

**Air**Start<sup>™</sup>10 APAP

CPAP



#### **ENGLISH**

## Welcome

The AirStart™ 10 APAP and AirStart 10 CPAP are ResMed's Automatic Positive Airway Pressure (APAP) and Continuous Positive Airway Pressure (CPAP) devices.

# $\Delta$ warning

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

### Indications for use

#### AirStart 10 APAP

The AirStart 10 APAP self-adjusting device is indicated for the treatment of obstructive sleep apnoea (OSA) in patients weighing more than 30 kg. It is intended for home and hospital use.

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

#### AirStart 10 CPAP

The AirStart 10 CPAP device is indicated for the treatment of obstructive sleep apnoea (OSA) in patients weighing more than 30 kg. It is intended for home and hospital use.

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

### Contraindications

Positive airway pressure therapy may be contraindicated in some patients with the following preexisting 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 device:

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

# At a glance

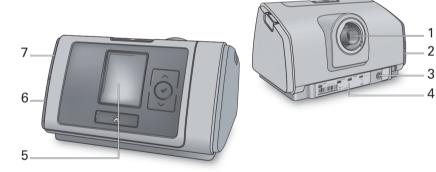
The AirStart 10 can include the following:

- Device
- Air tubing
- Standard filter (already inserted)
- · 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: SlimLine<sup>™</sup>, Standard
- Humidifier: Standard humidifier (for single patient use only, cannot be disinfected), cleanable humidifier (for multi-patient use, can be disinfected)
- Side cover (for use without humidifier)
- Filter: Hypoallergenic filter, standard filter
- Air10<sup>™</sup> DC/DC converter
- SD card reader
- Air10 USB adapter.

# About your device



- 1 Air outlet
- 2 Air filter cover
- 3 Power inlet
- 4 Serial number and device number
- 5 Screen
- 6 Adapter cover
- 7 SD card cover

## About the control panel

ල්

Start/Stop button

Press to start/stop therapy.

Press and hold for three seconds to enter power save mode

Up/Select/Down buttons

Press Up or Down to navigate the menu and press Select to choose an option.

Press Up or Down to adjust an option and press Select to save your change.

**企** 

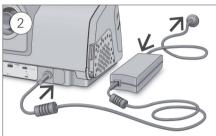
Home button

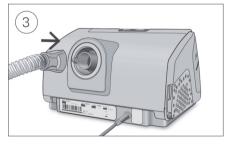
Press to return to the Home screen.

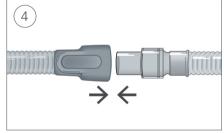
The Ramp Time icon 
is displayed on the screen when ramp is on.

# Setup









- 1. Place the device on a stable level surface.
- 2. Plug the power connector into the rear of the device. 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. Connect the free end of the air tubing firmly onto the assembled mask. See your mask user guide for detailed information.

Recommended masks are available on www.resmed.com.

# Starting therapy

- 1. Fit your mask.
- 2. Press Start/Stop.

You will know that therapy is on when the Sleep Report screen is displayed.



The current treatment pressure is shown in the centre of the screen.

During ramp time the pressure is gradually increasing and you will see a spinning circle. Once the prescribed treatment pressure is reached, the entire circle will be solid.

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

# Stopping therapy

- 1. Remove your mask.
- 2. Press Start/Stop.

The Sleep Report now 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.

### Power save mode

Your AirStart 10 device records your therapy data. 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.

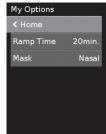
#### To exit power save mode:

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

## My Options

Your AirStart 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 Select to see your current settings. From here, you can personalise 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**, press Up or Down to highlight **Ramp Time** and then press Select.
- Press Up or Down to adjust the ramp time to your preferred setting and press Select to save the change.

## More options

Your care provider may have given you access to personalise a few more options.

Pressure Relief When Pressure Relief is enabled, you may find it easier to breathe out. This

can help you get used to therapy.

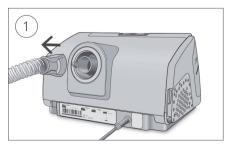
Mask This option shows your mask type setting. If you use more than one type of

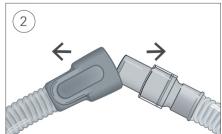
mask, adjust this setting when switching between masks.

# Caring for your device

It is important that you regularly clean your AirStart 10 device to make sure you receive optimal therapy. The following sections will help you with disassembling, cleaning, checking and reassembling your device.

