Rev 2.0

ResMed Ventilators and COVID-19

Information on applications in the treatment of patients with COVID-19

The information contained in this document is current as of March 23, 2020, and is based on currently available information that will continue to change over time. The information in this guide with respect to treatment is believed to have a reasonable basis. ResMed assumes no obligation to update the information in this presentation, whether as a result of new information or future events.

Rev 2.0

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Executive Summary

As a medical technology manufacturer of respiratory devices, including ventilators, ResMed has mobilized a global task force in response to the COVID-19 pandemic. Our guiding principle in responding to the COVID-19 pandemic is the preservation of life throughout the globe.

Access to ventilators will be important during this pandemic and ResMed has taken the necessary steps to prioritize manufacturing resources for devices that support higher acuity patients. However, as ventilator resources become stretched due to high demand, alternative ventilation options such as bi-level devices will be crucial to stabilizing or sustaining patients who require respiratory support.

This document aims to assist healthcare officials in understanding the application of ResMed's devices in providing ventilation support to patients with clinical syndromes due to COVID-19 infection. It is based on current information, which is changing rapidly. **The purpose is not to direct clinical practice but to provide clear information on the available ResMed products and their application.**

Use of Ventilation for Patients with COVID-19

Patients affected by COVID-19 have a range of symptoms and varying degrees of severity of illness. All patients should be assessed thoroughly, with the decision to monitor a particular patient in the inpatient or outpatient setting depending on clinical presentation and severity of illness, the patient's ability to engage in monitoring, home isolation, and the risk of transmission.[1]

According to the Center for Disease Control (CDC), patients with mild illness on presentation may not initially require hospitalization; however, their symptoms may worsen with progression to lower respiratory tract disease.[1] Many are diagnosed with pneumonia and subsequently develop hypoxemic respiratory failure or acute respiratory distress syndrome (ARDS). These patients are primarily managed with mechanical ventilation, both invasive and non-invasive, often with supplemental oxygen.[2] Published information shows that 6% of patients with COVID-19 require ventilation,[3] with numbers rising to 89% for those in the intensive care unit (ICU).[4] Of these, 47.2% received invasive ventilation and 41.7% received non-invasive ventilation.[4]

Invasive ventilation is important for critically ill patients

Several guidance documents for the management of critically ill patients with COVID-19 have been published;[1, 2] these are by and large based on the usual management of viral pneumonia with respiratory failure, with additional precautions to reduce risk of transmission. Current guidance from the World Health Organization (WHO) and others recommend early consideration for invasive ventilation for patients with severe COVID-19 who develop ARDS,[2, 5] and a strong preference for early use of invasive ventilation over non-invasive ventilation where appropriate and possible.[6] Additional information from the Handbook of COVID-19 Prevention and Treatment indicated that some severe patients progress to ARDS rapidly and intubation should be performed as early as possible if improvement in respiratory distress symptoms or PaO_2/FiO_2 is not observed.[7] Evidently, access to invasive ventilators will be critical

during this pandemic. However, the dramatic increase in patients requiring ventilator therapy may lead to ventilator scarcity. Emerging data from China show that only 25% of patients who died had received invasive ventilation, suggesting that ventilation resources may not have been available for critically ill patients.[8]

Governments around the world, recognizing the impending shortage, are working hard to prepare and deploy resources as quickly as possible. The UK government released a Specification on 22 March 2020 for minimally clinically acceptable ventilator systems that are considered suitable for hospital use in treating COVID-19. This specification guidance outlines the need for volume controlled (Pressure Regulated Volume control or pressure controlled ventilation) ventilation as well as bi-level devices while highlighting the monitoring and safety features expected of ventilators used in critical care situations.[9]

The U.S. Food and Drug Administration (FDA) released an enforcement guidance on 22 March 2020 which provides a policy to help expand the availability of ventilators and other respiratory devices during this pandemic. The guidance describes the FDA's intention to exercise enforcement discretion for certain deviations, such as the use of ventilators outside their cleared environment of use, and the use of devices indicated for sleep apnea (including noncontinuous ventilators delivering CPAP or bi-level positive airway pressure) to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimize aerosolization.[10]

Non-invasive ventilators can help in decompressing hospital census

In a recent discussion paper, the National Academy of Medicine stated that the use of bi-level devices could be a way to forestall the need for intubation and reduce days on a ventilator.[11] Bi-level devices provide non-invasive ventilation only, and could be used to stabilize less severe patients while allowing allocation of ventilators with invasive capabilities to critical cases, or sustain a patient long enough for an invasive ventilator to become available.[12]

