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RESMED

Stellar™ 150

INVASIVE AND NONINVASIVE VENTILATOR

Clinical Guide

English



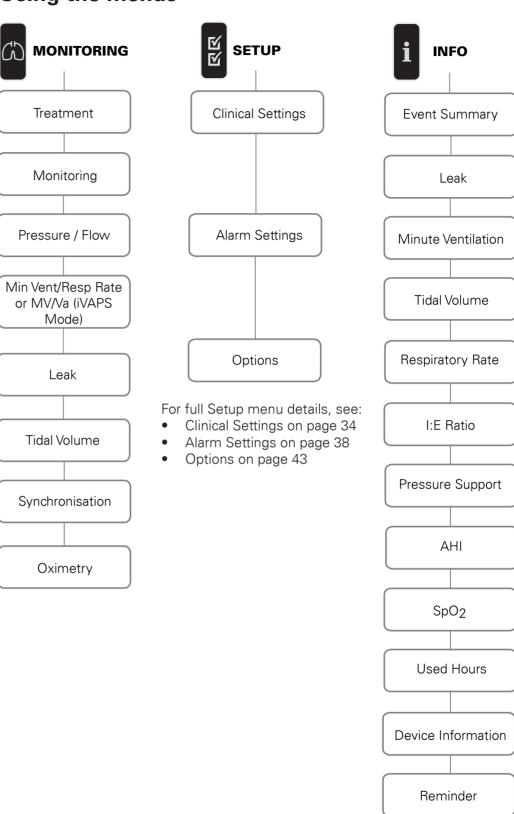
Setting up for non-invasive use



Setting up for invasive use



Using the menus



Respiratory Care Solutions

Making quality of care easy







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Introduction

Read the entire manual before using the device.

Indications for use

The Stellar 150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb/13 kg and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnea. The device is for noninvasive use, or invasive use (with the use of the ResMed Leak Valve). Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage.



CAUTION (USA ONLY)

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

Contraindications

The Stellar 150 is contraindicated in patients who are unable to endure more than brief interruptions in ventilation. The Stellar 150 is not a life support ventilator.

The use of the device may be contraindicated in patients with:

- 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.

The use of the Stellar 150 or pulse oximetry (including XPOD) is contraindicated in an MRI environment.

Adverse effects

Patients should report unusual chest pain, severe headache or increased breathlessness.

The following side effects may arise during the course of noninvasive ventilation with the device:

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











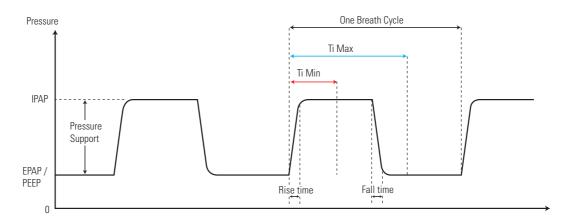
About Stellar 150 therapy modes

Stellar provides a number of therapy modes to suit a variety of ventilation requirements. Regardless of the mode, Stellar 150 assists spontaneous breathing by providing two pressures in response to the patient flow or a preset fixed time.

Common setting parameters

The inspiratory positive airway pressure (IPAP, or the sum of PEEP and Pressure Support/PS) assists inspiration. The lower expiratory positive airway pressure (EPAP or PEEP) eliminates exhaled air through the exhaust vent. This pressure also provides a stent to maintain an open upper airway, improves small airway recruitment and therefore oxygenation and may improve triggering in some patients with intrinsic PEEP.

The difference of the two pressures—Pressure Support/PS—contributes to improved patient ventilation.



Stellar provides the following modes:

- CPAP mode—a fixed pressure is delivered.
- S (Spontaneous) mode—the device senses the patient breath and triggers IPAP in response to an increase in flow, and cycles into EPAP at the end of inspiration. The breath rate and the respiratory pattern will be determined by the patient.
- ST (Spontaneous/Timed) or PS (Pressure Support) mode—the device augments any breath initiated by the patient, but will also supply additional breaths should the patient breath rate fall below the clinician's set 'backup' breath rate.
- T (Timed) mode—the fixed breath rate and the fixed inspiration time set by the clinician are supplied regardless of patient effort.
- PAC (Pressure Assist Control)—the inspiration time is preset in the PAC mode. There is no spontaneous/flow cycling. The inspiration can be triggered by the patient when respiratory rate is above a preset value, or time triggered breaths will be delivered at the backup breath rate.
- iVAPS (intelligent Volume Assured Pressure Support)—designed to maintain a preset target alveolar ventilation by monitoring delivered ventilation, adjusting the pressure support and providing an intelligent backup breath automatically. The iVAPS therapy mode is indicated for patients 66 lb (30 kg) and above.





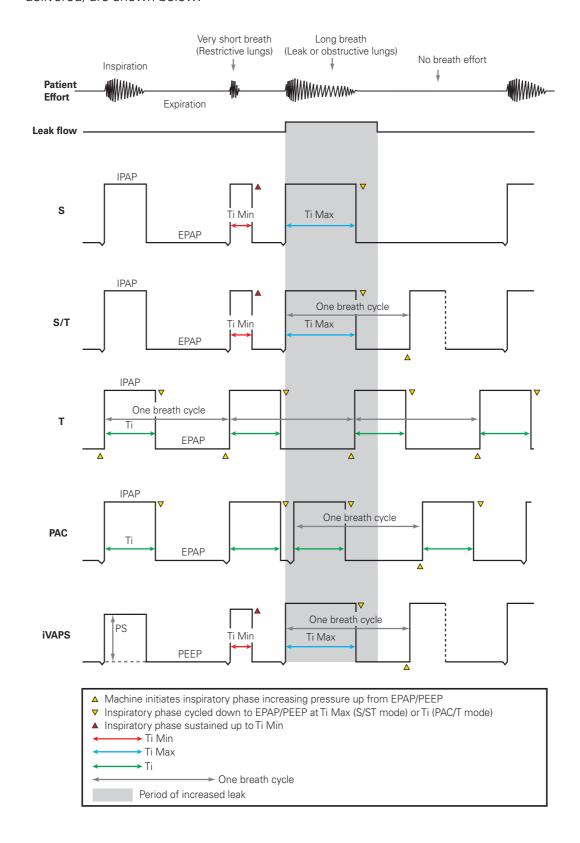








These therapy modes (excluding CPAP mode—where a single level of continuous pressure is delivered) are shown below.











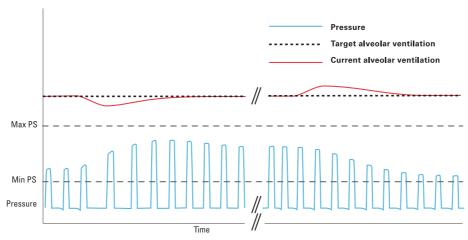


More about iVAPS

The iVAPS therapy mode is indicated for patients 66 lb (30 kg) and above.

You may prefer some assurance that the patient's ventilatory needs will be maintained if their condition varies. A variety of 'dual mode' schemes exist, that aim to combine the benefits of pressure target and volume target, most of which can be categorized generically as volume-assured pressure support, or VAPS modes.

With VAPS devices in general, the ventilatory assistance (pressure support) aims to automatically adjust to changes in patient condition over time, typically to maintain a target tidal volume



iVAPS offers the comfort and synchrony of pressure support, but with the assurance offered by a volume target. iVAPS has the following advantages over traditional VAPS schemes:

- iVAPS is a unique combination for a servo-controlled ventilator, in that iVAPS has the goal of regulating alveolar ventilation to a prescribed target, and iVAPS has a rapid but gentle servocontrol response. iVAPS is tuned to be fast enough to avoid blood-gas derangement associated with most breathing challenges, including during sleep, but is gentle enough to avoid disruption.
- iVAPS has an intelligent Backup Rate (iBR) which aims to keep 'out of the way' while the patient is breathing, yet during sustained apnea will mimic the patient's own breath rate. This contributes to iVAPS' ability to maintain its ventilation target and so stabilize blood gases even during sleep.
- iVAPS has ResMed's robust leak compensation feature (Vsync), a product of ResMed's long experience in noninvasive ventilation. This promotes synchrony and comfort even during significant leak.

Pressure support is adjusted continuously during the inspiration phase breath to breath, aiming to maintain target alveolar ventilation. If ventilation falls, pressure support is increased until the target is reached. Conversely, if alveolar ventilation rises above target, pressure support falls. The range of pressure support adjustment is constrained within Min PS and Max PS.

The rate of increase in pressure support can reach up to 0.7 cm H_2O/sec . The breath to breath changes in pressure support depend on the breath rate and how far the patient is from the target alveolar ventilation. Typically the change in pressure support does not exceed 3 cm H_2O per breath.

iVAPS provides benefits across a range of situations. For example, it can benefit patients with a progressive lung condition, because the ventilation target can be maintained despite degradation of lung mechanics or muscle function. Similarly, iVAPS offers advantage in nocturnal hypoventilation. iVAPS, by providing pressure support when required, is more comfortable and better tolerated.

Some key concepts important to clinical understanding of iVAPS operation are discussed below, ahead of guidance on the iVAPS setup procedure on Stellar 150. See "Configuring iVAPS" on page 48.







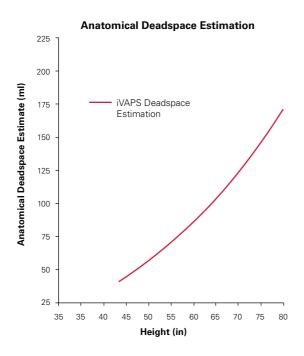






iVAPS targets alveolar ventilation. Alveolar ventilation was chosen because it is at the level of the alveoli that gas exchange occurs. Total ventilation includes the ventilation devoted to the conducting airways, whereas alveolar ventilation best represents the useful portion of ventilation that reaches the alveoli.

Alveolar ventilation cannot be measured directly, so iVAPS estimates it using a height approximated value of anatomical deadspace as shown in the graph below. **Anatomic deadspace** is the amount of breath that remains in the conducting airways, which does not reach alveoli and does not contribute to gas exchange. Its contribution is proportional to breath rate. By using alveolar ventilation as a servo-ventilation target, as opposed to tidal volume or total ventilation, the effect of respiratory rate change on effective ventilation is negated.



Adapted from Hart MC et al. Journal Applied Physiology. 18(3), p519-522. 1963

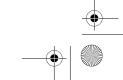
Target Patient Rate

iVAPS has a novel approach to providing a backup rate. Instead of mandating a fixed backup rate, iVAPS' **intelligent Backup Rate** (iBR) will shift automatically between two limits, according to the context. The benefit of this approach is improved synchrony, while maximizing iVAPS' ability to maintain the target ventilation, at *minimal pressure support*.

- During sustained apnea, the iBR will adopt a pre-configured **Target Patient Rate**. This Target Patient Rate defines the upper boundary for iBR. You set the Target Patient Rate to **match** the patient's average spontaneous rate (unlike a traditional backup rate).
- During spontaneous ventilation, the iBR adjusts to remain well in the background, at 2/3rd of the Target Patient Rate. This 'background' backup rate gives the patient maximum opportunity to spontaneously trigger.
- When spontaneous triggering ceases (eg, at the onset of an apnea), the iBR adjusts from its background frequency to its Target Patient Rate. It will adjust quickest typically (within 4-5 breaths) when ventilation is below the target ventilation.
- A single spontaneous triggered breath resets the iBR to its background rate (2/3rds of Target Patient Rate).





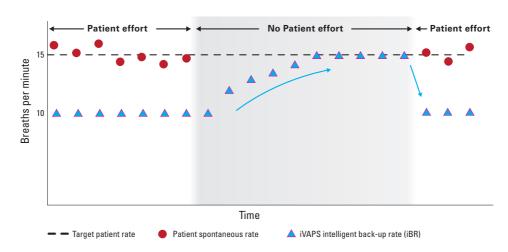






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iBR brings the patient back on target when back-up breaths are required



Min/Max PS

The default settings for maximum and minimum pressure support are normally adequate, but you may wish to alter them in some patients.

Min PS and Max PS define the range of pressure support adjustment available to the iVAPS algorithm as it regulates alveolar ventilation.

It is recommended that Max PS be set high enough to allow the alveolar ventilation target to be met, while exercising clinical judgement over considerations such as patient comfort and tolerance, lung mechanics, age, mask seal, etc.

It is recommended that Min PS is left at the level set when learning the patient's ventilation target unless the patient finds this too little for comfort.











Ensuring successful ventilation with Stellar

Successful ventilation, whether using a mask or tracheostomy tube, relies on improving gas exchange and reducing the work of breathing for the patient. Maintaining patient-device synchrony and managing leak is critical to achieving this.

A good device should help this by:

- monitoring and compensating for leak
- · accurately sensing the start and end of a patient's inspiratory effort for triggering and cycling
- · responding quickly to reach and maintain the set pressure
- offering flexibility of settings to accommodate pathological variations in the patient's respiratory timing/pattern.

Stellar effectively provides this capability through:

- Learn Circuit—method to calculate circuit impedance so that pressure can be controlled and estimated at the patient's airway
- Vsync— an automatic algorithm to compensate for unintentional leak
- Mask selection—a correct selection indicates to Stellar how much leak through the mask vent or ResMed Leak Valve can be expected as the therapy pressure varies
- Mask fit—ensures an optimal seal for the patient interface to avoid unintentional leak
- TiControl—offers control over the inspiratory time limits between which the patient can spontaneously cycle
- Trigger/Cycle sensitivities—five sensitivities for triggering and cycling offer flexibility to personalize therapy and accommodate a range of patient conditions
- Rise/Fall Time—adjustable duration for transitions to both inspiration and expiration offer opportunity for maximal comfort
- Pathology Defaults—offer a choice of disease-specific preset setting values to facilitate a quick and sensible starting point to therapy.

Learn Circuit

The Learn Circuit procedure permits optimal therapy and monitoring accuracy, by measuring and storing the breathing system impedance up to and including the vent. This allows the device to accurately estimate the therapy pressure. For more information on performing a Learn Circuit, see "Setup menu: Options" on page 43.

Vsync and mask selection

Stellar's unique leak management combines **Vsync** and Mask Selection to monitor leak ie, unintentional mask leak and vent leak, and effectively compensate for its potentially detrimental effect on therapy.

It is important for a device to monitor the patient's respiratory flow, which provides information about lung ventilation and timing of the patient's effort. Using the respiratory flow signal, the device is able to trigger and cycle breaths that synchronize closely with the patient's effort.

Leak flow, both unintentional and from the mask/inline vent, adds to the Total Flow measured by the device's flow sensor and obscures the true Respiratory Flow. Without leak compensation, this would cause asynchronous triggering and cycling, as well as inaccurate data monitoring which may impact clinical decision-making.

Stellar is able to extract the patient's Respiratory Flow from the Total Flow. It uses information from Mask Selection to accommodate for mask/in-line Vent Leak, and Vsync to compensate for Unintentional Leak. That is:

Estimated Respiratory Flow = Total Flow – (Vent Leak + Unintentional Leak)

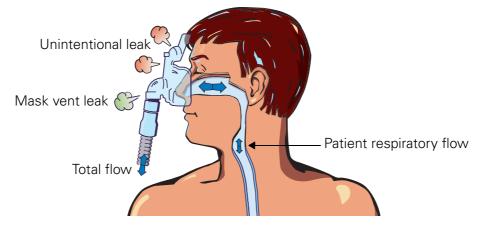




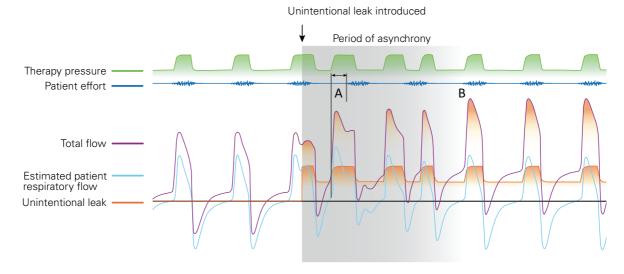








Unintentional leak may arise due to factors such as poor mask fit, mask movement during sleep, and fast therapy pressure transitions. When an unintentional leak is introduced (see below graph), synchrony between the device and the patient is disrupted. The increased flow from a leak can be interpreted as patient inhalation and cause the ventilator to trigger from EPAP to IPAP out of time with the patient's actual effort (A). Vsync responds rapidly to correct the disruption and restore synchrony within 2-6 breaths (B) depending on the patient's respiratory rate and the size of the leak.



