

# **Astral**<sup>™</sup>series



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# Introduction

The Astral device provides mechanical ventilation to both ventilation dependent and non-dependent patients. It delivers pressure and volume ventilation through either a valve or leak circuit, and is compatible with a range of accessories to support specific use cases.

The information in this guide applies to both the Astral 100 and the Astral 150 devices. Where information applies to only one of these devices, that device will be specified.

This User Guide is for a patient or carer user, and does not contain all the information provided in the Clinical Guide.



- Read the entire manual before using the Astral device.
- Use the Astral device only as directed by a physician or healthcare provider.
- Use the Astral device only for the intended use as described in this manual. Advice contained in this manual does not supersede instructions given by the prescribing physician.
- Install and configure the Astral device in accordance with the instructions provided in this guide.

# **A** CAUTION

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

## Indications for use

The Astral device provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.



The Astral device is not intended for use as an emergency transport ventilator.

## Contraindications

The Astral device is contraindicated in patients with the following pre-existing conditions:

- pneumothorax or pneumomediastinum
- pathologically low blood pressure, particularly if associated with intravascular volume depletion
- cerebrospinal fluid leak, recent cranial surgery or trauma
- severe bullous lung disease
- dehydration.

#### Adverse effects

Patients should report unusual chest pain, severe headache or increased breathlessness. The following side effects may arise during use of the device:

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

# General warnings and cautions

The following are general warnings and cautions. Further specific warnings, cautions and notes appear next to the relevant instruction in the manual.

A warning alerts you to possible injury.

# **M** WARNING

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if the device or the power supply are dropped or mishandled discontinue use and contact your healthcare provider.
- For ventilator-dependent patients, always have alternate ventilation equipment available, such as a back-up ventilator, manual resuscitator or similar device. Failure to do so may result in patient injury or death.
- The Astral device is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.
- Ventilator-dependent patients should be continuously monitored by qualified
  personnel or adequately trained carers. These personnel and carers must be capable of
  taking the necessary corrective action in the event of a ventilator alarm or malfunction.
- The Astral device is not intended to be operated by persons (including children) with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.
- The Astral device is not intended to be operated by patients unless they have been given adequate instruction concerning the operation of the device by a person responsible for the patient's safety.
- The Astral device must not be used in the vicinity of an MRI device.
- The effectiveness of ventilation and alarms should be verified including after any ventilation or alarm setting change, any change in circuit configuration, or after a change to co-therapy (eg, nebulisation, oxygen flow).
- The Astral device and AC Power Supply can get hot during operation. To prevent possible skin damage do not leave the Astral device or AC Power Supply in direct contact with the patient for extended periods of time.

A caution explains special measures for the safe and effective use of the device.

# **A** CAUTION

- Repairs and servicing should only be performed by an authorised ResMed service representative.
- The airflow for breathing produced by the device can be as much as 6°C higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 35°C.
- Do not expose the device to excessive force, dropping or shaking.

A **note** advises of special product features.

#### Notes:

• For assistance and reporting of issues associated with the Astral device, contact your Health Care Provider or authorised ResMed representative.

# The Astral device

The following images describe the components of the Astral device.



# Description

- Adapter port
  Can be fitted with single limb adapter, single limb leak adapter or double limb adapter (Astral 150 only).
- 2 Handle
- Inspiratory port (to patient)
  Provides an outlet for pressurised air to be delivered to the patient via the patient circuit. Includes  $FiO_2$  sensor on the Astral 150. The  $FiO_2$  sensor is an optional accessory on the Astral 100.
- 4 Ethernet connector (service use only)
- 5 USB connector (for download to ResScan)

- 6 Mini USB connector (service use only)
  7 DC power inlet
  8 Device on/off push button
  9 SpO<sub>2</sub> Sensor connector
  10 Remote alarm five pin connector
  11 Low flow oxygen input (up to 30 L/min)
- The Astral device interface

Air inlet (complete with hypoallergenic filter)

12

The interface of the Astral device comprises several different features described in the following image.



# Description

- 1 Touch screen
- 2 Power source indicators
  - AC (mains power supply)
  - DC (external battery or car accessory adapter)
  - Internal battery

3 Therapy on/off indicator



## Device ready

Constant green display when the device is turned on but not ventilating.



## **Device ventilating**

Flashes blue when the device is ventilating and the Ventilation LED setting is 'ON'. Otherwise is 'OFF'.

4 Alarm mute/reset button

Illuminates when an alarm is triggered and flashes when the sound is muted.

5 Alarm bar

Flashing red

High priority alarm

Flashing yellow

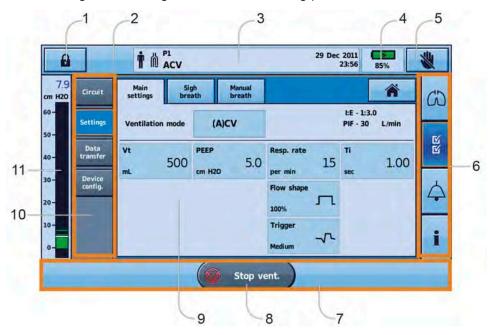
Medium priority alarm

Constant yellow

Low priority alarm

# Touch screen

The main method of interacting with the Astral device is via the touch screen. The display on the touch screen changes according to the function being performed.



## Description

1 Clinical mode access button

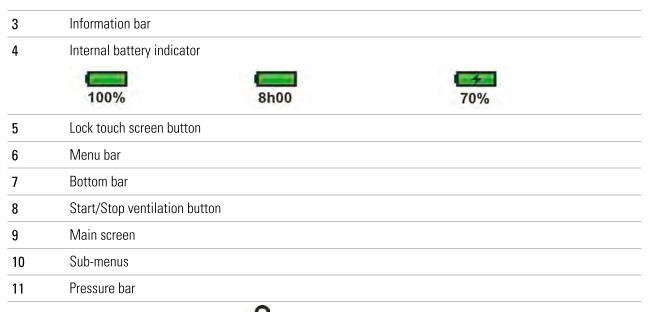




Manual breath button 2



only shown if enabled

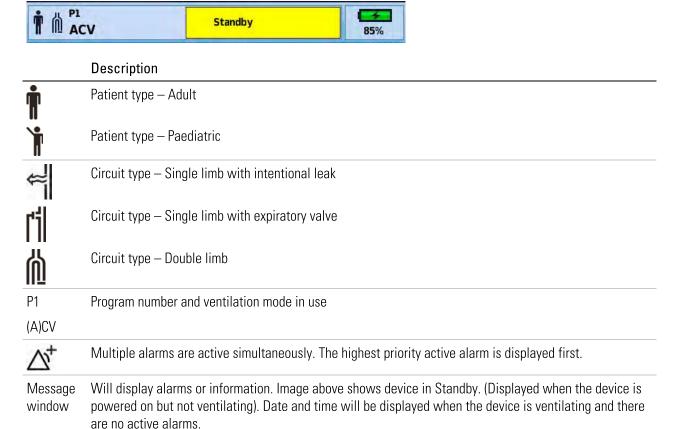


Note: Do not access Clinical mode unless directed by a clinician.

to new information messages by a single beep.

## Information bar

The Information bar is displayed at the top of the touch screen. The Information bar displays the operating status of the device, including patient type, current circuit configuration, programs, information messages, ventilation status, alarms and power status.



Information messages are displayed in blue text. If the device Alert tone setting is 'On', you will be alerted

# Menu bar

The Menu bar provides access to the four main menus in the Astral device.



#### Monitors menu

View real-time patient data in either waveform or monitoring formats including pressure, flow, leak, tidal volume, synchronisation and oximetry.



## Setup menu

Configure and view ventilation therapy and device settings.



#### Alarms menu

Configure and view alarms including alarm volume.



#### Information summary menu

View therapy statistics, used hours, events, reminder and device information.

# Bottom bar

The Bottom bar changes with the function of the device.

It can display buttons to Stop or Start ventilation and Apply or Cancel functions.

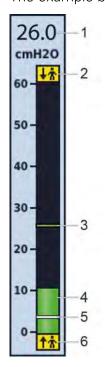


# Main screen

The Main screen displays the monitoring data, ventilation and device controls. Each function is accessed through the various menus and tabs.

## Pressure bar

The Pressure bar displays real-time therapy data while the Astral device is ventilating. Patient pressure is shown as a bar graph. Peak inspiratory pressure is shown as a numerical value and watermark. Spontaneously triggering and cycling is indicated by **1** and **1**. The example below displays the pressure bar when a patient is spontaneously breathing.



	Description
1	Peak inspiratory pressure (PIP) value
2	Spontaneous cycled breath marker—indicates patient-cycled breath
3	Peak inspiratory pressure marker
4	Current pressure
5	Positive end expiratory pressure (PEEP) setting
6	<b>1</b> Spontaneous triggered breath marker—indicates patient-triggered breath

# Using the Astral device



Make sure the area around the device is dry, clean and clear of bedding or clothes or other objects that could block the air inlet. Blocking the cooling vents could lead to overheating of the device. Blocking the air inlet could lead to patient injury.

# **A** CAUTION

- To prevent possible damage to the ventilator, always secure it to its stand or place it on a flat, stable surface. For mobile situations, ensure the Astral device is contained within its mobility bag.
- Ensure the device is protected against water if used outdoors.

# Using the Astral device for the first time

When using the Astral device for the first time, ResMed recommends you first perform a functional test. A functional test will ensure the device is in proper working order before starting therapy. Information to assist you in resolving any issues is available in Troubleshooting.



If any of the following checks fail, contact your Healthcare provider or ResMed for assistance.

#### To perform a functional test:

- 1. Turn off the device by pressing the power switch at the back of the device.
- Check the condition of the device and accessories.
   Inspect the device and all accessories. Damaged components should not be used.
- Check the patient circuit setup.
   Check the integrity of the patient circuit (device and provided accessories) and that all connections are secure.
- 4. Turn on the device and test alarms.

# **A** WARNING

## If no alarm sounds, do not use the ventilator.

Press the power switch at the back of the device to turn on the device. Check that the alarm sounds two test beeps and the LEDs for the alarm signal and the alarm mute/reset button flash. The device is ready for use when the Patient Home screen is displayed.

5. Disconnect the device from the mains and external battery (if in use) so that the device is powered by the internal battery. Check that the Battery Use alarm is displayed and the battery LED is on.

**Note:** If the charge state of the internal battery is too low an alarm occurs. See Troubleshooting (see page 55).

- 6. Reconnect the external battery (if in use) and check that the LED for the DC power supply is lit. The External DC Power Use alarm will be displayed and the Alarm LED will light.
- 7. Reconnect the device to mains power.
- 8. Check the pulse oximeter sensor (if in use).
  - Attach the accessories according to the set up descriptions. From the Monitoring menu, go to the Monitoring screen. Check that the values for SpO<sub>2</sub> and pulse are displayed.
- 9. Check the oxygen connection (if in use). Check for damage to hoses or leaks. Check remaining capacity of oxygen cylinders.
- 10. Perform a Learn Circuit.

# Powering on the device

To power on the Astral device, simply press the green power on/off button at the back of the device. The device will perform a system check as shown on the main screen.

On completion of the system check, the Patient Home screen and active program is displayed.

Note: Settings configured in the active program will be used when ventilation is started.



#### Helpful hint!

If more than one program displays on the Patient Home screen, the active program will be highlighted orange. For further information, see Programs (see page 17).

For information on powering the Astral device, see Power (see page 35).

# Powering off the device

The Astral device can only be powered off when ventilation is stopped.

Removing AC power does not power off the device. The device remains powered on internal battery.