A Philips Healthcare webinar on respiratory management for severe COVID-19 patients showed the impact non-invasive ventilation devices have had in treating patients with COVID-19 in China and Italy.[13] During the webinar, Professor Cheng Rongchang discussed cases of COVID-19 patients using non-invasive ventilation with bi-level devices; he shared that *"four out of sixteen patients in the ICU were managed with non-invasive ventilation and avoided intubation"*. Professor Stefano Nava, the chief of the Respiratory and Critical Care Unit at Sant' Orsola Hospital in Bologna, Italy, shared his experiences of desperate shortages of ventilators and the need to triage patients by their respiratory symptoms, with non-invasive ventilation used for those who needed more than just supplementary oxygen and moving to intubation if non-invasive ventilation could not improve their oxygen levels. These experiences of physicians treating severe and critical COVID-19 patients in China and Italy has confirmed the ability of triaging some patients to non-invasive ventilation. As always, patient selection is important and all patients must be monitored closely for deterioration.

While non-invasive ventilation is not ideal for the most severe or critical cases of COVID-19, this therapy type could be useful in decompressing hospital census. Based on current literature and anecdotal

evidence from the field, it appears that bi-level devices or non-invasive ventilators may be useful in the following scenarios:

1. When a patient needs support for respiratory insufficiency, but has not deteriorated into more severe hypoxemia, ARDS, or any other clinical scenario where invasive ventilation is more appropriate.
2. To decompress ICU census, after a patient is extubated and recovering from invasive ventilation, and help mitigate the risk of reintubation, to allow an invasive ventilator to be cleaned and serviced and circulated back into use on another patient.
3. To decompress hospital census, allowing patients who still need some respiratory support to transition to the home or other non-hospital facilities (e.g. rehabilitation center, skilled nursing facility, etc.) on devices that are already used in millions of homes every day.
4. The patient needs intubation but there are no more invasive ventilators, non-invasive ventilation could be useful to bridge the time to intubation. This situation is the highest risk and not ideal therefore the patient must be closely monitored. Some evidence suggests this may only be helpful for a short time (e.g. less than 2 hours).[7]

In the Philips Healthcare webinar, Professor Stefano Nava recounted the experience from Italy where ICU beds and equipment were fully utilized and entire hospitals were dedicated for the treatment of patients with COVID-19.[13] Practicality became the key to dealing with the influx of patients requiring treatment, with those with mild symptoms being sent home for monitoring.[13] For countries facing this public health emergency, and where ICU capacity is insufficient to meet demand, it will be important to provide ventilation solutions to support patients into the sub-acute or out of hospital care environments.

Utilizing oxygen

Hypoxemia can present due to impaired respiratory functions by COVID-19. Oxygen supplementation treatment may correct hypoxemia, relieving secondary organ damage caused by respiratory distress and hypoxemia. Evidence suggests that controlled oxygen therapy may be helpful,[5] and this can be done with invasive or non-invasive ventilation by oxygen entrainment into the circuit or patient interface.

Protecting healthcare workers to mitigate infection risk

Some concerns have emerged regarding the risk of dispersion of aerosolized virus when utilizing non-invasive ventilation. However, evidence suggests that non-invasive ventilation procedures are more likely to produce large droplets (>10 μm) rather than aerosols, and that these are largely confined to within one meter due to their large mass.[14] This suggests that the risk of droplet dispersion as a result of use of non-invasive ventilation or bi-level devices may not be that different to that of any COVID-19 patient in the hospital who is coughing or sneezing.

Additionally, an experts' panel determined that non-invasive ventilation systems with a good interface fitting do not create widespread dispersion of exhaled air.[15] Recommendations have been published to support good mask fit to reduce aerosols, including use of full face masks.[16] Nonetheless, the risk of

aerosol dispersion needs to be mitigated with appropriate isolation of patients and the use of Personal Protective Equipment (PPE) for healthcare workers, such as N95 masks/respirators and eye protection,[5] which are standard protective equipment in a COVID-19 ICU.[17]

Recommended methods for reducing risk of virus spread include using suitable masks and filters, appropriate PPE and isolation techniques (see **Figure *1***).