Unintentional leak flow varies with changes to therapy pressure or the size of the leak opening. Vsync calculates changing leak by:

- · monitoring average pressure and flow
- assuming that on average volume delivered to the patient is equal to volume exhaled by the patient
- using this information to continuously estimate the size of the leak opening as it changes
- calculating the air flowing through the opening, knowing its size and the therapy pressure.





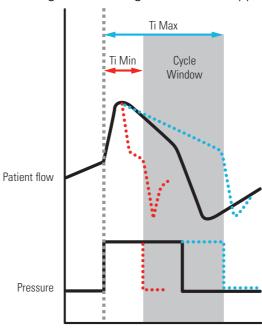






TiControl

TiControl™ allows the clinician to set minimum and maximum inspiratory time limits. Ti Min and Ti Max can be set to either side of the patient's ideal spontaneous inspiratory time, ensuring adequate time for gas exchange and offering a 'window of opportunity' to cycle into EPAP.



For some patients whose inspiratory effort or flow are weak and insufficient, Ti Min prevents the premature cycling to EPAP. Premature cycling to EPAP can result in insufficiently supported breaths.

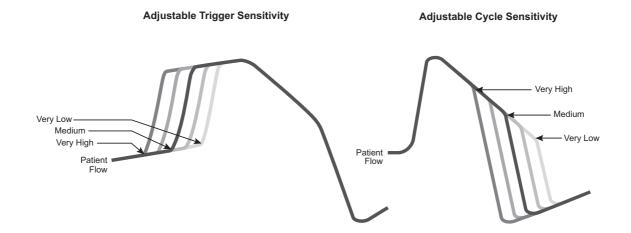
When breath detection becomes difficult due to excessive leak or inhibited exhalation effort or flow, Ti Max effectively prevents prolonged inspiration. See "Setting TiControl" on page 56.

Trigger/Cycle sensitivities

Under normal conditions, the device triggers (initiates IPAP) and cycles (terminates IPAP and changes to EPAP) as it senses the change in patient flow. Patient breath detection is enhanced by the device's automatic leak management feature—Vsync.

In addition, the device has five adjustable trigger/cycle sensitivities to optimize the sensing level according to patient conditions.

For more information, see "Trigger/cycle sensitivities" on page 57. For characteristic data, see "Technical specifications" on page 64.



















Rise/Fall Time

Rise Time sets the time taken for the device to reach the set inspiratory pressure after triggering. The greater the Rise Time value, the longer it takes for pressure to increase from EPAP to IPAP. A controllable Rise Time allows the clinician to optimize the patient's work of breathing, comfort and synchrony.

Fall Time sets the time taken for the device to reach the set expiratory pressure after cycling. The greater the Fall Time value, the longer it takes for pressure to decrease from IPAP to EPAP. Adjustable Fall Time may in certain patients improve breathing comfort and synchrony. For more information, see "Advanced Settings - Factory default settings and parameter ranges" on page 37.

Pathology Defaults

The Pathology Defaults offer a choice of disease-specific preset setting values to facilitate efficient commencement of therapy. You can select from four sets of respiratory system mechanics. Before use you will need to review the set parameters on the Clinical Settings screen.

Setting	S	ST	_	PAC	iVAPS	Obstructive lung disease	Restrictive lung disease	Obesity Hypoventilation Syndrome	Normal lung mechanics
IPAP [cm H ₂ O]	✓	✓	✓	✓		13	11	15	11
EPAP or PEEP [cm H ₂ O]	✓	✓	✓	✓	✓	5	5	7	5
PS [cm H ₂ O]	✓	✓	✓	✓		8	6	8	6
Rise Time [ms]*	✓	✓	✓	✓	✓	150	300	300	200
Fall Time [ms]*	✓	✓	✓	✓	✓	200	200	200	200
Trigger sensitivity	✓	✓		✓	✓	Medium	Medium	Medium	Medium
Cycle sensitivity	✓	✓			✓	High	Low	Medium	Medium
Min PS [cm H ₂ O]					✓	4	4	4	2
Max PS [cm H ₂ O]					✓	20	20	18	20
Ti Min [sec]	✓	✓			✓	0.3	0.5	0.5	0.5
Ti Max [sec]	✓	✓			✓	1.0	1.5	1.5	1.5

^{*}The Rise/Fall Time milliseconds scale is an approximate only.













Stellar 150 at a glance



The Stellar 150 comprises:

- Stellar 150 device Hypoallergenic air filter AC Power cord Carry bag 6' 6" (2 m) air tubing
- ResMed USB stick Low pressure oxygen connector.

The following optional components are compatible with Stellar 150:

• 9' 10" (3 m) air tubing • SlimLine™ air tubing • clear air tubing (disposable) • H4i™ heated humidifier • Antibacterial filter • Heat moisture exchanger filter (HMEF) • ResMed XPOD oximeter • Nonin™ pulse oximetry sensors • FiO₂ monitoring kit (external cable, T-piece adapter) • FiO₂ monitoring sensor • Stellar Mobility bag • ResMed Leak Valve • Tubing wrap.

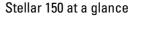


WARNING

The Stellar 150 should only be used with air tubing and accessories recommended by ResMed. Connection of other air tubing or accessories could result in injury or damage to the device.

ResMed regularly releases new products. Please check the catalogue of ventilation accessories on our website at www.resmed.com.





















Patient interface

Both masks and tracheostomy tubes can be used with Stellar. To set the patient interface type go to the *Setup* menu, select *Clinical Settings*, then *Advanced Settings*.

For information on using masks, see the mask manual. For a full list of compatible masks for this device, see the Mask/Device Compatibility List on www.resmed.com on the **Products** page under **Service & Support**. If you do not have internet access, please contact your ResMed representative.

Humidification

A humidifier is recommended especially for patients experiencing dryness of the nose, throat or mouth. For information on using a humidifier as part of:

- noninvasive ventilation, see "Setting up for noninvasive use" on page 14.
- invasive ventilation, see "Setting up for invasive use" on page 16.

Internal battery



CAUTION

Over time, the capacity of the internal battery will decrease. This depends on individual use and ambient conditions. As the battery degrades, it could lead to battery related alarms and or system errors. ResMed recommends the battery be tested after two years to assess the remaining battery life. Testing and replacement of the internal battery should only be performed by an authorized service agent.

Note: The battery duration depends on the state of charge, the environmental conditions, the condition and age of battery, the device settings and the patient circuit configuration.

In case of a mains power disruption, the device will operate using the internal battery if there is no external battery connected to the device. The internal battery will operate for approximately two hours under normal conditions (see "Technical specifications" on page 64). The power status of the battery is displayed on top of the LCD screen. Check the battery status regularly while operating the device with the internal battery and connect the device in time to mains power or alternatively to the external battery.

Additionally the Internal battery use alarm will be displayed. Press the Alarm mute button to clear the alarm.

To recharge the internal battery, connect the device to mains power. It can take up to three hours to fully recharge the internal battery, however this can vary depending on environmental conditions and if the device is in use.

The internal battery has to be discharged and recharged every six months.

Maintenance

The internal battery has to be discharged and recharged every six months.

- 1 Remove the power cord while the Stellar 150 is turned on (stand-by or in operation) and let the device operate with the internal battery to a charge level of 50%.
- 2 Reconnect the power cord to the mains power. The internal battery will be fully recharged.

Storing

If the device is stored for a longer period the internal battery should be at the charge level of approximately 50% to increase the durability.

Note: Check the charge level every six months, if necessary recharge the internal battery to a charge level of 50%.















ResMed USB stick

A ResMed USB stick may be used with the device either to help you to monitor the patient's treatment, to provide the patient with updated device settings or to transfer settings from one device to another. For more information, see "Data management" on page 52.

Use on an aircraft

ResMed confirms that the Stellar 150 can be used during all phases of air travel without further testing or approval by the airline operator. See "Technical specifications" on page 64.

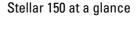
Mobile use

The Stellar Mobility bag allows the Stellar to be used in mobile situations, eg, in a wheelchair. For setup and correct use, see the Stellar Mobility Bag User Guide. For extended mobile use, the ResMed Power Station II external power supply unit can be used as an additional power source. Limitations apply to the use of oxygen with the Stellar Mobility Bag. For more information, contact your local ResMed representative.

Remote Alarm

The Remote Alarm may be used to transfer audible and visual alarms by a direct cable connection. For more information on using the Remote Alarm, see the Remote Alarm user guide.















Setting up for noninvasive use

WARNING



- The air filter cover protects the device in the event of accidental liquid spillage onto the device. Ensure that the air filter and air filter cover are fitted at all times.
- · Make sure that all the air inlets at the rear of the device and under the device and vents at the mask are unobstructed. If you put the device on the floor, make sure the area is free from dust and clear of bedding, clothes or other objects that could block the air inlets.
- Hoses or tubes must be non-conductive and antistatic.
- · Do not leave long lengths of the air tubing or the cable for the finger pulse sensor around the top of the bed. It could twist around the patient's head or neck while sleeping.



CAUTION

- Be careful not to place the device where it can be bumped or where someone is likely to trip over the power cord.
- · Make sure the area around the device is dry and clean.

Notes:

- ResMed recommends using the AC power cord supplied with the unit. If a replacement power cord is required, contact your ResMed Service Centre.
- · Place the device on a flat surface near the head of the bed.



- 1 Connect the power cord.
- 2 Plug the free end of the power cord into a power outlet.
- 3 Attach the H4i heated humidifier to the front of the Stellar 150. If the H4i is not in use, and if applicable, connect the antibacterial filter firmly onto the air outlet of the device (see "Attaching an antibacterial filter" on page 21).

Note: Other external humidifiers can be used for noninvasive setup. ResMed recommends using a breathing system (including antibacterial filter, air tubings, external humidifier) with an impedance of maximum 2 cm H_2O at 30 L/min, 5 cm H_2O at 60 L/min and 16 cm H_2O at 120 L/min.

- 4 Connect one end of the air tubing firmly onto the air outlet of the H4i.
- 5 Connect the mask system to the free end of the air tubing.







- 6 Select the mask type (select Setup menu, then Clinical Settings, then Advanced Settings).
- 7 Perform Learn Circuit (see "Setup menu: Options" on page 43).

Attaching the H4i heated humidifier

The Stellar 150 can be used with the H4i heated humidifier for noninvasive use when stationary. It will be automatically detected when the Stellar 150 is turned on.

A humidifier is recommended especially for patients experiencing:

- · nasal stuffiness/congestion
- rhinnorhea following the use of mask ventilation
- · dryness of the nose, throat or mouth
- patients with thick secretions (eg, cystic fibrosis, bronchiectasis, etc)
- patients using oxygen.

Humidification may be required for patients who experience nasal and upper airway dryness as a consequence of the high flow of air being directed through the nasal and oral passages. It may also be required in those individuals who have tenacious secretions.

Mouth leaks occurring during the use of positive pressure therapy can significantly increase nasal resistance. This increase in nasal resistance associated with mouth leaks may be prevented by fully humidifying the inspired air. In most cases, using heated humidification is the most effective way to decrease nasal resistance.

For information on using the H4i, see the H4i user guide.



WARNING

- Always place the H4i on a level surface below the level of the patient to prevent the mask and tubing from filling with water.
- Make sure that the water chamber is empty and thoroughly dried before transporting the humidifier.
- The H4i humidifier is not intended for mobile use.
- · Do not overfill the water chamber, as during use this will cause water to spill into the air circuit.
- For optimal accuracy and synchrony, perform Learn Circuit with a change of the circuit configuration, in particular when adding or removing high impedance components (eg, antibacterial filter, external humidifier, water trap, nasal pillow type mask or air tubing). See "Setup menu: Options" on page 43.



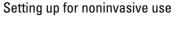
CAUTION

Check the air circuit for water condensation. Use a water trap or a tubing wrap if humidification is causing water condensation within the tube.

Notes:

- · A humidifier increases resistance in the air circuit and may affect triggering and cycling, and accuracy of display and delivered pressures. Therefore perform the Learn Circuit function (see "Setup menu: Options" on page 43). The device adjusts the airflow resistance.
- The heating feature of the H4i is disabled when the device is not mains powered.



















Setting up for invasive use

The Stellar 150 can be used invasively only with the ResMed Leak Valve.



WARNING

- Make sure that all the air inlets at the rear of the device and under the device and vents at the mask or at the ResMed Leak Valve are unobstructed. If you put the device on the floor, make sure the area is free from dust and clear of bedding, clothes or other objects that could block the air inlets.
- · Replace the HMEF regularly as specified in the instructions provided with the HMEF.
- The H4i is contraindicated for invasive use. An external humidifier approved for invasive use is recommended according to EN ISO 8185 with an absolute humidity of > 33 mg/L and a maximum flow within the technical specifications of Stellar 150.
- For optimal accuracy and synchrony, perform Learn Circuit with a change of the circuit configuration, in particular when adding or removing high impedance components (eg, antibacterial filter, external humidifier, water trap, nasal pillow type mask or air tubing). See "Setup menu: Options" on page 43.



CAUTION

When using a humidifier, use a water trap and check the air circuit regularly for accumulated water.

Notes:

- When the mask type is set to **Trach**, the Non-Vented Mask alarm will be automatically enabled to alert the user when the ResMed Leak Valve has no vent holes or when the vent holes are blocked.
- ResMed recommends using a breathing system (including antibacterial filter, air tubings, external humidifier and ResMed Leak Valve) with an impedance of maximum 2 cm H₂O at 30 L/min, 5 cm H₂O at 60 L/min and 16 cm H₂O at 120 L/min.



- 1 Connect the power cord.
- 2 Plug the free end of the power cord into a power outlet.
- **3** Connect the antibacterial filter firmly onto the air outlet of the device.











- - •
- 4 Connect the external humidifier to the other side of the antibacterial filter.

 *If not using an external humidifier, connect the HMEF to the ResMed Leak Valve (at step 9).
- **5** Connect the air tubing to the external humidifier.
- **6** Connect the ResMed Leak Valve to the air tubing. Position the ResMed Leak Valve so that air from the vent holes does not blow directly onto the patient's chest.



WARNING

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 Stellar to the patient.

- 7 Select the mask type Trach (select Setup menu, then Clinical Settings, then Advanced Settings).
- **8** Perform Learn Circuit (see "Setup menu: Options" on page 43).
- **9** If an external humidifier is not being used, connect the HMEF to the patient side of the ResMed Leak Valve.
- **10** Connect the catheter mount.
 - ** The ResMed Leak Valve or the HMEF can be connected to standardized tracheostomy interfaces including connector pieces like catheter mounts.

The catheter mount and the external humidifier are not part of the ResMed component.

Setting up for home therapy

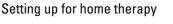
You may be required to set up a device for a patient to use at home. There are a number of things to be aware of:

- Before sending the device home with a patient and to ensure the same therapy is delivered then, parameters and oxygen levels for the configuration must be set to match the way in which it will be used in the patient's home (eg, same mask system, with the humidifier connected, the oxygen line entrained at the same place, the same oxygen source, filters in the same position, and same length air tubing) so that the therapy is working correctly. Make sure the alarms are working as expected (see "Testing the alarms" on page 40).
- 2 Set the device to Patient mode 🗓.
- **3** Make sure that the patient has a contact phone number in case of emergency. A good place to write this is in the front of the User Guide.





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Working with other optional accessories

Attaching a pulse oximeter



WARNING

Only use compatible NONIN finger pulse sensors.



