ResMed Ventilators and COVID-19 FAQs

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

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Use of Ventilation for Patients with COVID-19

What are points to consider when assessing COVID-19 patients with regard to monitoring?
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

Which COVID-19 patients may require ventilation?
According to the Centers for Disease Control and Prevention (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 Patients presenting with low oxygen saturation and increased respiratory rate will require oxygen supplementation, which can be delivered through a nasal cannula, mask or non-invasive ventilation. Those that fail to respond and subsequently develop hypoxemic respiratory failure or acute respiratory distress syndrome (ARDS) may require mechanical ventilation.2

What is non-invasive ventilation vs. invasive ventilation?
Non-invasive ventilation 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 percentage of COVID-19 patients require ventilation?
Early data from China 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.5 Emerging data from Italy, the epicenter of the COVID-19 outbreak in Europe, showed that 99% of patients with COVID-19 admitted to ICUs required respiratory support, of which 88% received invasive ventilation and 11% received non-invasive ventilation.5

What is the current guidance on using invasive ventilation for critically ill patients?
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,2,6 and a strong preference for early use of invasive ventilation over non-invasive ventilation where appropriate and possible.7 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 PaO₂/FiO₂ is not observed.8
How can non-invasive ventilation be used to provide initial care for patients requiring respiratory support?

In a discussion paper published on 5 March 2020, the U.S National Academy of Medicine indicated that the use of non-invasive ventilation therapy, such as continuous positive airway pressure (CPAP) or bi-level positive airway pressure (bi-level PAP), could be a way to forestall the need for intubation and reduce days on a ventilator. Since then, there has been a growing evidence base on the significance of supplemental oxygen combined with either CPAP and bi-level PAP in the early stages of COVID-19, and in the prevention of further respiratory deterioration in patients with the disease.

What is CPAP vs. bi-level PAP?

CPAP is a non-invasive ventilation mode which provides a constant steady pressure to keep the lungs expanded. Bi-level PAP is a non-invasive ventilation mode that delivers 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. Most CPAP and bi-level PAP devices are compatible with supplementary oxygen, which can be entrained into the circuit or patient interface.

In what scenarios may non-invasive ventilators be useful in patients with confirmed or suspected COVID-19?

Governments and health administrations around the world have now issued guidance documents on the use of non-invasive ventilators, including CPAP and bi-level PAP devices, in patients with confirmed or suspected COVID-19. These guidelines are informed by published evidence, established clinical guidelines and case reports from clinicians in China and Italy, and recommend the use of non-invasive ventilation 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 facilitate extubation and recovery from invasive ventilation. This will also allow an invasive ventilator to be cleaned and serviced and circulated back into use on another patient.
3. To shorten hospital stay, allowing patients who still need some respiratory support and rehabilitation to transition to the home or non-hospital facilities.

Recently published treatment guidelines stress the need for clear escalation criteria or treatment ceilings when starting COVID-19 patients on non-invasive ventilation, in order to ensure patients are moved to invasive ventilation quickly if they are not responding or deteriorate quickly. While non-invasive ventilation is not ideal for the most severe or critical cases of COVID-19, this therapy type is important in supporting triage, assisting with supplementary oxygen delivery in less severe cases and reducing reliance on invasive ICU ventilators.
Adaptations to help bridge ventilator shortages

How are concerns for ventilator scarcity being addressed by the U.S. Food and Drug Administration (FDA)?

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 non-continuous 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.¹⁴

Converting non-invasive ventilation devices for invasive use

Is there available research that supports the use of bi-level PAP in intubated patients?

Given the anticipated shortage of mechanical ventilators in many countries, there have been calls for the use of bi-level PAP in intubated patients on an emergency basis. Evidence presented in a white paper by Syneos Health suggests that Volume Assured Pressure Support (VAPS), a mode available on newer bi-level devices, can in the right setting work as a bridge of support to deliver ventilation via an endotracheal tube until a conventional ventilator becomes available.¹⁵ It should be noted, however, that the evidence available for this is limited and at best, rudimentary. If a bi-level PAP device is to be used in intubated patients for invasive ventilation, at minimum, a rigorous external monitoring system, with all of the functionality and alarms that are required for monitoring critically ill and mechanically ventilated patients, needs to be in place.

How is the American Association of Respiratory Care (AARC) discussing the use of bi-level devices for invasive ventilation?

In the context of addressing the overwhelming demand for ventilators in the current pandemic, the American Association of Respiratory Care (AARC) has posted a video on their website to discuss the use of bi-level devices for invasive ventilation, including suggested circuit setup, humidification method, initial ventilation settings, and best practice for monitoring patients on these repurposed bi-level devices.¹⁶

Does ResMed support the use of bi-level devices for invasive ventilation?

Understanding that this application is likely to happen, ResMed is preparing advice for clinicians to improve patient safety when adapting ResMed bi-level devices for invasive use. While ResMed is neither agreeing nor objecting to this use case, bilevel devices used invasively should not be considered lightly, and should only be resorted to by a physician if there is a dire need to support the patient’s condition.