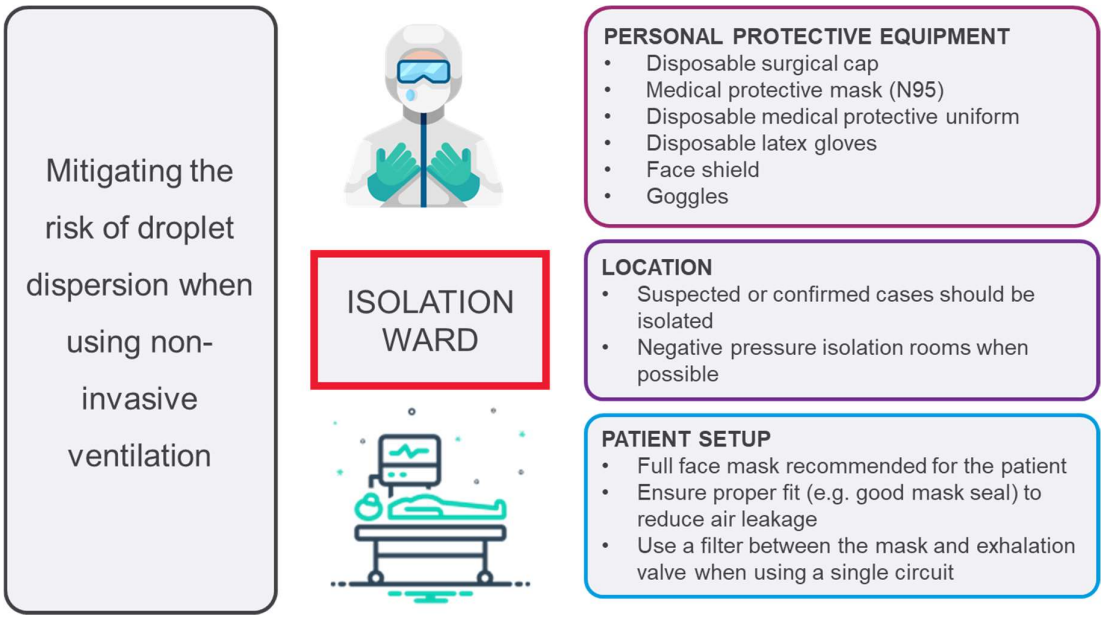

Figure 1. Mitigating risk of droplet dispersion when using non-invasive ventilation.[1, 7]

Clinical training for non-invasive ventilation

The principles of invasive ventilation and non-invasive ventilation are very similar, so training healthcare professionals (e.g. anesthesiologists, emergency physicians, intensivists, nurses, and respiratory therapists) who are well-versed in invasive ventilation to provide non-invasive ventilation should create few burdens. The two primary changes between invasive ventilation and non-invasive ventilation are the circuit configurations and the modes of ventilation utilized. There are fewer required circuit components when initiating non-invasive ventilation, so the burden is expected to be less than that of initiating invasive ventilation.

The most challenging part of setting up non-invasive ventilation is training care givers to properly fit a mask. Poor mask fit can cause discomfort or intolerance, spread exposure to health care providers and reduce therapy effectiveness. The ability to anticipate, prevent and manage mask-related problems will be important for non-invasive ventilation success.

ResMed offers online tutorials of device setups, quick setup guides, suggested non-invasive ventilation settings and remote webinar trainings for users, all tools which largely allow for independent clinician setup of devices.

The method of ventilation is an important clinical decision to be made by the treatment team under rapidly evolving clinical guidelines for COVID-19 patients, availability of ventilation technology, clinical settling and availability of personal protective equipment for healthcare workers. The following information about ResMed devices is designed to assist and inform these decisions by clarifying applications and features of different devices.

ResMed Ventilators and Bi-level Devices – Application and Features

ResMed manufactures a range of ventilators and bi-level devices. These devices are indicated for hospital and home use, and have the flexibility for use in various clinical scenarios (see **Figure 2**). It should be noted, however, that these are **not** the same as ventilator equipment typically used in high acuity situations in hospital ICUs.

