



ResMed

AirMini™



User guide
English

Rx Only



ResMed.com/AirMiniApp



Welcome

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

WARNING

Read this entire guide before using the machine.

CAUTION

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

Indications for use

The AirMini self-adjusting system is indicated for the treatment of obstructive sleep apnea (OSA) in patients (female patients with mild to moderate OSA when using AutoSet for Her treatment mode) weighing more than 66 lb (30 kg).

It is intended for home and hospital use.

Contraindications

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

- severe bullous lung disease
- pneumothorax
- 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:

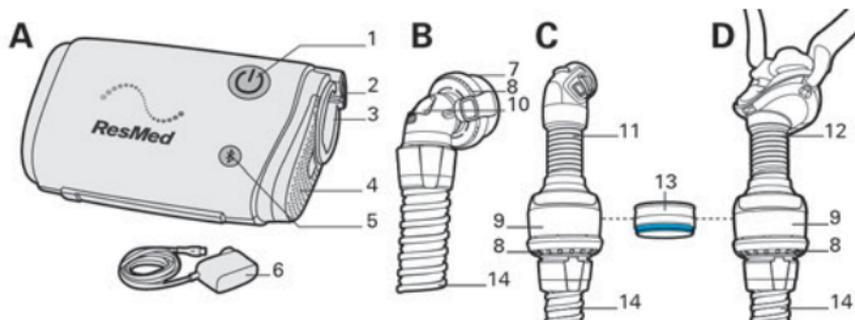
- drying of the nose, mouth, or throat
- nosebleed
- bloating
- ear or sinus discomfort
- eye irritation
- skin rashes.

At a glance

The AirMini system includes the following:

- AirMini: the AirMini machine, power supply unit, drawstring bag and one of the following:
 - AirMini setup pack - F20: Air tubing, F20 connector OR
 - AirMini setup pack - N20: Air tubing, N20 connector, HumidX, HumidX Plus OR
 - AirMini mask pack for P10: Air tubing, AirFit P10 for AirMini mask (M), P10 cushion (S), P10 cushion (L), HumidX, HumidX Plus, AirFit P10 headgear clips.

Your AirMini system



Your AirMini system is comprised of the AirMini machine and one mask pack or one setup pack.

- | | | | |
|---|--|----|--|
| A | AirMini machine | 6 | 20W power supply unit |
| B | F20 connector for AirMini and air tubing | 7 | F20 connector for AirMini |
| C | N20 connector for AirMini and air tubing | 8 | Vent |
| D | AirFit P10 for AirMini and tubing | 9 | Vent module |
| 1 | Start/Stop button | 10 | Anti Asphyxia Valve (AAV) |
| 2 | Power inlet | 11 | N20 connector for AirMini |
| 3 | Air outlet | 12 | AirFit P10 for AirMini |
| 4 | Air filter cover | 13 | Heat moisture exchanger - HumidX (blue) and HumidX Plus (gray) |
| 5 | Bluetooth® button | 14 | AirMini tubing |

Your machine is compatible with ResMed's F20 and N20 series masks and with the AirFit P10 for AirMini. Make sure all parts and accessories used with the machine are compatible. For compatibility information, refer to www.resmed.com for more information.

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.

HumidX and HumidX Plus

The HumidX and HumidX Plus are waterless humidifiers. These are designed to provide more comfort by improving the moisture level in the air you breathe and offering relief from possible dryness.

The HumidX is a good starting point for finding the right level of humidification. The HumidX Plus will improve the humidity level further and is useful when the ambient humidity level is very low (eg, high altitudes, on an aircraft).

The HumidX and HumidX Plus can be used with the N20 connector for AirMini and AirFit P10 for AirMini only.

The HumidX and HumidX Plus must be replaced within 30 days of opening the HumidX/HumidX Plus pack.

Setting up and starting therapy

Using your mask

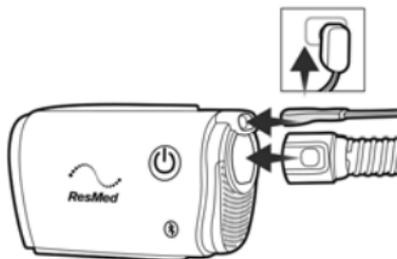
Before you set up your machine, make sure you use a compatible mask. For a full list of compatible masks for this device, see the Mask/Device Compatibility List on www.resmed.com/downloads/masks. If you do not have internet access, please contact your ResMed representative.

For information on fitting your mask, refer to the mask user guide.

Use your AirMini machine only as directed by your physician or healthcare provider.

