

DOC NO	288156
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REV	1

SPECIFICATION – PRINTED MATERIALS

Rev	Change Note	Date document drafted	Document prepared by (Name)	Document Checked by (Name)
1	K001608-00	24 July 2018	Melanie Theaker	Lisa Oliver or delegate refer to change note.

AirCurve 10 ST-A User Guide AMER Multi

1. ORACLE DESCRIPTION

AirCurve10 ST-A UG AMER MULTI

2. TRANSLATION DESCRIPTION

Refer to the Change History on the English source listed for summary of changes in each version.

Rev	English source	This translation replaces...
1	288009r4 plus changes shown below	288131

3. PRINT DETAILS

Print according to master spec R370-7240

4. RESMED QC INSPECTION

For general sampling and inspection requirements, refer to AWI203-002 Appendix A, Printed or Unprinted Materials and Labels, Criteria 1, 2, 3, 4, 5, 6, 8 and 9

Additional requirement

a) None

5. FOR ALL OTHER REQUIREMENTS, REFER TO RESMED SUPPLIER MANUAL AQP119.

6. CHANGE HISTORY

Section	Update
Tech Specs	Update of Wireless approval certificate id to add information for 4G FCC ID: 2ACHL-AIR104G IC ID: 9103A-AIR104G
Tech Specs	Update of Classification to be IEC 60601-1:2005+A1:2012
Tech Specs	Update of Wireless information to match Machine data for Tech comms rev 65
Cleaning	Add warning 'Regularly clean the tubing assembly, water tub and mask for optimal therapy and to prevent the growth of germs that can adversely the patient's health.

ResMed

AirCurve™10

ST-A

User guide



ResMed

AirCurve™ 10

ST-A

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AirCurve™ 10 | ST-A



User guide

User guide

English | Français | Español | Português

Welcome

The AirCurve™ 10 ST-A is a bilevel positive airway pressure device.

WARNING

Read this entire guide before using the device.

CAUTION

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

Indications for use

AirCurve 10 ST-A

The AirCurve 10 ST-A is indicated to provide non-invasive ventilation for patients weighing more than 30 lb (13 kg) with respiratory insufficiency or obstructive sleep apnea (OSA).

The iVAPS mode is indicated for patients weighing more than 66 lb (30 kg).

The AirCurve 10 ST-A 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

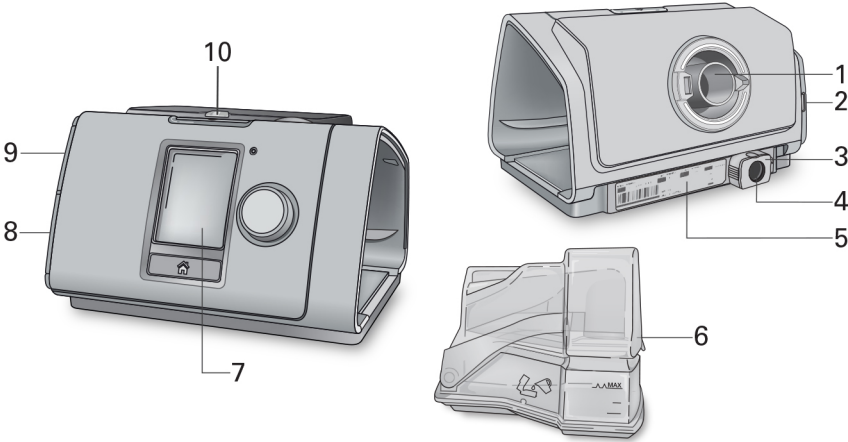
The AirCurve 10 includes the following:

- Device with HumidAir™ integrated humidifier
- Water tub
- 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
- Water tub: Standard water tub, cleanable water tub (can be disinfected)
- 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 (water tub)
- 7 Screen
- 8 Adapter cover
- 9 SD card cover
- 10 LED alarm indicator

About the control panel



Start/Stop button



Dial



Home button

Press to start/stop therapy.
Press and hold for three seconds to enter power save mode.