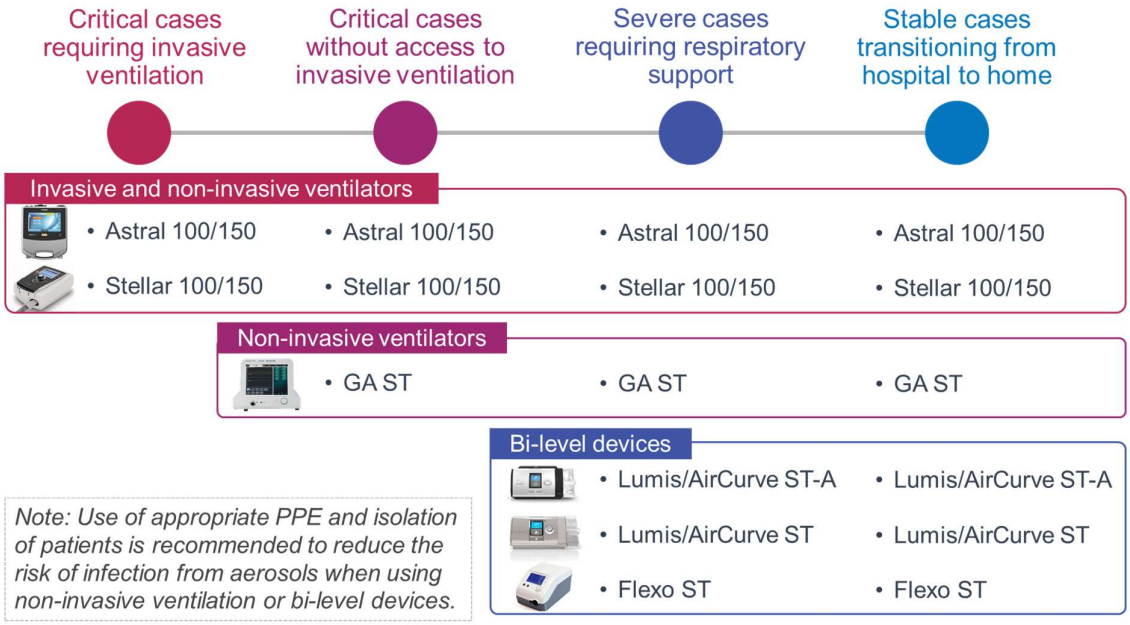

Figure 2. ResMed and Curative ventilators and bi-level devices in various clinical scenarios

The FDA in their COVID-19 ventilator enforcement guidance encourages applications to distribute in the U.S. ventilators and respiratory devices that have been approved in other jurisdictions;[10] this increases the ability of manufacturers like ResMed to respond.

The ResMed range of ventilators and bi-level devices capable of providing respiratory support to patients at various stages of dependency is shown below (see **Figure 3**).

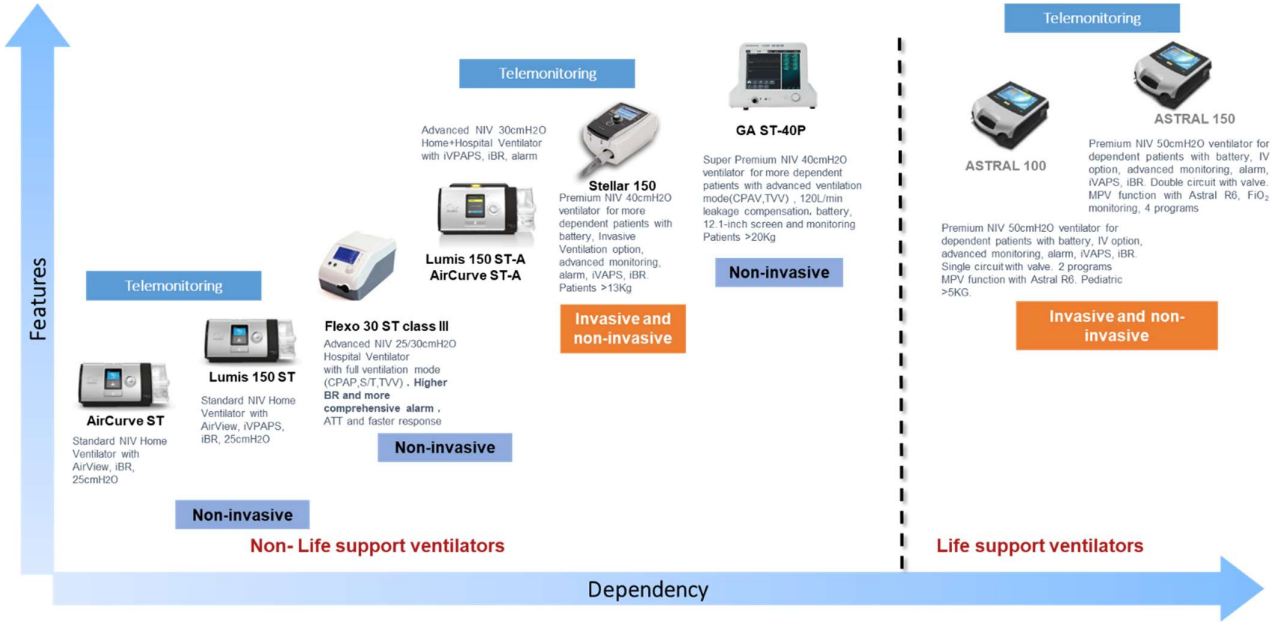

Figure 3. ResMed and Curative ventilators and bi-level devices

What is the difference between non-invasive and invasive ventilation?

Non-invasive ventilation (NIV) is a form of mechanical ventilation where air is delivered to the patient through a mask or mouthpiece. **Invasive ventilation** is used when sufficient ventilation cannot be achieved using non-invasive methods so air is delivered through a tube inserted into the trachea either via intubation or tracheotomy.

What is a bi-level device?