Set up your machine

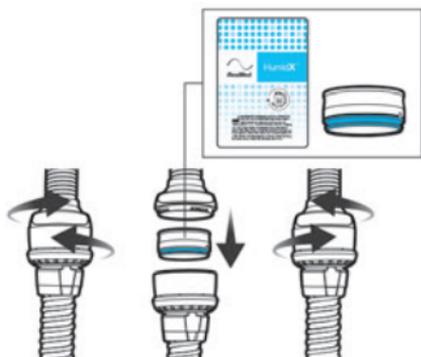
1. Plug the power supply unit into the machine and the power outlet. The connector has an angled edge so that the power cord can only be inserted into the machine one way.
2. Connect the gray end of the AirMini tubing firmly to the air outlet.



Add optional humidification (for N20 or AirFit P10 for AirMini only)

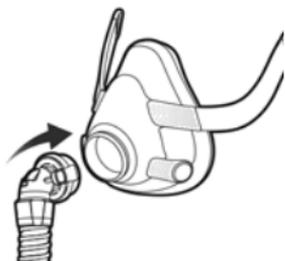
To insert the HumidX or HumidX Plus:

1. Open the connector by gently twisting it.
2. Hold the HumidX/HumidX Plus at the sides, with the colored side pointing down and insert it.
3. Gently push together the connector and twist until it locks in place.

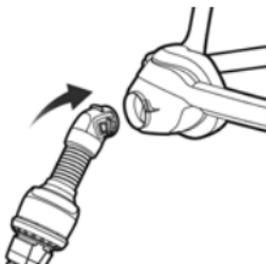


Connect your mask

1. Fit your mask as instructed in the mask user guide.
2. Attach the connector to your mask.



F20 Series



N20 Series



AirFit P10 for AirMini

Start therapy

1. Start therapy by pressing the Start/Stop button or breathe normally if SmartStart™ is enabled.



Stop therapy

1. Remove your mask.
2. 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.

Pressure Relief

When Pressure Relief is enabled and turned on, you may find it easier to breathe out. This can help you get used to therapy.

Note: Pressure Relief must first be enabled by your provider.

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.

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 StoreSM or the Google Play store.

1. 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 consent to the use of cookies, to accept ResMed's terms of use and privacy policies, and to permit the AirMini app to upload your therapy data to the cloud.

Four links on the Welcome page provide access to additional information about cookie use, ResMed's terms of use and privacy policies and uploading data to the cloud:

- To open and read an explanation of the way cookies are used to improve your experience with the AirMini app, click the **Learn More** link.

Tap **Done** (iOSTM) or the Back button (AndroidTM) to return to the Welcome page.

- To open and read ResMed's terms of use, click the **Terms** link.

Tap **Done** (iOS) or the Back button (Android) to return to the Welcome page.

- To open and read ResMed's privacy notice, click the **Privacy** link.

Tap **Done** (iOS) or the Back button (Android) to return to the Welcome page.

- To learn more about data privacy, click the **my data** link.

Tap **Done** (iOS) or the Back button (Android) to return to the Welcome page.

To provide consent and accept policies:

- To provide consent for the use of cookies, leave the cookies check box selected. To deny consent for the use of cookies, deselect the box.

Note: The check box for cookie consent is selected by default. Therefore, no action is required to provide your consent.

- To accept ResMed's terms of use and privacy notice, select the terms and privacy check box.
- To provide consent for the AirMini app to upload data to the cloud, select the data upload box.

Notes:

- If you agree to allow the AirMini app to upload your therapy data to the cloud, it will be uploaded from the AirMini app to a secure server.
 - After you have agreed to have your data uploaded, these data transfers can be turned on or off in the **Preferences** section of the **More** menu.
 - Once you turn on data transfers in the **Preferences** section of the **More** menu, all available therapy data on the device will be uploaded to the cloud, not just data generated from that date forward.
 - Data will continue to be uploaded to the cloud until you turn off the transfers in the **Preferences** section of the **More** menu.
 - If you turn off data transfers in the **Preferences** section of the **More** menu, data generated from that point forward will not be uploaded to the cloud. However, data transferred to the cloud previously will remain in the cloud.
4. Once selections are complete on the Welcome page, tap **Continue**.
 5. 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.

6. 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  is displayed in the top right corner of the AirMini app.

Bluetooth status indicators

| | |
|---|---|
|  Bluetooth indicator light is flashing blue. | Your machine is in discoverable mode and ready for pairing. |
|  Bluetooth indicator light is constantly blue. | Your machine is connected to your smartphone. |
|  Bluetooth indicator light is constantly white (airplane mode). | Bluetooth on your machine is disabled. |
| 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 and AirFit P10 for AirMini contain a vent system to prevent carbon dioxide build-up 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 HumidX/HumidX Plus and follow the cleaning and maintenance instructions to prevent the growth of germs that can adversely affect your health.