Turning off the device must be done manually and must be performed before leaving the device disconnected from AC power for any extended period of time. Failure to do so may result in battery depletion and activation of alarms.

To power off the device, press the green on/off button at the back of the device and follow the on-screen prompts. To ensure the device is fully powered down, touch the screen.

**Note:** While the device remains connected to external mains power, the internal battery continues to charge.

# Starting and stopping ventilation

Your clinician has set up one or more ventilation programs for your therapy. If more than one program has been set up, follow the directions given by your clinician for when and how each program should be used.

**Note:** If using the device for the first time, ResMed recommends performing a functional test before starting ventilation. See Using the Astral device for the first time (see page 10).

#### To start ventilation:

- 1. Press the green on/off button at the back of the device (if power is not already on).
- 2. Press Start vent. Ventilation is started.
- 3. Add oxygen if required.

## To stop ventilation:

Ventilation can be stopped at any time and from any screen.

- 1. If oxygen is connected, turn off the oxygen.
- 2. Press and hold Stop vent.
- 3. Release when prompted.
- 4. Press Confirm. Ventilation is stopped.

# Locking and unlocking the touch screen

The touch screen can be unlocked at any time.

To manually lock the touch screen, from the Information bar press is locked the button is highlighted orange.

# . When the touch screen

#### Unlocking the touch screen

Touch the screen anywhere and follow the on-screen prompts.

# Navigating the menus

The Astral device has four menus accessible via the Menu bar. Each menu is further broken down into various sub-menus.

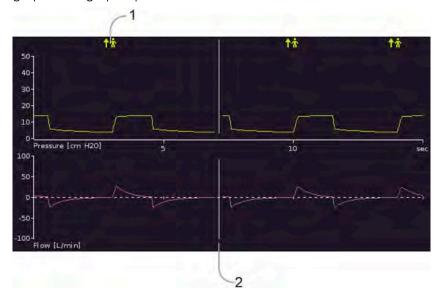
# Monitors menu

The Monitors menu allows you to view real-time ventilation data and is comprised of three submenus:

- Waveforms
- Monitoring
- Trends

## Waveforms

The Waveforms screen displays the last 15 seconds of patient airway pressure and flow in a graph. The graph updates in real-time.



#### Description

- 1 Spontaneous triggered breath marker—indicates patient-triggered breath.
- White vertical cursor—indicates the current position and moves from left to right.

## Monitoring screen

The Monitoring screen displays all measured parameters in numerical form.



#### Helpful hint!

Your care provider may ask you to access this screen and report values from time to time.

#### Trends screen

The Trends screen shows the 5th and 95th percentile values, as well as the median for the last 30 days for each of the following parameters:

- Leak
- Minute ventilation
- Peak inspiratory pressure
- Tidal volume
- Respiratory rate
- Inspiratory time
- SpO<sub>2</sub>
- Pulse rate
- FiO<sub>2</sub>



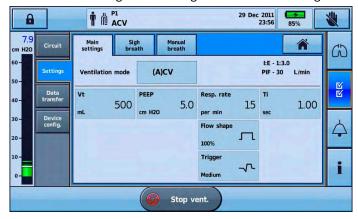
Information is displayed as bar graphs, with two graphs per screen.

Use the up and down scroll arrows to cycle through the graphs.

# ≦ Setup menu

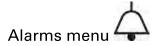
The Setup menu displays four different sub-menus:

- Circuit—to view the circuit
- Settings—to view the ventilation mode and access Manual Breath and Sigh Breath screens
- Data Transfer—to transfer data between the device and a personal computer via a USB stick
- Device Config.—to change the device configuration.

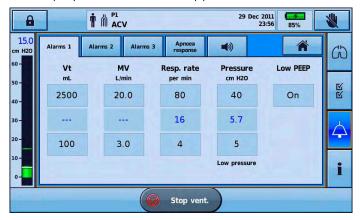


## Helpful hint!

Therapy and alarm settings can be viewed 'read only' without risk of modification, provided the Clinical mode remains locked.



The Alarms menu displays the individual thresholds for each alarm to trigger. Real-time values are displayed between the upper and lower thresholds.



# Information menu

The Information menu is comprised of two sub-menus:

- Events—all logged event activity that has taken place is displayed. A breakdown of specific alarms, settings or system events can also be viewed.
- Device—information about the actual device is displayed, eg, Model and Serial numbers, software versions, internal battery health along with the hours since the last service and patient hours used.



# Device settings

The configurable settings are described in the following table.

Alert Tone  Sets alert tones to on or off.  Default: On  Alarm Volume  Sets the volume level of the alarm system.  Settings from 1, 2, 3, 4 or 5.  Default: 3  Auto power off  Automatically powers off the device after 15 minutes of inactivity.  Conditions: The device is in Ventilation standby mode (not ventilating), is being powered by the Internal battery or an External battery and there are no active alarms.  Default: On  Display Brightness  Sets the brightness of the screen from Auto with a selection of five different brightness levels.  Default: Auto  Backlight timeout  Allows the screen backlight to turn off (go black) if the screen has not been touched for two minutes or more and there are no active alarms.  Setting to 'Off' will mean the screen back-light will be permanently on.  Default: On  Rotate Display  Flips the current orientation of the display.  Device Vent LED  Sets the status of the Ventilation active LED to On or Off during ventilation.  Default: On  Date  Allows setting of the day, month and year of the current date.	Device setting	Description
Alarm Volume  Sets the volume level of the alarm system.  Settings from 1, 2, 3, 4 or 5.  Default: 3  Auto power off  Automatically powers off the device after 15 minutes of inactivity.  Conditions: The device is in Ventilation standby mode (not ventilating), is being powered by the Internal battery or an External battery and there are no active alarms.  Default: On  Display Brightness  Sets the brightness of the screen from Auto with a selection of five different brightness levels.  Default: Auto  Backlight timeout  Allows the screen backlight to turn off (go black) if the screen has not been touched for two minutes or more and there are no active alarms.  Setting to 'Off' will mean the screen back-light will be permanently on.  Default: On  Rotate Display  Flips the current orientation of the display.  Device Vent LED  Sets the status of the Ventilation active LED to On or Off during ventilation.  Default: On	Alert Tone	Sets alert tones to on or off.
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Backlight timeout  Allows the screen backlight to turn off (go black) if the screen has not been touched for two minutes or more and there are no active alarms.  Setting to 'Off' will mean the screen back-light will be permanently on.  Default: On  Rotate Display  Flips the current orientation of the display.  Device Vent LED  Sets the status of the Ventilation active LED to On or Off during ventilation.  Default: On	Display Brightness	Sets the brightness of the screen from Auto with a selection of five different brightness levels.
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Default: On	Rotate Display	Flips the current orientation of the display.
	Device Vent LED	Sets the status of the Ventilation active LED to On or Off during ventilation.
Date Allows setting of the day, month and year of the current date.		Default: On
	Date	Allows setting of the day, month and year of the current date.
Time Allows setting of the hours and minutes of the current time.	Time	Allows setting of the hours and minutes of the current time.
Language Sets the current language of the device selected from the list of available languages.	Language	Sets the current language of the device selected from the list of available languages.

## Adjusting device settings

Access adjustable device settings from the Setup menu and select Device Config.



The current active selections are highlighted in orange.

To change settings, simply select another of the available options. The revised setting is highlighted in orange.

# **Programs**

Programs on the Astral device can be configured by your clinician to provide you with alternate treatment options. For example, a clinician can set up programs for sleeping versus daytime use, or for use during exercise or physiotherapy. Programs allow for different circuit, ventilation and alarm settings.

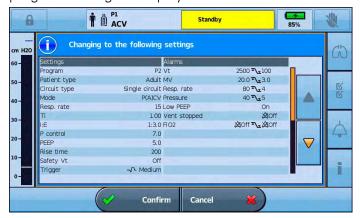
The Astral device comes with one active program. Your clinician can configure up to three additional programs (if available).

If any additional programs have been set up, they can be selected from the Patient home screen. You can change between programs while the Astral device is delivering ventilation. Changing between programs will cause ventilation and alarm settings to change, as configured by your clinician.



# To change between programs:

1. From the Patient home screen, select the program you want to use. A summary of the program settings is displayed.



2. Press **Confirm** to proceed with the change. The selected program becomes active and will be highlighted orange.



**Note:** To change to a program with a different circuit type, you will need to stop ventilation. When you have changed the circuit and the program, you can restart ventilation.

## Helpful hint!

If more than one program has been set up, follow the directions given by your clinician for when and how each program should be used.

## Manual Breath feature

Your clinician may have enabled the Manual Breath feature. This feature allows a larger than normal breath to be delivered.

To deliver a manual breath, press



# Sigh Breath feature

Your clinician may have enabled the Sigh Breath feature. This feature delivers a larger 'sigh' breath at a regular interval.

If configured, the Astral device will beep with a Sigh Alert prior to the Sigh Breath.

## To turn the Sigh Alert on or off:

- 1. From the Setup menu, select **Settings**.
- 2. Set Sigh Alert on or off.
- 3. Press **Apply** to proceed with the change.

# Travelling with the Astral device



The Astral device should not be operated while in the Carry Bag. To ventilate while travelling, use the Mobility Bag accessory.

When travelling with the Astral device:

- The Astral device should always be packed in its carry bag when not in use to prevent damage to the device.
- The carry bag is for carry-on luggage only. The carry bag will not protect the Astral device if it is put through checked baggage.
- For your convenience at security stations, it may be helpful to keep a printed copy of the user guide in the Astral carry bag to help security personnel understand the device and refer them to the following statement.
- ResMed confirms that the Astral device meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160, section 21, category M) for all phases of air travel.

# Assembling patient circuits



- Use a double limb circuit for direct measurement of exhaled volumes. In this configuration, the expired volume is returned to the ventilator for independent measurement. (Astral 150 only)
- The Astral device does not support monitoring of exhaled volumes when used with a single limb circuit with expiratory valve.
- The patient circuit should be arranged so as not to restrict movement or pose a strangulation risk.
- Only use circuit components that comply to the relevant safety standards including ISO 5356-1 and ISO 5367.

# **⚠** CAUTION

For paediatric use, ensure that the patient circuit type fits and is suitable for use with a child. Use a paediatric patient type for patients that weigh less than 23 kg and normally require less than 300 mL tidal volume.

# Circuit options

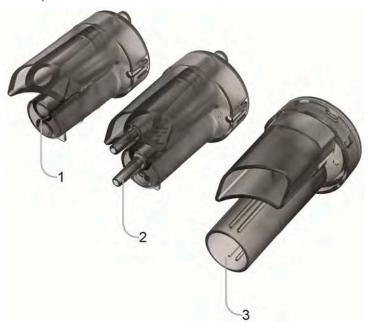
The Astral device supports a range of circuits with the use of interchangeable circuit adapters. Breathing circuits may be of 10, 15 or 22 mm diameter.

The following table may assist in selecting suitable circuits and settings for different patient types

Tidal volume range	Recommended patient type setting	Suitable circuit diameters	
50 mL to 300 mL	Paediatric	10 mm, 15 mm or 22 mm	
> 100 mL	Adult	15 mm or 22 mm	

# Circuit adapters

There are three circuit adapters:



	Adapter		For use with
1	Single limb leak	₩	Single limb circuit with intentional leak
2	Single limb	ſΊ	Single limb circuit with expiratory valve (expiratory valve integrated into the circuit)
3	Double limb (Astral 150 only)	Щ	Double limb circuit (expiratory valve integrated into the adapter) OR single limb circuit with intentional leak

A Learn Circuit should be performed after any change of circuit. Astral will provide accurate therapy as long as the Learn Circuit is passed. See Learn Circuit (see page 25).