Bi-level devices are considered ventilatory equipment and provide non-invasive ventilation only. These devices deliver two distinct pressures, one for inhalation and the second for exhalation; the change in pressures leads to flow of air in and out of the lungs. Bi-level devices are not cleared or approved by local regulatory authorities for use with intubation or tracheotomy. In most European and North American countries, most of these devices are not utilized by physicians for invasive ventilation because they lack alarms, sophisticated monitoring or modes, and their pressure generation is not sufficient to care for those with significant lung injury. However, some advanced bilevels are suitable for invasive ventilation and cleared in several jurisdictions for that use.

Invasive and non-invasive ventilators

Astral 100/150

Of the ResMed range of invasive and non-invasive ventilators, the Astral life-support ventilator provides the most comprehensive set of modes and settings and delivers both pressure and volume ventilation. The ResMed Astral 150 is the most comprehensive—it comes with all the standard features of the standard Astral 100 plus double limb circuit capabilities, which complements the use of an inspiratory and expiratory antibacterial/antiviral filter and a non-vented mask to reduce risk of contamination to healthcare professionals. The device allows addition of supplemental oxygen (no oxygen blender; low pressure oxygen only) at the air inlet up to 30L/min and provides monitoring of FiO_2. The ability to use an active circuit may help reduce particle spread. The device can generate higher pressures needed to care for an acutely ill patient. The option to have four pre-set settings may make it easier for less experienced staff taxed during the global health crisis to run the device. These devices also include remote monitoring that can facilitate “telehealth” or remote management of patients, as well as the ability to centralize telemonitoring of devices in a “war room” configuration

Stellar 100/150

The ResMed Stellar 100/150 is a non-invasive ventilator with invasive capabilities when combined with the ResMed leak valve, and is indicated for ventilation of non-dependent, spontaneously breathing patients. The Stellar 100/150 can be safely used in those recovering from acute lung injury such as ARDS or those with milder underlying lung disease. The device also allows addition of supplemental oxygen at the air inlet up to 30L/min and provides monitoring of FiO_2 with an additional FiO_2 monitoring sensor attached. This device has an internal battery and can be used for transport within a hospital. Physicians consider this device a good option for step down units.

Non-invasive ventilators

GA ST series

The GA ST series is a non-invasive ventilator indicated for ventilation of spontaneously breathing individuals. It is equipped with two oxygen input methods, high-pressure oxygen and low-pressure oxygen. The device allows addition of supplemental oxygen at the air inlet and is capable of providing up to 100% FiO_2. The maximum oxygen flow rate with low-pressure is 30 L/min. An oxygen mixer is also available for greater oxygen concentration accuracy. The use and replacement of the air inlet filter and main flow bacteria filter between patients and at regular intervals will reduce the risk of patient or ventilator contamination. This device is sold under the company name Curative, a ResMed family company.

Bi-level devices for non-invasive ventilation

Lumis and AirCurve

The Lumis and AirCurve range of ResMed devices[18] are bi-level devices indicated to provide non-invasive ventilation for patients with respiratory insufficiency. A "backup" rate can be set to ensure that patients still receive a minimum number of breaths per minute if they fail to breathe spontaneously. The ST-A variant comes with fixed and adjustable alarms to alert the user/caregiver in case of therapy issues and may be more appropriate for the ward environment than the ST variant, which is possibly more suitable for when a patient is discharged to a home environment. If necessary, supplemental oxygen up to 15 L/min can be connected to the air outlet of the Lumis and AirCurve range, but monitoring of FiO_2 is not done by the device. An additional oximetry adapter can be attached to measure SpO_2 if needed. These devices also include remote monitoring that can facilitate “telehealth” or remote management of patients, as well as the ability to centralize telemonitoring of devices in a “war room” configuration.

Flexo ST series

The Flexo ST series is a bi-level device that provides non-invasive ventilator support for patients with respiratory insufficiency. Like the Lumis and AirCurve range, a timed backup mode allows the minimum number of breaths per minute to be set in the event that the patient slows or ceases respiratory efforts. The highest end of the Flexo ST series provides inspiratory pressures up to 30 cmH_2O and includes adjustable alarms to alert the user/caregiver in case of therapy issues. The Flexo device is not designed or intended to be used with supplemental oxygen. This device is sold under the company name Curative, a ResMed family company.

Summary of device specifications

Key specifications of ResMed ventilators and bi-level devices are provided in the table below (see ***Table 1***). Comprehensive information on these devices, their specific indications for use, modes and features is set forth in the Appendices.

