:2015 (CPAP 模式)测量：

| | |
|---|---|
| Slimline: | 33 dBA，正负2 dBA |
| 标准： | 33 dBA，正负2 dBA |
| SlimLine或标准和湿化： | 35 dBA，正负2 dBA |

声明的双数字噪音发声值符合ISO 4871:1996标准。

报警音量设定

低（标称 54 dBA）、中等 （标称 60 dBA）、高（标称 73 dBA）

物理特征 - 装置和增湿器

| | |
|---|---|
| 尺寸（高 x 宽 x 深）： | 116 毫米 x 255 毫米 x 150 毫米 |
| 空气输出口（符合 ISO 5356-1:2004 标准）： | 22 毫米 |
| 重量（装置和可清洁增湿器）： | 1336 g |
| 机壳材料： | 阻燃性工程热塑塑料 |
| 水槽容量： | 至最高水位时为380毫升 |
| 可清洁增湿器 - 材料： | 注塑成型塑料、不锈钢和硅胶密封条 |

温度

| | |
|---|---|
| 加热板最高温度： | 68°C |
| 断开： | 74°C |
| 气体最高温度： | ≤ 41°C |

空气过滤器

| | |
|---|---|
| 标准： | 材料： 聚酯非织物纤维<br>平均计重效率 >对约7微米的尘埃为75% |
| 低过敏原性： | 材料： 聚丙烯载体中的丙烯酸和聚丙烯纤维<br>功效： >对约7-8微米的灰尘为98%; ><br>对约0.5微米的灰尘为80% |

在飞机上使用

ResMed确认装置在空中旅行的所有阶段均满足美国联邦航空管理局(FAA)的要求（RTCA/DO-160，第 21节，M类）。

无线模块

| | |
|---|---|
| 应用的技术: | 3G 2G GSM |

操作过程中，建议装置最少距身体 2 厘米。不适用于面罩、管线和附件。

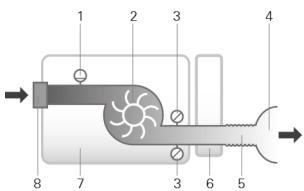
工作压力范围

| | |
|---|---|
| S、ST、T、PAC、iVAPS： | 2 至 30 cm $H_2O$（2 至 30 hPa） |
| CPAP | 4 至 20 cm $H_2O$ (4 至20 hPa) |

补充性供氧

| | |
|---|---|
| 最大流量： | 15 升/分 (S、ST、T、PAC、CPAP), 4 升/分(iVAPS) |

气流量通道




1. 流量传感器
2. 通风机
3. 压力传感器
4. 面罩
5. 空气管线
6. 增湿器
7. 装置
8. 进气口过滤器

设计寿命

| | |
|---|---|
| 装置，电源装置： | 5年 |
| 可清洁增湿器： | 2.5年 |
| 空气管线： | 6个月 |

一般信息

患者将为操作员。

操作者位置

装置的设计是允许在伸手可及的位置操作。操作者应将其视线放在与屏幕垂直的平面呈 30 度的范围内。

增湿器性能

| 面罩压力 cm $H_2O$ (hPa) | RH 标称输出 % | | 系统标称输出 AH[1], BTPS[2] | |
|---|---|---|---|---|
| | 设置4 | 设置8 | 设置4 | 设置8 |
| 3 | 85 | 100 | 6 | >10 |
| 4 | 85 | 100 | 6 | >10 |
| 10 | 85 | 100 | 6 | >10 |
| 20 | 85 | 90 | 6 | >10 |
| 25 | 85 | 90 | 6 | >10 |
| 30 | 85 | 90 | 6 | >10 |

[1] AH — 绝对湿度，以毫克/升为单位

[2] BTPS —饱和压力体温

空气管线

| 空气管线 | 材料 | 长度 | 内径 |
|---|---|---|---|
| ClimateLineAir | 柔软塑料和电子元件 | 2 米 | 15 毫米 |
| ClimateLineAir Oxy | 柔软塑料和电子元件 | 1.9 米 | 19 毫米 |
| SlimLine | 柔软塑料 | 1.8 米 | 15 毫米 |
| 标准 | 柔软塑料 | 2 米 | 19 毫米 |
| 3 米 | 柔软塑料 | 3 米 | 19 毫米 |