CAUTION

Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: excessive ambient light, excessive motion, electrosurgical 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 hemoglobin concentrations, cardiogreen or other intravascular dyes, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, artificial nails or fingernail polish, or a sensor not at heart level.

Note: The pulse oximeter does not meet the defibrillation-proof requirement as per IEC 60601-1: 1990, clause 17.h.



- 1 Connect the plug of the finger pulse sensor to the plug of the pulse oximeter.
- Connect the plug of the pulse oximeter at the rear of the device.To view the oximetry values, from the *Monitoring* menu, select *Monitoring*.











WARNING

- Oxygen flow must be turned off when the device is not operating, so that unused oxygen does not accumulate within the device and create a risk of fire.
- ResMed strongly recommends adding oxygen into Stellar's oxygen inlet at the rear of the device. Entraining 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 alarms (eg, High Leak alarm, Non-vented mask alarm). If used in this way, therapy and alarm operation must be verified each time oxygen flow is adjusted.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen supply in well-ventilated rooms.
- The breathing system and the oxygen source must be kept at a minimum distance of 6' 6" (2 m) away from any sources of ignition (eg, electrical devices).
- · Use only certified, clean oxygen sources.
- · Oxygen must not be used while the device is being operated within the mobility bag.



Note: Up to 30 L/min at maximum oxygen pressure of 50 mbar (0.73 psi) can be added.

Starting therapy using oxygen

- **1** Fit the oxygen connector to the oxygen inlet of the device.
- **2** Attach the other end of the oxygen supply tubing to the oxygen supply.
- Press to start treatment.

 Ensure you complete titration with the same circuit configuration that the patient will be using at home.
- **4** Turn on oxygen.

Stopping therapy using oxygen

- **1** Turn off oxygen.
- 2 Press **(a)** to stop treatment.













CAUTION

Do not use the FiO₂ monitoring sensor with the H4i humidifier.

Preparing to use a new sensor

- **1** Before use, leave the FiO_2 monitoring sensor open to the air for 15 minutes.
- **2** Attach a new FiO₂ monitoring sensor (as shown below).
- **3** Perform the sensor calibration (see "Setup menu: Options" on page 43).

Note: The FiO_2 monitoring sensor must be replaced every 12 months.



Connecting a sensor

- **1** Connect the air tubing to the T-piece adapter.
- **2** Connect the FiO₂ monitoring sensor to the T-piece adapter.
- **3** Connect the adapter to the air outlet of the device.
- **4** Connect one end of the cable to the FiO₂ monitoring sensor.
- **5** Connect the other end of the cable to the rear of the device.
- **6** Start calibration (see "Setup menu: Options" on page 43). This should be repeated periodically as per the facility policy.











Attaching an antibacterial filter

The use of an antibacterial filter can be recommended as per facility policy. One antibacterial filter—product code 24966—can be purchased separately from ResMed.

Regularly check the filter for entry of moisture or other contaminants. The filter must be replaced according to the manufacturer's specifications.

Note: ResMed recommends using a filter with a low impedance (less than 2 cm H₂O at 60 L/min, eg, PALL BB 50 filter).



WARNING

- An antibacterial filter is mandatory if the device is used on multiple patients.
- Do not use the antibacterial filter (product code 24966) with the H4i.



- 1 Fit the antibacterial filter to the air outlet of the device.
- 2 Attach the air tubing to the other side of the filter.
- 3 Attach the mask system to the free end of the air tubing.
- 4 Perform the Learn Circuit function (see "Setup menu: Options" on page 43). From the Setup menu, select Options. This enables the device to compensate for the impedance introduced by the filters.









Working with other optional accessories









About the control panel



Key	Function
Start/Stop	 Starts or stops treatment. Extended hold for at least three seconds starts the mask-fitting feature.
Alarm mute	 During therapy: Press once to mute an alarm. Press a second time to un-mute an alarm. If the problem is still present, the alarm will sound again after two minutes (see "Working with alarms" on page 25). In stand-by mode: Extended hold for at least three seconds starts the LED and the alarm buzzer test.
Menu keys	Press the appropriate menu button (Monitoring, Setup, Info) to enter and scroll through the relevant menu.
Push dial	Turning the dial allows you to scroll through the menu and change settings. Pushing the dial allows you to enter into a menu or confirm your choice.











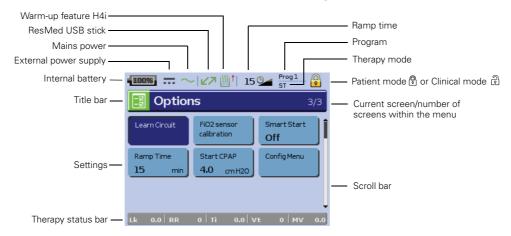




The LCD screen

The LCD screen displays the menus, treatment screens and alarm status.

Values on this LCD screen and other screens throughout the Clinical Guide are examples only.



Starting therapy

Performing a functional test

Perform a functional test under any of the following circumstances:

- · prior to the initial use of Stellar
- · in between patients
- on long-term use patients, periodically as per the facility policy.

If any problems occur, see "Troubleshooting" on page 58. Please also check other provided User Instructions for troubleshooting information.

- 1 Turn off the device by pressing the power switch at the back of the device.
- 2 Check condition of device and accessories.

Inspect the device and all the provided accessories. If there are any visible defects, the system should not be used.

3 Check the circuit configuration.

> Check the integrity of the circuit configuration (device and provided accessories) according to the setup descriptions in this Clinical Guide and that all connections are secure.

4 Turn on the device and check alarms.

Press the power switch at the back of the device once to turn on the device.

Check that the alarm sounds a test beep and the LEDs (visual indicator) for the alarm signal and the Alarm mute button flash. The device is ready for use when the *Treatment* screen is displayed. If the display shows the Reminder screen, follow the instructions, then press 🖾 to display the *Treatment* screen.

5 Check batteries.

> 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 will be displayed and the battery LED is on.

Note: If the charge state of the internal battery is too low, or if the battery is empty an alarm occurs. See the Alarm troubleshooting section on page 58 for further information.

Reconnect the external battery (if in use) and check that the LED for the external power supply is lit. The External DC power use alarm will be displayed and the Alarm LED will light. Reconnect the device to the mains.









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6 Check the H4i heated humidifier (if in use).

Check that the warm-up feature is displayed on the *Treatment* screen. Start the warm-up feature. Check that the humidifier warm-up symbol is displayed on top of the screen.



You can use the warm-up feature to pre-heat the water in the humidifier prior to starting treatment. The humidifier will be automatically detected when the device is turned on. The *Treatment* screen provides the option to start warming the humidifier. If the humidifier is heating, the related symbol is displayed at the top of the LCD screen.

For more information, see the H4i User Guide.

Note: The H4i in heating mode can only be used when the device is connected to mains supply.

7 Check the FiO₂ monitoring sensor (if in use).

Start the FiO_2 sensor calibration. Select *Setup* menu, then *Options* (see "Setup menu: Options" on page 43). Follow the instructions on the display.

8 Check pulse oximeter (if in use).

Attach the accessories according to the setup descriptions (see "Attaching a pulse oximeter" on page 18). From the *Monitoring* menu, go to the *Monitoring* screen. Check that the values for SpO₂ and Heart rate are displayed.

9 Check oxygen connection (if in use).

Attach the accessories according to the setup descriptions (see "Adding supplemental oxygen" on page 19).

Starting therapy



WARNING

Always ensure that the values in the ventilator therapy and alarm settings are appropriate before starting therapy.

Notes:

- When the device is turned on it operates in Patient mode where settings are restricted. You can switch the device into Clinical mode, see "Setup menu" on page 34.
- Always ensure that you verify the correct operation of triggering and cycling, and activation of High Leak alarm.
- **1** Press the power switch at the back to turn on the device.
- 2 To start treatment press or if the SmartStart function is enabled instruct the patient to breathe into the patient interface and treatment will begin.

Note: When the ResMed Leak Valve is used, check that the anti-asphyxia valve (membrane) within the ResMed Leak Valve stays closed during the entire breathing cycle. Increase the EPAP if necessary.











Stopping therapy

You can stop therapy at any time, simply remove the patient interface and press **(a)** to stop airflow **or** if SmartStart/Stop is enabled, simply remove the patient interface, and treatment will stop automatically.

Notes:

- SmartStop may not work if **Full face** or **Trach** is selected as mask type; the High Leak alarm or the Low Min Vent alarm is enabled; "Confirm Therapy Stop" is enabled; or the mask-fitting feature is running.
- When the device is stopped and operating in standby mode with an integrated humidifier connected, it will continue to blow air gently to assist cooling of the humidifier's heater plate.
- Masks with high resistance (eg, pediatric masks) may cause the operation of the SmartStop feature to be restricted.
- When using with oxygen, turn off oxygen flow when stopping therapy.

Turning off the power

- **1** Stop the therapy.
- Press the power switch at the back of the device once and follow the instructions on the display.

 Note: To disconnect the device from the mains power pull out the mains plug from the power

Working with alarms

socket.



WARNINGS

- Carefully review the alarm settings prior to use to ensure that the alarm settings are appropriate for each individual patient.
- This device is not intended to be used for vital signs monitoring. If vital signs monitoring is required, a dedicated device should be used for this purpose.

The device is fitted with alarms to alert you to changes that will affect the patient's treatment.



Alarm messages are displayed along the top of the screen. High priority alarms are displayed in **red**, medium priority alarms in **yellow** and low priority alarms in **light blue**. The Alarm LED lights **red** during high priority alarms and **yellow** during medium and low priority alarms.

The alarm volume can be set Low, Medium or High. From the *Setup* menu, select *Alarm Settings*. After the set value has been confirmed, the alarm will sound and the alarm LED lights.

For more information on reviewing and changing alarm settings, see "Setup menu: Alarm Settings" on page 38.









Starting therapy





You can mute an alarm by pressing 🖾 once. By pressing the Alarm mute key again, the alarm sounds again. When an alarm is muted, the Alarm mute key LED will light constantly. For a high or medium priority alarm, if after two minutes the problem is still present, the alarm will sound again. Any active low priority alarm will be permanently muted and the Internal Battery Use alarm will be cleared until the alarm condition is fulfilled again.

Fixed alarms

High priority alarms:

- · Circuit disconnected—when leak exceeds 105 L/min (1.75 L/sec) for at least 15 sec
- Over pressure
- Blocked tube
- Internal battery empty—when its charge level is less than 15%, the system may stop operating in as little as two minutes
- Pressure sensor failure (system failure 7)
- Motor failure (system failure 6)
- Critical software failure (system failure 38)

Medium priority alarms:

- · High temperature (internal components such as
- System failure (self test, flow sensor, software, calibration)
- Internal battery low—when its charge level falls below 30%

Low priority alarms:

- External DC power use
- Internal battery use
- Kevpad failure
- Finger sensor failure
- System failure (software, system component)
- Disconnected FiO₂ sensor
- Disconnected XPOD pulse oximetry
- · High temperature attention (internal components such as motor)

User adjustable alarms

High priority alarms:

· Non-Vented Mask

Medium priority alarms:

- · Low Min Vent
- High Leak
- High Pressure
- Low Pressure
- · High Respiratory Rate
- · Low Respiratory Rate

Low priority alarms:

- · High FiO₂ level
- Low FiO₂ level
- Low SpO₂ level

Resetting alarms

When the Alarm mute key is pressed during therapy for at least three seconds, the following alarm messages and the audible alarm will be temporarily cleared:

- High Pressure
- · Low Pressure
- · High Leak
- Non-Vented Mask
- · Low Min Vent

- High Breath Rate
- · Low Breath Rate
- High FiO₂
- Low FiO₂
- Apnea
- Low SpO₂

Tailoring treatment setup options **Setting Ramp**

If the patient experiences difficulty falling asleep with full pressure, they may wish to make use of Ramp where the pressure starts very gently and slowly increases to the set treatment pressure over a selected time period (see "Setup menu: Options" on page 43).

The Treatment screen following shows Max Ramp set at 15 minutes, while the graph shows the pressures experienced during ramp while in bilevel mode.















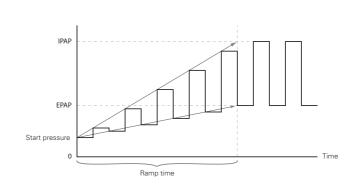




CAUTION

EPAP/PEEP and Pressure Support achieve their configured values at the end of the ramp period. Some patients require full support from the commencement of therapy. Ramp may not be appropriate in such cases.





Programs



Up to two sets of therapy settings, ie, Programs, can be saved for convenient retrieval. They are stored while in the Clinical Settings menu. If both, ie, dual, is selected, the patient can choose the program to use on the Treatment screen. If only a single program is selected, the option does not display.

Single or dual programs can be set in the Setup menu, Options, Configuration menu.

The Program names can be personalized using ResScan (eg, Day and Night).

Using mask-fit

The patient can use mask-fit to help you fit the mask properly. This feature delivers constant treatment pressure for a three-minute period, prior to starting treatment, during which the patient can check and adjust the mask-fit to minimize leaks. The mask-fit pressure is the set CPAP or EPAP pressure or 10 cm H₂O, whichever is greater.

- 1 Instruct the patient to lie down in bed or in their typical usage position and to put the mask on according to the mask user guide.
- 2 Hold down for at least three seconds until pressure delivery starts.
- 3 Adjust the mask, mask cushion and headgear until the patient has a good mask-fit. After three minutes at the mask-fit pressure, the prescribed treatment mode and pressures will commence. Mask-fit can be stopped at any time by pressing .

Notes:

- Press for at least three seconds during mask-fit to start treatment immediately. The Treatment screen will be displayed.
- The mask-fitting feature is disabled when the mask type Trach is selected.
- Availability of this feature is country dependent.







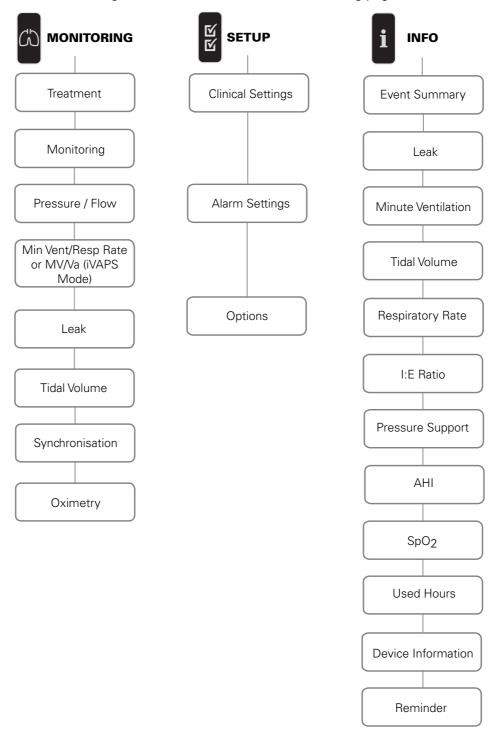






Using the menus

The device has three menus (*Monitoring, Setup, Info*) accessed by the equivalent buttons on the right of the LCD screen. In each menu there are screens that display settings, device or therapy information. The menu structure is the same in Patient and Clinical modes. Differences mainly exist in the settings that will be described in the following pages.