Table 1. Key specifications of ResMed and Curative ventilators and bi-level devices

	Astral 100/150	Stellar 100/150	GA ST*	Lumis/AirCurve ST-A	Lumis/AirCurve ST	Flexo ST*
Invasive Capability	Yes	Yes (leak valve with tracheostomy)	No	No	No	No
Non-invasive Capability	Yes	Yes	Yes	Yes	Yes	Yes
Max Pressure (cmH_2O)	50	40	40	30	25	30
O_2 Entry Location	Inlet	Inlet	Inlet	Outlet	Outlet	N.A.
Max O_2 Flow Rate (L/min)	30	30	30	15	15	N.A.
FiO_2 Monitoring/Alerts	Yes	Yes	Yes	No	No	No
Humidification	External	Integrated or External	External	Integrated or External	Integrated or External	External
Alarms	Yes	Yes	Yes	Yes	No	Yes
Internal battery	Yes	Yes	Yes	No	No	No
External battery	Yes	Yes		Yes	Yes	No
Telemonitoring	Yes	Yes	No	Yes	Yes	No
Modes	CPAP, (S)T, P(A)C, (A)CV, P(A)CV, P-SIMV, V-SIMV, PS, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, CPAV, TVV-t, TVV-ST, TVV-APCV	CPAP, S, ST (optional iBR), T, PAC, iVAPS	*AirCurve*: CPAP, S, ST, T *Lumis*: CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, TVV

*GA ST and Flexo ST are devices offered by Curative, a subsidiary of ResMed.

Reprocessing of ResMed Devices

The novel coronavirus that causes the disease COVID-19, SARS-CoV-2, is an enveloped virus. This means that it can be inactivated with the appropriate disinfectant product when used according to the label directions. The U.S. Environmental Protection Agency has published a list of disinfectants that meets its criteria for use against SARS-CoV-2.[19] This authorized list of disinfectants is comprised of many commonly used disinfectants and is being actively updated as more information emerges.

Published guidance from health authorities reinforce the need to maintain standard cleaning and disinfection procedures.[20] For each ResMed device, these cleaning and disinfection procedures are provided in the device's associated clinical guide, user guide or service manual. To prevent cross-contamination, antibacterial filters are used on air intake and circuits, and circuit accessories are to be replaced or sterilized. Instructions are also provided in the materials and method for cleaning surfaces.

References and Notes

[1] Centers for Disease Control and Prevention. Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19). Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html March 22, 2020

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[18] Lumis and AirCurve are essentially the same device, with different country variant naming, specific indications for use of variants of the Lumis and AirCurve device may vary by region.

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APPENDIX– Device Specifications

Device availability will vary by region.

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
Indications for use	The Astral 100/150 devices provide continuous or intermittent ventilatory support for patients weighing more than 5 kg (11 lb) who require mechanical ventilation. The iVAPS mode with optional AutoEPAP is intended for patients weighing more than 30 kg (66 lb). The Astral device is intended to be used in home, institution/ hospital and portable applications for both invasive and non-invasive ventilation. The Astral device is not intended for use as an emergency transport ventilator.	The Stellar 100/150 is intended to provide ventilation for non-dependent, spontaneously breathing adult and paediatric patients (13kg/30 lb and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnoea. The device is for noninvasive use, or invasive use (with the use of the ResMed Leak Valve).	The GA non-invasive ventilator is an assist ventilator and is intended to augment patient breathing. It is intended solely for spontaneously breathing individuals who require mechanical ventilation: patients with respiratory failure, chronic respiratory insufficiency, or obstructive sleep apnea in a hospital or other institutional settings under the direction of a physician. The ventilator is intended to support patients weighing 20 kg (44 lb) or greater	The Lumis 150 ST-A device is indicated to provide non-invasive ventilation for patients weighing more than 13 kg/30 lb or more than 30 kg/66 lb in iVAPS mode with respiratory insufficiency or obstructive sleep apnoea (OSA). It is intended for home and hospital use.	The AirCurve 10 ST-A is indicated to provide non-invasive ventilation for patients weighing more than 30 lb (13 kg) with respiratory insufficiency or obstructive sleep apnea (OSA). The AirCurve 10 ST-A is intended for home and hospital use.	The Lumis 150 VPAP ST device is indicated to provide non-invasive ventilation for patients weighing more than 13 kg/30 lb or more than 30 kg/66 lb in iVAPS mode with respiratory insufficiency or obstructive sleep apnoea (OSA). It is intended for home and hospital use.	The AirCurve 10 ST device is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for home and hospital use.	Flexo Bi-level positive airway pressure therapy device is used to provide non-invasive ventilatory support of mechanical ventilation for • Patients who are independent and spontaneously breathing • Patients with respiratory insufficiency and sleep breathing disorders It can provide both a stable continuous positive airway pressure and a bi-level positive airway pressure. It is not a life support ventilator. It is intended to be used in the home or professional medical environment.
Device Type	Mechanical ventilator for life support	Mechanical ventilator non-life support	Mechanical ventilator non-life support	Bi-level/BiPAP with alarms	Bi-level/BiPAP with alarms	Bi-level/BiPAP	Bi-level/BiPAP	Bi-level/BiPAP