## Disassembling





- 1. Hold the cuff of the air tubing and gently pull it away from the device.
- 2. 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.

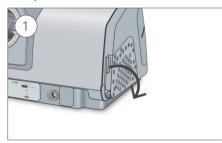
- 1. Wash the air tubing in warm water using mild detergent. Do not wash in a dishwasher or washing machine.
- 2. Rinse the air tubing thoroughly and allow to dry out of direct sunlight and/or heat.
- 3. Wipe the exterior of the device with a dry cloth.

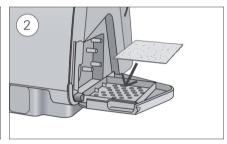
## Checking

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

- 1. Check the air tubing and replace it if there are any holes, tears or cracks.
- Check the air filter and replace it at least every six months.Replace more often if there are any holes or blockages by dirt or dust.

### To replace the air filter:





- 1. Open the air filter cover and remove the old air filter. The air filter is not washable or reusable.
- 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 air tubing is dry, you can reconnect it to the device.

- 1. Connect the air tubing firmly to the air outlet located on the rear of the device.
- 2. Connect the free end of the air tubing firmly onto the assembled mask.

## Therapy data

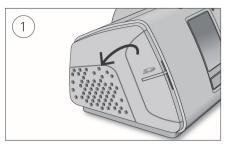
Your AirStart 10 device records your therapy data for you and your care provider so they can view and make changes to your therapy if required.

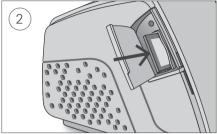
#### SD card

Your therapy data is stored 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.

#### 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.

# Travelling

You can take your AirStart 10 device with you wherever you go. Just keep the following in mind:

- Use the travel bag provided to prevent damage to the device.
- Make sure you have the appropriate power cord for the region you are travelling to. For information on purchasing, contact your care provider.

# Travelling by plane

Your AirStart 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 AirStart 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.

# **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.	
My mouth is very dry and uncomfortable		
Air may be escaping through your mouth.  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 a	m not getting enough air)
Ramp may be in progress. Wait for air pressure to build up or turn Ramp Time off.	
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 Select to turn it back on.
Power may not be connected.	Connect the power supply and make sure the plug is fully inserted.

# Device messages

Device message/possible cause	Solution
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.
Tubing blocked, check your tubing	
Air tubing may be blocked.	Check the air tubing and remove any blockages. Press Home or Select to clear the message and then press Start/Stop to restart the device.
SD card error, remove your card and press Start to b	egin therapy
SD card may not be inserted correctly.	Remove and reinsert the SD card.
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 $\widehat{\blacksquare}$ to the unlock position $\widehat{\blacksquare}$ and then re-insert it.
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 Home or Select 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.
All other error messages, for example, System fault, i	refer to user guide, Error OXX
An unrecoverable error has occurred on the device.	Contact your care provider. Do not open the 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.
- Make sure the power cord and plug are in good condition and the equipment is not damaged.
- Keep the power cord away from hot surfaces.
- If you notice any unexplained changes in the performance of the device, if it is making
  unusual sounds, if the device or the power supply are dropped or mishandled, or if the
  enclosure is broken, discontinue use and contact your care provider or your ResMed
  Service Centre.
- Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorised ResMed service agent.
- Beware of electrocution. Do not immerse the device, power supply or power cord in water.
   If liquids are spilled into or onto the device, unplug the device and let the parts dry. Always
   unplug the device before cleaning and make sure that all parts are dry before plugging it
   back in.
- Supplemental oxygen must not be used while smoking or in the presence of an open flame.
- Always make sure that the device is turned on and airflow generated before the oxygen supply is turned on. Always turn the oxygen supply off before the device is turned off, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Do not perform any maintenance tasks while the device is in operation.
- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the device is not recommended. They
  may result in increased emissions or decreased immunity of the device.

# ⚠ CAUTION

- Use only ResMed parts and accessories with the device. Non-ResMed parts may reduce the effectiveness of the treatment and/or damage the device.
- Use only vented masks recommended by ResMed or by the prescribing doctor with this
  device. Fitting the mask without the device blowing air can result in rebreathing of exhaled
  air. Make sure that the mask vent holes are kept clear and unblocked to maintain the flow
  of the fresh air into the mask.
- Be careful not to place the device where it can be bumped or where someone is likely to trip over the power cord.
- Blocking the air tubing and/or air inlet of the device while in operation could lead to overheating of the device.
- Keep the area around the device dry, clean and clear of anything (eg, clothes or bedding) that could block the air inlet or cover the power supply unit.
- Incorrect system setup may result in incorrect mask pressure reading. Ensure the system is correctly set up.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturising or antibacterial soaps or scented oils to clean the device, the water tub or air tubing. These solutions may cause damage or affect the humidifier performance and reduce the life of the products.