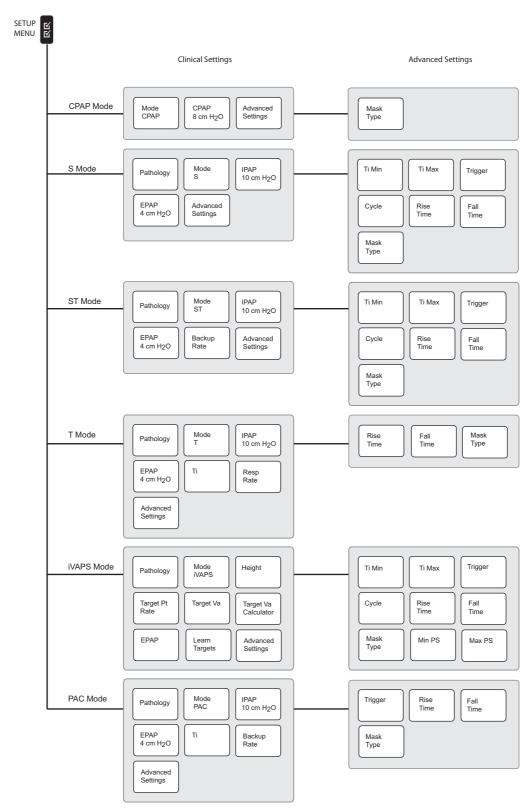








Setup menu: Clinical Settings



Note: When the Option Multi Program is set to dual, the setting Program is displayed in the Clinical Settings menu. See "Setup menu: Clinical Settings" on page 34.



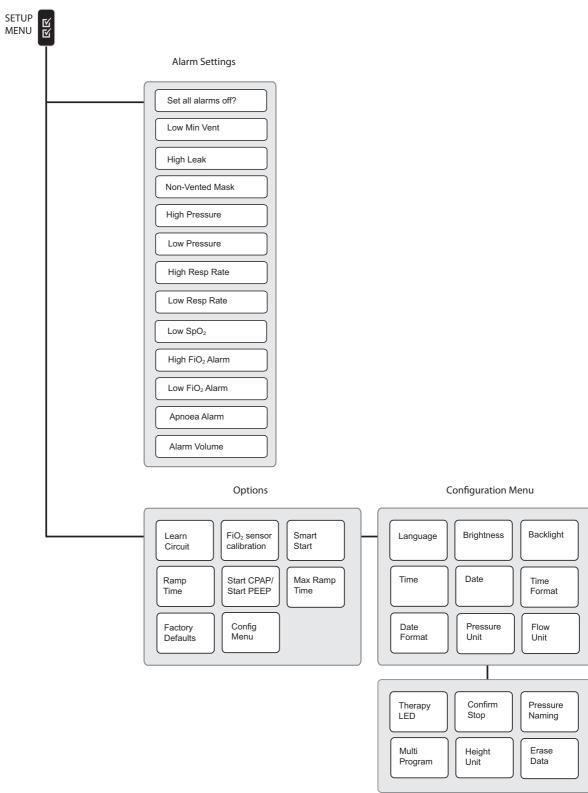








Setup menu: Alarm Settings and Options











Monitoring menu





Screen 1: Treatment

- 1 Pressure bar graph with the set pressure limits and measured pressure.
- 2 Machine breath indicators:



Machine cycled breath:

- ▲ the inspiratory phase is sustained up to Ti Min.
- The inspiratory phase is cycled down to EPAP/PEEP at Ti Max (S/ST mode) or Ti (PAC/T mode).

Machine triggered breath:

- _ the machine initiates the inspiratory phase increasing pressure up from EPAP/PEEP.
- 3 Set Ramp (see "Setting Ramp" on page 26).
- 4 Warm-up the humidifier (see step 6 on page 24).
- 5 Set program (see "Programs" on page 27).
- 6 The Therapy status bar allows you to view treatment data while therapy is running.

Therapy status bar - parameter descriptions

Parameter	Range (Resolution)	Description
Leak (Lk)	0–120 L/min (1 L/min)	Current average unintentional leak. Leak is an output of the Vsync algorithm (see "Learn Circuit" on page 7). Unintentional leak is calculated by subtracting expected interface vent flow (based on the Mask Type in the <i>Settings</i> menu) from total leak. Averaging is typically over 2-6 breaths and can be shorter in the presence of unstable leak.
Respiratory Rate (RR)	5–60 bpm (1 bpm)	The number of breaths per minute, averaged over the last five breaths. A breath is considered as a respiratory cycle if it exceeds 50 mL, either spontaneously or machine triggered.
Inspiration Time (Ti)	0.1-4 sec (0.1 sec)	The duration of the ventilator inspiratory phase. This is a set Ti value in Timed and PAC modes.
Tidal Volume (Vt)	50–3000 mL (10 mL)	Tidal Volume is an estimate of quantity of inhaled air per breath, calculated as an integral of respiratory flow: based on the leak flow, the mask vent flow and the total flow rate. The display is based on a five-breath moving average, updated every breath.
Minute Ventilation (MV)	0.6–60 L/min (0.1 L/min)	Minute Ventilation is the product of Respiratory Rate and Tidal Volume. The display is based on a five-breath moving average, updated every breath.

Note: Preferences for pressure and flow units can be set in the in the Setup menu, Options, Configuration menu.















Screen 2: Monitoring

- 1 Pressure bargraph with the set pressure limits.
- 2 The following therapy parameters are displayed:
 - Leak, Vt, RR, Ti (refer to Therapy status bar in Treatment screen).
 - Alveolar Ventilation (Va): minute volume without deadspace (Unit: L), displayed in iVAPS mode.
 - Inspiration to expiration ratio per breath (I:E).
 - Pulse oximeter measurements from Nonin: Heart rate and SpO₂ are both averaged over four beats of the pulse. Data is only displayed when an oximeter is connected to the device.
 - FiO₂: Average fraction of oxygen level in the air outlet. Displayed when an oxygen sensor is connected.

Note: The SpO_2 and FiO_2 values are not appropriate to be used for diagnostic purposes.



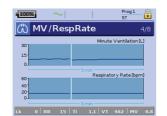
Screen 3: Pressure/Flow

Pressure: Therapy pressure refreshed at 10 Hz (0.1 sec)

Flow: Estimated respiratory flow refreshed at 10 Hz (0.1 sec) (Unit: L/min, L/sec)

Each graph displays the last 20 seconds of data.

You can scroll back to view past data from the start of the session. Press sthen turn it anti-clockwise.



Screen 4: Minute Ventilation/Respiratory Rate

The last five minutes of data averaged over five breaths are displayed.



Screen 4: (iVAPS only) Minute Ventilation/Alveolar Ventilation

The last five minutes of data averaged over five breaths are displayed.

Alveolar Ventilation has a guideline of Target Va.



Screen 5: Leak

Average instantaneous leak: Sampled variably depending on leak change (Unit: L/min, L/sec).

Pressure/Flow graph: Therapy pressure and estimated respiratory flow sampled at 10 Hz ($0.1~{\rm sec}$).

Each graph displays the last 20 seconds of data.



Screen 6: Tidal Volume

The last 14 breaths of data averaged over five breaths are displayed.

















Screen 7: Synchronisation

Diagram of the measured inspiration phases of the last 20 breaths.

The last 20 breaths of measured inspiration time (sec). The height of the bar indicates the inspiration time. In S/ST modes, Ti Min/Ti Max thresholds are shown as Min/Max.

- Settings changed. Alarm activated.

Additional information is displayed on the Event summary page.

- A The inspiratory phase is sustained up to Ti Min (S/ST mode).
- The red bar indicates for how long the inspiratory phase is sustained up to Ti Min (S/ST mode) or Ti (PAC/T mode).
- The inspiratory phase is cycled down to EPAP/PEEP at Ti Max (S/ST mode) or Ti (PAC/T mode).
- ▲ The machine initiates the inspiratory phase increasing pressure up from EPAP/PEEP.



Screen 8: Oximetry

SpO₂: The oxygen saturation level.

Heart Rate: Display of heart rate measurement (Unit: BPM).

Each graph displays the last 10 minutes.

Error trace: Displays errors in measuring oximetry data.





Monitoring menu







The Setup menu allows you to view and change therapy, alarm and device settings.

Accessing Clinical mode

CAUTION

- ullet For home treatment the device must be set to Patient mode lacktriangle
- · Only trained and authorized personnel must make changes to clinical settings.

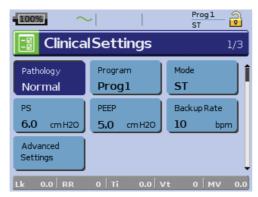


To activate Clinical mode ①, hold down and I simultaneously for at least three seconds. You will be prompted for how long the device should stay in this mode. After the set period of inactivity or next power cycle (power on/off), the device automatically switches back to the patient mode and the device beeps.

When Clinical mode is enabled, the lock symbol in the header changes to unlocked and the device beeps.

Setup menu: Clinical Settings

On this screen, Clinical Settings are displayed according to the set therapy mode and can be changed. Additional settings are located on the *Advanced Settings* screen.





Return to Clinical Settings

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Factory default settings and parameter ranges

Parameter Mo		Mode					Default	Description
	CPAP	S	ST (PS)	—	ivaps	PAC		
Pathology		✓	✓	√	✓	✓	Normal	Disease-specific preset setting values to facilitate efficient commencement of therapy (see page 10).
								Note: If the default pathology settings have been changed, the button is marked with an asterisk.
								Options : Obstructive, restrictive, normal, obesity hypoventilation
Program	✓	✓	✓	√	✓	✓	Prog 1	The program setting is only available if the option Multi program in the <i>Configuration</i> menu is set to Dual. Clinical settings and alarms can be stored in two different programs (see page 27).
								Note: The program name can be set via ResScan. Options: Prog 1, Prog 2
Mode	✓	√	✓	✓	✓	✓	ST	Sets the therapy mode (see page 2).
								Options: CPAP, S, ST (PS), T, iVAPS, PAC
CPAP	✓						8.0 cm H ₂ O	Continuous Positive Airway Pressure
								Sets the fixed treatment pressure (in CPAP mode).
								Note: When changing from CPAP to bilevel mode, the set CPAP pressure becomes the new IPAP and EPAP pressure.
								Options : 4–20 cm H ₂ O; 0.2 cm H ₂ O increments
IPAP		✓	✓	✓		✓	11.0 cm H ₂ O	Inspiratory Positive Airway Pressure
								IPAP is the pressure which will be delivered to the patient when the device is triggered into inspiration.
								Options: 3–40 cm H ₂ O; 0.2 cm H ₂ O increments
EPAP or		✓	✓	✓	✓	✓	5.0 cm H ₂ O	Expiratory Positive Airway Pressure
PEEP								EPAP is the pressure which will be delivered to the patient when the device is cycled into expiration (see page 57).
								Options : 3–25 cm H ₂ O (always below or equal to IPAP);
								0.2 cm H ₂ O increments
PS		√	√	✓		✓	6.0 cm H ₂ O	Pressure support; PS = IPAP-EPAP
								The pressure support is the pressure increase (above EPAP/PEEP) delivered during inspiratory phase.
								Options: 0–37 cm H ₂ O; 0.2 cm H ₂ O increments
Ti				✓		✓	1.5 sec	Sets the inspiratory time.
								Options: 0.2–4 sec or 2/3 of one breath cycle defined by Respiratory or Backup Rate; 0.1 sec increments
Backup Rate			✓			✓	10 bpm	Sets the breaths per minute (bpm). Options: 5–60 bpm, 1 bpm increments
								options of oblight, indigitalities



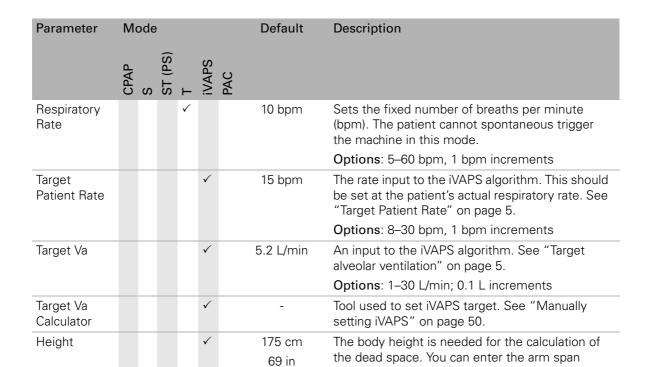


Setup menu

Learn Targets







increments

Targets" on page 48.

✓

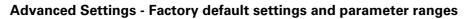
Options: 110-250 cm (43 in - 98 in); 5 cm (2 in)

Tool used to set iVAPS targets. See "Using Learn









Parameter	Mode		Default	Description				
	CPAP	S	ST (PS)	⊢	ivaps	PAC		
Min PS					✓		2 cm H ₂ O	Minimum pressure support in iVAPS mode. Options : 0-20 cm H_2O (Min PS always below Max PS); 0.2 cm H_2O increment
Max PS					✓		20 cm H ₂ O	Maximum pressure support in iVAPS mode. Options: 0-30 cm H ₂ O; 0.2 cm H ₂ O increments
Rise Time		1	✓	✓	✓	V	200	Rise Time sets the time taken for the device to pressurize to IPAP (see page 10). Notes: The Rise/Fall Time milliseconds scale is an approximate only. The actual Rise Time achieved is influenced by factors including compliance, resistance, leak, pressure differential and patient breathing patterns. Prolonged Rise Time inhibits pressurisation; Care should be taken to ensure Rise Time is set according to the patients inspiratory flow and work of breathing. Patients with a high work of breathing, short Ti and fast Respiratory Rate will require shorter rise times than those with lower Respiratory Rate, quiet breathing and normal Ti. Options: min, 150–900 (limited to 2/3 of Ti Max or Ti); 50 increments
Fall Time		√	√	√	✓	✓	200	 Fall Time sets the time taken for the device to depressurize to EPAP/PEEP when cycling occurs (see page 10). Notes: The Rise/Fall Time milliseconds scale is an approximate only. The actual Fall Time achieved is influenced by factors including compliance, resistance, leak, pressure differential and patient breathing patterns. Options: min, 100–400; 100 increments
Ti Min		✓	✓		✓		0.5 sec	Sets the minimum limit on the time the device spends in IPAP (see page 9). Options: 0.1 sec—Ti Max; 0.1 sec increments
Ti Max		✓	✓		✓		1.5 sec	Sets the maximum limit on the time the device allows the patient to spend in inspiration (see page 9). Options: 0.3–4 sec or 2/3 of one breath cycle defined by Backup Rate; 0.1 sec increments
Trigger		✓	✓		✓	✓	Medium	Sets the sensitivity for triggering. Triggering occurs when inspiratory flow increases above a certain level and the device changes from EPAP to IPAP (see page 9). Options: very high, high, medium, low, very low

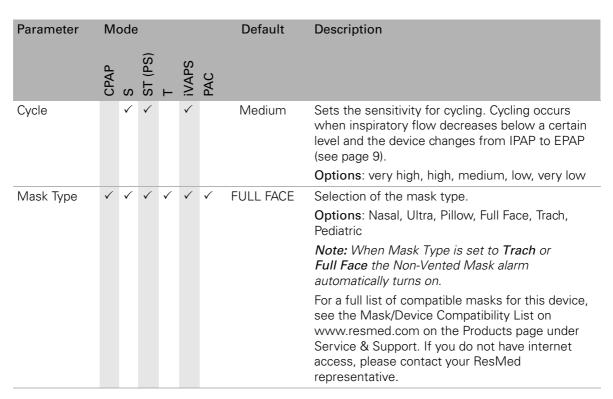












Setup menu: Alarm Settings





The following alarms that can be set in while in Clinical mode.

