

# **Air**Mini<sup>™</sup>



User guide English | Deutsch | Français | Italiano Nederlands | العربية | Norsk | Svenska | Suomi







#### **FNGLISH**

#### Welcome

The ResMed AirMini™ system combines ResMed's AirMini selfadjusting pressure machine, masks and the AirMini by ResMed™ App.



# **⚠** WARNING

Read this entire guide before using the machine.

## Indications for use

The AirMini self-adjusting system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 30 kg. It is intended for home and hospital use.

### Clinical benefits

The clinical benefit of CPAP therapy is a reduction in appoeas. hypopnoeas and sleepiness, as well as improved quality of life.

The clinical benefit of humidification is the reduction of positive airway pressure related side effects.

## Contraindications

Positive airway pressure therapy may be contraindicated in some patients with the following pre-existing conditions:

- severe bullous lung disease
- pneumothorax
- pathologically low blood pressure
- dehydration
- cerebrospinal fluid leak, recent cranial surgery, or trauma.

# 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 machine:

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

# At a glance

The AirMini system includes the AirMini machine, a power supply unit, a drawstring bag, and one of the following:

- AirMini setup pack F30: air tubing and full face connector
- AirMini setup pack F20: air tubing, full face connector and HumidX™ F20
- AirMini setup pack N20: air tubing, N20 connector, HumidX and HumidX Plus
- AirMini mask pack for N30: air tubing, AirFit™ N30 for AirMini mask (M), N30 cushion (S), N30 cushion (SW), HumidX and HumidX Plus
- AirMini mask pack for P10: air tubing, AirFit P10 for AirMini mask (M), P10 cushion (S), P10 cushion (L), HumidX, HumidX Plus and AirFit P10 headgear clips

# Your AirMini system



- 1. Start/Stop button
- 2. Power inlet
- 3. Power outlet
- 4. Air Filter cover
- 5. Bluetooth button
- 6. 20W Power supply unit

Your AirMini machine is designed to work with ResMed's AirMini app. However, the AirMini app is not essential to operate the machine. For more information on the AirMini app, refer to Using your machine with the AirMini app or the AirMini app Patient eHelp.

Make sure all parts and accessories used with the machine are compatible. For compatibility information, refer to ResMed.com.

## Mask Connectors

The AirMini machine is compatible with ResMed masks. For a full list, see the Mask/Device Compatibility list on ResMed.com/downloads/masks.

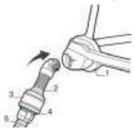
Note: Not all masks are available in all regions.

# Full face mask connector (for use with compatible full face masks)



- 1. Full face mask
- 2. Anti-Asphyxia Valve (AAV)
- Vent
- 4. AirMini tubing

# Nasal mask connector (for use with compatible nasal masks)



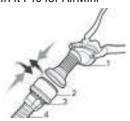
- 1. Nasal mask
- 2. Nasal connector
- 3. Vent module
- 4. Vent
- 5. AirMini tubing

AirFit N30 for AirMini



- 1. AirFit N30 for AirMini
- 2. Vent module
- 3. Vent
- 4. AirMini tubing

AirFit P10 for AirMini



- 1. AirFit P10 for AirMini
- 2. Vent module
- 3. Vent
- 4. AirMini tubing

# Humidification

The AirMini system uses a waterless humidifier that is designed to provide more comfort to your therapy. This will improve the moisture level in the air you breathe and offer relief from possible dryness.

There are different types of waterless humidifiers that vary depending on the mask and therapy requirements:



 HumidX F20 - used with the masks to provide more comfort during therapy.



- HumidX<sup>™</sup> (blue) starting point for finding the right level of humidification.
- HumidX Plus (gray) improves the humidity level further and is useful when the ambient humidity level is very low (eg high altitudes, on an aircraft).

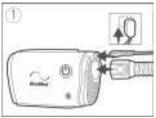
#### Notes:

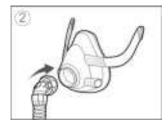
- The waterless humidifier should not be washed or immersed in water as this will affect the performance of therapy.
- The humidifier must be replaced within 30 days of opening the sealed pack.
- The humidifier is for single-patient, multiple-use only.