Turn to navigate the menu and press to select an option.
Turn to adjust a selected option and press to save your change.

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)

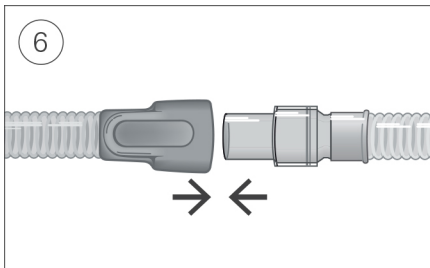
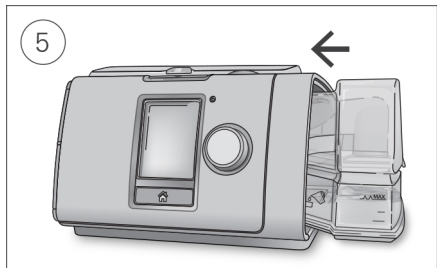
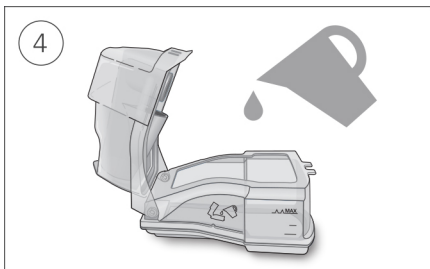
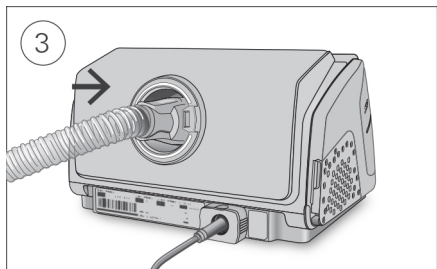
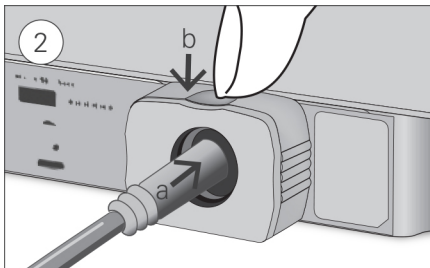
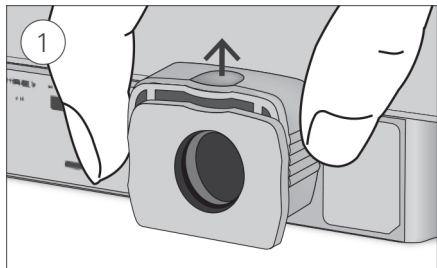


No wireless connection



Airplane Mode

Setup



CAUTION

Do not overfill the water tub 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 water tub and fill it with distilled water up to the maximum water level mark. Do not fill the water tub with hot water.
5. Close the water 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.

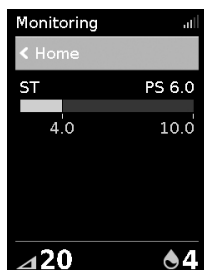
Recommended masks are available on www.resmed.com.

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 AirCurve 10 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 AirCurve 10 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:

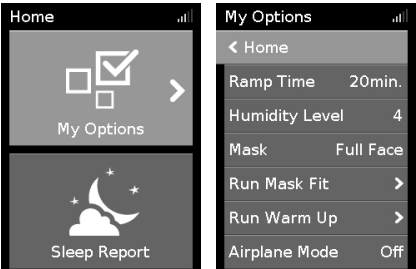
- Press and hold Start/Stop for three seconds.
The screen goes black.

To exit power save mode:

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

My Options

Your AirCurve 10 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.

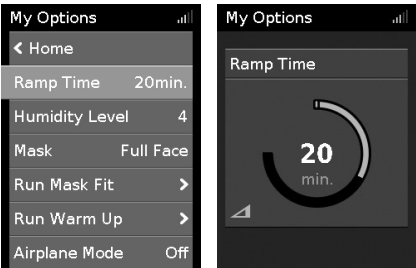


Highlight **My Options** and press the dial to see your current settings. From here, you can personalize your options.