Alarm Setting	Default	Description
Set all alarms off?	Yes	Sets all user selectable alarms off.
		Note: When the mask type is set to Trach the Non-Vented Mask alarm will stay ON.
Low Min Vent (Low minute ventilation)	On, 2 L	Sets the minimum minute ventilation. Activates at least 30 sec after the measured level remains below the set limit. ¹
		Range: On, Off, 2–30 L, 1 L/min increments
High Leak	On	Enables/disables High Leak alarm. When enabled, leaks > 40 L/min (0.7 L/sec) for > 20 sec result in the alarm sounding and a High leak message. 1
		Options: On, Off







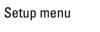




Alarm Setting	Default	Description
Non-Vented Mask	On	This alarm activates within 30 sec of therapy being delivered with a non-vented interface attached or a vented mask with occluded vents.
		Note: When the mask type is set to Full Face or Trach the Non-Vented Mask alarm will be enabled automatically to ensure the circuit configuration has an intentional leak. It can then be turned off for Full Face. Options: On, Off
High Pressure	On, 35 cm H ₂ O	Sets the high pressure limit. Activates when the pressure exceeds the set limit in two consecutive cycles or for a period of 5 sec.
		Range: On, Off; 4–45 cm H ₂ O, 1 cm H ₂ O increments
Low Pressure	On, - 5 cm H ₂ O	Sets the maximum drop in pressure with reference to a set IPAP or CPAP pressure during the inspiration phase. Activates when the pressure drops by more than the set level within 18 sec.
		 Notes: This alarm is not enabled in iVAPS mode. When SmartStart/Stop is enabled, SmartStop activates before the Low Pressure alarm.
		Range: On, Off, -2 to -10 cm H_2O , 1 cm H_2O increments
High Respiratory Rate	Off	Sets the maximum respiratory rate. Activates when the measured respiratory rate exceeds the set level for four breath cycles.
		Note: This alarm is not enabled in T mode.
		Range: On, Off, 5-60 bpm, 1 bpm increments
Low Respiratory Rate	Off	Sets the minimum allowed respiratory rate. Activates when the measured respiratory rate remains below the set level for four breath cycles.
		Note: This alarm is not enabled in T mode.
		Range: On, Off, 5-30 bpm, 1 bpm increments
Low SpO ₂	Off	Sets the minimum allowed ${\rm SpO_2}$ value. Activates when the measured ${\rm SpO_2}$ level remains below the set level for at least 5 sec.
		Note: This alarm is only selectable when the pulse oximetry accessory is connected. Page: Op. Off. 70.95%: 1% increments.
Llieb FiO	Off	Range: On, Off, 70-95%; 1% increments
High FiO ₂	Off	Sets the maximum allowed average oxygen fraction. Activates when the measured FiO ₂ fraction is greater than the set level for more than 15 sec.
		Note: This alarm is only selectable when the FiO ₂ monitoring sensor is connected.
		Range: On, Off, 30–100%, 1% increments
Low FiO ₂	Off	Sets the minimum allowed average oxygen fraction. Activates when the measured FiO ₂ fraction is less than the set level for more than 15 sec.
		Note: This alarm is only enabled when the ${\rm FiO_2}$ monitoring sensor is connected.
		Range: On, Off, 18–80%, 1% increments











Alarm Setting	Default	Description
Apnea	On, 20 s	Sets the maximum apnea time. Activates when there is no inspiration (either patient or machine triggered) detected from the previous beginning of inspiration. Two consecutive inspirations (either patient or machine triggered) resets the Apnea alarm.
		Range: On, Off, 10-60 sec, 1 sec increments
Alarm Volume	High	Sets the alarm volume.
		Options: Low, medium, high

¹ When the High Leak or Low Min Vent alarms are set to ON, SmartStop is automatically disabled.

Testing the alarms

When the device is turned on, the Alarm LED and the Alarm mute key LED will flash, and the alarm will sound to confirm that the alarm is working. If required, you can test the alarm manually by holding down the Alarm mute button for at least three seconds when therapy is not running and no alarm is active.

Initial setup

- 1. Turn off all configurable alarms.
- 2. Set up the device with the air tubing attached, but no mask.
- 3. Set Ramp Time to 0 mins.
- 4. Set SmartStart/Stop to Off.

Alarm simulation

Alarm	Testing interval
High Pressure	
1. On the Setup, Clinical Settings menu, set Mode to T and EPAP to 4 cm $\rm H_2O$.	On patient titration.

- 2. Set Pressure Support to 10 cm H_2O .
- 3. On the Setup, Alarm Settings menu, set All alarms off to Yes.
- 4. Now set the High Pressure Alarm Setting to 7 cm $\rm H_2O$, and change the alarm to be On.
- 5. Block the air tubing.
- 6. Start ventilation.

Low Pressure

- 1. Set the Low Pressure Alarm to -2 cm H₂O.
- 2. Set IPAP and EPAP to 25 cm H_2O .
- 3. Start ventilation.
- 4. Partially block the open end of the tube with your hand. The alarm activates within 15 seconds. If the Blocked Tube or Circuit Disconnected Alarm activates repeat the test.
- 5. Stop therapy.

Low Min Vent (Low minute ventilation)

- 1. Set the Low Min Vent Alarm to 30 L/min.
- 2. Start ventilation.
- 3. Partially block the open end of the tube with your hand so that the measured MV in the therapy status bar displays lower value than 30 L/min. The alarm activates within 30 seconds. If the Blocked Tube or Circuit Disconnected Alarm activates repeat the test.
- 4. Stop therapy.

On patient titration.

On patient titration.















Alarm Testing interval

High Respiratory Rate

1. On the Setup, Clinical Settings menu, set Mode to ST and Backup Rate to 30 bpm.

Each new patient.

- 2. On the Setup, Alarm Settings menu, set All alarms off to Yes.
- 3. Now set High Resp Rate Alarm Setting to 10 bpm, and change the alarm to be On.
- 4. Block the air tubing.
- 5. Start ventilation.

Low Respiratory Rate

1. On the Setup, Clinical Settings menu, set Mode to ST and Backup Rate to 10 bpm.

Each new patient.

- 2. On the Setup, Alarm Settings menu, set All alarms off to Yes.
- 3. Now set Low Resp Rate Alarm Setting to 30 bpm, and change the alarm to be On.
- 4. Block the air tubing.
- 5. Start ventilation.

Low FiO₂

- 1. Connect FiO₂ cell.
- 2. Calibrate the FiO₂ cell.
- 3. On the Setup, Clinical Settings menu, set Mode to T.
- 4. Set Respiratory Rate to 10 bpm.
- 5. On the Setup, Alarm Settings menu, set All alarms off to Yes.
- 6. Now set Low FiO2 Alarm Setting to 80%, and change the alarm to be On.
- 7. Start ventilation.

High FiO₂

- 1. Connect the FiO₂ cell.
- 2. Calibrate the FiO₂ cell.
- 3. Set the High FiO₂ Alarm setting to 30%.
- 4. Start ventilation.
- 5. Start O₂ supply to provide higher FiO₂ level than alarm threshold. The alarm activates within 15 seconds.

Always when oxygen is used and the FiO2 cell has been recalibrated.

Always when oxygen is

used and the FiO₂ cell

has been recalibrated.

High Leak

This test must be carried out using the patient's actual circuit and interface (including catheter mount and cannula if in use). If oxygen is in use, include the oxygen flow entrained to the oxygen inlet at the rear of the device.

On each new patient.

- 1. On the Setup, Clinical Settings menu, set Mode to T and Respiratory Rate to 30 bpm.
- 2. Set the High Leak Alarm to ON.
- 3. Start therapy.
- 4. Partially block the air tubing.

The alarm is triggered when leak exceeds 40 L/min (0.67 L/sec) for at least 20 sec. If too much leak occurs, the Circuit Disconnected alarm may be activated.

Circuit Disconnected

- 1. Disconnect air tubing at the device air outlet.
- 2. Start therapy.

If your configuration does not adequately trigger this alarm, it is due to the resistance of your accessories—not the device. Consider using the High Leak, Low Minute Ventilation, Low Pressure, Low Respiratory Rate and Apnea alarms.

If required for the patient particularly if the High Leak alarm has been disabled, to avoid rebreathing if the air circuit becomes disconnected at the device during the therapy.















Alarm	Testing interval
Non-Vented Mask	
 With the device set up to deliver therapy using the patient's mask and circuit, start therapy. Block the mask's vent holes. The alarm should sound within 30 sec. 	When considered necessary by the clinician.
Blocked Tube	
 Start therapy. Block the air tubing with your hand. The alarm is triggered when tubing is blocked for at least 15 sec. 	If required for the patient.
FiO ₂ sensor disconnected	
 With the device set up to deliver therapy, and the FiO₂ cell and circuit connected, start therapy. Disconnect the FiO₂ cell. The alarm should sound within 5 sec. 	If required for the patient.
SpO ₂ Finger Sensor Failure	
 Connect the finger sensor. Start therapy. Disconnect the sensor or remove it from the patient's finger. 	If measurement problems are expected with the finger sensor.

Completing alarm testing

The alarm should sound within 30 sec.

Return all settings to their original settings appropriate to the patient ahead of delivering therapy.













Setup menu: Options

The optional device settings are available from the *Options* menu and its *Configuration* submenu.



Parameter	Default	Description
Learn Circuit ¹	-	 If in use, turn off the oxygen flow. Select the mask type. Set up the air circuit including accessories and patient interface. Note: For invasive use, do not connect a catheter mount, tracheostomy tube or HMEF). Leave the air circuit unobstructed and open to the air. Press to start the Learn Circuit. Wait for the device to complete its automated tests (<30 sec). <p>The results are displayed when complete. If the circuit configuration has been successfully learnt, displays. If unsuccessful, displays (see "Troubleshooting" on page 58). </p>
FiO ₂ Sensor Calibration ¹	-	The device starts the calibration of the FiO₂ monitoring sensor to measure the oxygen concentration of the breathable air. 1. Press to start the FiO₂ sensor calibration. 2. Wait for the device to complete its calibration. The results are displayed when complete. Note: Turn off the oxygen flow.
SmartStart/ Stop	Off	If enabled, the device will start automatically when the patient breathes into the patient interface and will stop automatically (SmartStop) when the mask is taken off. This means the Start/Stop key does not have to be pressed to begin/end treatment. Note: The SmartStop feature is disabled if: Full face or Trach is selected as mask option High leak or Low minute ventilation alarms are set to ON Mask fit operation is proceeding Confirm therapy stop option is enabled. Options: On, Off
Ramp Time ¹	Off	If Max Ramp Time has been set, the patient may select any value up to this time. Options: 0 min-Max Ramp Time (max 45 minutes, 5 minutes increments)
Start CPAP	4.0 cm H ₂ O	Sets the pressure at the beginning of the Ramp Time in CPAP mode. Options: $4 \text{ cm H}_2\text{O-CPAP}$, $0.2 \text{ cm H}_2\text{O}$ increments
Start EPAP or Start PEEP	4.0 cm H ₂ O	Sets the pressure at the beginning of the ramp time in bilevel modes (S, ST/PS, T, iVAPS, PAC). Options: 3 cm H ₂ O–EPAP, 0.2 cm H ₂ O increments









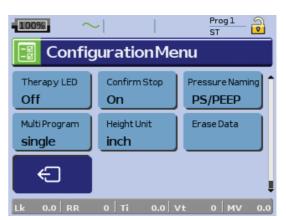


Parameter	Default	Description
Max Ramp	Off	Maximum setting for Ramp Time.
Time		Options: 0-45 min; 5 minute increments
		Note: If the Max Ramp Time is set to 0 min the Ramp Time setting does not appear in Patient mode.
Factory Defaults	-	Resets machine default settings. You will be asked to confirm your selection.
		Note: Restoring factory defaults will not affect the Motor run hours, logged data (eg, patient therapy data), the clock or the reminder settings.

¹ Parameter can be set by the patient.

Setup menu: Configuration Menu





Parameter	Default	Description
Language ¹	English	Sets the display language.
		Options: Depending on regional configuration
Brightness ¹	70%	Sets the LCD backlight brightness.
		Options : 20-100%, 10% increments
Backlight ¹	Auto	Enables the LCD and keypad backlight.
		If the AUTO setting is selected the backlight turns dark after five minutes without any actions and turns on again if any button is pressed again or an alarm occurs.
		Options: On, Auto
Time ¹	-	Sets the current time.
		Note: Changing the time setting backwards will erase all logged data.
		Options: hours, minutes, seconds
Date ¹	-	Sets the current date.
		Note: Changing the date setting backwards will erase all logged data.
		Options: day, month, year
Time Format ¹	12 hrs	Sets the time format.
		Options: 24 hrs,12 hrs
Date Format ¹	mm/dd/	Sets the date format.
	уууу	Options: dd/mm/yyyy, mm/dd/yyyy
Pressure Unit	cm H ₂ O	Selection of the display units for pressure.
		Options: cm H ₂ O, hPa
Flow Unit	L/min	Selection of the display units for flow.
		Options: L/min, L/sec











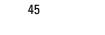


Parameter	Default	Description
Therapy LED	On	Enables or disables the therapy LED. If enabled, the blue therapy LED in the Start/Stop button is lit while the device is delivering therapy. Options: On, Off
Confirm Stop	On	This feature helps to avoid anyone inadvertently stopping therapy. When enabled (On), if you press during therapy, the <i>Confirm Stop</i> screen will appear. If YES is selected, therapy stops. If NO is selected or any other key is pressed, therapy continues. Options: On, Off
Pressure Naming	IPAP/ EPAP	Choose the terminology type used through the screens displays. Options: PS/PEEP, IPAP/EPAP
Multi Program	single	You have the option to define two different programs for therapy and alarm settings. The program selection can be made in the <i>Clinical Settings</i> menu if this option is set to dual. If dual is selected, the patient can select between the two programs in the <i>Treatment</i> screen.
		Options: single, dual
Height Unit	inches	Selection of the unit of measure for patient height for iVAPS setup. Options: cm/inches
Erase Data	-	You can erase the following data that is logged during therapy. Used hours (therapy run hours) High resolution data (patient flow, therapy pressure, oximetry data) Breath-by-breath data (eg, pressure and flow related data) Summary data (statistics in the Summary menu) Alarm events Settings changes System events (eg, learn circuit passed/cancelled). When erasing the data you will be prompted to confirm the action before the data is erased. Note: Motor run hours, Power on hours and all settings cannot be reset with this option.

1 Parameter appears in both the patient and clinical mode.

To return to the Options screen press the Return button $\label{eq:continuous}$









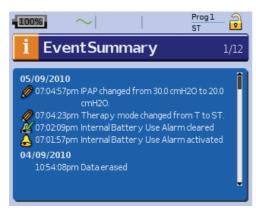




Info menu

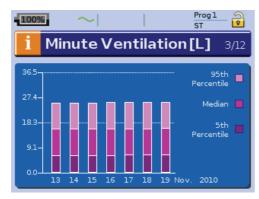
The *Info* menu provides event summary, therapy results, device information and reminders. Stellar 150 stores usage and summary data up to 365 treatment sessions. The stored data can be accessed in the *Info* menu or using ResScan.

Event Summary



Event summary displays the summary of three types of events: changes in settings, alarms and system events (eg, data erased, connection of ResMed USB stick). There are up to 200 events of each type, displayed in chronological order, with the most recent event displayed at the top by default.

General therapy information



Information on the following categories is displayed for a period of seven days, where each day is defined as from midday to midday:

- Leak
- Minute Ventilation
- · Tidal Volume
- · Respiratory Rate
- I:E ratio
- · Pressure Support
- AHI
- SpO₂.

Press and turn the Push Dial to view data for data up to 365 days in the past. The statistical data is displayed in a bar graph in 5th and 95th percentile and median values. These values are averaged across total therapy duration per day.

Note: If therapy is not running for at least 10 minutes, data will not be captured.









Apnea/Apnea Hypopnea Index

This screen displays the apneas and hypopneas measured per hour for one day. The daily index values will be displayed for a period of seven days and can be compared to data from the last 365 days.

An **apnea** is scored when flow decreased by more than 75% of baseline (ie, to 25% or below from the baseline) for more than 10 seconds. An **hypopnea** is scored when flow decreases to 50% but greater than 25% of baseline for more than 10 seconds. The **Apnea Index (AI)** and **Apnea Hypopnea Index (AHI)** are calculated by dividing the total number of events that occurred by the total mask-on therapy period in hours.

Note: The accuracy of apnea and hypopnea logging are degraded by high mask leak.