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
Patient Weight	>5 kg (all modes except iVAPS) >30 kg (iVAPS)	≥13 kg (all modes except iVAPS) ≥30 kg (iVAPS)	≥20 kg	>13 kg (all modes except iVAPS) ≥30 kg (iVAPS)	>13 kg (all modes except iVAPS) ≥30 kg (iVAPS)	>13kg (all modes except iVAPS) ≥30kg iVAPS	>30kg	-
Ventilation Delivery Specifications								
Patient Interface	non-invasive invasive	non-invasive Invasive (with the use of ResMed leak valve)	non-invasive	non-invasive	non-invasive	non-invasive	non-invasive	non-invasive
Circuit Type	Single valve Single leak Double	single leak	single leak	single leak	single leak	single leak	single leak	single leak
Pressure or Volume cycled	Pressure Volume	Pressure	Pressure	Pressure	Pressure	Pressure	Pressure	Pressure
Operating Pressure Range	2-50 cmH_2O: (S)T, P(A)C, iVAPS 3-20 cmH_2O: CPAP 0-50 cmH_2O: PS, P-SIMV, V-SIMV	2-40 cmH_2O: S, ST, T, PAC, iVAPS 4-20 cmH_2O: CPAP	4-40 cmH_2O	2 - 30 cmH_2O: S, ST, T, PAC, iVAPS 4-20 cmH_2O: CPAP	3-30 cmH_2O: S, ST, T, PAC, iVAPS 4-20 cmH_2O: CPAP	2-25 cmH_2O: S, ST, T, PAC, iVAPS 4-20 cmH_2O: CPAP	3-25 cmH_2O: S,ST, T 4-20 cmH_2O: CPAP	4-30 cmH_2O: S, T, ST, APCV 4-20 cmH_2O: CPAP
Therapy Modes	CPAP, (S)T, P(A)C, (A)CV, P(A)CV, P-SIMV, V-SIMV, PS, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, T, ST, APCV, CPAV, TVV-t, TVV-ST, TVV-APCV	CPAP, S, ST (optional iBR), T, PAC, iVAPS	CPAP, S, ST (optional iBR), T, PAC, iVAPS	CPAP, S, ST (optional iBR),T, PAC, iVAPS	CPAP, S, ST, T	CPAP, S, T, ST, APCV, TVV
Performance Specifications								
Pressure Support Range	-	0-38 cmH_2O 0-30 cmH_2O (in iVAPS mode)	0-38 cmH_2O	0-28 cmH_2O	0-27 cmH_2O	0-23 cmH_2O	0-22 cmH_2O	0-26 cmH_2O
Intended Volume Range	Adult: 100 - 2,500 mL, Paed: 50 - 300 mL: (A)CV, V-SIMV	50-3000 mL	200-2000 mL	100–2500 mL	100-2500 mL	100-2500 mL	100-2500 mL	50-2500 mL
Supplementary Oxygen – Max Flow	30 L/min	30 L/min	30 L/min	15 L/min (S, ST, T, PAC, CPAP) 4 L/min (iVAPS)	15 L/min (S, ST, T, PAC, CPAP) 4 L/min (iVAPS)	15 L/min (S, ST, T, PAC, CPAP) 4 L/min (iVAPS)	15 L/min (S, ST, T)	n/a