加热空气管线断开温度： ≤ 41°C

备注：

- 制造商保留修改这些规格的权利，恕不另行通知。
- 加热空气管线的电气接头端仅可以与装置端的空气输出口兼容并用，不得连接到面罩上。
- 不得使用导电或防静电的空气管线。
- 显示的温度和相对湿度设置非测量数值。

显示的值

| 值 | 范围 | 显示分辨率 |
|---|---|---|
| 空气输出口处的压力传感器： | | |
| 面罩压力 | 2–30 cm $H_2O$ (2–30 hPa) | 0.1 cm $H_2O$ (0.1 hPa) |
| 流量派生值： | | |
| 漏气 | 0 - 120 升/分 | 1 升/分 |
| 潮气量 | 0-4000毫升 | 1 毫升 |
| 呼吸频率 | 0–50 BPM | 1 BPM |
| 分钟通气量 | 0 - 30 升/分 | 0.1 升/分 |
| 吸气时间 | 0.1 - 4.0 秒 | 0.1 秒 |
| I:E 比 | 1:100–2:1 | 0.1 |

| 值 | 准确性[1] |
|---|---|
| 压力测量[1]： | |
| 面罩压力[2] | ±[0.5 cm $H_2O$ (0.5 hPa) +测量值的4%] |
| 流量和流量派生值[1]: | |
| 流量 | 在 0 至 150 升/分正压流量时为 ±6 升/分或读数的 10%，取较大者 |
| 漏气[2] | 在 0 至 60 升/分时为 ±12 升/分或读数的 20%，取较大者 |
| 潮气量[2,3] | ±20% |
| 呼吸频率[2,3] | ±1.0 BPM |
| 分钟通气量[2,3] | ±20% |

[1] 结果以 STPD（干燥标准温度和压力）表示。在 20 °C 的工作温度下为 101.3 kPa，干燥。

[2] 准确性可能因为存在漏气、补充性供氧、潮气量 < 100 毫升或分钟通气量 < 3 升/分而降低。

[3] 测量准确性根据针对居家护理通气支持装置的 EN ISO 10651-6:2009（图 101 和表 101），使用标称 ResMed 面罩排气口流量确认。

测量系统不确定性

依照 ISO 80601-2-70:2015，制造商的测试设备的测量不确定性为：

| | |
|---|---|
| 对于流量测量值 | ± 1.5升/分或读数的 2.7%(取较大者) |
| 对于容积测量值（< 100 毫升） | ± 5 毫升或读数的 6%（取较大者） |
| 对于容积测量值（≥ 100 毫升） | ± 20 毫升或读数的 3%（取较大者） |
| 对于压力测量值 | ± 0.15 cm $H_2O$ (0.15 hPa) |
| 对于时间测量值 | ± 10 毫秒 |

压力准确性

根据ISO 80601-2-70:2015标准，在10 cm H2O 条件下的最大静态压力变化

| | 标准空气管线 | SlimLine 空气管线 |
|---|---|---|
| 不使用湿化 | ± 0.5 cm $H_2O$ | ± 0.5 cm $H_2O$ |
| 使用湿化 | ± 0.5 cm $H_2O$ | ± 0.5 cm $H_2O$ |

根据 ISO 80601-2-70:2015 标准的最大动态压力变化

不使用湿化和标准空气管线 的装置/使用湿化和标准空气管线的装置

| 压力[cm $H_2O$] | 10 BPM | 15 BPM | 20 BPM |
|---|---|---|---|
| 4 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 8 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 12 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 16 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 20 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 25 | 0.3 / 0.3 | 0.5 / 0.4 | 0.7 / 0.7 |

不使用湿化 和SlimLine空气管路的装置/使用湿化和SlimLine空气管路的装置

| 压力[cm $H_2O$] | 10 BPM | 15 BPM | 20 BPM |
|---|---|---|---|
| 4 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 8 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 12 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 16 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 20 | 0.5 / 0.5 | 0.5 / 0.5 | 0.8 / 0.8 |
| 25 | 0.4 / 0.3 | 0.6 / 0.5 | 0.8 / 0.8 |