# 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.

90W	power	supply	unit
-----	-------	--------	------

AC input range: 100–240V, 50–60Hz 1.0–1.5A. Class II

115V. 400Hz 1.5A. Class II (nominal for aircraft use)

DC output: 24V =-- 3.75A

Typical power consumption: 53W (57VA)
Peak power consumption: 104W (108VA)

**Environmental conditions** 

Operating altitude:

Operating temperature: +5°C to +35°C

Note: The air flow for breathing produced by this therapy device can be higher than the temperature of the room. Under extreme ambient temperature conditions (40°C) the

device remains safe.

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

Sea level to 2,591 m; air pressure range 1013 hPa to

738 hPa

Storage and transport temperature: -20°C to +60°C

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

#### Electromagnetic compatibility

The AirStart 10 complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2:2007, for residential, commercial and light industry environments. It is recommended that mobile communication devices are kept at least 1 m away from the device.

Information regarding the electromagnetic emissions and immunity of this ResMed device can be found on www.resmed.com. on the Products page under Service and Support.

#### EN 60601-1:2006 classification

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

### Sensors

Pressure sensor: Internally located at device outlet, analogue gauge pressure

type, -5 to +45 cm  $H_2O$  (-5 to +45 hPa)

Flow sensor: Internally located at device inlet, digital mass flow type, -70

to +180 L/min

#### Maximum single fault steady pressure

Device will shut down in the presence of a single fault if the steady state pressure exceeds:

30 cm H<sub>2</sub>O (30 hPa) for more than 6 sec or 40 cm H<sub>2</sub>O (40 hPa) for more than 1 sec.

#### Sound

Pressure level measured according to EN ISO 17510-1:2009 (CPAP mode):

SlimLine: 26.6 dBA with uncertainty of 2 dBA Standard: 26.6 dBA with uncertainty of 2 dBA 26.6 dBA with uncertainty of 2 dBA

Power level measured according to EN ISO 17510-1:2009 (CPAP mode):

SlimLine: 34.6 dBA with uncertainty of 2 dBA
Standard: 34.6 dBA with uncertainty of 2 dBA

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

Physical - device	
Dimensions (H x W x D):	116 mm x 205 mm x 150 mm
Air outlet (complies with ISO 5356-1:2004):	22 mm
Weight:	1106 g
Housing construction:	Flame retardant engineering thermoplastic
Temperature	
Maximum heater plate:	68°C
Cut-out:	74°C
Maximum gas temperature:	≤ 41°C
Air filter	
Standard:	Material: Polyester non woven fibre Average arrestance: >75% for ~7 micron dust
Hypoallergenic:	Material: Acrylic and polypropylene fibres in a polypropylene carrier Efficiency: >98% for ~7-8 micron dust; >80% for ~0.5 micron dust

#### Aircraft use

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

### Operating pressure range APAP, CPAP: 4 to 20 cm H<sub>2</sub>O (4 to 20 hPa) Supplemental oxygen Maximum flow: 4 L/min Pneumatic flow path 1 Flow sensor 2. Blower 3. Pressure sensor 4. Mask 5. Air tubina 6. Side cover 7. Device 8 Inlet filter Design life Device, power supply unit: 5 years

## Air tubing: General

Cleanable humidifier:

The patient is an intended operator.

#### Air tubing

Air tubing	Material	Length	Inner diameter
SlimLine	Flexible plastic	1.8 m	15 mm
Standard	Flexible plastic	2 m	19 mm

2.5 years 6 months

#### Notes:

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

### Displayed values

Value	Range	Display resolution
Pressure sensor at air outlet:		
Mask pressure	4-20 cm H <sub>2</sub> O (4-20 hPa)	0.1 cm H <sub>2</sub> O (0.1 hPa)
Flow derived values:		
Leak	0–120 L/min	1 L/min
Value	Accuracy	
Pressure measurement <sup>1</sup> :		
Mask pressure <sup>2</sup>	$\pm [0.5 \text{ cm H}_20 (0.5 \text{ hPa}) + 4\% \text{ of measure}$	d value]
Flow and flow derived values <sup>1</sup> :		
Flow	±6 L/min or 10% of reading, whichever	is greater, at 0 to 150 L/min positive flow
Leak <sup>2</sup>	±12 L/min or 20% of reading, whichever is greater, 0 to 60 L/min	

<sup>&</sup>lt;sup>1</sup> Results are expressed at ATPD (Ambient Temperature and Pressure, Dry).