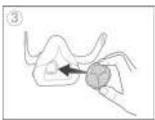
# Setting up and starting therapy

Use your AirMini machine only as directed by your physician or healthcare provider. For information on fitting your mask, refer to the mask user guide.

# Using the full face connector



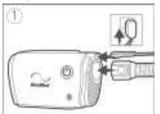


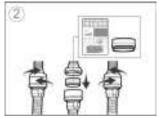


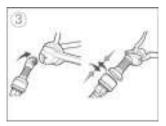


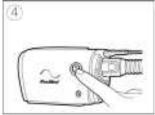
- Plug the power supply unit into the machine and power outlet.
   Connect the gray end of the AirMini tubing firmly to the air outlet.
- 2. Attach the connector to your mask.
- To add optional humidification: With the ResMed logo facing away, insert the HumidX F20 into the air inlet of the F20 mask until it clicks in place.
- Fit the mask as instructed in the mask user guide. Press the Start/Stop button or breathe normally if SmartStart™ is enabled.

# Using the nasal or the pillows connector









- Plug the power supply unit into the machine and power outlet.
   Connect the gray end of the AirMini tubing firmly to the air outlet.
- To add optional humidification: Open the connector by gently twisting it. Hold the HumidX at the sides, colored side pointing downwards and insert it. Gently push together the connector and twist until it locks in place.
- Fit the mask as instructed in the mask user guide. Attach the connector to your mask.
- Press the Start/Stop button or breathe normally if SmartStart™ is enabled

## Stop therapy

- 1. Remove your mask.
- Press the Start/Stop button or wait until the machine stops if SmartStop is activated.

# Comfort features

Ramp Time, Pressure Relief and SmartStart are enabled on your machine.

### Ramp Time

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

#### SmartStart

When SmartStart is turned on, therapy starts automatically when you breathe into your mask.

## SmartStop

When SmartStop is turned on, therapy stops automatically after a few seconds when you remove your mask.

# **Expiratory Pressure Relief**

Designed to make therapy more comfortable, Expiratory Pressure Relief (EPR) maintains optimal treatment during inhalation and reduces the delivered mask pressure during exhalation.

## Changing comfort features

Your AirMini machine has been set up for your needs by your provider, but you may find that you want to make small adjustments to comfort settings to make your therapy more comfortable.

For more information about comfort settings, or for information on changing these settings, refer to the AirMini app Patient eHelp.

# Using your machine with the AirMini app

Your AirMini machine can be used with ResMed's AirMini app. Once you have paired and connected your machine to your smart device via Bluetooth, you can start and stop therapy, change comfort settings and view your therapy data via the AirMini app. Data sent via Bluetooth is encrypted to protect your privacy.

## Connecting your machine and smart device

Before connecting the AirMini machine to a smart device, ensure that the latest version of the AirMini app is installed on the smart device. If not, download the app from the App Store<sup>SM</sup> or the Google Play store.

- Ensure your machine is set up correctly and plugged into a power source.
- 2. On your smart device, enable Bluetooth.
- 3. Open the AirMini app.

The first time you open the AirMini app, you will be asked to:

- provide consent for the use of analytics
- · accept ResMed's terms of use and privacy notice
- provide consent for the AirMini app to upload data to the cloud.
   Select the necessary check boxes to provide consent and accept policies.

#### Notes:

- The check box for analytics consent is selected by default.
- From time to time, the terms of use may be updated and you
  may be required to provide consent again.
- If you agree to allow the AirMini app to upload your data to the cloud, it will be uploaded from the AirMini app to a secure server.
- There are two distinct data upload features:

Background data upload – allows the app to upload all data that has not already been uploaded to the cloud without any user interaction (ie, app automatically uploads data whenever new data is available and active internet connection is present). You must provide consent to enable this feature as it is disabled by default. This feature can be enabled or disabled anytime on the **More** screen.

On-demand data upload – clinician or patient-initiated feature that uploads all data that has not already been sent to the cloud. This feature can be used by clinician or patient regardless if background data upload consent has been provided. To use this feature, the app must have active Bluetooth connection with the AirMini.