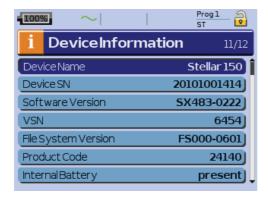
Used Hours



Used Hours during the last seven days of treatment are displayed in a bar graph and can be compared to the data of the last 365 days. The daily recordings start at 12 noon and finish at 12 noon on the following day (eg, on November 20th the patient took a nap from 2 p.m. to 3 p.m., the second therapy session on that day started at 10 p.m. and stopped at 7 a.m. on November 21st. The time is displayed on the vertical axis. The horizontal axis displays the date of the recording. The related average, minimum and maximum values are displayed as numeric values per week.

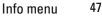
Used Hours (within the graph legend) displays how long the device has been used for treatment since the first treatment session or data was last erased.

Device information



This screen shows the serial number (displayed as Device SN), software version and other component versions. Data on this screen may be requested for servicing or as part of problem-solving by a technician.



















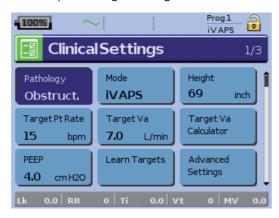
You can use the Reminders menu to alert the patient to specific events; for example, when to replace their mask, when to replace the filter and so on. Using ResScan, you can select which Reminder message to show when and its recurrence frequency (Off, 1–24 months). The reminder appears in yellow as the date approaches (within 10% of the reminder period). The reminder also displays when the device is powered on. Patients can clear a reminder message by selecting 'Reset', which clears the current reminder date to OFF, or displays the next pre-set Reminder date.

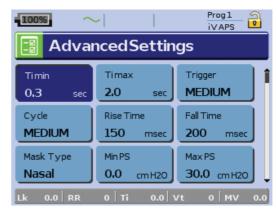
Note: When the motor run hour is below two hours, Reminders can be set, but will not display. After two hours of the motor running, the correct date displays.

Configuring iVAPS

There are two ways in which you can configure iVAPS mode:

- using Learn Targets—which learns the patient's breathing pattern and calculates the targets automatically; or
- directly entering the targets.





Using Learn Targets

Learn Targets monitors the patient's resting ventilation, with the goal of learning the patient's Target Alveolar Ventilation and Target Patient Rate in preparation for iVAPS mode. It is recommended that the patient be set up in a quiet place, preferably with a distraction to ensure they don't fall asleep.

During Learn Targets, the device delivers two pressures; EPAP/PEEP and Pressure Support without backup breath (like S mode). These parameters are available on the *Learn Targets* screen.

- 1 Perform a Learn Circuit on the current circuit configuration, ensuring you select the appropriate mask setting (see "Setup menu: Options" on page 43).
- **2** Set Pathology Defaults (see "Pathology Defaults" on page 10).
- **3** Select iVAPS mode.
- **4** Enter the patient Height (approximate or arm span).







- ¥ | *****

- **5** Connect the patient.
- 6 Select Learn Targets.

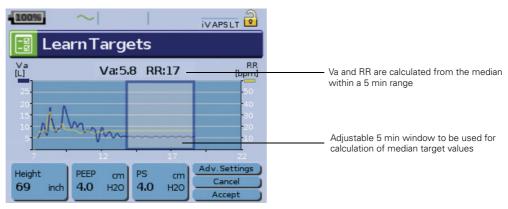
The device has to be in Standby to commence the Learn Targets procedure.

- I Turn on oxygen if in use.
- Configure primary therapy controls.
 Enter the preliminary EPAP or PEEP (see page 57).
 It is recommended that you start at 4–6 cm H₂O which most patients can tolerate.
- III Adjust Pressure Support.

The level of Pressure Support during the Learn Targets procedure should be individually assessed. Excessive Pressure Support during the learn session can result in an alveolar ventilation target that is in excess of the patient's metabolic need. For patients who enjoy adequate daytime ventilation but who have significant problems during sleep (ie, OHS), the goal is to capture the resting daytime ventilation with minimal Pressure Support such that the patient is breathing comfortably but not excessively ventilated. For patients with significant daytime hypercapnia, an increased pressure support (ie, 6-10 cm H₂O) may be appropriate, ie, such that an assisted daytime ventilation is measured.

IV View data.

The Learn Targets screen displays a blank graph on which up to 15 min of live data (monitored Alveolar Ventilation (Va) and Respiratory Rate (RR)) will be plotted as time passes. The values are calculated from the median within a 5 min range. You can select the 5 min portion that best represents stable Va and RR, by using the dial to highlight the 5 min of interest. It is recommended to choose where the lines of Va and RR look stable, usually 10–15 minutes after starting this process.



- V If the target values are viewed as:
 - acceptable, select **Accept**, and therapy will commence in iVAPS mode. Typically, Va should be below 7 L/min for non-COPD patients and below 11 L/min for COPD patients.
 - not acceptable, or to exit Learn Targets without altering settings, select **Cancel**. This stops the Learn Targets process, the menu returns to *Clinical Settings*, and therapy terminates.
- **7** Press *Monitoring* or *Info* key to scroll through the related pages (eg, Breath Rate, MV, Vt) if necessary. When press *Setup* menu key you come back to Learn Targets.



CAUTION

Because Cancel will terminate therapy, the patient should be disconnected from the ventilator unless ventilation is to be resumed immediately.

- **8** Review the secondary therapy settings in *Advanced Settings* (eg, Min PS, Max PS), see "Min/ Max PS" on page 6.
- **9** Start therapy.
- Refine EPAP/PEEP to suit the type of therapy required. For more information, see "Assessing the clinical outcome" on page 51.









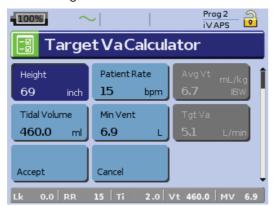


Manually setting iVAPS

While the Learn Targets procedure offers the best means of obtaining an initial ventilation estimate, iVAPS also allows manual entry of its target, using an entered minute ventilation, spontaneous rate, and patient height. From these iVAPS can calculate the target alveolar ventilation and adopt its Target Patient Rate.

- 1 Perform a Learn Circuit on the current circuit configuration, ensuring you select the appropriate mask setting (see "Setup menu: Options" on page 43).
- 2 Set Pathology Defaults (see "Pathology Defaults" on page 10).
- **3** Select iVAPS mode.
- 4 Configure primary therapy controls.

 Enter the preliminary EPAP or PEEP (see page 57). It is recommended that you start at 4–6 cm H₂O which most patients can tolerate.
- **5** Select Target Va calculator.



- I Enter the patient's Height.
- II Enter the patient's spontaneous breath rate.
- III Enter a previously measured Minute Ventilation (MV) or Tidal Volume (Vt).

Note: Press Monitoring or Info key to scroll through the related pages (eg, Breath Rate, MV, Vt) if necessary.

IV Check the Target Va.

The calculator returns a Target Alveolar Ventilation (Tgt Va) using this information to estimate anatomical deadspace.

Target Va = [Tidal Volume - Deadspace (Height)] × Patient Rate

= Minute Ventilation - [Deadspace (Height) × Patient Rate]

The Target Va Calculator displays an estimate of the Average Tidal Volume (Avg Vt) as a function of ideal body weight (IBW).

Average Vt (mL/kg) = Tidal Volume / $[48 + 0.91 \times (Height - 152.4)]^{1}$

Note: Typically, Va should be below 7 L/min for non-COPD patients and below 11 L/min for COPD patients.

- V Accept to apply this Target Va to iVAPS therapy settings.
- **6** Review the secondary therapy settings in *Advanced Settings* (eg, Min PS, Max PS), see "Min/ Max PS" on page 6.
- **7** Connect the patient.
- **8** Start therapy.









Adapted from DA Dongelmans et al. Determinants of Tidal Volumes with Adaptive Support Ventilation: A Multicenter Observational Study. Critical Care and Trauma, 2007. 107 (3). P932 -937







9 Refine EPAP/PEEP to suit the type of therapy required. For more information, see "Assessing the clinical outcome" on page 51.

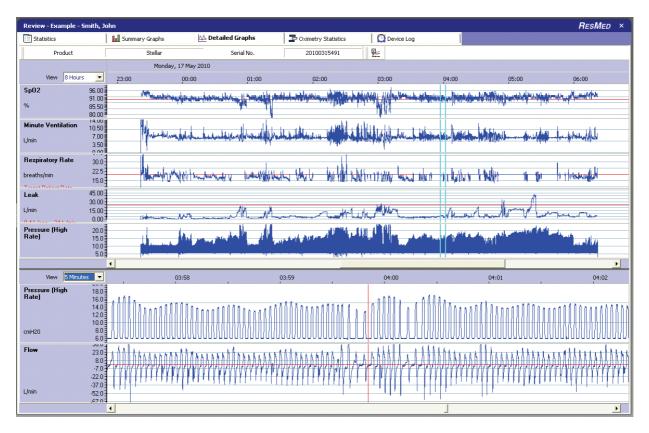
Assessing the clinical outcome

If the patient sleeps well on the Stellar 150 and SpO₂, if available, shows adequate oxygen saturation throughout the night, this can be a good indication of successful therapy.

ResScan may assist you assessing the therapy outcome. A close look at the Detail graph in statistics is useful to evaluate the quality of treatment. Splitting the screen allows you to view

- overview of navigation window (8 hrs) with SpO₂, pressure, leak, minute ventilation
- detail window (5 min), showing leak, flow, pressure may present a suggestion to readjust the settings or mask.

For more information, see "Data management" on page 52.



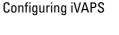
It is ideal to observe changes of pressure support level (or IPAP) throughout the session or night. If the pressure support remains at the same level for a long period of time (often towards at maximum pressure support level), it may indicate:

- · the Target Va is too high
- Max PS is set too low to adequately maintain the ventilation
- EPAP is too low to treat upper airway obstruction.

Hints to identify upper-airway obstruction include:

- episodes of desaturation
- · small flattened breaths on the flow trace
- large levels of pressure support without associated respiratory flow.





















Data management

Apart from the data available to view directly on the device, you can view and update data via ResMed's applications that assist with compliance management. These are ResScan and EasyCare Tx.

When using ResScan, you can view therapy data as well as change settings on the device. To transfer data between the device and a PC, you can use the ResMed USB Stick.

Use EasyCare Tx for the remote display of real-time (live) data and adjustment of settings.

For more information, see the PC application's manual.

There are two data ports at the rear of the device for connecting a USB stick (see "Stellar 150 at a glance" on page 11). Therapy and device data can be stored on it or read from it.



WARNING

Do not connect any device to the data ports other than specially designed devices recommended by ResMed. Connection of other devices could result in injury, or damage to the Stellar 150 (see "General warnings and cautions" on page 70).



CAUTION

Do not disconnect the ResMed USB stick while data transfer is in progress. Otherwise loss of data or incorrect data may result. The download time depends on the data volume.

Notes:

- You cannot connect two ResMed USB sticks simultaneously for data communication.
- If data transfer is not possible or failed please read the troubleshooting section.
- Do not store files on the USB stick other than those created by the device or application. Unknown files may be lost during data transfer.
- 1 Plug the ResMed USB stick to one of the two USB connections on the rear side of the device. The first dialogue for the USB data transfer is displayed automatically on the LCD. The device checks if there is enough memory capacity on the USB stick and if readable data is available.
- 2 Select one of the available options
 - · Read settings

You will be prompted to decide if the device should read the ResScan configuration or the device configuration. The ResScan configuration contains settings changes. The device configuration contains settings of another device. To read the device configuration the device has to be in clinical mode. The device configuration must contain a different serial number.

Write settings

Settings of the device will be stored on the ResMed USB stick.

Write settings and loggings

Settings and loggings (eg, breath-by-breath data) of the device will be stored on the ResMed USB stick.

- Cancel
- 3 Confirm the data transfer.















Cleaning and maintenance

The cleaning and maintenance described in this section should be carried out regularly. This also helps to prevent the risk of cross contamination. Refer to the mask, humidifier and other accessories user guide for detailed instructions for care and maintenance.



WARNING

- Beware of electric shock. Do not immerse the device, pulse oximeter or power cord in water. Turn off the device, unplug the power cord from the power socket and the device before cleaning and be sure that it is dry before reconnecting.
- The mask system and air tubing are subject to normal wear and tear. Inspect them regularly for damage.



CAUTION

The Stellar 150 cannot be sterilized.

Daily

Disconnect the air tubing from the device (and humidifier, if used) and hang it in a clean, dry place until next use. If the device is visibly soiled, wipe the exterior surfaces of the device and the pulse oximeter (if used) with a damp cloth and mild detergent.



CAUTION

- Do not hang the air tubing in direct sunlight as the tubing may harden over time and eventually crack.
- Do not use bleach, chlorine, alcohol or aromatic-based solutions (including all scented oils), moisturizing or antibacterial soaps to clean the air tubing or the device on a daily basis (other than the approved cleaning agents Mikrozid[®] AF or CaviCide[®]). These solutions may cause hardening and reduce the life of the product.
 The use of cleaners and disinfecting solutions containing alcohol (other than the approved cleaning agents) is acceptable for periodic cleaning of the device, such as for cleaning between patients or especially for service periods, but not recommended for daily use.

Weekly

- 1 Remove the air tubing from the device and the patient interface.
- 2 Wash the air tubing in warm water using mild detergent.
- **3** Rinse thoroughly, hang and allow to dry.
- **4** Reconnect the air tubing to the air outlet and patient interface.
- If the device is visibly soiled, wipe the exterior surfaces of the device and the pulse oximeter (if used) with a damp cloth and mild detergent.

Monthly

- 1 Wipe the exterior of the device and the pulse oximeter (if used) with a damp cloth and mild detergent.
- **2** Visually inspect the air filter to check if it is blocked by dirt or contains holes.













Replacing the air filter

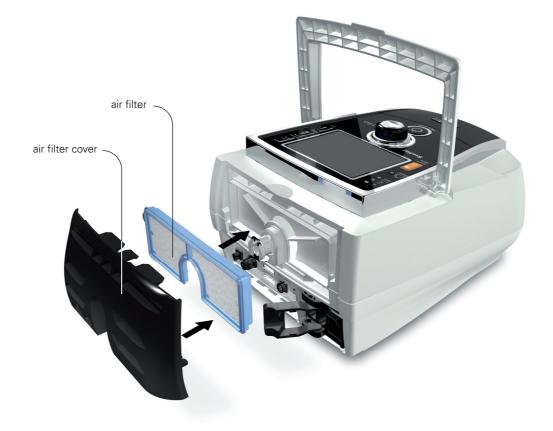
Replace the air filter every six months (or more often if necessary).



WARNING

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

- 1 Remove the air filter cover at the back of the device.
- 2 Remove and discard the old air filter.
- 3 Insert a new filter.
- 4 Refit the air filter cover.















Multipatient use



WARNING

- An antibacterial filter is mandatory if the device is used on multiple patients.
- In a mulitpatient use environment, you must perform the following before the device is provided to a new patient:

Air filter and the antibacterial filter

Replace

Mask Reprocess; Cleaning, disinfection and sterilization instructions are

available from the ResMed website, www.resmed.com/masks/

sterilization/americas. If you do not have Internet access, please contact

your ResMed representative.

Air tubing Replace the air tubing. Alternatively, consult the air tubing instructions for

cleaning and disinfection information.

Device Disinfect the Stellar 150 as follows:

Use an anti-bacterial cleaning/disinfectant solution such as Mikrozid[®] AF or CaviCide[®] with a clean non-dyed disposable cloth to clean and disinfect the exterior surfaces of the device. Wipe all accessible surfaces of the device, including the air outlet (avoid liquid entering any openings in the device). Follow the manufacturer's recommended cleaning instructions. As instructions for humidifiers vary, see the user guide for the humidifier

in the Formultination the application the property of the H4 is water shapes

in use. For multipatient use environment, use the H4i water chamber

(disposable) in place of the H4i reusable water chamber.

Servicing



CAUTION

Humidifier

Inspection and repair should only be performed by an authorized agent. Under no circumstances should you attempt to open, service or repair the device yourself.