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
Supplementary Oxygen – where to add	Device oxygen inlet	Device oxygen inlet	Device oxygen inlet	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	Device air outlet (eg. Side port of ClimateLineAir Oxy tube), mask	n/a
SpO2 measurement	Optional accessory	Optional accessory	Optional accessory	Optional accessory	Optional accessory	Optional accessory	Optional accessory	n/a
FiO2 monitoring	Optional accessory	Optional accessory	Optional accessory	n/a	n/a	n/a	n/a	n/a
Internal Battery Runtime	8 hours (a new battery under normal conditions)	3 hours (a new battery under normal conditions)	4 hours	n/a	n/a	n/a	n/a	n/a
	Lithium-Ion battery, 14.4 V, 6.6 Ah, 95 Wh	Lithium-Ion battery, 14.4 V, 2.75 Ah, 40 Wh						
Humidification	External	Integrated or External	External	Integrated or External	Integrated or External	Integrated or External	Integrated or External	External
Safety								
Max single fault pressure	90 cmH_2O	60 cm H_2O (in all modes)	-	30 cmH_2O for >6 s, or	30 cmH_2O for >6 s, or	30 cmH_2O for >6 s, or	30 cmH_2O for >6 s, or	-
				40 cmH_2O for >1 s	40 cmH_2O for >1 s	40 cmH_2O for >1 s	40 cmH_2O for >1 s	
Design Life	Device: 8 years	Device: 5 years	Device: 10 years	Device, PSU: 5 years	Device, PSU: 5 years	Device, PSU: 5 years	Device, PSU: 5 years	Device: 5 years
		Air Tubing: 6 months		Cleanable Humidifier: 2.5 years	Cleanable Humidifier: 2.5 years	Cleanable Humidifier: 2.5 years	Cleanable Humidifier: 2.5 years	
				Air Tubing: 6 months	Air Tubing: 6 months	Air Tubing: 6 months	Air Tubing: 6 months	
Alarms	Total power failure	Power fail	High/low pressure	Power fail	Power fail	n/a	n/a	Patient circuit disconnect
	Circuit disconnection	Blocked tube	High/low oxygen pressure	Blocked tube	Blocked tube			
	Low Pressure, High Pressure	Tube disconnected, System fault	No oxygen supply	Tube disconnected	Tube disconnected			High inspiratory pressure
	Obstruction	High temperature, Internal battery low/empty	High/low inspiratory pressure	High leak	High leak			

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
	Apnea	Over pressure	Patient circuit disconnection	Non-vented mask	Non-vented mask			Apnea
	Low / High MVe , Low / High MVi	High leak	Low/failed internal battery	Apnea	Apnea			
	Low / High Vte, Low / High Vti	Non-vented mask	Internal battery powering	Low SpO2 (when oximeter connected)	Low SpO2 (when oximeter connected)			Low tidal volume
	Low / High Resp rate	Low minute ventilation	external battery powering	Low minute ventilation	Low minute ventilation			
	High leak	Apnea	Power return	System fault	System fault			Low minute volume
	Ventilation stopped	High/Low pressure	Tube disconnected					
	Low / High SpO_2	High/Low respiratory rate,	High extremity pressure					High/low leak
	Low / High pulse rate	High/Low FiO_2	High/low external battery voltage					
	Low / High FiO_2	Low SpO_2	Pressure sensor failure					
	NV mask/Rebreathing		Communication error with main board					
	Incorrect circuit adapter		Cooling fan speed too low					
	Critically low battery		Blocked airway path					
	Incorrect circuit attached		High/low leak					
	Safety reset complete		Apnea					
	Battery inoperable		Low MV					
	Low / High PEEP		High/low BPM					
	Device overheating		High/low VT					
	Pressure line disconnected		High/low TVV					
	Self-test failed							
	Flow sensor not calibrated							

	Astral 100/150	Stellar 100/150	GA ST-40P*	Lumis 150 ST-A	AirCurve ST-A	Lumis 150 ST	AirCurve ST	Flexo ST30*
	No SpO2 monitoring							
	No FiO2 monitoring							
	Internal battery degraded							
	Low internal battery							
	Circuit fault							
	Using internal battery							
	Battery 1 fault, Battery 2 fault							
	Power fault/No charging							
	PEEP blower failure							
	System Fault alarms							
Environmental								
Operating Temperature	32°F to 104°F (0°C to 40°C)	+32°F (0°C) to + 95°F (35°C)	+5°C to +40°C	+41°F to +95°F (+5°C to +35°C)	+41°F to +95°F (+5°C to +35°C)	+41°F to +95°F (+5°C to +35°C)	+41°F to +95°F (+5°C to +35°C)	+5°C to +35°C
Operating Humidity	5 to 93% non-condensing	10%–95% non-condensing	10 to 93% non-condensing	10 to 95% relative humidity, non-condensing	10 to 95% relative humidity, non-condensing	10 to 95% relative humidity, non-condensing	10 to 95% relative humidity, non-condensing	10%–95% non-condensing
Storage and Transport Temperature	-13°F to 158°F (-25°C to 70°C)	-4°F (-20°C) to +140°F (60°C)	-20°C to +55°C	-4°F to +140°F (-20°C to +60°C)	-4°F to +140°F (-20°C to +60°C)	-4°F to +140°F (-20°C to +60°C)	-4°F to +140°F (-20°C to +60°C)	-20°C to +55°C
Storage and Transport Humidity	5 to 93% non-condensing	10%–95% non-condensing	10 to 93% non-condensing	5 to 95% relative humidity, non-condensing	5 to 95% relative humidity, non-condensing	5 to 95% relative humidity, non-condensing	5 to 95% relative humidity, non-condensing	10%–95% non-condensing

*GA ST and Flexo ST are devices offered by Curative, a subsidiary of ResMed.