For additional information, links are also provided on the Welcome page:

- Learn More explanation of the way analytics are used
- Terms ResMed's terms of use
- Privacy ResMed's privacy notice
- my data information about data privacy.
- 4. Once selections are complete on the Welcome page, tap Continue.
- On your machine, press the Bluetooth button when prompted by the AirMini app.

When the light starts to flash blue \$, Bluetooth is enabled on your AirMini machine and ready to connect.

- On your smart device, tap Connect.
   When your AirMini machine is discovered, the machine name appears in the machine selection list.
- 7. Select the machine name from the list to connect.
- 8. The first time you pair your AirMini machine with your smart device, you will need to perform the authentication procedure.
  - When prompted by the AirMini app, authenticate by entering the four-digit key located on the back of your machine.

Alternatively, you can tap **Scan code**. If permission has not been granted already, you will be prompted by the AirMini app to allow the use of your smart device's camera and then to position the machine's QR code within the camera's viewing frame.

Note: The QR code is located on the back of your AirMini machine.



#### 9. Tap Done.

When successfully connected, the Bluetooth connection icon \* i) is displayed in the top right corner of the AirMini app.

#### Bluetooth status indicators

ŝ	Bluetooth indicator light is flashing blue.	Your machine is in discoverable mode and ready for pairing.
•	Bluetooth indicator light is constantly	Your machine is connected to your

blue. smartphone.

Bluetooth indicator light is constantly Bluetooth on your machine is disabled. white (airplane mode).

Bluetooth indicator light is off. Your machine is not connected to your smartphone.

Note: Once therapy starts, the indicator light will start to fade.

# Cleaning and maintenance

It is important that you regularly clean your AirMini machine to make sure you receive optimal therapy. The following sections will help you with disassembly, cleaning and checking your machine.



# ↑ WARNING

- As part of good hygiene, always follow cleaning instructions. Some cleaning products may damage the air tubing and affect its function, or leave harmful residual vapours that could be inhaled if not rinsed thoroughly.
- The AirMini connectors, AirFit P10 for AirMini and AirFit N30 for AirMini contain a vent system to prevent carbon dioxide buildup in the mask. The vent system must be kept clean and clear of contamination in order to function correctly. Blocking or modifying the vent system may result in excessive carbon dioxide rebreathing.
- Regularly clean your AirMini tubing, connectors and mask components to receive optimal therapy and to prevent the growth of germs that can adversely affect your health.
- Regularly inspect the humidifier and follow the cleaning and maintenance instructions to prevent the growth of germs that can adversely affect your health.

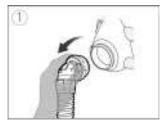


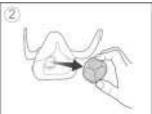
# ↑ CAUTION

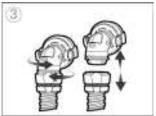
If any visible deterioration of a system component is apparent (cracking, discoloration, tears etc.), the component should be discarded and replaced.

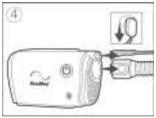
## Disassembling

#### Full face masks







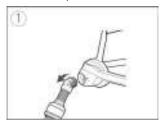


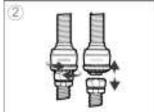
- Squeeze the side buttons on the connector and detach from the mask.
- 2. Remove the HumidX F20 from the mask.

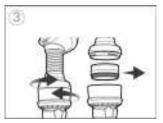
**Note:** The humidifier cannot be washed as this will affect the performance of therapy.

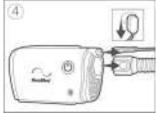
- 3. Disconnect the full face connector from the AirMini tubing by gently twisting and pulling it away.
- 4. Disconnect the AirMini tubing from the machine by pressing the side buttons on the cuff and pulling it away. Unplug the power supply unit from the power outlet and the machine.