When using a noninvasive interface, the measurement of patient exhaled gas volume may be affected by leak.

## Helpful hint!

Only use adapters and circuits as directed by your clinician.

# Fitting the circuit adapter

Before connecting the patient circuit, the adapter specific to the required circuit type must be fitted.

# To fit the adapter:

- 1. Turn over the device and place on a soft surface (to protect the LCD screen).
- 2. Press and hold the eject button. Pull the cover out towards you.
- 3. Lift the adapter out of the socket.
- 4. Replace with the new adapter, ensuring it sits firmly in the socket.
- 5. Place the cover over the enclosure, ensuring the runners on the device and the cover are aligned. Slide the cover back into place until the latch clicks.



# Connecting a single limb circuit with intentional leak

An intentional leak may be provided in-line using the ResMed Leak Valve or via an integrated mask vent.

When using a circuit with intentional leak, estimation of the patient respiratory flow is enhanced by ResMed's automatic leak management feature —Vsync. Vsync technology allows the device to estimate the patient respiratory flow and tidal volume in the presence of unintentional leak.

# **A** WARNING

- At low pressures, the flow through the mask vents may be inadequate to clear all exhaled gases, and some rebreathing may occur when using a single limb circuit with intentional leak.
- Ensure the vent holes at the mask or at the ResMed Leak Valve are unobstructed. Ensure the area around the vent holes is clear of bedding, clothes, or other objects and that the vents holes are not directed towards the patient.

#### To connect a single limb circuit with intentional leak:

- Check the device is fitted with the single limb leak adapter. Otherwise, change the adapter.
   Note: The Astral 150 can also support a single limb circuit with intentional leak using a double limb adapter.
- 2. Connect the inspiratory limb to the inspiratory port.
- 3. Attach any required circuit accessories (eg, humidifier or filter).
- 4. Select the circuit type and perform a Learn Circuit.
- 5. If using a non-vented mask or tracheostomy connector, attach a ResMed Leak Valve to the free end of the air tubing ensuring that the Leak Valve is as close as possible to the patient.
- 6. Attach the patient interface (eg, mask) to the Leak valve or the free end of the air tubing as appropriate and adjust the mask type setting on the Astral device.



# Connecting a single limb circuit for invasive use



Always set up the ResMed Leak Valve in the breathing circuit with the arrows and the symbol pointing in the direction of air flow from the Astral device to the patient.



For invasive ventilation, since the patient's upper respiratory system is bypassed by an artificial airway device (for example endotracheal or tracheostomy tube) humidification of the inspired gas is required to prevent lung injury.

# Connecting a single limb circuit with expiratory valve

To enable fast and accurate connection, use an Astral Quick Connect Single Limb Circuit. This custom accessory with its integrated proximal pressure sensor and expiratory valve control line, is designed specifically for use with Astral ventilators.

#### To connect an Astral 'Quick Connect' Single Limb Circuit with expiratory valve:

- 1. Check the device is equipped with the single limb adapter (otherwise change the adapter).
- 2. Connect the air tubing to the inspiratory port on the device.
- 3. Attach the Astral Quick Connect circuit to the single limb adapter on the device (see diagram below).
- 4. Attach any required circuit accessories (eg, humidifier or filter).
- 5. Select the circuit type and perform a Learn Circuit.
- 6. Attach a patient interface (eg, mask) to the connector on the pneumatic valve.

# Assembling patient circuits



# To connect a standard single limb valved circuit to the Astral:

- 1. Connect the Proximal pressure line to the upper connector of the Astral device single limb adapter.
- 2. Connect the PEEP control line to the lower connector of the Astral device single limb adapter.
- 3. Connect the air tubing to the inspiratory port of the device.
- 4. Attach any required circuit accessories (eg, humidifier or filter).
- 5. Select the circuit type and perform a Learn Circuit.
- 6. Attach a patient interface (eg, mask) to the connector on the pneumatic valve.



# Connecting a double limb circuit (Astral 150 only)

The Astral device measures exhaled air flowing through the double limb circuit adapter. This enables patient-exhaled tidal volume to be accurately measured and monitored.

#### To connect a double limb circuit:

- 1. Ensure the device is fitted with the double limb adapter (otherwise change the adapter).
- 2. Connect the ends of the air tubing to the inspiratory and adapter ports on the device.
- 3. Attach any required circuit accessories (eq. humidifier or filter).
- 4. Select the circuit type and perform a Learn Circuit.
- 5. Attach a patient interface (eg, mask) to the end of the air tubing.



# Learn Circuit

In order to support a wide range of circuit configurations and accessories, the Astral device provides a Learn Circuit function to determine the impedance and compliance characteristics of the circuit. As part of the Learn Circuit functionality the Astral performs a device self-test where the Oxygen cell and expiratory flow sensors are checked and calibrated.



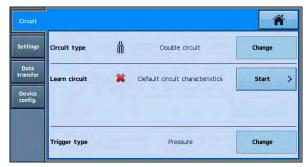
To ensure optimum and accurate performance, it is recommended that the Learn Circuit function be performed with every change of circuit and at regular intervals not less than once per month.

Do not connect patient interfaces prior to performing the Learn Circuit. Patient interfaces include any components placed after the single circuit's expiratory valve or exhalation port, or double limb circuit's 'Y' piece (eg. HMEF, catheter mount, mask, tracheostomy tube).

# To perform a Learn Circuit:

- 1. From the Setup main menu, select the Circuit sub-menu.
- 2. Press Start and follow the on-screen prompts.

Do not connect patient interfaces prior to performing the Learn Circuit. Patient interfaces include any components placed after the single circuit's expiratory valve or exhalation port, or double limb circuit's 'Y' piece (eg. HMEF, catheter mount, mask, tracheostomy tube).



The prompts will guide you through a number of steps including:

- With the patient interface disconnected from the patient connection port, the Astral device will characterise the impedance of the inspiratory path.
- With the patient connection port sealed, the Astral device will characterise the total circuit compliance, and then the impedance of the expiratory path.

A test result screen is displayed if any of the tests fail, otherwise the Learn Circuit function has been successfully completed and you will be returned to the Main settings page.



The following icons are used to report the Learn Circuit results.

Icon		Description
	Ok	Learn Circuit has passed.
	Caution!	Circuit resistance is high. The device will use the learned circuit characteristics. Accuracy of control and monitoring may not be met. Ensure that ventilation and alarms are effective before proceeding further.
	Warning!	Learn Circuit has failed. Default circuit characteristics will be applied.
		Accuracy of control and monitoring will be degraded. Ensure that ventilation and alarms are effective before proceeding further.
		Care must be taken to ensure the resistance of the ventilator breathing circuit is appropriate to the patient size. Should ventilation cease for any reason, the patient must overcome this resistance in order to breath.
		The International Standards Organisation (ISO) has judged that patients ventilated with tidal volumes in excess of 300 mL should use breathing circuits with a resistance no more than 6 cm $\rm H_2O$ pressure drop at a flow rate of 30 L/min.
		The Astral Learn Circuit applies a pass/fail threshold of 6 cm $H_2O$ at 30 L/min in Adult range, and 6 cm $H_2O$ at 15 L/min in Paediatric range.

# Helpful hint!

In the event of a Caution or Warning on the Learn Circuit results screen, ventilation can proceed. Contact your Clinician to report these results.

# Accessories

For a full list of accessories, see the Ventilation accessories guide on www.resmed.com on the Products page under Service and Support. If you do not have internet access, please contact your ResMed representative.



Before using any accessory, always read the accompanying User Guide.

#### Helpful hint!

Only use accessories as directed by your clinician. Replace accessories according to the manufacturer's instructions.

# Optional accessories



The Astral device should only be used with accessories recommended by ResMed. Connection of other accessories could result in patient injury or damage to the device.

The Astral device is compatible with a range of accessories as follows:

- ResMed External Battery
- Astral DC adapter
- Astral Mobility Bag
- ResMed Hospital Trolley
- ResMed Remote Alarm II
- Pulse Oximeter
- Astral Desktop stand.

# Attaching patient circuit accessories

# **M** WARNING

- Adding or removing circuit components can adversely affect ventilation performance.
   ResMed recommends performing a Learn circuit every time an accessory or component is added to or removed from the patient circuit.
- Do not use electrically conductive or anti-static air tubing.

## Attaching a humidifier

A humidifier or HME is recommended for use with the Astral device.

# ⚠ WARNING

- For invasive ventilation, since the patient's upper respiratory system is bypassed by an artificial airway device (for example endotracheal or tracheostomy tube) humidification of the inspired gas is required to prevent lung injury.
- Always place the humidifier on a level surface below the level of the device and the patient to prevent the mask and tubing filling with water.
- Only use humidifiers that comply to the relevant safety standards, including ISO 8185 and set up the humidifier according to the manufacturer's instructions.
- Monitor the air tubing for water condensation and / or spillage from the humidifier.
   Use appropriate precautions to prevent water in the circuit transferring to the patient (eg, a water trap).

For non-invasive ventilation, for patient experiencing dryness of the nose, throat or mouth, humidification of the inspired gas will prevent subsequent irritation and discomfort.

# **A** CAUTION

Make sure that the water tub is empty and thoroughly dried before transporting the humidifier.

#### To attach a humidifier to a patient circuit:

- 1. Connect a length of air tubing to the inspiratory port on the device.
- 2. Connect the other end of the air tubing to the inlet port on the humidifier.
- 3. Connect the patient circuit to the outlet port on the humidifier.

The image below shows proper use of a humidifier in combination with a double limb circuit.



When using heated humidification with a double limb circuit, condensation may form in the expiratory flow sensor if the air is cooled to below its dew point. Condensation may also form in the patient circuit and is most likely to form at high humidity settings and low ambient temperatures.

Condensation forming in the expiratory flow sensor may cause a loss of expiratory flow measurement and compromised therapy.

#### Accessories

To prevent condensation at the Expiratory flow sensor, always follow the manufacturer's instructions on how to prevent condensation and regularly check the patient circuit for condensation.

To ensure accurate therapy, Astral's Learn Circuit function should be performed.

# Attaching a Heat Moisture Exchange (HME)

HME's are passive humidification systems that retain heat and moisture from the patient's exhaled gases via an internal membrane. An HME should not be used with active humidification. An HME can be used with the Astral device with a double limb circuit or single limb circuit with integrated valve.



#### WARNING.

Only use HMEs that comply to the relevant safety standards, including ISO 9360-1 and ISO 9360-2.

Place the HME between the patient end of the circuit and the patient interface.



Do not connect patient interfaces prior to performing the Learn Circuit. Patient interfaces include any components placed after the single circuit's expiratory valve or exhalation port, or double limb circuit's 'Y' piece (eg. HMEF, catheter mount, mask, tracheostomy tube).

# Attaching an antibacterial filter



- Regularly check the antibacterial filter and expiratory valve for signs of moisture or other contaminants, particularly during nebulisation or humidification. Failure to do so could result in increased breathing system resistance and/or inaccuracies in expired gas measurement.
- Only use antibacterial filters that comply to the relevant safety standards, including ISO 23328-1 and ISO 23328-2.



The antibacterial filter must be used and replaced according to the manufacturer's specifications.

#### To attach an antibacterial filter:

- 1. Fit the antibacterial filter to the inspiratory port of the device.
- 2. Connect the air tubing to the other side of the filter.
- 3. Perform the Learn Circuit function.
- 4. Attach the patient interface to the free end of the air tubing.