This product should be inspected by an authorized ResMed service centre five years from the date of manufacture, except for the internal battery which ResMed recommends be tested after two years to assess the remaining battery life. Prior to this, the device is intended to provide safe and reliable operation provided that it is operated and maintained in accordance with the instructions provided by ResMed. Applicable ResMed warranty details are provided with the device at the time of original supply. Of course, 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.





Cleaning and maintenance









Clinical titration guide

Mouth leaks

If mouth leaks are a persistent problem, the patient may benefit from humidification, a chin strap or a full face mask. The chin strap fits over the patient's head and helps to hold their mouth closed during the night. Full face masks cover both the nose and mouth, preventing mouth leaks, and are available from ResMed. Contact your supplier for more details or see www.resmed.com. ResScan detailed data also provides a visual representation of leak.

Setting TiControl

The Ti Max and Ti Min settings (S, ST and iVAPS mode) allow you to vary the minimum and maximum amount of inspiratory time (see "Ensuring successful ventilation with Stellar" on page 7).

Setting Ti Max

Under conditions of high or variable leaks (eg, mouth leak), or where respiratory flow is restricted (eg, COPD), Ti Max provides an inspiratory time limit which prevents late cycling and can provide a better match to the patient's ideal inspiratory time.

Ti Max can be set between 0.3–4 sec or 2/3 of one breath cycle defined by Backup Rate. So for a patient with a Backup Rate of 15 bpm (ie, one breath cycle of 4 sec), the maximum value that can be set for Ti Max would be 2.6 sec.

Note: Care should be taken not to set Ti Max shorter than the patient's actual inspiratory time, as this may lead to a decrease in the effectiveness of pressure support and result in discomfort for the patient. If the patient complains that inspiratory time is too short, consider increasing the value.

- 1 Observe the patient's inspiration time and respiratory pattern.
- 2 Set the Ti Max slightly longer (eg, 1.5 sec for an adult patient) than the patient's spontaneous inspiratory time, (eg, if the patient has a spontaneous inspiratory time of 1.5 sec, a Ti Max time of 1.6 sec may be chosen).

Note: For COPD patients, ensure the resultant I:E ratio is at least 1:2 (ideally 1:3) to allow sufficient time for exhalation. You may need to shorten Ti Max or readjust the cycle sensitivity to provide a more appropriate I:E ratio.

Setting Ti Min

Ti Min may be useful in patients who have a tendency to cycle inspiration early (or prematurely). Patients with restrictive disorders (eg, chest-wall deformity, neuromuscular diseases) often have a decreased compliance of the respiratory system which when using PS modes tends to contribute to early flow cycling. Patients in this situation may complain that the device finishes inspiration before they do. Lengthening the Ti Min setting may help to ensure that an appropriate inspiratory time, and thus minute ventilation, is maintained in these conditions.

Most patients with obstructive pulmonary disease do not have problems with premature cycling, therefore the Ti Min setting can remain at the default setting.

Note: Care should be taken not to set Ti Min longer than the patient's spontaneous inspiratory time, as this may fight against the patient attempts to exhale, creating discomfort and increased work of breathing. If the patient complains that inspiratory time is too long, consider reducing the value.

- **1** Observe the patient's inspiration time and spontaneous respiratory rate. (The measured Ti and I:E ratio on the *Monitoring* and *Synchronisation* screen may help.)
- Adjust the Ti Min in accordance with the measured Ti (see table below). Check that the patient doesn't feel that the inspiratory time is too long. The patient's spontaneous rate can be found in the monitoring summary.













3 Observe the patient to determine if the Ti Min should be shortened (eg, 0.2 or 0.3 sec shorter than patient inspiration time).

TiControl calculation guide

The following table is a guide to selecting the Ti Max and Ti Min values that best correspond to the patient's respiratory rate (ideally while using the ventilator at rest).

Patient breaths per min	T _{tot} = 60 ÷ breaths per min	I:E = 1:2 (eg, normal lungs)		= 1:1 tive lungs)	I:E = 1:3 (eg, obstructive lungs)
	(sec)		Ti Min	Ti Max	Ti Max
10	6	2	1.0	2.5	1.5
15	4	1.3	1.0	1.7	1.3
20	3	1.0	0.8	1.5	1.0
25	2.4	0.8	0.7	1.2	0.8
30	2	0.7	0.6	1.0	0.7
35	1.7	0.6	0.5	0.8	0.7
40	1.5	0.5	0.5	0.7	0.7

EPAP/PEEP

The appropriate setting of PEEP (or EPAP) is fundamental to modern ventilation practice, across most modes of therapy. Examples of its use include:

- Recruiting and/or maintaining lung volume, aiding gas exchange, improving lung compliance, or minimizing lung injury.
- In obstructive lung disease—to offset intrinsic PEEP, to reduce work of breathing, and/or maximize effective triggering.
- To splint open or stabilize the upper-airway during sleep.

For nocturnal ventilation, a starting pressure of 5 cm H_2O is recommended. If there is any indication of symptoms such as daytime sleepiness, obesity, an anatomically narrow airway or neuromuscular disease, or pressure support frequently reaching the maximum level, an additional 1-3 cm H_2O may be helpful.

Stellar provides monitoring—such as optional integrated SpO₂ and high resolution flow data—to assist with titrating EPAP/PEEP in order to maintain upper airway patency. Evidence of desaturation or flow limitation may lead to EPAP/PEEP adjustment.

Trigger/cycle sensitivities

High trigger sensitivity decreases the flow threshold necessary for the device to move from EPAP to IPAP, making it easier for the patient to trigger. So, for example, for patients who have insufficient inspiratory effort (flow), set the trigger setting to 'High' or 'Very High' to increase sensitivity to patient effort. So the patient needs to exert less effort to trigger the device.

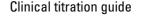
Less sensitive settings—'Low' and 'Very Low'—provide flexibility for patients prone to auto-triggering, caused by restrictive lung diseases and cardiogenic artefact. Cardiogenic artefact refers to impulses within in the respiratory flow signal that originate from cardiac activity rather than respiratory effort. It can result in false triggering, if the impulses exceed the trigger flow threshold.

High cycle sensitivity will result in an earlier transition from IPAP to EPAP and low cycle sensitivity will delay this transition. For example, for patients who cannot maintain inspiratory flow, or who complain of having their breath 'cut off', set the cycle setting to 'Low' or 'Very Low' which will delay the transition from IPAP to EPAP. This will tend to prolong inspiratory time.

For characteristic data, see "Technical specifications" on page 64.













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

Alarm troubleshooting

The most common reason for an alarm to sound is because the system has not been properly assembled. Check that the air tubing has been properly attached to the device and patient interface (and humidifier if used).

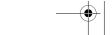
Notes:

- The alarm actions listed below are based on having the appropriate alarm settings for the patient's therapy. When a user 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 multiple alarms are active simultaneously, the alarm with the highest priority will be displayed first.
- If an alarm activates repeatedly, discontinue use and return the device for servicing.

Problem/Possible cause	Action
LCD: Internal Battery Empty!	
The remaining battery charge is below 15%. The device can be powered by the internal battery for maximum 2 minutes.	Connect the device to mains power.
	Note: In case of a total power failure, the therapy settings will be stored and therapy will resume when the device is powered again.
LCD: System Failure!	
Component failure. The device stops delivering air pressure (system	 Power-off the device. Power-on the device again.
failure 6, 7, 9, 22, 38). Therapy cannot be started (system failure 21).	If the problem persists return the device for servicing.
Component failure (system failure 8, 25).	 Power-off the device, if the system failure is continuously present. Power-on the device again.
	If the problem persists return the device for servicing.
	ilure (system failure 6), pressure sensor failure 8), calibration fault (system failure 9), self test failure ilure 22), system component failure (system failure
LCD: Over Pressure!	
The device generates a pressure that is greater than 59 cm H ₂ O. Treatment will be stopped.	 Power-off the device. Check that the air tubing is connected properly Power-on the device again. Start Learn Circuit function. Note: If the alarm activates repeatedly internal components may be defective. Discontinue use and return the device for servicing.
LCD: Blocked Tube!	
	1. Check the air path for any blockages.















Problem/Possible cause	Action
LCD: High Temperature [10, 11, 12, 23]!	
The temperature inside the device is too high. Treatment may lead to stop.	Ensure the ambient temperature is within the specified operating range. If the problem persists within the specified operating conditions please return the device for servicing.
LCD: High Pressure!	
Therapy pressure exceeds pre-set alarm level.	 Stop treatment. Check the alarm and pressure settings. Re-start treatment.
LCD: Low Pressure!	
The air tubing is not connected properly.	 Check the air circuit integrity and reconnect. If the alarm doesn't get cleared, stop treatment. Re-start treatment.
LCD: Circuit disconnected!	
The air circuit is not connected properly.	 Check the air circuit integrity and reconnect. If the alarm is not cleared, stop treatment. Re-start treatment.
LCD: Low Minute Ventilation!	
Minute ventilation level has dropped below the alarm setting level.	 Reassess the patient to ensure adequate therapy. Ensure the alarm setting is appropriate for the patient.
LCD: High Respiratory Rate!	
The respiratory rate level has exceeded the preset alarm level.	 Reassess the patient to ensure adequate therapy. Ensure the alarm setting is appropriate for the patient.
LCD: Low Respiratory Rate	
The respiratory rate level has dropped below the pre-set alarm level.	 Reassess the patient to ensure adequate therapy. Ensure the alarm setting is appropriate for the patient.
LCD: High Leak!	<u> </u>
High mask leak for more than 20 seconds.	 Adjust the mask to minimize leak (see "Using mask-fit" on page 27). Check the air circuit integrity and reconnect. Check that the anti-asphyxia valve is fully closed.
LCD: Non-Vented Mask!	
 Connection of a non-vented mask. Mask vents may be blocked. ResMed Leak Valve is missing or vent is blocked. 	 Ensure the mask has vents. Ensure the mask vents are not blocked. Ensure the ResMed Leak Valve is installed and that the vent is not blocked. Ensure oxygen (if in use) has only been connected at the rear of the device.
LCD: Apnea!	
The device detects an apnea that has exceeded the pre-set alarm level.	 Reassess the patient to ensure adequate therapy. Ensure the alarm setting is appropriate for the patient.
LCD: Internal Battery Low!	
The internal battery capacity is below 30%.	Connect the device to mains power.













Problem/Possible cause	Action
LCD: Low SpO2!	
SpO ₂ has dropped below pre-set alarm level.	 Check the attachment of the sensor. Reassess the patient to ensure adequate therapy.
LCD: SpO2 finger sensor failure!	
The finger sensor is not connected properly or delivers faulty values.	Check if the finger sensor is attached properly to the finger and connection to the pulse oximeter.
LCD: Xpod oximeter disconnected!	
The pulse oximeter is disconnected.	Check if the pulse oximeter is connected properly to the device.
LCD: Low FiO2 Level!	
FiO ₂ has dropped below the pre-set alarm level.	 Perform FiO₂ sensor calibration. Reassess the patient to ensure adequate therapy.
LCD: High FiO2 Level!	
FiO ₂ has exceeded the pre-set alarm level.	 Perform FiO₂ sensor calibration. Reassess the patient to ensure adequate therapy.
LCD: FiO2 sensor disconnected!	
The FiO ₂ monitoring sensor is not connected.	Connect the ${\rm FiO_2}$ monitoring sensor or replace it with a new one.
LCD: Keypad Failure!	
One of the keys was held down for more than 10 sec or got stuck.	Remove any blockages from the keypad.
LCD: Attention: High Temp [42, 43, 44, 49	5]!
The temperature inside the device is high.	Ensure the ambient temperature conditions are within the specified operating range.
LCD: Internal Battery Use!	
The device is using the internal battery.	Check if the power cord is properly connected to the device if you want to run from mains power. Press the Alarm mute button (to cancel the alarm.
LCD: External DC Power Use!	
The device is powered by an external battery.	Check if the AC power cord is properly connected to the device if you want to run from mains power.
	Note: The alarm will be cleared automatically after one minute.











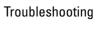


Other troubleshooting

Problem/Possible cause	Action	
No display		
Power failure. The device stops delivering air pressure.	Remove the mask or the catheter mount from the tracheostomy tube until power is restored.	
Power not connected or device is not switched on.	Ensure the power cord is connected and pres the switch at the back of the device once.	
Treatment pressure seems low		
Ramp time is in use.	Wait for air pressure to build up.	
Air filter is dirty.	Replace air filter.	
Air tubing is kinked or punctured.	Straighten or replace tubing.	
Air tubing is not connected properly.	Connect the air tubing firmly at both ends.	
Mask and headgear not positioned correctly.	Adjust position of mask and headgear.	
Plug(s) missing from access port(s) on mask.	Replace plug(s).	
Pressure required for treatment may have changed.	Conduct a clinical assessment and adjust pressure if necessary.	
There is a large impedance (eg, antibacterial filter) in the air circuit.	Perform the Learn Circuit function.	
Humidifier control dial set too high, resulting in accumulation of water in the air tubing.	Turn humidifier control down and empty the water from the air tubing.	
Treatment pressure seems high		
Pressure required for treatment may have changed.	Conduct a clinical assessment and adjust pressure if necessary.	
There is a change in the impedance in the circuit configuration.	Perform the Learn Circuit function.	
The device does not start when the patien	t breathes into the mask	
SmartStart/Stop not on.	Enable SmartStart/Stop.	
Breath is not deep enough to trigger SmartStart.	Ask the patient to take a deep breath in and ou through the mask.	
There is excessive leak.	Adjust position of mask and headgear.	
Plug(s) missing from port(s) on mask.	Replace plug(s).	
Air tubing is not connected properly.	Connect firmly at both ends.	
Air tubing is kinked or punctured.	Straighten or replace tubing.	
There is a large impedance (eg, antibacterial filter) in the air circuit.	Perform the Learn Circuit function.	
The device does not stop when the patient	t removes their mask	
SmartStart/Stop is disabled.	Enable SmartStart/Stop.	
Use of a full face mask or tracheostomy tube.	SmartStart is disabled if Full Face or Trach are selected as interface.	
Incompatible accessories (eg, humidifier or mask system) with high resistance being used.	Use only equipment as recommended and supplied by ResMed.	
High Leak or Low Min Vent alarms are set to On.	SmartStop is disabled when High Leak or Low Min Vent alarms are set to On.	
"Confirm stop" is enabled.	Disable Confirm stop.	
High Leak Alarm is enabled, but alarm doe during treatment	s not activate when the mask is removed	
Incompatible air delivery system being used.	Use only equipment as recommended and supplied by ResMed.	













Problem/Possible cause	Action
Pressure settings are too low for the air delivery components being used.	Perform the Learn Circuit function to adjust the therapy pressure according to the patients air tubing system.
Learn Circuit failed	
 The circuit configuration is inappropriate as the impedance detected is too high. Too many components have been included or the impedance of accessories in use is above ResMed's recommendation, eg, type of filter, external humidifier, air tubing. 	Review the components included in the circuit configuration and adjust as appropriate, then rerun Learn Circuit (see "Setup menu: Options" on page 43).
The delivered airflow is not humid/heated	although the H4i humidifier is in use
The humidifier is not properly attached.	Correctly attach the humidifier.
The humidifier does not heat.	The device is currently powered by battery use or not connected to the mains.
The humidifier does not work.	Return the device and the humidifier for servicing.
The water chamber is empty.	Fill the water chamber of the humidifer.
Date or time in data files is wrong	
Date or time on the device is wrong.	Correct the current time and date in the <i>Options</i> menu.
	Note: Changing the time or date setting backwards will erase all logged data.
Unable to read or write settings from USB	stick
Wrong Serial number.	Please check the serial number of the Stellar 150 in the <i>Device Information</i> screen of the <i>Summary</i> menu. Write the Serial number via ResScan on the USB stick.
USB stick contains unreadable data.	 Store the file once again on the USB stick and try again to readout data. If the problem persists return the USB stick for servicing. The USB stick contains data of the same device.
USB stick is not compliant with USB 2.0.	Use only equipment as recommended and supplied by ResMed.
USB stick contains no data.	Transfer data to the USB stick either form another device or from ResScan.
USB stick is defective.	Return the USB stick for servicing.
Unable to write settings to USB stick	
There is not enough space on the USB stick.	Connect the USB stick to a PC and delete data that is not needed. Reconnect the USB stick to the Stellar 150 then retry writing data to the USB stick.
USB stick is not compliant with USB 2.0 or write protected.	Use only equipment as recommended and supplied by ResMed.
USB stick is defective.	Return the USB stick for servicing.
Data transfer failed	
Incorrect data.	Try data transfer again. If the problem persists return the USB stick for servicing.