压力准确性 - 双水平

根据 ISO 80601-2-70:2015 标准的最大动态压力变化。

不使用湿化和标准空气管线的装置 /使用湿化和标准空气管线的装置

| 呼吸频率 | 吸气压力（cm $H_2O$ [hPa]）平均值，标准差 | | | | | |
|---|---|---|---|---|---|---|
| | 6 | 10 | 16 | 21 | 25 | 30 |
| 10 BPM | -0.09, 0.01 / -0.22, 0.01 | -0.01, 0.07 / -0.22, 0.01 | 0.07, 0.05 / -0.24, 0.01 | -0.03, 0.09 / -0.29, 0.03 | 0.12, 0.01 / -0.26, 0.02 | 0.12, 0.01 / -0.14, 0.02 |
| 15 BPM | 0.02, 0.08 / -0.22, 0.01 | 0.12, 0.01 / -0.22, 0.01 | 0.15, 0.01 / -0.26, 0.01 | 0.15, 0.01 / -0.31, 0.02 | 0.16, 0.12 / -0.30, 0.02 | 0.20, 0.05 / -0.22, 0.02 |
| 20 BPM | 0.17, 0.01 / -0.23, 0.01 | 0.21, 0.01 / -0.28, 0.01 | 0.25, 0.01 / -0.34, 0.01 | 0.21, 0.17 / -0.38, 0.02 | 0.32, 0.02 / -0.40, 0.03 | 0.34, 0.02 / -0.34, 0.03 |
| 呼吸频率 | 呼气压力 (cm $H_2O$ [hPa]) 平均值，标准差 | | | | | |
| | 2 | 6 | 12 | 17 | 21 | 25 |
| 10 BPM | -0.14, 0.01 / -0.27, 0.01 | -0.16, 0.01 / -0.29, 0.02 | -0.11, 0.10 / -0.34, 0.02 | -0.16, 0.05 / -0.33, 0.01 | -0.17, 0.05 / -0.33, 0.02 | 0.04, 0.17 / -0.21, 0.01 |
| 15 BPM | -0.16, 0.01 / -0.25, 0.01 | -0.20, 0.01 / -0.33, 0.02 | -0.20, 0.05 / -0.35, 0.01 | -0.21, 0.05 / -0.38, 0.02 | -0.23, 0.08 / -0.38, 0.02 | 0.04, 0.21 / -0.25, 0.01 |
| 20 BPM | -0.27, 0.01 / -0.37, 0.01 | -0.26, 0.02 / -0.34, 0.01 | -0.25, 0.01 / -0.38, 0.01 | -0.29, 0.01 / -0.43, 0.02 | -0.31, 0.01 / -0.45, 0.03 | -0.13, 0.23 / -0.31, 0.01 |

使用湿化 和SlimLine空气管路的装置/使用湿化和SlimLine空气管路的装置

| 呼吸频率 | 吸气压力（cm $H_2O$ [hPa]）平均值，标准差 | | | | | |
|---|---|---|---|---|---|---|
| | 6 | 10 | 16 | 21 | 25 | 30 |
| 10 BPM | -0.26, 0.01 / -0.52, 0.01 | -0.25, 0.02 / -0.53, 0.02 | -0.24, 0.02 / -0.53, 0.01 | -0.25, 0.02 / -0.54, 0.02 | -0.20, 0.02 / -0.51, 0.02 | -0.07, 0.09 / -0.18, 0.02 |
| 15 BPM | -0.26, 0.01 / -0.51, 0.01 | -0.25, 0.01 / -0.54, 0.01 | -0.26, 0.01 / -0.56, 0.01 | -0.31, 0.03 / -0.58, 0.02 | -0.30, 0.05 / -0.60, 0.03 | 0.18, 0.08 / -0.25, 0.02 |
| 20 BPM | -0.25, 0.02 / -0.52, 0.01 | -0.29, 0.02 / -0.58, 0.01 | -0.34, 0.02 / -0.62, 0.01 | -0.36, 0.02 / -0.67, 0.02 | -0.36, 0.03 / -0.69, 0.02 | 0.36, 0.02 / -0.40, 0.02 |
| 呼吸频率 | 呼气压力 (cm $H_2O$ [hPa]) 平均值，标准差 | | | | | |
| | 2 | 6 | 12 | 17 | 21 | 25 |
| 10 BPM | -0.28, 0.01 / -0.43, 0.01 | -0.30, 0.03 / -0.50, 0.01 | -0.30, 0.01 / -0.54, 0.01 | -0.33, 0.01 / -0.58, 0.01 | -0.34, 0.01 / -0.60, 0.02 | -0.27, 0.01 / -0.30, 0.01 |
| 15 BPM | -0.24, 0.02 / -0.37, 0.01 | -0.29, 0.02 / -0.47, 0.01 | -0.35, 0.01 / -0.55, 0.01 | -0.38, 0.01 / -0.62, 0.02 | -0.42, 0.02 / -0.66, 0.01 | -0.33, 0.01 / -0.36, 0.01 |
| 20 BPM | 0.05, 0.21 / -0.38, 0.01 | -0.31, 0.02 / -0.50, 0.02 | -0.37, 0.02 / -0.57, 0.02 | -0.43, 0.02 / -0.65, 0.02 | -0.48, 0.02 / -0.68, 0.02 | -0.43, 0.02 / -0.45, 0.01 |