#### Nasal masks, AirFit P10 for AirMini, AirFit N30 for AirMini









- For nasal masks: squeeze the side buttons on the connector and detach from the mask.
- 2. For nasal and pillow masks: disconnect the vent module from the air tubing by gently twisting it and pulling the two pieces apart.
- 3. Gently twist and pull the two pieces apart. If you are using the humidifier remove it from the vent module
  - **Note**: The humidifier cannot be washed as this will affect the performance of therapy.
- Disconnect the AirMini tubing from the machine by pressing the side buttons on the cuff and pulling it away. Unplug the power supply unit from the power outlet and the machine.

## Cleaning and replacing parts

Detach all components according to the disassembly instructions and make sure that the humidifier is removed and stored in a clean, dry location.

# Inspect the waterless humidifier (HumidX, HumidX Plus, HumidX F20)

- Check daily for any signs of damage or blockages caused by dirt or dust.
- 2. It must be replaced within 30 days after opening the sealed pack.
- 3. When the humidifier is not being used, store it in a clean, dry location.

Note: The humidifier cannot be washed.

## Clean the AirMini tubing

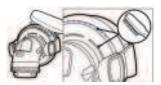
- Clean and check the air tubing each week. AirMini tubing should be replaced at least every six months.
- Wash the AirMini tubing in warm water using a mild liquid detergent.
- 3. Rinse thoroughly and allow to dry out of direct sunlight and/or heat.
- Check the AirMini tubing and replace it if there are any holes, tears or cracks.

Note: Do not wash the AirMini tubing in a dishwasher or washing machine.

#### Clean the F20 connector for AirMini

- 1. Clean and check the F20 connector daily. The connector should be replaced at least every six months.
- 2. Wash in warm water using a mild liquid detergent.
- Clean with a soft bristle brush paying particular attention to the vent holes.
- 4. Rinse well under running water. Shake to remove excess water and allow to dry out of direct sunlight.
- 5. Check that there is no dirt or dust in the vent holes.

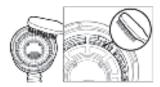
Note: Do not wash in a dishwasher or washing machine.



#### Clean the N20 connector for AirMini

- 1. Clean and check the N20 connector daily. The connector should be replaced at least every six months.
- 2. Wash the connector in warm water using a mild liquid detergent.
- 3. Clean with a soft bristle brush paying particular attention to the vent holes inside the connector.
- 4. Rinse well under running water. Shake to remove excess water and allow to dry out of direct sunlight.
- 5. Check that there is no dirt or dust in the vent holes.

Note: Do not wash in a dishwasher or washing machine.



## Cleaning the mask

Refer to the relevant mask user guide for instructions on cleaning the AirFit P10 for AirMini and AirFit N30 for AirMini masks.

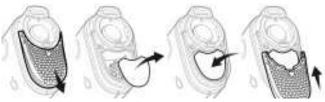
## Change the air filter

Replace at least every 6 months. It cannot be washed.

Check and replace it more often if there are any holes or blockages caused by dirt or dust.

To change the air filter:

- 1. Slide the air filter cover off and remove the old air filter.
- 2. Insert a new air filter and replace the air filter cover.



#### Notes:

- Make sure the air filter cover is fitted at all times to prevent water and dust from entering the machine.
- The use of ResMed approved hypoallergenic filter will result in a small reduction in the accuracy of the delivered pressure at high leaks.

## Cleaning the machine

Wipe the exterior with a dry cloth each week.

For mask cleaning instructions, see your mask user guide.

# Reprocessing

The AirMini tubing, AirMini connectors, vent module and waterless humidifiers must be discarded and replaced, as they cannot be disinfected and cannot be used between other patients.

# Traveling

You can take your AirMini machine with you wherever you go. Make sure you have the appropriate power supply for the region you are traveling to. For information on purchasing, contact your care provider.

## Traveling by airplane

For some airlines, medical devices do not count toward carry-on luggage limits. Please check with your airline for their policy regarding medical equipment.

