ResMed

Stellar™ series
Non-invasive/invasive ventilators

ENGLISH

Information – Stellar 150 with iVAPS/AutoEPAP modes

℞ Only

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).

The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 66 lb (30 kg).

Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage.

USA Note: The indications for use for iVAPS mode with optional AutoEPAP have not been cleared by the US FDA. The additional indications for iVAPS mode with optional AutoEPAP shown are permissible per US FDA Guidance, "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The original USA indications for use state:

> The Stellar 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.

Notes about AutoEPAP:

- AutoEPAP is only available in iVAPS mode (indicated for patients 66 lb/30 kg and above).
- AutoEPAP is contraindicated for invasive use.
- The purpose of AutoEPAP is to maintain upper airway patency. It automatically adjusts pressure in response to flow limitation or obstruction of the upper airway.
- EPAP is adjusted within Min EPAP and Max EPAP settings with the response depending on the degree of the upper airway obstruction.
- Pressure support is adjusted on top of the AutoEPAP.
- The AutoEPAP algorithm does not address any other titration target such as lung recruitment to improve oxygenation or offset intrinsic PEEP. Min EPAP should be set to treat lower airway conditions.

Reinforced warning/contraindication when setting up for use:

- The Stellar can be used invasively only with the ResMed Leak Valve (product code 24991), or using an uncuffed or deflated cuff tracheostomy tube with the ResMed Leak Port (product code 24976).
- Do not use the antibacterial filter (product code 24966) with the H4i heated humidifier. Humidification should not be used if antibacterial filters are mandatory in a multi-patient use environment.
- The H4i heated humidifier is contraindicated for invasive use.

Rev	Change Note	Date document drafted	Document prepared by (Name)	Document Checked by (Name)
1	K006321-00	26 Mar 2020	Terence Dang	Roberto Fermin (or delegate, refer to change note)

Stellar 150 COVID-19 Addendum AMER Eng

1. ORACLE DESCRIPTION

STELLAR COVID ADD

2. TRANSLATION DESCRIPTION

Refer to the Change History on the English source listed for summary of changes in each version.

Rev	English source	This translation replaces…
1	English within	NA

3. CHANGE HISTORY

REVISION 1

Section	Description
NA	Initial revision

4. PRINT DETAILS

DIMENSIONS:	A5 (210mm x 148mm) ±2 mm tolerance
STOCK	80 gsm offset
COLOUR	Black ink.
SPECIAL FINISHES	None
STYLE	Self-covered, double-sided

Art work: If re-typeset, the same styles and sizes must be maintained. Where the colours indicated differ between Print details (as stated above) and Art work, then the specifications provided for Print details should be followed.

Manufacturer: Outside printer. (Small quantities may be printed inhouse at 100% size)

5. RESMED QC INSPECTION

For general sampling and inspection requirements, refer to AWI203-002 Appendix A, Printed or Unprinted Materials and Labels, Criteria 1, 2, 3, 4, 5, 6, 8 and 9
Additional requirement
a) None

6. FOR ALL OTHER REQUIREMENTS, REFER TO RESMED SUPPLIER MANUAL AQP119.

Additional precautions when in contact with COVID-19 patients on non-invasive ventilation (NIV)

- Due to risk of dispersion of aerosolized virus during NIV, healthcare workers should use airborne protection by wearing respirators N95 or FFP2 standard or equivalent, eye protection, gloves and gowns; aprons should also be used if gowns are not fluid resistant.
- To prevent cross-contamination, combination antibacterial/antiviral filters should be used on circuits.
- Circuits and accessories are to be replaced or decontaminated and disinfected (refer to associated user/clinical guides or service manual for reprocessing method).
- Clean all surfaces with approved surface disinfectants.

Notes about the device

- This is NOT a life support ventilator.
- 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.
- In case of mains power disruption, the device will operate using the internal battery if there is no external battery connected to the device (operational duration is approximately 2 hours under normal conditions).
- This device is fitted with alarms to alert you to changes that will affect your treatment.
- Up to 30 L/min of oxygen flow can be entrained into Stellar's oxygen inlet at the rear of the device.

MANUFACTURER **ResMed Pty Ltd**
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153 Australia

ResMed.com