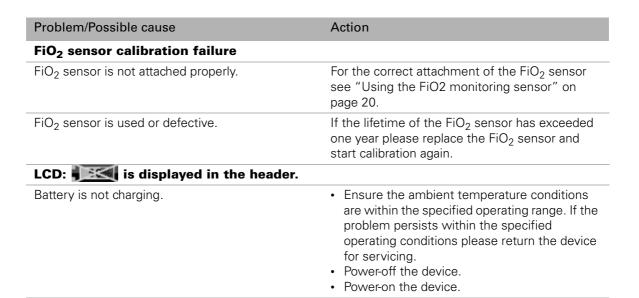
























Technical specifications

Operating pressure range	 IPAP: 3 cm H₂O to 40 cm H₂O (in S, ST, T, PAC mode) PS: 0 cm H₂O to 37 cm H₂O (in S, ST, T, PAC mode) EPAP/PEEP: 3 cm H₂O to 25 cm H₂O (in S, ST, T, iVAPS, PAC mode) CPAP: 4 cm H₂O to 20 cm H₂O (in CPAP mode only) Min PS: 0 cm H₂O to 20 cm H₂O (in iVAPS mode) Max PS: 0 cm H₂O to 30 cm H₂O (in iVAPS mode)
Maximum single fault pressure	60 cm H ₂ O (in all modes)
Maximum breathing resistance under single fault	2 cm H ₂ O at 30 L/min; 7.2 cm H ₂ O at 60 L/min
Therapy pressure tolerance	IPAP: \pm 0.5 cm H ₂ O \pm 10% of set pressure (end of inspiration) EPAP or PEEP: \pm 0.5 cm H ₂ O \pm 4% of set pressure CPAP: \pm 0.5 cm H ₂ O \pm 10% of set pressure
Flow accuracy	± 5 L/min or 20% measured value, whichever is greater
Maximum flow	> 200 L/min at 20 cm H ₂ O
Inspiratory trigger (nominal) characteristics	The minimum flow required to initiate IPAP by ASL5000 simulator with chronically weak efforts (R20, C20, BPM20):
	 For Very High setting: 2.4 L/min For High setting: 4.2 L/min For Medium setting: 6.0 L/min For Low setting: 10.2 L/min For Very Low setting: 15.0 L/min
	Accuracy $\pm 20\%$ or ± 2.0 /-1.5 L/min whichever is greater. When tested with IPAP = 15 cm H ₂ O, EPAP = 5 cm H ₂ O, Rise Time = Min, 6' 6" (2 m) air tubing, Ultra Mirage mask, zero leak.
Expiratory cycle (nominal) characteristics	The expiratory cycle occurs at the following flow rates: • For Very High setting: 50% of peak inspiratory flow • For High setting: 35% of peak inspiratory flow • For Medium setting: 25% of peak inspiratory flow • For Low setting: 15% of peak inspiratory flow • For Very Low setting: 8% of peak inspiratory flow. Accuracy +10%/-25% or ±1.3 L/min whichever is greater. When tested with IPAP = 15 cm H ₂ O, EPAP = 5 cm H ₂ O,
Sound pressure level	Rise Time = Min, 6' 6" (2 m) air tubing, Ultra Mirage mask, zero leak. 29 dBA as measured according to ISO 17510 – 1; 2002. 32 dBA with uncertainty of 3 dBA as measured according to ISO 17510 – 1:2007.
Alarm Volume Range	> 45 dBA - <85 dBA at 3' 3" (1 m); 3 steps: low, medium, high
Data storage	7 days of respiratory flow, calculated therapy pressure, SpO ₂ , pulse rate, breath-by-breath data (EPAP, pressure support, minute ventilation, leak, respiratory rate, tidal volume, inspiration time, expiration time, spontaneously or machine triggered or cycled breaths) 365 days of 5th -, 50th -, 95th percentile data (leak, SpO ₂ , minute
	ventilation, tidal volume, respiratory rate, I:E, pressure support, AHI, AI)
Dimensions (L x W x H)	9.1" x 6.7" x 4.7" (230 mm x 170 mm x 120 mm)
Weight	4.6 lb (2.1 kg)
Air outlet	0.9" (22 mm) taper, compatible with ISO 5356-1:2004 Anesthetic & Respiratory Equipment – Conical Connectors













_		
Pressure measurement	Internally mounted pressure transducer	
Flow measurement	Internally mounted flow transducer	
Power supply	AC 100–240V, 50–60Hz, 2.2 A, max. 65 W	
External DC Power Supply (isolated)	24V, 3 A	
Internal Battery	Lithium-Ion battery, 14.4 V, 1.6 Ah, 23 Wh	
	Operating hours: 2 h with a new battery under normal conditions (see below).	
	Patient type: home chronic; pressure: IPAP/EPAP 15/5 cm H ₂ O; mask type: Ultra Mirage; air tubing: 6' 6" (2 m); leak: 0; respiratory rate: 20 bpm; battery capacity: 100%	
	Patient type: hospital acute; pressure: IPAP/EPAP 20/5 cm H_2O ; mask type: Ultra Mirage; air tubing: 6′ 6″ (2 m); leak: 0; respiratory rate: 45 bpm; battery capacity: 100%	
Housing construction	Flame retardant engineering thermoplastic	
Environmental conditions	Operating temperature: +32°F (0°C) to + 95°F (35°C)	
Stellar 150	 Operating humidity: 10%–95% non-condensing 	
	 Storage and transport temperature: -4°F (-20°C) to +140°F (60°C); +122°F (+50°C*) 	
	 Storage and transport humidity: 10%–95% non-condensing 	
	• Air pressure: 680 hPa to 1,100 hPa; Altitude: 9,842′ 5″ (3,000 m) Note: The performance may be limited below 800 hPa.	
	*NONIN XPOD	
Electromagnetic compatibility	Product complies with all applicable electromagnetic compatibility requirements (EMC) according to IEC60601-1-2, for residential, commercial and light industry environments. For further details see "Guidance and manufacturer's declaration – electromagnetic emissions and immunity" on page 68.	
Air filter	Electrostatic fibre mesh with TPE frame structure.	
	Bacterial filtration efficiency of 99.540% on area weight 100g/m².	
Air tubing	Flexible plastic, 6' 6" (2 m) or 9' 10" (3 m) length (0.9"/22 mm diameter)	
SlimLine air tubing	Flexible plastic, 6' (1.83 m) length (0.6"/15 mm diameter)	
IEC 60601-1 classifications	 Class II (Clause 3.14—double insulation). This adherence means the need for an protective earthing (ie, an earthed plug) is not necessary. 	
	Type BF Continuous operation	
Air travel requirements	 Continuous operation Medical-Portable Electronic Devices (M-PED) that meet the Federal Aviation Administration (FAA) requirements of RTCA/DO-160 can be used during all phases of air travel without further testing or approval by the airline operator. ResMed confirms that the Stellar 150 meets RTCA/DO-160 requirements. 	
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Notes:

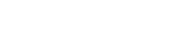
• The manufacturer reserves the right to change these specifications without notice.

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

• Pressure may be displayed in cm H_2O or hPa.











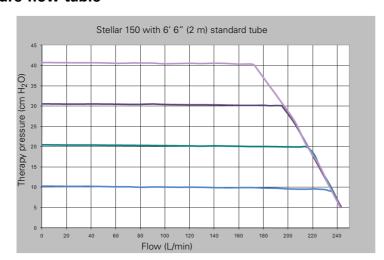


Displayed values

Value	Range	Accuracy	Display Resolution
Flow sensor in devic	e ¹		
Leak ^{2,3}	0–120 L/min	± 12 L/min or ± 20%, whichever is greater	1 L/min
Tidal volume ^{2,3}	50–3,000 mL	± 20% or 30 mL whichever is greater	10 mL
Respiratory rate	5–60 bpm	±1 bpm ⁴	1 bpm
Minute ventilation / Alveolar minute ventilation ²	0.6–60 L	± 0.5 L or 20% whichever is greater	0.1 L
Ti	0.0-4 sec	± 0.1 sec or ±10%, whichever is greater	0.1 sec
Pressure	0-40 cm H ₂ O	IPAP: ± 0.5 cm H ₂ O ± 10% of set pressure (end of inspiration); EPAP or PEEP: ± 0.5 cm H ₂ O ± 4% of set pressure CPAP: ± 0.5 cm H ₂ O ± 10% of set pressure	0.1 cm H ₂ O

- 1 Results may be inaccurate in the presence of leaks and may be affected by vent characteristics.
- 2 Results are expressed at STPH (Standard Temperature Pressure, ambient humidity)
- 3 Results may be inaccurate in the presence of leak and supplemental oxygen > 10 L/min. If necessary for therapy, use external monitoring.
- 4 Results may be inaccurate if the tidal volume is below 50 mL.

Pressure-flow table











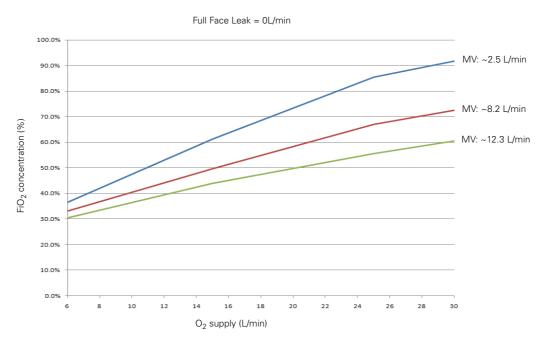




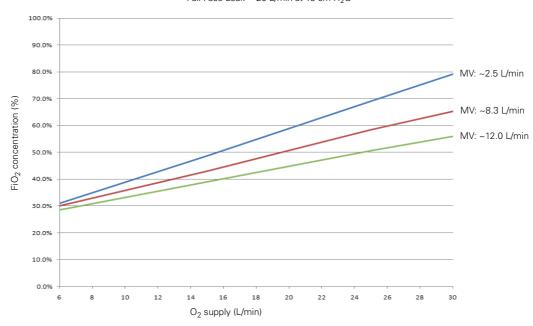


FiO₂ measurement

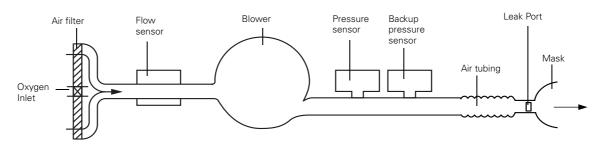
 FiO_2 concentration measurement at EPAP/IPAP 5/10 cm H_2O (blue curve), 5/20 cm H_2O (red curve) and 5/30 cm H_2O (green curve), R/C 5/20, respiratory rate 20 bpm, full face mask.







Pneumatic flow path















Guidance and manufacturer's declaration – electromagnetic emissions and immunity

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR11	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, including	
Harmonic Emissions IEC 61000-3-2	Class A	domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies		

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in

Warnings: The device should not be used adjacent to or stacked with other equipment

The use of accessories (e.g. humidifiers) other than those specified in this manual is not recommended. They may result in increased emissions or decreased immunity of the device

Guidance and manufacturer's declaration - electromagnetic immunity

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

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 interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	< 12 V (>95% dip in 240V) for 0.5 cycle 96 V (60% dip in 240 V) for 5 cycles 168 V (30% dip in 240 V) for 25 cycles <12 V (>95% dip in 240 V) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. 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.
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.
			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. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = 1.17 √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.17 \sqrt{P} 80 MHz to 800 MHz d = 2.33 \sqrt{P} 800 MHz to 2.5 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 metres (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. Interference may occur in the vicinity of equipment marked with the following symbol: ($\langle \psi \rangle$)

NOTE 1: Ut is the AC mains voltage prior to application of the test level.

NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.











^a 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.

 $^{^{\}rm b}$ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.







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

The device is 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

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 1.17 √P	800 MHz to 2.5 GHz d = 2.33 √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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 transmitte

NOTE 1.4 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Symbols

😵 Follow instructions for use; □ Class II equipment; 🕅 Type BF applied part; 🗘 Bell (Remote Alarm); IP31 Device is protected against solid foreign objects of 0.1" (2.5 mm) diameter and greater and vertically falling water drops; \Lambda Caution; \Lambda General warning sign (see H4i connector plug and AC connection on the device); ON/STAND-BY Standby or preparatory state for a part of equipment (power switch); O_2 Connection for oxygen supply; max 30 I/min (max 30 I/min); 🚓 Data port; 🖭 Canadian Standards Association; 🎜 Temperature limitation for storage and transport; 📍 Handle with care; 🔎 Maximum humidity; 🌴 Keep dry; Manufacturer; 1 Upside; REF Catalogue number; SN Serial number; Lot Batch code; Do not re-use;
 Use by date;
 Keep away from sunlight;
 Do not use if package is damaged; Latex-free

Environmental information This device must be disposed of in accordance with the laws and regulations of the country in which disposal occurs.

For further information regarding product disposal, please contact your local ResMed office or your specialist distributor, or visit our website at www.resmed.com.

Dispose of used air filters and air tubing according to the directives in your country.













General warnings and cautions

WARNINGS



A warning alerts you to possible injury.

- Read the entire manual before using the device.
- The device and the accessories are to be used for the specified intended use only.
- A User Guide is supplied with the device. Please ensure the patient has the User Guide.
- The device must only be used with masks (and connectors¹) recommended by ResMed, or by a clinician or respiratory therapist. A mask should not be used unless the device is turned on and operating properly. The vent hole or holes associated with the mask should never be blocked.

Explanation: The device is intended to be used with special masks (or connectors) which have vent holes to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most Positive Airway Pressure devices.

- In the event of power failure² or machine malfunction, remove the mask or the catheter mount from the tracheostomy tube.
- Explosion hazard—do not use in the vicinity of flammable anesthetics.
- The device should not be used with anesthetized patients, whose breathing depends entirely on mechanical ventilation.
- Do not use the device if there are obvious external defects, unexplained changes in performance.
- Only use original and approved ResMed accessories and parts.
- The use of an antibacterial filter is obligatory in situations in which cross contamination is possible.
- Use only accessories from the original package. If the packaging is damaged, the respective product must not be used, and should be disposed along with the packaging.
- Before using the device and the accessories for the first time, ensure that all components
 are in a proper condition and that their operational safety is guaranteed. If there are any
 defects, the system should not be used.
- Additional equipment connected to medical electrical equipment must comply with the
 respective IEC or ISO standards (e.g. 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.
- · No modification of this equipment is allowed.











¹ Ports may be incorporated into the mask or in connectors that are near the mask.

² During partial (below rated minimum voltage) or total power failure, therapy pressures will not be delivered. When power is restored, operation can be proceeded with no change to settings.









CAUTIONS

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

- · When using accessories, read the manufacturer's User Manual. For consumables, important information can be provided on the packaging. For more information, see "Symbols" on page 69.
- At low pressures, the flow through the mask vent holes may be inadequate to clear all exhaled gases, and some rebreathing may occur.
- The device may not be exposed to excessive force.
- If the device should fall accidentally on the ground, please contact an authorized service
- Pay attention to leaks and other unusual sounds. If there is a problem, contact an authorized service agent.

Note:

A note advises to special product features.

- The above are general warnings and cautions. Further specific warnings, cautions and notes appear next to the relevant instructions in the manual.
- Position the device ensuring the power cord can be easily removed from the power outlet.









General warnings and cautions







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.

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

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.

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