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

When using the machine on an airplane:

- When connected to power, disable Bluetooth (enter airplane mode) by pressing and holding the Bluetooth button \$\frac{1}{3}\$ for at least ten seconds until the indicator light is white.
- Do not use the AirMini app.
- Use the Start/Stop button on your machine to start therapy.
- To reconnect Bluetooth (exit airplane mode), press the Bluetooth button

# 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 machine.

Problem/possible cause	Solution		
Air is leaking from around my mask / Mask is too noisy			
Mask may be fitted incorrectly.	Make sure your mask is fitted correctly. See your mask user guide for fitting instructions or run the Mask Fit function using the AirMini app to check your mask fit and seal.		
The AirMini system may be assembled incorrectly.	Make sure your AirMini system is correctly assembled. Refer to Setting up and starting therapy for more information.		
Air pressure in my mask seems too low / It feels like I am not getting enough air			
Ramp may be in progress.	Using the AirMini app, confirm the Ramp function has been enabled. If so, wait for air pressure to build up or turn Ramp Time off using the AirMini app.		
HumidX or vent might be blocked.	Inspect the HumidX and vent for blockages or damage. Refer to Cleaning and maintenance for more information.		
HumidX may be wet.	The HumidX should be dry when starting therapy. Check if HumidX is wet and replace as necessary.		

Problem/possible cause	Solution		
I cannot start therapy			
Power may not be connected.	Connect the power supply unit and make sure the plug is fully inserted. The green indicator light on the power supply unit should be illuminated.		
	Check that the green indicator light above the Start/Stop button on the machine is also illuminated.		
My therapy has stopped			
The air tubing may be disconnected.	Ensure that the air tubing is properly connected. Press the Start/Stop button to continue therapy.		
You may have high leak and SmartStop	Make sure your mask is fitted correctly.		
enabled.	Alternatively, disable SmartStop.		
The Bluetooth indicator light is constantly white. I cannot pair to my machine			
Bluetooth is disabled.	Press the Bluetooth button for 3 seconds. When the Bluetooth indicator light flashes blue, the machine is ready for pairing.		
I cannot scan the QR code to pair my machine			
The camera is not focused or broken, or the QR code label is damaged.	You can pair your machine manually by entering into your smart device the four- digit key found on the back of your machine.		
The QR code label is unreadable.	Contact your care provider.		

Problem/possible cause	Solution		
The light above the Start/Stop button is flashing green			
An error has occurred on the machine.	Unplug your machine. Wait a few seconds and then plug it back in.		
	If the problem persists, contact your care provider. Do not open the machine.		
I am experiencing dryness (dry or blocked nose)			
Mask may be fitted incorrectly	Adjust and refit your mask to improve seal. Check that there is no air leaking from the mask.		
	If mask seal is good, try the HumidX Plus.		
I am using a waterless humidifier and I am getting uncomfortable droplets of water on my nose, mask or air tubing			
Humidity level is too high	If using the HumidX or HumidX F20: Remove the humidifier and try therapy without humidification.		
	If using the HumidX Plus: Try the HumidX instead. This will help to reduce the water droplets.		
	If you are still experiencing problems, contact your care provider.		
	Note: You may need to use a waterless humidifier when ambient humidity conditions change.		

Problem/possible cause	Solution		
The AirMini is not automatically reconnecting to my smart phone			
Bluetooth connection has dropped out	Ensure that your phone is not paired with any other Bluetooth device. If your phone is connected to other devices, ensure your AirMini machine is switched on and select AirMini from the list of connected devices on your smart device.		
	If AirMini fails to reconnect to Bluetooth, turn the AirMini machine off at the wall socket and turn on again after 10 seconds.		
	If your AirMini is still not pairing, repeat the instructions to connect your machine and smart device.		

# General warnings and cautions

# **⚠** WARNING

- Make sure that you arrange the air tubing so that it will not twist around the head or neck.
- · Keep the power cord away from hot surfaces.
- Regularly inspect power cords, cables, and power supply for damage or signs of wear. Discontinue use and replace if damaged.
- If you notice any unexplained changes in the performance of the machine, if it is making unusual sounds, if the machine 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 machine. 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 machine, power supply or power cord in water.
  - If liquids are spilled into or onto the machine, unplug the machine and let the parts dry.
  - Always unplug the machine before cleaning and make sure that all parts are dry before plugging it back in.
- Do not use with oxygen. Any sources of oxygen must be located more than 1 m away from the machine to avoid risk of fire and burns.
- Do not perform any maintenance tasks while the machine is in operation.
- Use only AirMini (eg air filter), masks and accessories that allow for normal breathing to avoid asphyxiation.