# **⚠** WARNING

- To prevent the risk of cross-contamination, an antibacterial filter is mandatory if the device is to be used on multiple patients.
- The expiratory module, internal antibacterial filter, expiratory flow sensor and cushion come into contact with exhaled gases but do not form part of the inspiratory pathway.

## Adding supplemental oxygen

Oxygen may be prescribed by your clinician.

The Astral device is designed to be compatible with levels of supplemental oxygen up to 30 L/min.

At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration will vary depending on the Ventilation mode and settings, patient breathing pattern, mask selection, and leak rate.



# **M** WARNING

- · Use only medical grade oxygen sources.
- Always ensure that the device is ventilating before the oxygen supply is turned on.
- Oxygen flow must be turned off when the device is not ventilating so that oxygen does
  not accumulate within the device enclosure. Explanation: Accumulation of oxygen
  presents a risk of fire. This applies to most types of ventilators.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well-ventilated rooms.
- Supplemental oxygen must be added into Astral's oxygen inlet at the rear of the device. Adding oxygen elsewhere, ie, into the breathing system via a side port or at the mask, has potential to impair triggering and accuracy of therapy/monitoring and impair alarms (eg, High Leak alarm, Non-vented mask alarm)
- The patient circuit and the oxygen source must be kept at a minimum distance of 2 m away from any sources of ignition.
- Monitor supplemental oxygen using the integrated FiO<sub>2</sub> sensor and alarms. To monitor the fraction of inspired oxygen, use an external O<sub>2</sub> monitor compliant with ISO 80601-2-55. Sampling should be taken from the connection to the patient interface.
- When operating Astral in its mobility bag do not add more than 6 L/min of supplemental oxygen.
- Astral is not designed for use with heliox, nitric oxide or anaesthetic gases.
- Do not position the Astral device on its side as this may affect FiO<sub>2</sub> monitoring accuracy.

#### To add supplemental oxygen:

- 1. Unlock the low flow oxygen inlet at the rear of the device by pushing up on the locking clip.
- 2. Insert one end of the oxygen supply tubing into the oxygen connector port. The tubing will automatically lock into place.
- 3. Attach the other end of the oxygen supply tubing to the oxygen supply.
- 4. Start ventilation
- 5. Turn on oxygen and adjust to the prescribed flow rate or FiO<sub>2</sub> level.





Supplemental oxygen can also added from an oxygen bottle (at 400kPA) however a flow regulator must be fitted to ensure the delivered oxygen remains at or below 30 L/min.

Before you remove supplemental oxygen from the device, ensure the Oxygen supply has been turned off.

#### To remove supplemental oxygen:

- 1. Unlock the low flow oxygen inlet at the rear of the device by pushing up on the locking clip.
- 2. Remove the oxygen supply tubing from the oxygen connector port.





#### Attaching a nebuliser

If required, a nebuliser can be used in conjunction with the Astral device. ResMed recommends Aerogen® nebuliser products.

### **⚠** WARNING

- Always connect an antibacterial filter to the expiratory inlet of the Astral device to protect the expiratory valve.
- Regularly check the antibacterial filter and expiratory valve for signs of moisture or other contaminants, particularly during nebulisation or humidification. Failure to do so could result in increased breathing system resistance and/or inaccuracies in expired gas measurement.
- Use of a gas jet nebuliser may affect ventilator accuracy. Monitor the patient and compensate for the gas volume introduced by the gas jet nebuliser as appropriate.
- For full details on using a nebuliser, see the User Guide that comes with that device.

Connect the nebuliser unit with a T-piece into the inspiratory limb of the breathing circuit before the patient.



Pictured above: Aeroneb® Solo in-line.

For full instructions for use, please consult the Aeroneb Solo System Instruction Manual.

### Attaching other accessories

#### Attaching a pulse oximeter

### **M** WARNING

Only use compatible NONIN<sup>TM</sup> finger pulse sensors\*.

### **A** CAUTION

Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: excessive ambient light, excessive motion, electromagnetic interference, blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.), moisture in the sensor, improperly applied sensor, incorrect sensor type, poor pulse quality, venous pulsations, anemia or low haemoglobin concentrations, cardiogreen or other intravascular dyes, carboxyhaemoglobin, methemoglobin, dysfunctional haemoglobin, artificial nails or fingernail polish, or a sensor not at heart level.

#### To connect the pulse oximeter:

- 1. Connect the plug of the finger pulse sensor to the plug of the pulse oximeter.
- 2. Connect the plug of the pulse oximeter to the SpO<sub>2</sub> (pulse oximeter) connector at the rear of the device.



\* Please refer to the Respiratory Care accessories catalogue for part numbers of oximeter accessories with confirmed compatibility.

Once you have attached the pulse oximeter, a message will briefly display in the information bar. Real-time SpO<sub>2</sub> and Pulse readings can be viewed from the Monitoring menu.



#### Attaching a remote alarm

The ResMed Remote Alarm II has been designed for use with Astral devices. The Remote Alarm II alerts you to an alarm that requires immediate attention. It triggers an audible and visual alarm when an alarm is triggered on the Astral device. For full instructions on using the Remote Alarm II, see the User Guide that comes with that device.

#### To connect the Remote Alarm II to the Astral device:

- 1. Connect one end of the alarm cable to the (3 pin) input connector on the remote alarm.
- 2. Connect the other end to the (5 pin) output connector located at the rear of the Astral device.



### **A** CAUTION

To remove the cable, pull firmly on the connector. Do not twist.

#### **Power**

### **M** WARNING

- Beware of electrocution. Do not immerse the device, power supply or power cord in water.
- 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.
- Explosion hazard—do not use in the vicinity of flammable anaesthetics.

The Astral device can be used with four different power sources:

- Mains power
- External battery
- Internal battery
- External DC power supply (eg, car 12V power outlet).

For information on power supplies and sources see the Technical Specifications.

#### Connecting to mains power

### **M** WARNING

Ensure that the power cord does not pose a tripping or choking hazard.

#### To connect to mains power:

- 1. Connect the DC plug of the supplied ResMed external power supply unit to the rear of the Astral device.
- 2. Before connecting the power cord to the ResMed power supply unit, ensure the end of the connector of the power cord is correctly aligned with the input socket on the power supply unit.
- 3. Plug the other end of the power cord into the power outlet.



**Note:** The power cord is equipped with a push-pull locking connector. To remove, grasp the power cord housing and gently pull the connector from the device. Do not twist its outer housing or pull on the cord.



#### Connecting to a ResMed Power Station (RPSII)

The RPSII provides the Astral device with electrical autonomy for eight hours of typical use. To use, connect the power cord of the RPSII to the DC inlet port on the device.

### **△** CAUTION

When using the Astral device with an RPSII, the internal battery will not be charged.



### Connecting the Astral External Battery

The Astral External Battery has been designed specifically for use with the Astral Series of ventilators. It is intended to provide Astral ventilators with an additional eight hours of electrical autonomy during typical use.

For full details on using the Astral External Battery, refer to the External Battery user guide.



#### Using the External Battery

Connecting a fully charged External Battery to the Astral device can provide up to a total of 16 hours power during typical use. A second fully charged External Battery can be connected to the Astral device to provide up to a total of 24 hours power during typical use. A maximum of two External batteries can be connected to the Astral device.

Once the External Battery is connected to the Astral device, the DC mains indicator on the User Interface will illuminate.

Information on system and battery charge levels can be accessed in one of two ways.

#### 1. Battery Indicator

The capacity of the External Battery will be added to the RunTime indicator on the Information bar of the Astral interface. (this may take a couple of minutes). The total will be the sum of the Astral internal battery plus either one or two external batteries.

Under normal operating conditions, the ventilator will display:

- Total system state of charge as a percentage when in ventilation standby mode or connected to mains power. The battery percentage is an average of all batteries connected to the system. Full details of individual battery capacities can be reviewed in the information page.
- Estimated remaining run time while delivering therapy.

#### 2. Battery information page

The battery information page can be accessed from the device information page. This screen will display the current charge level (0-100) for any batteries currently detected by the system, as well as the total system charge.



Do not attempt to connect more than two external batteries. Battery specific messages and alarms on the Astral device will not operate for any additional units.

Alarms and messages relating to the External Battery may occur from time to time. All message information will be displayed on the Astral user interface, and will be accompanied by an audible signal. Refer to the Alarms troubleshooting section for further information.

### Using the internal battery

An internal battery is included in the Astral device. It ensures a continuous power supply when mains power is disrupted and no external battery is connected to the device. When the Astral starts using the internal battery as its power source, you are notified by the **Internal battery use** alarm and with the internal battery power source indicator.

The internal battery operates for approximately eight hours under typical conditions. During ventilation, alarms will alert the user to a low battery condition. During standby, no alarms will be announced. The user should regularly check the battery status.

### **M** WARNING

- When using the Astral device as a backup ventilator, ensure the internal battery level is checked on a regular basis.
- As the battery ages, the available capacity decreases. When the remaining battery capacity is low, do not rely on the internal battery as the primary power supply.
- The internal battery should be replaced every two years, or when there is a noticeable reduction in usage time when fully charged.

### **A** CAUTION

- Revert to AC mains power when the remaining capacity of the battery is low.
- The internal battery may stop charging when ambient temperatures of 35°C or more are reached.
- The internal battery will be depleted if the device is left in storage for an extended period of time. During storage, ensure the internal battery is recharged once every six months.
- Storing the Astral device at temperatures exceeding 50°C for extended periods will accelerate battery ageing. This will not affect the safety of the battery or the device.

While connected to mains power, the internal battery continues to charge when the device is operating or in standby.

When the internal battery is being used to power the device, the amount of charge remaining in the battery is displayed in the information bar as shown in the following table.

Display	Description
100%	When the internal battery is in use, but the device is not ventilating, the battery charge level is displayed.
8h00	When the internal battery is in use during ventilation, the remaining usage is displayed as estimated by current operating conditions.
70%	When the internal battery is charging, the charge battery symbol and percentage charged is displayed.

For more information on the expected operating time of the internal battery see the Technical Specifications.

#### Battery run time

The internal battery powers the Astral device for eight hours under conditions typical to the chronic home ventilator-dependent patient.

Internal battery run time is determined by the:

- percent charge
- environmental conditions (such as temperature and altitude)
- condition and age of the battery
- device settings
- patient circuit setup and unintentional leak.

The internal battery should be replaced every two years or when there is a noticeable reduction in usage time when fully charged.

#### Storing and recharging

If the internal battery is not used, it must be discharged and recharged every six months.

It takes approximately four hours to fully recharge the internal battery from depletion; however this can vary depending on environmental conditions and the device operating state.

#### To prepare the internal battery for long-term storage:

- 1. Check that the battery charge level is between 50 and 100%. If not, charge the device to at least 50% prior to storage.
- 2. Remove the power cord from the Astral.
- 3. Turn off the device.

#### To recharge the internal battery:

- 1. Connect the device to mains power.
- 2. Charging commences as indicated by a flashing battery charging indicator symbol in the Information bar.

### Connecting to an external DC power source



- When using a car auxiliary adapter, start the car before plugging in the device's DC adapter.
- If the external DC power source drops to below 11V, the Astral will switch to internal battery.

#### To connect DC power:

- 1. Connect the DC plug of the external DC power supply unit to the rear of the device.
- 2. Plug the other end of the power cord into the power outlet.



### **Astral Carry Bag**

The Astral device should always be packed in its Carry Bag when not in use to prevent damage to the device.



The Astral should not be operated while in the Carry Bag. To ventilate while travelling, use the Astral Mobility bag.