注意：上表根据覆盖介于60.1%和88.8%之间的吸气相与介于66.1%和93.4% 之间的呼气相之数据得出。这些数据时隙在初始瞬时压力过高/过低期之后立即开始，在气流减弱到其起始点的一个相当绝对值、呼吸相行将结束之时结束（这与上面给出的%值范围相对应）。

设定压力下的流量（最大）

以下各项为根据 ISO 80601-2-70:2015 标准在指定空气管线末端所测得：

| 压力<br>cm $H_2O$(hPa) | Lumis和标准<br>升/分 | Lumis，湿化和标准<br>升/分 | Lumis和SlimLine<br>升/分 | Lumis，湿化和ClimateLineAir<br>升/分 |
|---|---|---|---|---|
| 4 | 180 | 143 | 162 | 151 |
| 8 | 168 | 135 | 151 | 142 |
| 12 | 157 | 136 | 140 | 135 |
| 16 | 144 | 134 | 128 | 121 |
| 20 | 131 | 123 | 117 | 109 |
| 25 | 120 | 115 | 96 | 84 |

## 指导和制造商的电磁辐射和抗干扰声明

医疗电气设备需采取特殊的电磁兼容性防范措施，需要根据本文档提供的电磁兼容性信息进行安装并投入使用。

按设计，Lumis装置符合电磁兼容性标准。然而，如果您怀疑装置的性能（如压力或流量）收到其他设备的影响，将装置从干扰的可能原因移开。

指导和制造商声明 —— 电磁辐射

该装置适用于以下指定的电磁环境中使用。该装置的客户或用户应确保装置在这样的环境中使用。

| 辐射测试 | 合规 | 电磁环境 —— 指导 |
|---|---|---|
| 射频辐射CISPR 11 | 1 组 | 装置仅将射频能量用于其内部功能。因此，其射频辐射非常低，不太可能对附近的电子设备造成任何干扰。 |
| 射频辐射CISPR 11 | B类 | 该装置适用于在所有建筑物使用，包括居住建筑物以及直接连接到供应用于居住用途的建筑物的公共低压电网的建筑物。 |
| 谐波辐射<br>IEC 61000-3-2 | A类 | |
| 电压波动/闪变辐射<br>IEC 61000-3-3 | 符合 | |

指导和制造商声明 —— 抗电磁干扰

该装置适用于以下指定的电磁环境中使用。该装置的客户或用户应确保装置在这样的环境中使用。

| 抗干扰测试 | IEC60601-1-2 测试水平 | 合规水平 | 电磁环境 —— 指导 |
|---|---|---|---|
| 静电放电(ESD)<br>IEC 61000-4-2 | ±6 kV接触<br>±8 kV空气 | ±6 kV接触<br>±8 kV空气 | 地板应为木质、水泥或瓷砖。如果地板铺设合成材料，相对湿度应至少为30%。 |
| 电快速瞬变/脉冲<br>IEC 61000-4-4 | ±2 kV，对于电源线<br>±1 kV，对于输入/输出线 | ±2 kV | 供电质量应该是典型的商业或医院环境的供电。 |
| 电涌<br>IEC 61000-4-5 | ±1 kV差分模式<br>±2 kV通用模式 | ±1 kV差分模式 | 供电质量应该是典型的商业或医院环境的供电。. |