- The use of accessories other than those specified for the machine is not recommended. This may result in increased electromagnetic emissions or decreased immunity of the machine and result in improper operation.
- The machine should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the machine should be observed to verify normal operation in the configuration in which it will be used.
- The AirMini mask systems and connectors are fitted with vents. The full face connector for AirMini is also fitted with an AAV. The AAV and vents have specific safety functions to prevent carbon dioxide build-up in the mask. The AAV and vents should be kept clean and not covered or blocked. The connectors should not be used if the vent or AAV are damaged as they will not be able to perform their safety functions. The connectors should be replaced if the valves of the vent or AAV are damaged, distorted or torn.
- The machine is not intended to be operated by persons (including children) with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.
- 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 13 ft (4 m) of X-ray or CT equipment. Never bring the device into an MR environment.

# **▲** CAUTION

- Use only ResMed AirMini parts (eg air inlet filter, battery, power supplies), masks and accessories with the machine. Non-ResMed AirMini parts may reduce the effectiveness of the treatment, may result in excess carbon dioxide rebreathing and/or damage the machine. For compatibility information, refer to ResMed.com for more information.
- Blocking the air tubing and/or air inlet of the machine while in operation could lead to overheating of the machine.
- Keep the area around the machine dry, clean and clear of anything (eg, clothes, pillows or bedding) that could block the air inlet or cover the power supply unit.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the machine or air tubing. These solutions may cause damage and reduce the life of the products. Exposure to smoke, including cigarette, cigar or pipe smoke, as well as ozone or other gases may damage the device. Damage caused by any of the foregoing will not be covered by ResMed's limited warranty.
- Do not insert any USB cable into the machine or attempt to plug the power supply unit into a USB device. This may cause damage to the machine or USB device.

**Note:** For any serious incidents that occur in relation to this device, these should be reported to ResMed and the competent authority in your country.

# Technical specifications

Units are expressed in cm H<sub>2</sub>O and hPa. 1 cm H<sub>2</sub>O is equal to 0.98 hPa.

Power supply unit

AC input range: 100–240V, 50–60Hz, 0.5-0.3A

115V, 400Hz for aircraft use, 0.4A

DC output: 24V \_\_\_\_\_\_ 0.83A

Typical power consumption: 6.3W Peak power consumption: 27W

If power is interrupted during therapy, the machine will automatically restart therapy

when power is restored.

AirMini power

Standby power consumption: 1 W

**Environmental conditions** 

Operating temperature: +5°C to +35°C

Note: Under extreme ambient temperature conditions (40°C) the air and parts of the

tubing near the mask may reach temperatures up to 43°C. These parts of

the tubing are not in contact with the user and the machine remains safe under these

extreme conditions.

Operating humidity: 10 to 95% relative humidity, non-

condensing
Sea level to 2,591 m; air pressure range

1013 hPa to 738 hPa

Storage and transport temperature: -25°C to +70°C

Storage and transport humidity: 5 to 95% relative humidity, non-

condensing

Air filter

Operating altitude:

Standard: Material: Polyester non woven fiber

Average arrestance: >75% when tested to

EN779

Hypoallergenic:	Material: Blended synthetic fibers in a polypropylene carrier Efficiency: >80% (average) when tested to EN 13274-7
AirMini machine	
Dimensions:	136 mm (W) x 84 mm (D) x 52 mm (H)
Weight:	300 g
Housing construction:	Flame retardant engineering thermoplastic
Air outlet:	Proprietary connector, 16mm inner
	diameter. Not compatible with
	EN ISO 5356-1 connectors.
AirMini air tubing	
Material:	Flexible plastic
Length:	1.9 m
Inner diameter	15 mm

#### Electromagnetic compatibility

The AirMini complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2:2014, for residential, commercial and light industry environments. Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended 10 cm separation distance. The AirMini has been designed to meet EMC standards. However, should you suspect that the machine performance (eg, pressure or flow) is affected by other equipment, move the machine away from the possible cause of interference.