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.
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

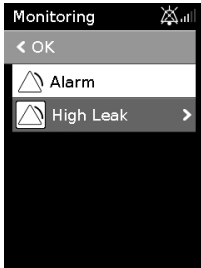
The device is fitted with an alarm feature that monitors your therapy and alerts you to changes that may affect your treatment.

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:

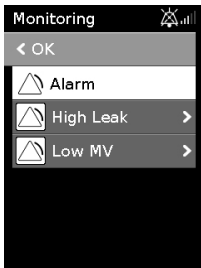
1. Press the dial. A list of activated alarms will appear and the flashing alarm mute icon  will be displayed in the top right corner of the screen. The alarm will be muted for 2 minutes.
2. To return to the previous screen, highlight OK and press the dial.

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 2 minutes, the alarm will re-occur.

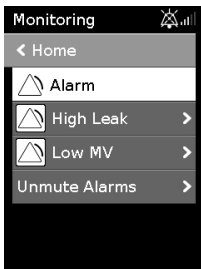
See the **Alarms troubleshooting** section for help with managing common alarm conditions.

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.

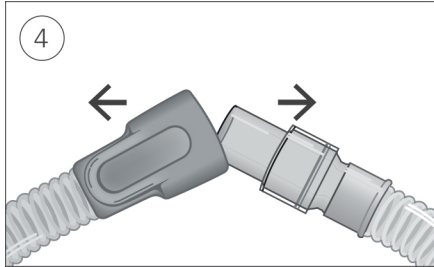
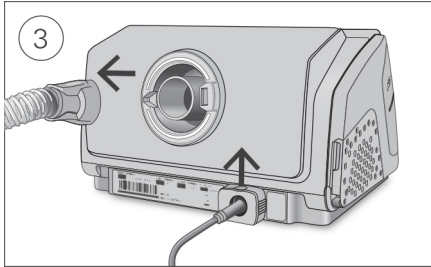
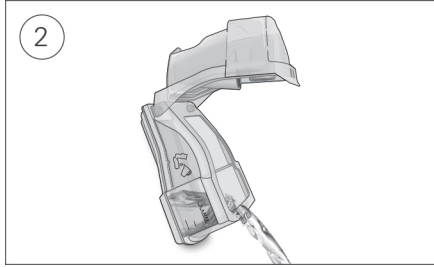
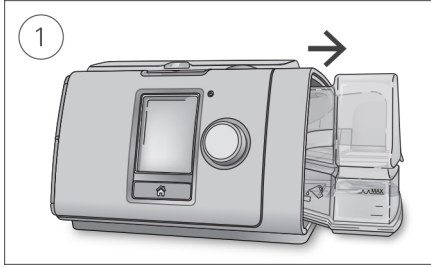
Caring for your device

It is important that you regularly clean your AirCurve 10 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 the tubing assembly, water tub and mak for optimal therapy and to prevent the growth of germs that can adversely affect the patient's health.

Disassembling



1. Hold the water tub at the top and bottom, press it gently and pull it away from the device.
2. Open the water tub 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.

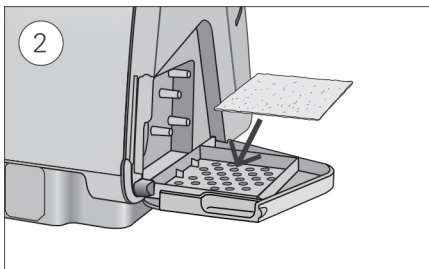
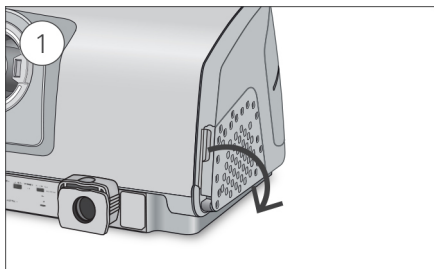
1. Wash the water tub and air tubing in warm water using mild detergent. Do not wash in a dishwasher or washing machine.
2. Rinse the water tub and air tubing thoroughly and allow to dry out of direct sunlight and/or heat.
3. Wipe the exterior of the device with a dry cloth.