#### To use the Carry Bag

- 1. Prior to placing the device in the Carry Bag, remove:
  - the power connection from the rear of the device
  - all patient circuit components
  - all accessories, including Remote Alarm and oximeter
  - the USB Stick.
- 2. Place the Astral device carefully into the Carry Bag, ensuring the handle is at the top and the screen faces the printed image on the bag.
- 3. Secure the Astral device in place by using the Velcro strap. (To ensure the most secure position, thread the Velcro strap through the handle and attach.)
- 4. Place the Power Supply unit and any heavy components in the side zippered pocket.
- 5. Ensure all zippers are completely closed and the device secure before lifting the Carry Bag.



Do not place any heavy or bulky objects in the zippered pocket on the inside front of the bag. This could result in damage to the LCD Touch screen.



### **Alarms**

The Astral device activates alarms to alert you to conditions that require attention to ensure patient safety. When an alarm is activated, the Astral device provides both audible and visual alerts, and displays an alarm message in the Alarm display on the Information bar.

As soon as the activation condition is met, the Astral device provides both audible and visual alerts without delay.



	Indicator	Description
1	Alarm display	Displays either the alarm message for the highest priority active alarm, or the last alarm not yet reset.
		Press the Alarm display for further alarm information.
		Certain conditions may result in multiple alarms. $\triangle^+$ indicates that there are multiple active alarms. Press $\triangle^+$ when displayed to view all alarms and respond appropriately. Alarms are displayed in order of priority.
2	Active Alarms screen	Displays the full set of active alarms. Will automatically display upon activation of an alarm in Patient mode.
3	Information menu	Some alarms clear automatically. To view a history of alarms, view the alarm log through the Information menu.

4	Alarm mute/reset button	<ul> <li>State:</li> <li>no light – no active alarms</li> <li>steady light – active alarm/s</li> <li>flashing light – alarm mute on.</li> </ul>
		<ul><li>This button also allows you to:</li><li>mute the audible alert</li><li>reset the currently displayed alarm (if permitted).</li></ul>
5	Alarm bar	Indicates the priority of the alarm in the Alarm display.

### Alarm priority

Alarms are classified into relative priority (high, medium and low) according to the severity and urgency of the alarm condition. Respond to all alarms. An immediate response is required for high priority alarms.

Alarm priority		Alarm bar	Audible alert
High	#	Red flashing light	10 beeps every 5 seconds
Medium	#	Yellow flashing light	3 beeps every 15 seconds
Low		Yellow steady	2 beeps every 25 seconds

### Helpful hint!

For suggestions on resolving most common alarms, see Troubleshooting (see page 55).

#### Alarms

The following list of alarms is ordered by relative importance within priority.

High priority alarms	Medium priority alarms	Low priority alarms
Total power failure *	High pressure	Power disconnected
Low Pressure	Low PEEP	Using internal battery
Obstruction / High Pressure	High PEEP	Battery 1 fault
High Pressure	Low pulse rate	Battery 2 fault
Apnoea	High pulse rate	Power fault / No charging
Low MVe	Device overheating	
Low MVi	Pressure line disconnected	
High MVi	Last self test failed	
High MVe	Flow sensor not calibrated	
Low Vte	No SpO <sub>2</sub> monitoring	
High Vte	No FiO₂ monitoring	
Low Vti	Low internal battery	
High Vti		
Low Resp rate		
High Resp rate		
High leak		
Ventilation stopped		
Low SpO <sub>2</sub>		
High SpO <sub>2</sub>		
Low FiO <sub>2</sub>		
High FiO <sub>2</sub>		
NV mask (blocked vent)		
Ventilation not started. Incorrect adapter		
Critically low internal battery		
Circuit fault		
Incorrect circuit		
Unexpected restart		
Internal Battery inoperable		

\* No LED will flash during a Total power failure alarm.

<sup>44</sup> 

### Viewing the active alarms

in the Alarm display indicates that there are multiple active alarms. Although multiple alarms can be active simultaneously, the Alarm display only shows the highest priority alarm. The full set of active alarms is displayed in the Active alarms screen.

When the highest priority alarm is cleared, the next highest priority alarm displays in the Alarm display.



#### To view the active alarms:

- 1. From any screen, press the Alarm display on the Information bar. The Active alarms screen is displayed. This screen contains a full list of currently active alarms, displayed in order of their relative priority.
- 2. Press **0K** to close the Active alarms screen and return to the previous screen.

### Muting alarms

You can temporarily mute the audible alert on the Astral device for a two minute period. The Alarm display and Alarm bar continue to display the alarm as usual. If after two minutes the alarm condition is still present, the audible alert will sound again.

You can also use the Alarm Mute in advance, to 'pre-silence' alarms that you expect to occur. This can be helpful during suctioning procedures or when intending to disconnect the patient from the ventilator for a short period.

#### To mute the audible alert on an active alarm:



The alarm is silenced for two minutes. During that period, is displayed on the Information bar and flashes.

**Note**: Pressing the Alarm mute/reset button again during the Alarm Mute period will reset the displayed alarm. See Resetting alarms (see page 46).

#### To silence alarms before they activate:

- 1. Press Alarm mute is active for two minutes. During that period, is displayed on the Information bar and flashes.
- 2. To cancel Alarm mute, press the flashing again.

#### Helpful hint!

You can adjust the volume of the audible alert. For information, see Device settings (see page 16). After any adjustment, make sure you can still hear the alarm clearly from a distance.

### Resetting alarms

Resetting an alarm removes that alarm from the Alarm display and the Active alarms screen, and turns off the visual and audible alerts. An active alarm should only be reset after the situation that caused the alarm has been attended to. If the alarm condition has not been corrected, the alarm will activate again.

The Astral device may automatically clear an alarm when the condition that triggered the alarm is corrected. When an alarm is cleared it no longer displays in the Active alarms screen and the audible and visual alerts cease.

When an alarm is cleared or manually reset, the Alarm display then shows the next highest priority active alarm.

Some alarms cannot be manually reset. For these alarms you must correct the cause of the alarm. Resolving the alarm will automatically clear the display.

#### To reset the displayed active alarm:

- 1. Press to mute the alarm. The button illuminates and flashes.
- 2. Press again to reset the alarm. The alarm message is removed from the Alarm display. It is also cleared from the Active alarms screen.

**Note**: You can carry out this procedure with the Active alarms screen open, if you want visibility of all the active alarms as you perform the reset.

#### To reset all active alarms:

1. Press the Alarm display on the Information bar. The Active alarms screen is displayed.



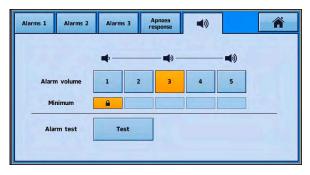
2. Press **Reset all** to reset multiple alarms. Only those alarms that can be reset, will be reset. Any remaining alarms will require user intervention and correction.

- 3. Complete any required action to resolve the remaining alarms.
- 4. Press **0K** to close the Active alarms screen and return to the previous screen.

### Adjusting the alarm volume

The volume level of the Astral device can be set from one to five (with five being the loudest). Your Clinician has pre-set a minimum volume level. Any settings below the set minimum are greyed out and are disabled from use.

In the example below, your Clinician has set the alarm minimum volume level at 1. This means you are free to increase or decrease the alarm Volume levels from '1' to '5'. If however, your Clinician had set the minumum volume level at '3', '1' and '2' would be disabled and greyed out from the Alarm volume selection.



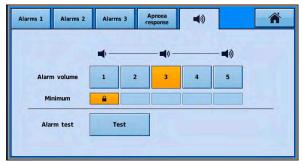
### Testing the alarm sounders and indicators

To confirm the alarm will sound as intended, regularly test the alarm.

The Astral device incorporates two alarm sounders. During an alarm condition both sounders are operated in parallel. To confirm the correct operation of each sounder, regularly perform the Alarm test function. During this test each sounder will be operated separately and in sequence.

#### To test the alarm sounders and indicators:

- Press . The Alarms screen is displayed.
- 2. Press . The Alarm volume screen is displayed.



3. Press **Test** to test the alarm. The alarm beeps **twice** and the LED flashes to indicate it is working correctly. Confirm the alarm beeps twice. Confirm the Alarm bar flashes red, then vellow. Confirm the mute button flashes.



If no alarm sounds, do not use the ventilator.



If only one beep is heard, or the Alarm bar does not flash red, then yellow, return the device for servicing.

### **Testing the Remote Alarm**

The Remote Alarm generates an audible and visual signal when an alarm is triggered on the ventilator.

### **A** CAUTION

A test of the Remote Alarm should be performed prior to initial use and every change of battery. Test the alarm periodically as per the facility policy. For dependent patients perform a test on a daily basis.

To test the Remote alarm, press ① on the Remote Alarm.

The following will occur:

- The alarm LED illuminates and the alarm sounds.
- The LED corresponding to the set volume illuminates.
- The Disconnect LED blinks if the alarm is not connected to the device and lights permanently if connected.
- The battery level LED corresponding to the battery level illuminates. Yellow LED if battery life is low, or green LED if battery life is good. (Replace the battery if the battery life is low).
- If a second Remote Alarm is connected, the second Remote Alarm will also sound.

#### Power alarms



Data cannot be saved while there is a Critically low internal battery or Battery inoperable alarm. Program selections made while these alarms are active may be lost if the device is restarted. Recording of ventilation data and alarms is suspended.

Alarm	Activates when
Low battery	Approximately 20 minutes of ventilation time remaining on internal battery power.
Critically low internal battery	Approximately 10 minutes of ventilation time remaining on internal battery power.
Total power failure	There is total loss of power due to failure of the internal battery, or a loss of external power while the internal battery is removed.
Power disconnected	The power source is changed from an external source to the internal battery.
Using internal battery	The Astral device is powered on and is using battery power.
Battery inoperable	The internal battery is faulty or has been removed.

### Detecting circuit disconnection and de-cannulation

Inadvertent disconnection of a circuit component or accidental removal of a cannula poses a hazard to a dependent patient. Unfortunately, no single alarm can reliably detect such an event due to the number of possible combinations of therapy settings, circuit configurations and patient interfaces.

However, Astral provides a number of alarms that can be configured by your clinician specifically for this purpose.



Alarm settings are sensitive to any changes to the circuit, ventilation settings or cotherapy. Test the effectiveness of the alarm after any of these changes are made.

### **A** CAUTION

Alarms should be configured and tested to ensure that circuit disconnection and decannulation is detected. We recommend configuring and testing multiple alarms and testing disconnection at the ventilator and at the cannula. Independent monitoring can be used as an alternative.

The following table provides the most appropriate alarms for use in detecting circuit disconnection.

	Pressure target modes	Volume target modes	
Single with leak	Low pressure alarm	N/A	
	Low Vt (expiratory) alarm		
	Low MV (expiratory) alarm		
	Apnoea alarm		
	Leak alarm		
	$SpO_2$ alarm		
Single with valve	Low pressure alarm	Low pressure alarm	
	Low Peep alarm	Low PEEP alarm	
	High Vt (inspiratory) alarm	Apnoea alarm	
	High Mv (inspiratory) alarm	SpO₂ alarm	
	Apnoea alarm		
	$SpO_2$ alarm		
Double with valve	Low pressure alarm		
	Low Vt (expiratory) alarm		
	Low Mv (expiratory) alarm		
	Apnoea alarm		
	Leak alarm		
	SpO <sub>2</sub>	<sub>2</sub> alarm	

#### Data management process

The most difficult disconnection to detect is a patient interface (eg, cannula, mask or mouthpiece) being disconnected from the patient.