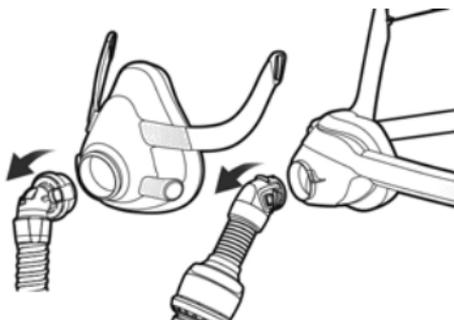
CAUTION

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

Disassembling

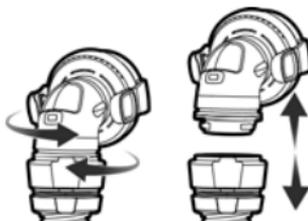
Remove the connector (F20 and N20 only)

1. Remove the connector from the mask by pressing the side buttons and pulling it away.



Disconnect the AirMini tubing (F20 only)

1. Disconnect the F20 connector from the AirMini tubing by gently twisting and pulling it away.



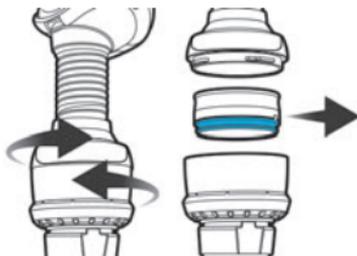
Disconnect the AirMini tubing (N20 and AirFit P10 for AirMini only)

1. Disconnect the vent module from the AirMini tubing by gently twisting it and pulling the two pieces apart.



Remove the HumidX/HumidX Plus (N20 and AirFit P10 for AirMini only)

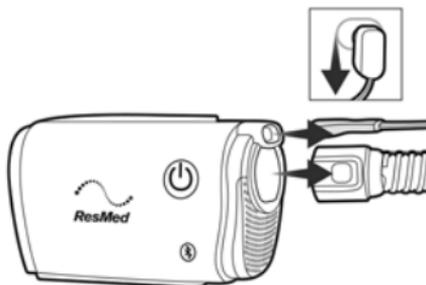
1. Disconnect the mask tube from the vent module by gently twisting and pulling the two pieces apart. If you are using the HumidX or HumidX Plus, remove it from the vent module.



Note: The HumidX and HumidX Plus cannot be washed.

Unplug the machine

1. Disconnect the AirMini tubing from the machine by pressing the side buttons on the cuff and pulling it away.
2. Unplug the power supply unit from the power outlet and the machine.



For mask disassembly instructions, refer to your mask user guide.

Cleaning and replacing parts

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

Inspect the HumidX/HumidX Plus

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

Note: HumidX/HumidX Plus cannot be washed.

Clean the AirMini tubing

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

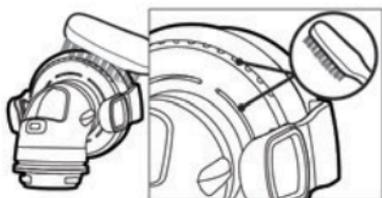
Note: Do not wash the AirMini tubing in a dishwasher or washing machine.

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, for example Ultra Joy dishwashing liquid.
3. 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.

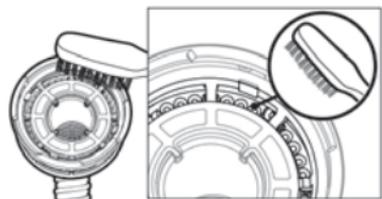
Note: Do not wash in a dishwasher or washing machine.



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, for example Ultra Joy dishwashing liquid.
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.



Clean the AirFit P10 for AirMini

Refer to your mask guide for cleaning instructions.

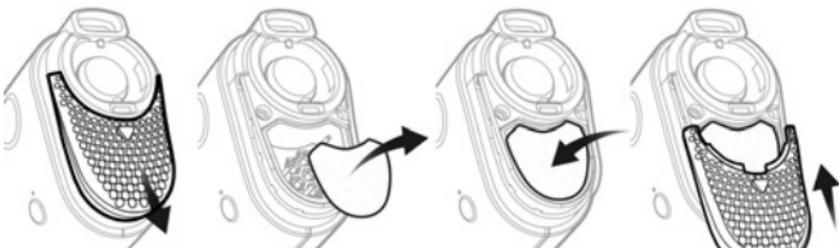
Change the air filter

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

1. Wipe the exterior with a dry cloth each week.

Reprocessing

The AirMini tubing, AirMini connectors, vent module and HumidX/HumidX Plus must be discarded and replaced, as they can not be disinfected and can not be used between other patients.