#### Pressure accuracy

### Maximum static pressure variation at 10 cm H<sub>2</sub>O (10 hPa) according to EN ISO 17510-1:2009

•		<u>.</u>
	Standard air tubing	SlimLine air tubing
Without humidification	$\pm 0.5 \text{ cm H}_2\text{O} (\pm 0.5 \text{ hPa})$	$\pm 0.5 \text{ cm H}_2\text{O} (\pm 0.5 \text{ hPa})$
With humidification	$\pm 0.5 \text{ cm H}_2\text{O ($\pm 0.5$ hPa)}$	$\pm 0.5 \text{ cm H}_2\text{O} (\pm 0.5 \text{ hPa})$

### Maximum dynamic pressure variation according to EN ISO 17510-1:2009

Device without humidification	ı and Standard aiı	tubing / Device with humidification	and Standard air tubing
Pressure [cm H <sub>2</sub> O (hPa)]	10 BPM	15 BPM	20 BPM
4	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
8	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
12	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
16	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
20	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
Device without humidification	and SlimLine air	tubing / Device with humidification a	and SlimLine air tubing

Pressure [cm H <sub>2</sub> O (hPa)]	10 BPM	15 BPM	20 BPM
4	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
8	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
12	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
16	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8
20	0.5 / 0.5	0.5 / 0.5	0.8 / 0.8

# Symbols

The following symbols may appear on the product or packaging.

😵 Read instructions before use. 🗥 Indicates a warning or caution. 📖 Follow instructions before
use. Manufacturer. EC REP European Authorised Representative. LOT Batch code.
REF Catalogue number. SN Serial number. DN Device number. On / Off. Device weight.
IP22 Protected against finger sized objects and against dripping water when tilted up to 15 degrees
from specified orientation. —— Direct current. 🕅 Type BF applied part. 🔲 Class II equipment.
"Humidity limitation. Temperature limitation. China pollution control logo 1. 🐠 🐠 China
pollution control logo 2.

<sup>&</sup>lt;sup>2</sup> Accuracy may be reduced by the presence of leaks and supplemental oxygen.

Rx Only Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician). MAX Maximum water level. Use distilled water only. Operating altitude. Atmospheric pressure limitation. Complies with RTCA DO-160 section 21, category M.



This device should be disposed of separately, not as unsorted municipal waste. To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment.

If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your ResMed device please contact your ResMed office, local distributor or go to www.resmed.com/environment.

## Servicing

Product

The AirStart 10 device is intended to provide safe and reliable operation when operated in accordance with the instructions provided by ResMed. ResMed recommends that the AirStart 10 device be inspected and serviced by an authorised ResMed Service Centre if there is any sign of wear or concern with device function. Otherwise, service and inspection of the products generally should not be required during their design life.

## Limited warranty

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

Troduct	vvarianty period
Mask systems (including mask frame, cushion, headgear and tubing)—exclusingle-use devices	uding 90 days
Accessories—excluding single-use devices	
Flex-type finger pulse sensors	
Humidifier water tubs	
Batteries for use in ResMed internal and external battery systems	6 months
Clip-type finger pulse sensors	1 year
CPAP and bilevel device data modules	
Oximeters and CPAP and bilevel device oximeter adapters	
Humidifiers and humidifier cleanable water tubs	
Titration control devices	
CPAP, bilevel and ventilation devices (including external power supply units)	) 2 years
Battery accessories	
Portable diagnostic/screening devices	

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.

Warranty period

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 organisation that has not been expressly authorised by ResMed to perform such repairs; c) any damage or contamination due to cigarette, pipe, cigar or other smoke; and d) 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.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

#### Further information

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





1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia

See www.resmed.com for other ResMed locations worldwide. For patent and other intellectual property information, see www.resmed.com/ip. Air10, AirStart, HumidAir and SlimLine are trademarks of ResMed Ltd. SlimLine is registered in U.S. Patent and Trademark Office. SD Logo is a trademark of SD-3C, LLC. © 2017 ResMed Ltd. 378143/3 2017-11