#### To test that alarms activate in the case of circuit disconnection:

- 1. With the breathing circuit configuration in place, start ventilating the patient then wait for a few cycles for ventilation to stabilise.
- 2. Disconnect the circuit at the patient interface then check that the alarm(s) configured to detect circuit disconnection activate.
- 3. Reconnect the circuit and check that the alarm(s) clear automatically.
- 4. Repeat steps 2 and 3, disconnecting the circuit at the device and / or at different connection points of concern.

### Data management process

Monitoring data from the Astral device can be viewed in the ResScan<sup>™</sup> patient management software. Data is transferred from the device to ResScan using a USB stick. Once downloaded to ResScan, the data can be viewed in several report formats to easily monitor treatment results and compliance.

#### To connect the ResMed USB to the Astral device:

Plug a USB stick into the USB connector at the rear of the device. The symbol is displayed in the Information bar to indicate the USB is attached.



To remove the USB stick, simply pull it out of the USB connector on completion of transfer. If data was being transferred at the time, a message in the Information bar alerts you to a failed transfer.



Only connect devices specially designed and recommended by ResMed to the data communication ports. Connecting other devices could result in patient injury, or damage to the Astral device.

#### To transfer data:

- 1. From the Settings menu select Patient Data from the Data Transfer sub-menu.
- 2. Press Save >. When the transfer is complete a status message is displayed.



- 3. Press Clear to acknowledge you have read the message and enable further transfers.
- 4. Remove the USB stick from the Astral device.
- 5. At the computer where ResScan is installed, plug the USB stick into the USB port.
- 6. Follow the download procedure specified in the ResScan User Guide.

### Cleaning and maintenance

The cleaning and maintenance described in this section should be carried out regularly.

Refer to the user guides for the patient interface, humidifier and other accessories in use for detailed instructions for care and maintenance of those devices.

### **M** WARNING

- A patient treated by mechanical ventilation is highly vulnerable to the risks of infection.
   Dirty or contaminated equipment is a potential source of infection. Clean the Astral device and its accessories regularly.
- Do not immerse the device, pulse oximeter or power cord in water. Always turn off and unplug the device before cleaning and be sure it is dry before plugging back in.



#### Clean only exterior surfaces of the Astral device.

When required, wipe the exterior of the device with a damp cloth using an approved mild cleaning solution.

For all circuit components, follow the manufacturer's recommendations for cleaning and maintenance.

### Weekly

- 1. Inspect the condition of the expiratory adapter for entry of moisture or contaminants. Replace as necessary.
- 2. Test the alarm sounders, see Testing the alarm sounders (see page 47).

#### Helpful hint!

For information on removing and replacing the expiratory adapter, see Fitting the circuit adapter (see page 21).

### Monthly

- 1. Inspect the condition of the air filter and check whether it is blocked by dirt or dust. With normal use, the air filter needs to be replaced every six months (or more often in a dusty environment).
- 2. Check the charge level of the internal battery by:
  - removing external power and operating the device on internal battery for a minimum of 10 minutes.
  - reviewing the remaining battery capacity, see Using the Internal battery (see page 38).
  - restoring external power once the test is complete.

### Replacing the air filter

Inspect the condition of the air filter and check whether it is blocked by dirt or dust. With normal use, the air filter needs to be replaced every six months (or more often in a dusty environment).



Do not wash the air filter. The air filter is not washable or reusable.

#### To remove and replace the air filter

- 1. Unlock the air filter cover by turning in an anti-clockwise direction.
- 2. Pull the air filter cover from the device.
- 3. Pull the air filter from the cover and discard.
- 4. Insert a new filter into the cover.
- 5. Insert the air filter and cover back into the device.
- 6. Turn in a clockwise direction to secure in place.



### Servicing



Inspection and repair should only be performed by an authorised agent. Under no circumstances should you attempt to service or repair the device yourself. Failure to do so could void your Astral device warranty, damage the Astral device or result in possible injury or death.

Note: Retain the original packaging of the Astral device for use when shipping to/from an authorised ResMed Service Centre.

#### Maintenance Timetable

The Astral device should be serviced by an authorised ResMed Service Centre according to the following schedule. The Astral device is intended to provide safe and reliable operation provided that it is operated and maintained in accordance with the instructions provided by ResMed. As with all electrical devices, if any irregularity becomes apparent, you should exercise caution and have the device inspected by an authorized ResMed Service Centre.

With regular servicing, the expected service life of an Astral device is 8 years.

Servicing schedule from the date of first use:

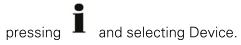
Recommended service interval	Conducted by	Instructions	
Every six months	Personnel who have been trained in the use of Astral	Replacement of the air filter (replace earlier if dirty).	
		Replacement of Single or Double limb circuit adapters if used.	
Two years	Qualified technician	Two year Preventative maintenance. Replacement of the internal battery and $FiO_2$ sensor if fitted.	
35,000 hours	Qualified technician	Pneumatic block Preventative maintenance.	

#### Internal Battery

The expected life of the internal battery is two years. The internal battery should be replaced every two years or when there is a noticeable reduction in usage time when fully charged. During storage ensure that internal battery is recharged once every six months.

#### **Device** information

Device information, including number of hours since the last service, can be found by





### Alarm troubleshooting

If there is a problem, try the following suggestions. If the problem cannot be solved, contact your care provider or ResMed.

The most common reason for an alarm to sound is because the system has not been properly assembled or a Learn Circuit has not been correctly performed for each program.

#### Notes:

- The alarm actions listed below are based on having the appropriate alarm settings for the patient's therapy. When an adjustable alarm is activated, re-confirm the alarm settings.
- The alarm log and alarm settings are maintained when the device is powered down and in the event of a power loss.
- If an alarm activates repeatedly, discontinue use, switch to a backup ventilator and return the device for servicing.

Alarm message	Action		
Apnoea	1.	Check the patient's status and airway.	
,	2.	Inspect the circuit and proximal lines for leak. Perform a Learn Circuit.	
Battery Inoperable	1.	If the device has been stored in extreme temperatures, wait until the device returns to room temperature.	
	2.	If the device has been stored for long periods of time, the battery may have discharged. Connect to mains power.	
	3.	If alarm persists, return the device for servicing.	
Circuit fault	1.	Perform a Learn Circuit.	
	2.	If the alarm persists, replace the circuit.	
Critically low internal battery	Connect the	e Astral to mains AC power and allow the battery to recharge.	
Device overheating	1.	Move the device to a cooler location.	
C	2.	Inspect the air inlet for foreign objects.	
	3.	Inspect the air inlet filter. If necessary, replace the air inlet filter.	
	4.	Inspect the cooling fan inlet and outlet for foreign objects.	
	5.	Remove the Astral from the mobility bag.	
	6.	Check the circuit for obstructions.	
	7.	Perform a Learn Circuit.	
Low pressure	1.	Check all circuit connections, especially the patient interface and the proximal sense line.	
	2.	Inspect the circuit and expiratory valve for damage or secretions.	
	3.	Perform a Learn Circuit.	
Flow sensor fault	Replace the	Replace the double limb adapter and perform a Learn Circuit.	
Flow sensor not calibrated	Perform a Learn Circuit.		
High $FiO_2$	1.	Check the patient's status.	
5 -	2.	Check and adjust the oxygen supply.	
	3.	Perform a Learn Circuit to recalibrate the oxygen sensor.	

Alarm message	Action	
High Leak	1. Check the pa	atient's status.
S	·	sircuit, expiratory valve and proximal lines for leak. When c for leaks around the mask.
	3. When using	vented therapy, check the mask type setting.
	4. Perform a Le	arn Circuit.
High MVe	1. Check the pa	atient's status.
ů	2. Inspect the e valve.	expiratory valve. If necessary, replace the expiratory
	3. Perform a Le	arn Circuit.
High MVi	1. Check the pa	atient's status.
_	2. Inspect the o	sircuit and expiratory module for leaks.
	3. Perform a Le	arn Circuit.
High PEEP	1. Check the pa	atient's status.
		circuit and expiratory valve for obstruction. When in use, struction in proximal lines.
	3. Perform a Le	arn Circuit.
High pressure	1. Check the pa	atient's status and airway.
	2. Inspect the o	circuit for obstruction.
	3. Perform a Le	arn Circuit.
High Pulse Rate	Check the patient's status	
High Resp Rate	1. Check the pa	atient's status.
	2. Perform a Le	arn Circuit.
High SpO <sub>2</sub>	Check the patient's status.	
High Vte	1. Check the pa	atient's status.
Ü	2. Inspect the $\epsilon$ valve.	expiratory valve. If necessary, replace the expiratory
	3. Perform a Le	earn Circuit.
High Vti	1. Check the pa	atient's status.
3	2. Inspect the o	circuit and expiratory module for leaks.
	3. Perform a Le	arn Circuit.
Incorrect circuit	<ol> <li>Check that the type selecter</li> </ol>	ne circuit is correctly connected and matches the circuit d.
	2. Inspect the o	sircuit, expiratory valve and proximal lines.
Last self-test failed	1. Perform a Le	arn Circuit.
	2. If problem po	ersists, return the device for service.
Low internal battery	Connect the Astral to mai	ns AC power to allow the battery to recharge.
Low $FiO_2$	1. Check the pa	atient's status.
- · · · - <u>-</u> <u>L</u>	2. Check for lea	
	3. Check the ox	tygen supply and connections to the device.
	4. Perform a Le	earn Circuit to recalibrate the oxygen sensor.

Alarm message	Action	
Low MVe	<ol> <li>Check the patient's status and airway.</li> </ol>	
	2. Inspect the circuit and the expiratory valve for obstruction or leaks.	
	3. Perform a Learn Circuit.	
Low MVi	<ol> <li>Check the patient's status and airway.</li> </ol>	
	2. Inspect the circuit for obstruction.	
	3. Perform a Learn Circuit.	
Low PEEP	<ol> <li>Check the patient's status.</li> </ol>	
	<ol><li>Inspect the circuit and the expiratory valve for obstruction or leaks.</li><li>When in use, check for obstructions in proximal lines.</li></ol>	
	3. Perform Learn Circuit.	
Low Pulse Rate	Check the patient's status.	
Low Resp Rate	1. Check the patient's status.	
·	2. Inspect the circuit and the proximal lines for leak.	
	3. Perform a Learn Circuit.	
Low SpO <sub>2</sub>	Check the patient's status.	
Low Vte	1. Check the patient's status and airway.	
	2. Inspect the circuit and the expiratory valve for obstruction or leaks.	
	3. Perform a Learn Circuit.	
Low Vti	<ol> <li>Check the patient's status and airway.</li> </ol>	
	2. Inspect the circuit for obstruction.	
	3. Perform a Learn Circuit.	
No FiO <sub>2</sub> monitoring	Perform a Learn Circuit to calibrate the oxygen sensor.	
No SpO <sub>2</sub> monitoring	1. Check the $SpO_2$ connection to patient's finger and the Astral.	
	2. If the alarm persists, use another $SpO_2$ oximeter or finger sensor.	
NV Mask	<ol> <li>Check that the mask vents are clear and unobstructed.</li> </ol>	
	2. Check the mask type setting.	
	3. Perform a Learn Circuit.	
	Note: This alarm could be impaired if supplementary oxygen is added at the mask or into the circuit.	
Obstruction /	Check the patient's status and airway.	
High pressure	<ol><li>Inspect the circuit and the expiratory valve for obstruction. When in use, check for kinks in proximal lines.</li></ol>	
	3. Perform a Learn Circuit.	
Pressure Line disconnected	1. Check the connection of the proximal sense line.	
	2. Perform a Learn Circuit.	