| 抗干扰测试 | IEC60601-1-2 测试水平 | 合规水平 | 电磁环境 —— 指导 |
|---|---|---|---|
| 电源输入线的电压骤降、短时中断和电压变化IEC 61000-4-11 | <5% Ut (>Ut骤降95%），0.5个周期<br>40% Ut（Ut骤降60%），5个周期<br>70% Ut（Ut骤降30%），25个周期<br><5% Ut (>Ut骤降95%），5秒 | <5% Ut (>Ut骤降95%），0.5个周期<br>40% Ut（Ut骤降60%），5个周期<br>70% Ut（Ut骤降30%），25个周期<br><5% Ut (>Ut骤降95%），5秒 | 供电质量应该是典型的商业或医院环境的供电。<br>如果该装置的用户需要在电源中断期间继续操作，建议用不间断电源对装置供电。 |
| 电源频率 (50/60 Hz) 磁场IEC 61000-4-8 | 3 A/m | 3 A/m | 电源频率磁场应处于典型的商业或医院环境中的典型位置的特性水平。 |
| 传导射频 IEC 61000-4-6 | 3 Vrms 150 kHz至80 MHz | 3 Vrms 150 kHz至80 MHz | 便携式和移动式射频通信设备不在比发射机频率使用的公式计算的推荐间隔距离更接近设备的任何部分（包括电缆）的地方使用。 |
| 辐射射频 IEC 61000-4-3 | 3 V/m 80 MHz至2.5 GHz | 3 V/m 80 MHz至2.5 GHz | 推荐间隔距离<br>$d = 1.2 \sqrt{P}$<br>$d = 1.2 \sqrt{P}$ 80 MHz至800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz至2.5 GHz<br>其中，（P）为根据发射器制造商规定的发射器的额定最大输出功率（单位：瓦（W）），d为推荐的间隔距离（单位：米（m））。如电磁现场调查确定的固定射频发射器的磁场强度，[a]应小于每个频率范围的合规水平。[b]<br>在标有以下符号的设备附近可能发生干扰： |

[a] 固定发射器（如无线电基站（蜂窝/无绳）电话和陆地移动无线电、业余无线电，AM和FM无线电广播和电视广播）的磁场强度理论上无法准确预测。为了评估固定射频发射器的电磁环境，电磁现场调查应予以考虑。如果装置使用位置测得的磁场强度超过上述适用的射频合规水平，应观察装置确保其工作正常。如果观察到不正常的表现，可能需要采取更多措施，如重新调整或搬迁装置。

[b] 在150 kHz至80 MHz的频率范围内，磁场强度应小于3 V/m。.

备注：

- Ut是在应用测试水平之前的交流电源电压。
- 在80 MHz和800 MHz，更高的频率范围适用。
- 这些准则可能并不适用于所有情况。电磁传播受结构、物体和人体的吸收和反射的影响。.

便携式和移动式射频通信设备和设备之间的推荐间隔距离

该装置预期在辐射射频干扰受控的环境中使用。该装置的客户或用户可以根据通信设备的最大输出功率通过维持如以下建议的便携式和移动射频通信设备（发射器）和装置之间最小距离，帮助防止电磁干扰。

| 发射器的额定最大输出功率 (W) | 根据发射器频率的间隔距离 (m) | | |
|---|---|---|---|
| | 150 kHz至80 MHz<br>d = 1.2 √P | 80 MHz至800 MHz<br>d = 1.2√P | 800 MHz至2.5 GHz<br>d = 2.3 √P |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

对于额定最大输出功率非上文列出的发射器，可以用适用于发射器的公式计算出建议间隔距离d（单位：米（m）），其中P是根据发射器制造商规定的发射器最大输出功率（单位：瓦（W））。

备注：

- 在80 MHz和800 MHz，更高的频率范围的间隔距离适用。
- 这些准则可能并不适用于所有情况。电磁传播受结构、物体和人体的吸收和反射的影响。

## 符号

以下符号可能出现在产品或包装上。

使用前阅读说明。 指示警告或注意。 使用前遵循说明。 制造商。
EC REP 欧洲授权代表。 LOT 批代码。 REF 目录号。 SN 序列号。 DN 装置号。 开启 / 关闭。 装置重量 IP22 当向指定方向倾斜15 度时，防止手指大小的物体和滴水进入。 直流电。
BF 型应用部件。 II 类设备。 湿度限制。 温度限制。 无电离辐射
Rx Only 仅凭处方销售（在美国，联邦法律规定这些装置只能由医生出售或遵照医嘱销售。）
MAX 最高水位。 DISTILLED WATER ONLY 仅使用蒸馏水。 工作海拔高度。 大气压限制。 符合 RTCA DO-160 第 21 部分类别 M。 磁共振不安全（不要在磁共振成像装置附近使用）。
中国标志，产品不含有害物质。 中国标志，产品环保使用期限10/20年。