For mask cleaning instructions, see your mask user guide.

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 www.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  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. |

| Problem/possible cause | Solution |
|--|---|
| 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. |
| 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 enabled. | Make sure your mask is fitted correctly. Alternatively, disable SmartStop. |

| Problem/possible cause | Solution |
|---|--|
| 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. |
| 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. |
| Humidification may be required | Try therapy using the HumidX |

| Problem/possible cause | Solution |
|--|---|
| I am using the HumidX/HumidX Plus and I am getting uncomfortable droplets of water on my nose, mask or air tubing | |
| Humidity level is too high | If using the HumidX: Remove the HumidX and try therapy without humidification. |
| | If using the HumidX Plus: Try the Humid X 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 the HumidX/HumidX Plus when ambient humidity conditions change. |

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.
- Make sure the power cord and plug are in good condition and the equipment is not 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 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 F20, N20 and P10 connectors for AirMini are fitted with vents. The F20 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, 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 www.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.
- 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.

Technical specifications

Units are expressed in cm H₂O and hPa. 1 cm H₂O 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: +41°F to +95°F (+5°C to +35°C)

Note: Under extreme ambient temperature conditions (104°F/40°C) the air and parts of the tubing near the mask may reach temperatures up to 109°F/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

| | |
|------------------------------------|---|
| Operating altitude: | Sea level to 8,500' (2,591 m); air pressure range 1013 hPa to 738 hPa |
| Storage and transport temperature: | -13°F to +158°F (-25°C to +70°C) |
| Storage and transport humidity: | 5 to 95% relative humidity, non-condensing |

Air filter

| | |
|-----------------|---|
| 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: | 5.4" (W) x 3.3" (D) x 2.1"(H) 136 mm (W) x 84 mm (D) x 52 mm (H) |
| Weight: | 10.6 oz (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: | 6'2" (1.9 m) |
| Inner diameter: | 0.6" (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.

Aircraft use

ResMed confirms that machine meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-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 0.43" (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.

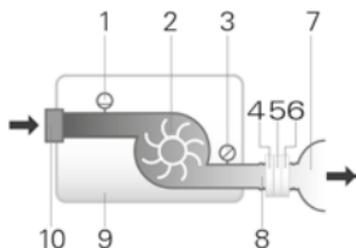
Operating pressure range

| | |
|---------------------------------|---|
| AutoSet, AutoSet For Her, CPAP: | 4 to 20 cm H ₂ 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 H₂O (30 hPa) for more than 6 seconds or 40 cm H₂O (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, P10 connectors only)
 7. Mask
 8. Air tubing
 9. Machine
 10. Inlet filter
-

Pressure accuracy

Maximum static pressure variation at 10 cm H₂O (10 hPa) according to ISO 80601-2-70:2015:

Tested with full face mask: ± 0.5 cm H₂O (0.5 hPa)

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

Machine with full face mask

| Pressure [cm H ₂ O (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 H ₂ O (hPa) | AirMini machine and AirMini air tubing L/min (including uncertainty) |
|---------------------------------------|---|
| 4 | 119 |
| 8 | 116 |
| 12 | 112 |
| 16 | 108 |
| 20 | 105 |

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 $\pm 2.7\%$ of reading (whichever is greater) |
| For measures of static pressure | ± 0.15 cm H ₂ O (hPa) |
| For measures of dynamic pressure | ± 0.27 cm H ₂ 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 ISO 80601-2-70:2015 (CPAP mode) 29 dBA with uncertainty of 2 dBA

Power level measured according to ISO 80601-2-70:2015 (CPAP mode) 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 with mask 19 dBA with uncertainty of 3 dBA

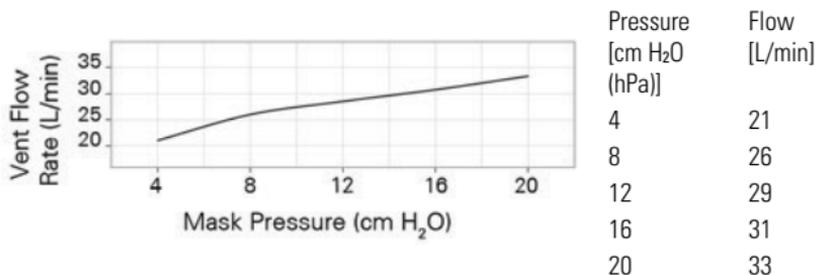
Air tubing connected to AirMini N20 or P10 connectors with mask 15 dBA with uncertainty of 3 dBA