### Alarm troubleshooting

Alarm message	Action	
Power disconnected	If intending to use external power:	
	<ol> <li>Check the power cable connection between the mains or battery, the power supply pack and the device.</li> </ol>	
	<ol><li>If using an external battery, check the external battery charge level and replace/charge if empty.</li></ol>	
	3. If using mains AC, check the supply output.	
	<ol> <li>If the problem continues, try an alternative external supply type (i.e. Mains AC, Mains DC or External Battery).</li> </ol>	
Shallow breathing	1. Check the patient's status.	
v	2. Inspect the circuit and proximal lines for obstructions or leak.	
	3. Perform a Learn Circuit.	
System fault	1. Perform a Learn circuit.	
	<ol><li>If problem persists, or the device fails self test, return the device for service.</li></ol>	
Total power failure	1. Check the patient's status and airway.	
•	2. Connect the device to AC mains.	
	<ol><li>Check the battery charge level of the internal and external (if applicable) battery.</li></ol>	
	The total power failure alarm can only be silenced by connecting the device to AC mains power.	
Unexpected restart	The device detected a fault and was reset.	
·	Check the patient's status.	
Using internal battery	Confirm operation on internal battery is intended or restore external power.	
Ventilation not started. Incorrect adapter	Check that the correct expiratory adapter is installed for the selected circuit type.	
·	2. Perform a Learn Circuit.	
Ventilation stopped	Confirm it is appropriate to stop ventilation.	
Ventilation stopped / High pressure	The hardware pressure safety limit was exceeded. If problem recurs, return the device for service.	

### General troubleshooting

Issue	Action	
Condensation forming in circuit	Condensation may form due to high humidity settings and low ambient temperatures. Adjust humidifier settings in accordance with manufacturer's instructions.	
Touch screen damaged or non- responsive	If you are unable to power off the Astral device normally, use the following forced shutdown procedure:	
	<ol> <li>Disconnect any external power source (eg. AC mains or external battery).</li> </ol>	
	<ol> <li>Press and hold the green on/off button and the alarm mute/reset button for at least 10 seconds. After 10 seconds the alarm bar will flash yellow.</li> </ol>	
	3. Release both buttons. Astral will then power off.	
	<ol> <li>The Astral device can be powered back on by pressing the on/off button and used as intended.</li> </ol>	

## **Technical specifications**

Operating pressure range	Single limb with valve or double limb with valve:	
	Expiratory: 3 hPa	
	Inspiratory: 50 hPa	
	Single limb with intentional leak:	
	Expiratory: 2 hPa	
	Inspiratory: 50 hPa	
	CPAP:	
	3 to 20 hPa	
	Maximum working pressure limit:	
	10 to 55 hPa	
	Forced cycling occurs if the Pressure alarm limit is exceeded.	
Operating tidal volume range (volume	Adult patient type: 100 to 2500 mL	
control modes)	Paediatric patient type: 50 to 300 mL*	
Maximum single fault pressure	60 hPa (in all modes)	
Breathing resistance under single fault*	Paediatric circuit (at 15 L/min)	
	Inspiration: 2.2 hPa	
	Expiration: 2.4 hPa	
	Adult circuit (at 30 L/min)	
	Inspiration: 5.7 hPa Expiration: 4.2 hPa	
Operational range for circuit resistance	Paediatric patient setting:	
and compliance**	Circuit resistance range (circuit with intentional leak):	
	0 to 8 hPa at 60 L/min	
	Circuit resistance range (circuit with valve):	
	0 to 20 hPa at 60 L/min	
	Circuit compliance range:	
	0 to 4 mL / hPa	
	Adult patient setting: Circuit resistance range (circuit with intentional leak):	
	O to 20 hPa at 120 L/min	
	Circuit resistance range (circuit with valve):	
	0 to 35 hPa at 120 L/min	
	Circuit compliance range:	
	0 to 4 mL / hPa	
Maximum flow	220 L/min	
Inspiratory trigger (nominal)	Inspiratory trigger occurs when patient flow exceeds trigger setting.	
characteristics	Double limb with valve (flow trigger): 0.5 to 15.0 L/min	
	Single limb with valve or double limb with valve: 1.6 to 10.0 L/min (in five steps)****	
	Single limb with intentional leak:	
	2.5 to 15.0 L/min (in five steps)	

Expiratory cycle (nominal) characteristics	Cycle occurs when inspiratory flow declines to the set percentage of peak inspiratory flow.	
	Single limb with valve or double limb with valve:	
	5 to 90%	
	Single limb with intentional leak:	
	8 to 50% (in five steps)	
Sound pressure level	$35 \pm 3$ dBA as measured according to ISO80601-2-12:2011.	
Sound power level	$43 \pm 3$ dBA as measured according to ISO80601-2-12:2011	
Alarm volume range	59 - 89 dBA (in five steps)	
Data storage	7 days of high-resolution airway pressure, respiratory flow and delivered volume (sampled at 25 Hz).	
	7 days of breath-related therapy data (sampled at 1 Hz).	
	365 days of statistical data per program.	
Dimensions (L x W x H)	285 mm x 215 mm x 93 mm	
Weight	3.2 kg	
Inspiratory port / double limb adapter	22 mm taper, compatible with ISO 5356-1:2004 Anaesthetic & Respiratory Equipment — Conical Connectors	
Pressure measurement	Internally mounted pressure transducers	
Flow measurement	Internally mounted flow transducers	
Power supply	AC 100–240V, 50–60Hz, 90 W 3.75 A continuous, 120 W / 5A peak	
	115V/400 Hz	
External DC Power Supply	12 - 24V DC 90 W, 7.5 A / 3.75 A	
Internal Battery	Lithium-lon battery, 14.4 V, 6.6 Ah, 95 Wh	
	Operating hours (best case): 8 h with a new battery under normal conditions (see below).	
	Test conditions: Adult, P(A)CV mode, P control: 20 cm $H_2O$ , PEEP: Off, Rate: 15 bpm, Ti: 1.2 sec.	
	Note: Time may vary with environmental conditions.	
	Total lifetime: 3,000 hours of operation on internal battery	
	Operating hours (worst case) > 4 hour run time under the following conditions:	
	· · · · · · · · · · · · · · · · · · ·	

### **Technical specifications**

Environmental conditions	Operating temperature: 0°C to 40°C
	Charging temperature: 5°C to 35°C
	Operating humidity: 5 to 93% RH non-condensing
	Storage and transport temperature (inside packaging): -20°C to 50°C
	Storage and transport temperature (outside of packaging): -25°C to 70°C
	Note: Storing the Astral device at temperatures exceeding 50°C for extended period of time mayl accelerate battery ageing. Refer to Using the internal battery (see page 38)
	Storage and transport humidity: 5 to 93% RH non-condensing
	Air pressure: 1100 hPa to 700 hPa Altitude: 3000 m
	Note: The performance may be limited below 800 hPa / 2000m.
	IP22 (Protected against finger sized objects. Protected against dripping water when tilted up to 15 degrees from specified orientation.) When placed horizontally on flat surface, or vertically with handle up.
	IP21 (Protected against finger sized objects and against vertically dripping water) When placed on a desktop stand or when used with the ResMed Hospital trolley.
Oxygen measurement	Internally mounted oxygen sensor.
	1,000,000 % hours at 25°C
Electromagnetic compatibility	Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments.
	It is recommended that mobile communication devices are kept at least one metre away from the device.
	For further details see "Guidance and manufacturer's declaration – electromagnetic emissions and immunity" (see page 65).
Aircraft use	Medical-Portable Electronic Devices (M-PED) that meet the Federal Aviation Administration (FAA) requirements of RTCA/D0-160 can be used during all phases of air travel without further testing or approval by the airline operator.
	ResMed confirms that the Astral meets the Federal Aviation Administration (FAA) requirements (RTCA/D0-160, section 21, category M) for all phases of air travel.
	IATA classification for internal battery: UN 3481 — Lithium-Ion batteries contained in equipment.
Automotive use	Product complies with ISO 16750-2 Road Vehicles - Environmental Conditions and Testing for Electrical and Electronic Equipment - Part 2: Electrical Loads" - 2nd Edition 2006, Tests 4.2, 4.3.1.2, 4.3.2, 4.4, 4.6.1 and 4.6.2. The functional status classification shall be Class A.
	Product complies with ISO7637-2 "Road Vehicles - Electrical Disturbance by Conduction and Coupling - Part 2 Electrical Transient Conduction Along Supply Lines Only" - 2nd Edition 2004, Section 4.4 Transient Immunity Test. The functional status classification shall be Class A to test level III and Class C to test level IV.

Data connections	The Astral device has three data connection ports (USB connector, mini US connector, and Ethernet port). Only the USB connector is for customer use.
	The USB connector is compatible with the ResMed USB stick.
Recommended patient circuit components and compatible accessories	Refer to www.resmed.com.
IEC 60601-1 classifications	Class II (double insulation)
	Type BF
	Continuous operation
	Suitable for use with oxygen.
Applied parts	Patient interface (Mask, endotracheal tube or tracheostomy tube)
	Oximeter
Operator position	The device is designed to be operated within arm's length. An operator should position their line of sight within an angle of 30 degrees from a plane perpendicular to the screen.
	The Astral device complies with IEC60601-1:2005 legibility requirements.

This device is not suitable for use in the presence of a flammable anaesthetic mixture.

The life of oxygen cells is described by hours used multiplied by the % of oxygen used. For example 1 000 000 % hours oxygen cell will last for 20 000 hours at 50%  $FiO_2$  (20 000 x 50 = 1 000 000) or 40 000 hours at 25%  $FiO_2$  (40 000 x 25 - 1 000 000). Astral's oxygen cell will last for 25,000 hours (1041 days) at 40%  $FiO_2$ 

Note: The manufacturer reserves the right to change these specifications without notice.

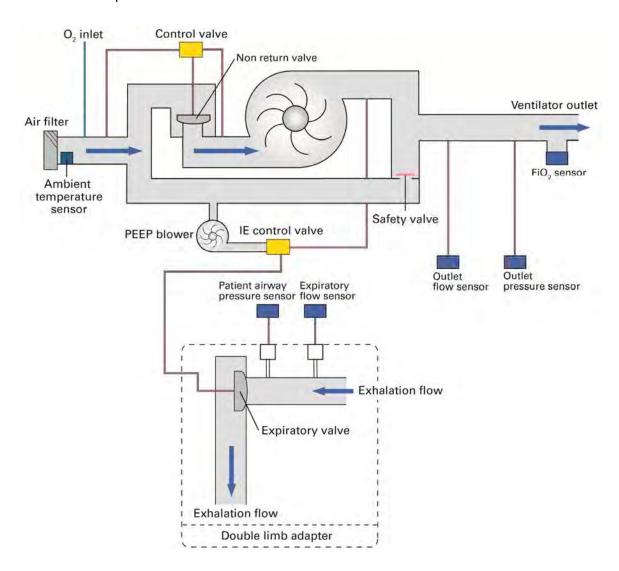
<sup>\*</sup> The International ventilator standard indicates that Paediatric patient type is intended to be used for a patient receiving less than 300 mL, however Astral permits adjustment of 'Vt' setting parameter up to 500 mL for cases where 'Vt' is set such that it compensates for leak in the breathing circuit.

<sup>\*\*</sup> Limits are the sum of device and circuit impedance.

<sup>\*\*\*</sup> Learn Circuit function will fail if a circuit outside the acceptable range is attached.

<sup>\*\*\*\*</sup> Individual configurations may be more sensitive.