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Ventilating multiple patients on a single ventilator

What is the AARC’s stance on ventilating multiple patients on a single ventilator?
Noting the potential shortage of ventilators, there have been suggestions on the internet that purport ventilating multiple patients on a single ventilator. A joint statement issued by the AARC strongly advises clinicians against the sharing of ventilators as it could lead to poor outcomes and high mortality rates for all patients cohort.17

What is the U.S. Department of Health and Human Services (HHS), the Federal Emergency Management Agency (FEMA), and the FDA’s stance on co-venting?
The U.S. Department of Health and Human Services (HHS) and the Federal Emergency Management Agency (FEMA) recognize that using one ventilator for two patients is a possible crisis standard-of-care strategy contemplated by many centers.18 In an open letter published on the HHS website, the Assistant Secretary for Health and the U.S. Surgeon General advised that co-venting be considered only as an absolute last resort and for a limited amount of time.18 An assembly of technical documents developed by academic leaders was published along with the letter to provide an example of the type of circuits, setups, and anticipated problems that one might face if this strategy was employed in a crisis care, life-or-death situation.

The official statement from the FDA on co-venting is: “FDA does not object to... placing more than one patient on mechanical ventilation when the number of patients who need invasive mechanical ventilation exceeds the supply of available ventilators and the usual medical standards of care has been changed to crisis care in the interest of preserving life. The FDA’s no objection applies during the duration of the declared COVID–19 emergency.”18 FDA is reviewing ventilators and associated accessories for co-venting as part of their Emergency Use Authorization (EUA).

Protecting healthcare workers to mitigate infection risk

Does using non-invasive ventilation heighten the risk of dispersion of aerosolized virus?
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.19 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.
What is the expert opinion on the importance of mask fit to prevent widespread dispersion of exhaled air?

An experts’ panel determined that non-invasive ventilation systems with a good interface fitting do not create widespread dispersion of exhaled air. Recommendations have been published to support good mask fit to reduce aerosols, including use of full-face masks. A recently published evidence-based comparison of official recommendations for infection control looked at the exhaled air dispersion from different oxygen therapy methods, concluding that CPAP via oronasal (full face) mask and non-invasive ventilation via helmet mask with an inflatable neck cushion are the ventilatory support methods that allow the minimum room air contamination.

What measures can be taken to mitigate risk of droplet dispersion when using non-invasive ventilation?

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 gloves, disposable shirts, goggles, N95 masks/respirators and eye protection, which are now considered standard protective equipment in a COVID-19 ICU. In addition, the use of appropriate and compatible expiratory valve filters for single-limb non-invasive ventilators may also help to reduce the risk of virus spread in the open patient room.

Recommended methods for reducing risk of virus spread include using suitable masks and filters, appropriate PPE and isolation techniques (see Figure 1).
Clinical training for non-invasive ventilation

Are there foreseeable obstacles in 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.

What are the challenges in setting up non-invasive ventilation?
The most challenging part of setting up non-invasive ventilation is training caregivers 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.

What are points to consider when choosing the proper method of ventilation?
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 setting and availability of personal protective equipment for healthcare workers.

ResMed Ventilators and Bi-level Devices – Application and Features

What ventilators and bi-level devices does ResMed manufacture for North America?
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
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should be noted, however, that these are not the same as ventilator equipment typically used in high acuity situations in hospital ICUs.

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 FiO₂. 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\textsubscript{2} with an additional FiO\textsubscript{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.

The Stellar 150 has been authorized for emergency use in healthcare settings in the U.S. to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the FDA’s Emergency Use Authorization (EUA). The EUA for Stellar includes expanded warnings appropriate to critical care, including information on using Stellar 150 with an endotracheal tube. A list of ventilators authorized under the EUA can be found on the FDA website.

**Bi-level devices for non-invasive ventilation**

**Lumis and AirCurve**
The Lumis and AirCurve range of ResMed devices 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\textsubscript{2} is not done by the device. An additional oximetry adapter can be attached to measure SpO\textsubscript{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.

The European Lumis ST variant has been authorized for emergency use in healthcare settings in the U.S. to treat patients during the COVID-19 pandemic, subject to the conditions set forth in the FDA’s EUA. The AirCurve ST device has been authorized for emergency use in the U.S. for expanded indications to include respiratory insufficiency. The EUA for Lumis and AirCurve ST includes expanded warnings appropriate to critical care.

**Reprocessing of ResMed Devices**

**What is the guidance on disinfectant procedures for the novel coronavirus?**
The novel coronavirus that causes the disease COVID-19, SARS-CoV-2, is an enveloped virus. Viruses of this type are susceptible to common disinfection methods. The U.S. Environmental Protection Agency has published a list of disinfectants that meets its criteria for use against SARS-CoV-2. This authorized list of disinfectants is comprised of many commonly used disinfectants and is being actively updated as new information emerges.
How should ResMed devices be cleaned?
Published guidance from health authorities reinforce the need to maintain standard cleaning and disinfection procedures. 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


5. Grasselli G, Zangrillo A, Zanella A et al. Baseline Characteristics and Outcomes of 1591 Patients Infected With SARS-CoV-2 Admitted to ICUs of the Lombardy Region, Italy JAMA. 2020


10. NHS. Guidance for the role and use of non-invasive respiratory support in adult patients with coronavirus (confirmed or suspected) [26 March 2020 Version 2].


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