The AirMini complies with Part 15 of the FCC Rules and Industry Canada license-exempt RSS standards. Operation is subject to the following two conditions: This machine may not cause harmful interference, and this machine must accept any interference received, including interference that may cause undesired operation.

FCC ID: QOQBT121, IC: 5123A-BGTBT121

Additional information regarding the FCC Rules and IC compliance for this machine can be found on www.resmed.com/downloads/devices.

# Declaration of Conformity (DoC to the Radio Equipment Directive) $oldsymbol{\mathsf{C}}$

ResMed declares that the AirMini device (models 381xx) is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU (RED). A copy of the Declaration of Conformity (DoC) can be found on Resmed.com/productsupport

This radio equipment operates with the following frequency bands and maximum radiofrequency power: Bluetooth Class 2. 2402 to 2480 MHz, 4dBM.

#### Aircraft use

ResMed confirms that machine meets the Federal Aviation Administration (FAA) requirements (RTCA/D0-160, section 21, category M) for all phases of air travel.

#### Wireless technology

Technology used: Bluetooth

Connection types: SPP, iAP2, GATT Frequency: 2402 to 2480 MHz

Max RF power output: +4 dBm
Operating range: 10 m (Class 2)

It is recommended that the machine is at a minimum distance of 1.1cm from the body during operation. Not applicable to masks, air tubing or accessories.

## IEC 60601-1 (Edition 3.1) classification

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

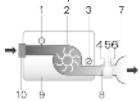
#### Operating pressure range

AutoSet, AutoSet For Her, CPAP: 4 to 20 cm H<sub>2</sub>O (4 to 20 hPa)

#### Maximum single fault steady pressure

Machine 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 seconds or 40 cm  $H_2O$  (40 hPa) for more than 1 second

## Pneumatic flow path



- 1. Flow sensor
- 2. Blower
- 3. Pressure sensor
- 4. AAV (F20 connector only)
- 5. Vent
- 6. HumidX (N20, N30 and P10 connectors only)
- 7. Mask
- 8. Air tubing
- 9. Machine
- 10. Inlet filter

## Pressure accuracy

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

Tested with full face mask:  $\pm 0.5$  cm  $H_2O$  (0.5 hPa)

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

Machine with full face mask

Pressure [cm H₂O (hPa)]	10 BPM	15 BPM	20 BPM
4	0.5	0.7	1.0
8	0.5	0.7	1.0
12	0.5	0.7	1.0
16	0.5	0.7	1.0
20	0.5	0.7	1.0

## 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 H₂O (hPa)	AirMini machine and AirMini air tubing L/min (including uncertainty)
4	119
8	116
12	112
16	108
20	105

#### Measurement system uncertainties

ISO 80601-2-70:2015 (CPAP mode)

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

manaratarer e teet equipment io.	
For measures of flow	$\pm$ 1.5 L/min or $\pm$ 2.7% of reading (whichever is greater)
For measures of static pressure	$\pm 0.15$ cm $H_2O$ (hPa)
For measures of dynamic pressure	$\pm 0.27 \text{ cm H}_2\text{O (hPa)}$
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 time	± 10 ms

Note: ISO 80601-2-70:2015 stated accuracies and test results provided in this manual for these items already include the relevant measurement uncertainty from the table above.

#### Sound

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

Pressure level measured according to 29 dBA with uncertainty of 2 dBA ISO 80601-2-70:2015 (CPAP mode)

Power level measured according to 37 dBA with uncertainty of 2 dBA

The A-weighted sound pressure level measured according to ISO 17510:2015:

Air tubing connected to AirMini F20 connector 19 dBA with uncertainty of 3 dBA with mask

Air tubing connected to AirMini N20, N30 or P10 15 dBA with connectors with mask

15 dBA with uncertainty of 3 dBA  $\,$ 

The A-weighted sound power level measured according to ISO 17510:2015:

Air tubing connected to AirMini F20 connector with mask

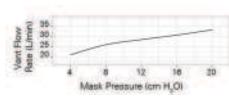
27 dBA with uncertainty of 3 dBA  $\,$ 

Air tubing connected to the AirMini N20,N30 or P10 connectors with mask

23 dBA with uncertainty of 3 dBA

# Pressure flow curve (ISO 17510:2015)

The patient is an intended operator.