#### Pneumatic flow path



# Guidance and Manufacturer's Declaration Electromagnetic Emissions & Immunity

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document. This declaration currently applies for the following ResMed devices:

Astral<sup>™</sup> Series of Ventilators.

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

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

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments,
with or without USB adapter		including domestic establishments and those
with or without Oximeter adapter		directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
with or without specified accessories		
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	
with or without specified accessories		

### **⚠** WARNING

- 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.
- Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (eg, IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

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

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

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short	<5% Ut (>95% dip in Ut) for 0.5 cycle	<12V (>95% dip in 240V) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply	40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles	96V (60% dip in 240V) for 5 cycles 168V (30% dip in 240V) for 25 cycles	If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 5 sec	<12V (>95% dip in 240V) for 5 sec	The internal battery will provide backup power of eight hours.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF	10 V/m	10 V/m	Recommended separation distance
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	$d = 1.17 \sqrt{P}$
			$d = 0.35 \sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$
			$d = 0.70 \sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$
			Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:

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

<sup>b</sup>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

#### Notes:

- Ut is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

Rated maximum output	Separation distance according to frequency of transmitter (m)
nower of transmitter	

(W)	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.70	1.11	2.21
100	11.70	3.50	7.0

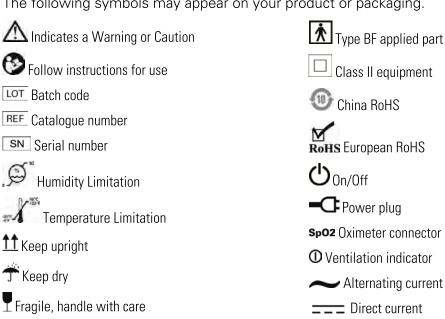
#### Technical specifications

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

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

### **Symbols**

The following symbols may appear on your product or packaging.



A Recyclable

Fire if damaged

Manufacturer

**ECREP** European Authorised Representative

CE Labelling in accordance with EC directive 93/42/EEC

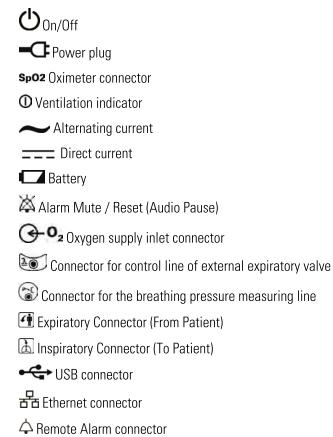
Canadian Standards Association

 $m R_{0$ nly Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician.)

Device weight

**IP22** Protected against finger sized objects. Protected against dripping water when tilted up to 15 degrees from specified orientation.

**Li-Ion** Lithium Ion battery



Remote Alarm Test button



#### **Environmental information**

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

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

### Standards compliance

The Astral meets the following standards:

- IEC 60601-1 Medical Electrical Equipment General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests
- IEC 60601-1-8 General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 10651-2 Lung ventilators for medical use Particular requirements for basic safety and essential performance Part 2: Home care ventilators for ventilator-dependent patients
- ISO 10651-6 Lung ventilators for medical use Particular requirements for basic safety and essential performance Part 6: Home care ventilatory support devices.

### Training and support

Training and support materials are available from the ResMed website, www.resmed/astral/support. If you do not have internet access, please contact your ResMed representative.

### 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.

Warranty period	
90 days	
6 months	
1 year	
,	
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; 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.

## Appendix A: Definitions

### Ventilation settings definitions

The available settings will vary with the selection of the ventilation mode. Each mode details the settings available.

Setting	Definition  Apnoea Definition sets the type of breath which must be delayed for an apnoea to be detected.	
Apnoea Definition		
Apnoea Interval (T apnoea)	Apnoea Interval (T apnoea) sets the period without breath or spontaneous breath required for an apnoea to be detected.	
Apnoea Response	Apnoea Response sets the behaviour of the ventilator when an apnoea is detected.	
Circuit Type	Circuit Type sets whether a Double limb circuit, Single limb circuit with expiratory valve or Single limb circuit with intentional leak is in use.	
CPAP	Continuous Positive Airway Pressure (CPAP) sets the pressure maintained throughout a spontaneous breath.	
Cycle	Cycle (also known as Expiratory Trigger) sets the threshold where start of expiration within a breath is detected.	
Cycle Sensitivity	Cycle Sensitivity sets the sets the threshold where start of expiration within a breath is detected.	
EPAP	Expiratory Positive Airway Pressure (EPAP) sets the pressure to be delivered to the patient during expiration.	
Flow shape	Sets the target flow waveform for the delivery of mandatory controlled volume breaths.	
Inspiratory duration option (Insp Duration Option)	Inspiratory duration option (Insp Duration Option) sets whether Inspiration Time (Ti) or Peak Inspiratory Flow (PIF) is used to configure volume controlled breaths.	
Interval	Sigh interval sets the period between sigh breaths.	
IPAP	Inspiratory Positive Airway Pressure (IPAP) sets the pressure to be delivered to the patient during inspiration.	
Magnitude	Magnitude sets the size of the manual or sigh breath delivered relative to the size of the normal ventilation breath. Separate magnitude settings are available for configuration of manual or sigh breaths.	
Manual Breath	Manual Breath sets whether a manual breath is available for delivery.	
Mask Type	Mask Type sets the type of mask or in-line vent in use when the circuit type is single with leak.	
Patient type	Select from Adult or Paediatric. This setting configures the default values and ranges available for ventilation settings and determines circuit resistance acceptance criteria applied in the Learn Circuit.	
PEEP	Positive End Expiratory Pressure (PEEP) sets the pressure maintained during exhalation.	

Setting	Definition	
PS	Sets the pressure support above PEEP to be delivered during inspiration for pressure supported breaths (spontaneous breaths).	
PS Max	Maximum Allowed Pressure Support (PS Max) sets the maximum pressure support above PEEP allowed to achieve the target safety tidal volume.	
P control	Pressure control (P control) sets the pressure support above PEEP to be delivered during inspiration for pressure assisted breaths.	
P control max	Maximum allowed pressure control (P control max) sets the maximum pressure control above PEEP allowed to achieve the target safety volume.	
PIF	Peak Inspiratory Flow (PIF) sets the maximum delivered flow for volume controlled breaths.	
Resp. rate	Respiratory rate (Resp. rate) sets the breaths per minute (bpm) to be delivered by the ventilator to the patient. The measured respiratory rate may be greater due to patient triggered breaths.	
Rise Time	Rise time sets the time taken for the ventilator to reach inspiratory pressure for pressure controlled breaths.	
Sigh Alert	Sigh alert sets whether the ventilator gives a single beep just prior to delivery of a sigh breath.	
Sigh Breath	Sigh Breath sets whether a magnified breath (a sigh breath) will be delivered at the sigh interval.	
Interval	Sigh interval sets the period between sigh breaths.	
Ti	Inspiration time (Ti) sets the duration of the inspiratory phase of a breath.	
Ti Max	Maximum inspiratory time (Ti Max) sets the maximum duration of the inspiratory phase of a breath.	
Ti Min	Minimum Inspiratory Time (Ti Min) set the minimum duration of the inspiratory phase of a breath.	
Trigger	Sets the trigger threshold above which the ventilator triggers a new breath.	
	The trigger is blocked for the first 300 ms following the start of exhalation.	
Trigger type	Trigger type sets whether a pressure based trigger threshold or flow based trigger threshold is used when a Double circuit is selected.	
Vt	The Tidal Volume (Vt) sets the volume of gas, measured in mL, to be delivered to the patient in a mandatory controlled volume breath.	
Safety Vt	Safety tidal volume (Vts) sets the target minimum tidal volume (Vt) for each ventilator delivered breath.	

### Measured and calculated parameter definitions

The following measured and calculated parameters are displayed during configuration or during ventilation. Each Ventilation mode details the parameters displayed.

Parameter	Definition
FiO <sub>2</sub>	Average of percentage of Oxygen delivered to circuit.
l:E	I:E is the ratio of the inspiratory period to the expiratory period.
	The measured I:E ratio is displayed as a monitored parameter during ventilation.
	The expected I:E ratio is calculated and displayed on the settings screens if the Resp. rate setting is not set to Off.
Leak	Leak is the average unintentional leak. It is reported as a percentage for Double limb circuits and as a flow for Single limb circuits with intentional leak.
	The measured Leak is displayed as a monitored parameter during ventilation.
MVe	Expiratory Minute Volume (MVe) is the product of the respiratory rate and expired tidal volume averaged over the last eight breaths.
	The measured MVe is displayed as a monitored parameter during ventilation.
MVi	Inspiratory Minute Volume (MVi) is the product of the respiratory rate and inspired tidal volume averaged over the last eight breaths.
	The measured MVi is displayed as a monitored parameter during ventilation.
Pressure	Pressure is the current airway pressure of the patient as measured at the patient port.
	The measured Pressure is displayed as a monitored parameter during ventilation.
PEEP	End expiratory pressure (PEEP) is the airway pressure measured 50 ms prior to the end of the last expiration.
	The measured PEEP is displayed as a monitored parameter during ventilation.
Pmean	Mean airway pressure of the patient over the last breath.
% Spont cycle	% Spont cycle is the percentage of breaths that are spontaneously cycled over the past 20 breaths.
% Spont trig	% Spont trig is the percentage of breaths that are spontaneously triggered over the last 20 breaths.
	The measured %Spont Trig is displayed as a monitored parameter during ventilation.
PIF	Peak Inspiratory Flow (PIF) is the maximum flow reached during the last inspiration.
	The measured PIF is displayed as a monitored parameter during ventilation.
	The expected PIF is calculated and displayed for volume controlled breaths on the settings screens when the Inspiratory Phase Duration Option is set to Ti.
PIP	Peak Inspiratory Pressure (PIP) is the maximum airway pressure reached during the last inspiration.
	The measured PIP is displayed as a monitored parameter during ventilation.

### Appendix A: Definitions

Parameter	Definition
Pulse rate	The measured Pulse rate (pulse) is displayed as a monitored parameter when a pulse oximeter is used.
Resp. rate	Respiratory rate (Resp. rate) is the number of breaths per minute averaged over the last eight breaths.
	The measured Resp. rate is displayed as a monitored parameter during ventilation.
RSBI	Rapid Shallow Breathing Index (RSBI) is calculated by dividing the breath rate by Tidal Volume.
	The measured RSBI is displayed as a monitored parameter during ventilation.
SpO <sub>2</sub>	The measured Oxygen Saturation (SpO $_2$ ) is displayed as a monitored parameter when a pulse oximeter is used.
Te	Expiratory time Te is the period in seconds of the last expiratory phase.
	The measured Te is displayed as a monitored parameter during ventilation.
Ti	Inspiratory time Ti is the period in seconds of the last inspiratory phase.
	The measured Ti is displayed as a monitored parameter during ventilation.
	The expected Ti is calculated and displayed for volume controlled breaths on the settings screens when the Inspiratory Phase Duration Option is set to PIF.
Vte	Expiratory Tidal Volume (Vte) is the volume expired during the last breath.
	The measured Vte is displayed as a monitored parameter during ventilation.
Vti	Inspiratory Tidal Volume (VTi) is the volume inspired during the last breath.
	The measured VTi is displayed as a monitored parameter during ventilation.





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ResMed Corp 9001 Spectrum Center Boulevard San Diego CA 92123 USA

[ECIREP] ResMed (UK) Ltd 96 Jubilee Ave Milton Park Abingdon Oxfordshire OX14 4RW UK

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