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 or P10 connectors with mask 23 dBA with uncertainty of 3 dBA

Pressure flow curve (ISO 17510:2015)



Resistance

Inspiratory and expiratory resistance with AAV open to atmosphere (ISO 17510:2015) F20 connector

Inspiration at 50L/min 0.7 cm H₂O (hPa)

Expiration at 50L/min 0.5 cm H₂O (hPa)

AAV Pressures (ISO 17510:2015) F20 connector

Open-to-atmosphere pressure 0.9 cm H₂O (hPa)

Closed-to-atmosphere pressure 1.0 cm H₂O (hPa)

Design life

Machine, power supply unit: 5 years

Air tubing, connectors: 6 months

HumidX: 30 days

General

The patient is an intended operator.

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)  Indicates a warning or caution (IEC 60601-1)  Follow instructions before use (IEC 60601-1)  Manufacturer. (ISO 15223-1) **EC REP** European Authorized Representative (ISO 15223-1) **LOT** Batch code (ISO 15223-1) **REF** Catalog number (ISO 15223-1) **SN** Serial number (ISO 15223-1) **DN** 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  Atmospheric pressure limitation (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

F2503)  Replace 30 days after opening.  Do not use if package is damaged. (ISO 15223-1).



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.

Servicing

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 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 in the following table:

| Product | Warranty period |
|--|-----------------|
| <ul style="list-style-type: none"> Mask systems (including mask frame, cushion, headgear and tubing)—excluding single-use devices Accessories—excluding single-use devices | 90 days |
| <ul style="list-style-type: none"> Batteries for use in ResMed internal and external battery systems | 6 months |
| <ul style="list-style-type: none"> CPAP machine (including external power supply units) | 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.

Warranty information for Australian customers

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

In addition to your rights and remedies under Australian Consumer Law (and any other applicable law), ResMed Ltd ABN 30 003 765 142 of 1 Elizabeth Macarthur Drive, Bella Vista NSW 2153 (ResMed) warrants that your ResMed product will be free from defects in material and workmanship from the date of purchase for the period specified below.

| Product | Warranty period |
|---|-----------------|
| <ul style="list-style-type: none">Mask systems (including mask frame, cushion, headgear and tubing)—excluding single-use devicesAccessories—excluding single-use devices | 90 days |
| <ul style="list-style-type: none">Batteries for use in ResMed internal and external battery systems | 6 months |
| <ul style="list-style-type: none">CPAP machine (including external power supply units) | 2 years |

To make a claim under this warranty you should contact the ResMed accredited outlet from which you purchased your ResMed product or send your claim to ResMed at 1 Elizabeth Macarthur Drive, Bella Vista NSW 2153 (phone number (02) 8884 1000) (email: reception@resmed.com.au). All claims under this warranty must be accompanied by your original receipt.

You will then need to deliver the ResMed product you claim is defective to the ResMed accredited outlet from which you purchased your ResMed product or your closest ResMed accredited outlet at your expense. A similar product will normally be lent to you by your ResMed accredited outlet while your product is assessed.

The product you claim as defective must be delivered from the ResMed accredited outlet to the ResMed Service Centre within the relevant warranty period referred to above. ResMed will not be responsible for the cost of the transport of your ResMed product to the ResMed

Service Centre. You must pay any necessary costs to the ResMed accredited outlet. If ResMed determines that your warranty claim is valid, we will return the repaired product, or a replacement product, to your ResMed accredited outlet at ResMed's expense. If ResMed determines that your warranty claim is valid you may claim any reasonable expenses you have incurred in making the claim by posting to us at 1 Elizabeth Macarthur Drive, Bella Vista NSW 2153 a claim in writing attaching original receipts for the expenses claimed. If ResMed determines that your warranty claim is not valid, we will notify your ResMed accredited outlet by providing a quotation of the cost of repair. Your ResMed accredited outlet will then contact you and you will have the option of taking up the quotation offer, valid for 30 days, or have your product returned unrepaired to your ResMed accredited outlet at ResMed's expense.

This manufacturer's warranty is void on product sold, or resold, outside the region of original purchase. Manufacturer's warranty claims on defective product must be made by the initial consumer at the point of purchase or to us directly as specified above.

This warranty gives you specific legal rights. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

If you are provided with a replacement or repaired product, the warranty continues to apply to the replacement or repaired device but does not continue beyond the original warranty period referred to above.

If you have any questions or would like the address of your nearest ResMed accredited outlet, please contact our friendly customer service consultants.

Further information

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



ResMed Ltd

MANUFACTURER 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia

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