Checking

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

1. Check the water 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 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 it 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 water tub 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 water tub and fill it with distilled room temperature water up to the maximum water level mark.
3. Close the water tub 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 AirCurve 10 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 then transferred to your care provider wirelessly, if wireless network is available, or via an SD card.

Data transmission

Your AirCurve 10 device has the capability of cellular communication so that your therapy data can be transmitted to your care provider to improve the quality of your treatment. It also allows your care provider to update your therapy settings in a more timely manner or upgrade your device software to ensure you receive the best therapy possible.

The data is usually transmitted after therapy has stopped. In order to make sure that your data is transferred:

- Leave your device connected to the power outlet at all times.
- Make sure that it is not in Airplane Mode.
- Check the Wireless signal strength icon  for adequate wireless coverage.

Notes:

- 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.

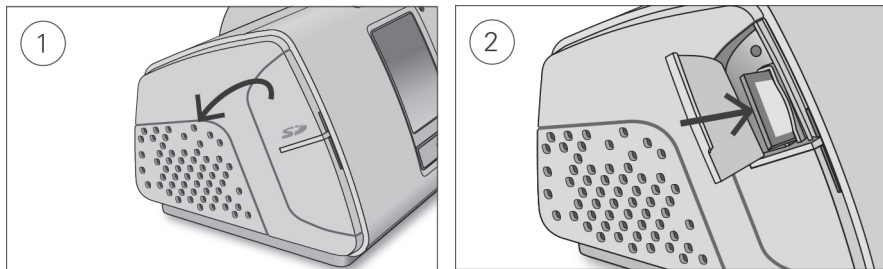
Please be aware that within the wireless network, the availability and quality of the network may be affected by terrain, buildings, and the weather. Wireless communication depends on network availability. Coverage is not available everywhere and varies by service.

SD card

An alternative way for your therapy data to be transferred to your care provider is 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.

Traveling

You can take your AirCurve 10 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 water tub 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.

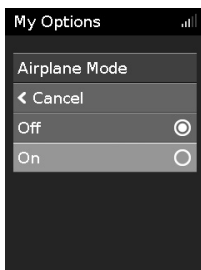
Traveling by plane

Your AirCurve 10 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 AirCurve 10 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 water tub is completely empty and inserted into your device. The device will not work without the water tub 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 water tub 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. 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. 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. 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. 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 water tub is leaking	
Water tub may not be assembled correctly.	Check for damage and reassemble the water tub correctly.
Water tub may be damaged or cracked.	Contact your care provider for a replacement.
My therapy data has not been sent to my care provider	
Power may not be connected.	Connect the power supply and make sure the plug is fully inserted. 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) and away from other communication devices. 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) and away from other communication devices. If instructed to do so, send the SD card to your care provider. The SD card also contains your therapy data.

Problem/possible cause	Solution
Device may be in Airplane Mode.	Turn off Airplane Mode, see Traveling by plane.
Data transfer is not enabled for your device.	Talk to your care provider about your settings.
My screen and buttons are flashing but there is no alarm sound or message	
Software upgrade is in progress.	Software upgrade takes approximately 10 minutes to complete.
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	
Water tub may not be inserted properly.	Make sure the water tub is correctly inserted.
Water tub seal may not be inserted properly.	Open the water tub 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.

Problem/possible cause	Solution
Displays message: Apnea detected	
The device detects an apnea that has exceeded the pre-set alarm.	Breathe normally to disable the alarm. If the problem persists contact your care provider.
Displays message: Low SpO₂ detected	
SpO ₂ has dropped below the pre-set alarm level.	Check the attachment of the sensor. If the problem persists contact your care provider.
Displays message: No SpO₂ 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 fully inserted into the device. Note: the retention clip should be in the open position when inserting the plug. For instructions refer to the Setup section. 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.