Pressure [cm H <sub>2</sub> O (hPa)]	Flow [L/min]
4	21
8	26
12	29
16	31
20	33

#### Resistance

Inspiratory and expiratory resistance with AAV open to atmosphere (ISO 17510:2015)	F20 connector
Inspiration at 50L/min	0.7 cm H <sub>2</sub> O (hPa)
Expiration at 50L/min	0.5 cm H <sub>2</sub> O (hPa)
AAV Pressures (ISO 17510:2015)	F20 connector
Open-to-atmosphere pressure	0.9 cm H <sub>2</sub> O (hPa)
Closed-to-atmosphere pressure	1.0 cm H <sub>2</sub> O (hPa)
Design life	
Machine, power supply unit:	5 years
Air tubing, connectors:	6 months
HumidX:	30 days

#### Notes:

- The manufacturer reserves the right to change these specifications without notice.
- The mask system does not contain PVC, DEHP or phthalates.
- This product is not made with natural rubber latex.

# **Symbols**

The following symbols may appear on the product or packaging. Read instructions before use. (IEC 60601-1) A Indicates a warning or caution. (IEC 60601-1) Tellow instructions before use. (IEC 60601-1) Manufacturer. (ISO 15223-1) EC REP European Authorized Representative. (ISO 15223-1) Batch code. (ISO 15223-1) REF Catalog number. (ISO 15223-1) Serial number. (ISO 15223-1) Device number, On / Off. (IEC 60601-1) IP22 Protected against finger sized objects and against dripping water when tilted up to 15 degrees from specified orientation. (IEC 60601-1-11) \_\_\_\_ Direct current. (IEC 60601-1) Type BF applied part.( IEC 60601-1) Class II equipment. (IEC60601-1) Humidity limitation. (ISO 15223-1) Temperature limitation. (ISO 15223-1) Non-ionising radiation. (IEC60601-1-2) Bluetooth. (Bluetooth Brand guide) Rx Only Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician). (21 CFR 801) Operating altitude. (ISO 15223-1) Complies with RTCA DO-160 section 21, category M. MR unsafe (do not use in the vicinity of an MRI device). (ASTM



Replace 30 days after opening. Do not use if

package is damaged. (ISO 15223-1).





device Importer

See symbols glossary at ResMed.com/symbols.



# Environmental information (EU directive 2012/19/EE Waste Electrical and Electronic Equipment (WEEE))

This machine should be disposed of separately, not as unsorted municipal waste. To dispose of your machine, 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 machine please contact your ResMed office. local distributor or go to www.resmed.com/environment.

# Servicina

The AirMini machine is intended to provide safe and reliable operation when operated in accordance with the instructions provided by ResMed. ResMed recommends that the AirMini machine 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 desian life.

# Limited warranty

ResMed Pty Ltd (hereafter 'ResMed') warrants that your ResMed product shall be free from defects in material and workmanship from the date of purchase for the period specified below.

Product		Warranty period
Mask systems (includi and tubing)—excludin	ng mask frame, cushion, headgear g single-use devices	90 days
Accessories—excluding	ng single-use devices	
Batteries for use in Re systems	sMed internal and external battery	6 months
CPAP machine (includi	ng external power supply units)	2 years

This warranty is only available to the initial consumer. It is not transferable.

During the warranty period, if the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components.

This limited warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs; c) any damage or contamination due to cigarette, pipe, cigar or other smoke; d) any damage caused by exposure to ozone, activated oxygen or other gasses and e) any damage caused by water being spilled on or into an electronic device.

Warranty is void on product sold, or resold, outside the region of original purchase. For product purchased in a country in the European Union ("EU") or European Free Trade Association ("EFTA"), 'region' means the EU and EFTA.

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.

Visit ResMed.com for the latest information on ResMed's Limited Warranty.

### Further information

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