## 有害物质（仅限中国）

| 部件名称 | 有害物质 | | | | | |
|---|---|---|---|---|---|---|
| | 铅 (Pb) | 汞 (Hg) | 镉 (Cd) | 六价铬 (Cr6) | 多溴联苯 (PBB) | 多溴联苯醚 (PBDE) |
| 90W 电源装置 | X | O | O | O | O | O |

O：表示该部件所有均质材料中的有毒及有害物质含量低于 GB/T 26572-2011 中规定的浓度限值要求。

X：表示部件的至少一种均质材料中的有毒及有害物质含量超过 GB/T 26572-2011 中规定的浓度限值要求。

90W AC 适配器的环保用户期限 (EFUP) 按此处标志所示。某些部件可能有不同的 EFUP，会另有标识。只有当产品在用户指南规定的条件下运行时，EFUP 才有效。

除非另有说明，否则 Lumis 设备的环保用户期限 (EFUP) 按此处标志所示。某些部件可能有不同的 EFUP，会另有标识。只有当产品在用户指南规定的条件下运行时，EFUP 才有效。


环保信息

此装置需单独处置，不得作为不分类的市政废物处置。处置该装置时应该使用所在地区的适当收集、再利用和回收系统。按其设计，这些收集、再利用和回收系统可以减少对自然资源的危害，防止危险物质破坏环境。

如果需要了解有关这些处置系统的详细信息，请与所在地的废物管理部门联系。标有十字的垃圾筒标志表示您可使用这些处置系统。要了解有关ResMed装置的回收和处置信息，请与ResMed办事处或当地的经销商联系，或浏览以下网站：www.resmed.com/environment。

## 维修

按照ResMed提供的说明操作时，Lumis装置将会提供安全可靠的运行。
如果Lumis装置有磨损现象或者您对装置的功能有任何顾虑，ResMed建议应由授权的ResMed服务中心进行检查和维修。 否则，在设计使用寿命期间，产品通常不需要进行保养和检查。

## 有限保修

ResMed 有限公司（以下简称“ResMed”）保证，自购买日算起，在以下规定的期间内，您购买的 ResMed 产品没有材料和制造工艺方面的缺陷。

| 产品 | 保修期 |
|---|---|
| • 面罩系统（包括面罩框架、护垫、头带和管线） - 不包括一次性使用装置<br>• 配件 - 不包括一次性使用装置<br>• 柔性手指脉搏传感器<br>• 湿化器水槽 | 90 天 |
| • ResMed 内外电池系统使用的电池 | 6个月 |
| • 夹式手指脉搏传感器<br>• CPAP和双水平装置数据模块<br>• 血氧仪和CPAP和双水平装置血氧仪适配器<br>• 增湿器的可清洗水槽<br>• 滴定式控制装置 | 1年 |
| • CPAP、双水平装置和通气装置（包括外部供电装置）<br>• 增湿器<br>• 电池配件<br>• 便携式诊断/筛查装置 | 2年 |

该保修只适用于最初消费者。 不得转让。

如果在正常使用下产品出现故障，ResMed 将根据其具体选择对有缺陷的产品或任何元件予以修理或更换。

此有限保修不包括：a)因使用不当、滥用、改装或修改产品所造成的任何损坏；b)由未获得ResMed明确维修授权的维修机构实施的维修工作；以及c)香烟、烟斗、雪茄或其它烟制品所造成的任何损坏或污染。

如果产品被在最初购买地区以外销售或再销售，此保修则无效。

必须由原始消费者在购买处对有缺陷产品提出保修声明。

此保修代替所有其它明示或暗示的保修，其中包括对产品适销性或某特定用途适用性的任何暗示保修。某些国家/地区不允许限制暗示保修的时间期限，因此以上限制也许不适用于您。

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本保修授予您某些特定合法权利，您可能还有不同地区规定的其它权利。
有关保修权利的详细信息，请与当地的 ResMed 分销商或 ResMed 办事处联系。

## 补充信息

如果您有任何问题或需要关于如何使用本装置的更多信息，请联系您的保健服务提供商。

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