WHITE PAPER

Intensive care ventilators

A primary option for treatment of COVID-19 patients in the ICU

GETINGE

Summary & recommendations regarding ventilators

Intensive care ventilators are normally found in the hospital Intensive Care Unit. This category of ventilators support lung protective ventilation recommended by several international guidelines and the World Health Organization (WHO). An intensive care ventilator must be considered as the primary option during the monitoring and treatment of COVID-19 patients in the ICU.

Ventilation management functions for COVID-19	Intensive care ventilators	Emergency and transport ventilators	Solutions included in Servo-u ventilator system
Complete set of invasive ventilation modes	✓	✗	PC, PRVC, VC, PS, VS and Bi-Vent/APRV with automatic patient circuit compensation.
Complete set of non-invasive ventilation modes	✓	✗	NIV PC, NIV PS and NIV NAVA with automatic leakage compensation.
High flow oxygen therapy	✓	✗	HFT with optional patient respiratory drive monitoring.
Basic monitoring	✓	✗	Pressure, flow and volume waveforms. Tidal volume/PBW, Driving pressure, Cdyn, $etCO_2$ and 72 hour multi-parameter trending.
Advanced monitoring	✓	✗	Monitoring of patient respiratory drive (Edi, P0.1), patient effort (ΔPes), over-distension (Stress index), Transpulmonary pressure (PLee, PLei and PL drive) and Carbon-dioxide production ($VtCO_2$).
Visual decision support	✓	✗	Servo Compass including VT/PBW, Plateau and Driving pressure for assessment of lung-protective ventilation at a glance.
Lung recruitment and PEEP titration tools	✓	✗	Auto SRM, Auto RM and Open Lung Tool (with breath-by breath trending, recruitability assessment and record keeping).
Weaning and ventilator liberation tools	✓	✗	Automode and NAVA to assure both lung and diaphragm protective ventilation.

Background

Mechanical ventilation is life saving for patients with respiratory failure and is a key component in the fight against the new coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). It can also damage the lungs if the pressures or volumes are not carefully monitored and controlled[1]. Therefore, mechanical ventilation must be carefully applied in a balance between insufficient ventilation and ventilation-induced lung injury (VILI) – which has a strong impact on long-term outcome and disabilities.

Mechanical ventilation can either be invasive, via a tube in the airways, or non-invasive through a face mask or nasal prongs. However, in many cases the patient's condition will require intubation, e.g., with severe lung injury or disease.

Transport & emergency ventilators with COVID-19

When the recently mass-produced ventilators from new entrants to the industry were reviewed, it was found that most of them had a functionality comparable to today's transport or emergency ventilators (See Appendix for classification of ventilators). Transport and emergency ventilators are mainly used for the short term and for patients who are in stable condition. However, these ventilators unfortunately do not fulfill the technical specifications published by WHO – which describe the minimum requirements that invasive and non-invasive ventilators must comply with to ensure quality, safety and effectiveness when used for the management of COVID-19[2].

It is also well-known that these simpler ventilators cannot generate the precise air delivery needed to treat patients with acute respiratory distress syndrome (ARDS)[3,4] and they are lacking decision support tools for lung protective ventilation. In a crisis situation, these ventilators are a better alternative compared to manual ventilation ("bagging"), however they do not take the place of the intensive care ventilators.

ECRI, a worldwide organization that conducts independent medical device evaluations, clearly states that, in the case of shortages of intensive care ventilators during the COVID-19 pandemic, health care providers should select from available ventilation devices in the following suggested order of preference[5]:

1. Intensive care ventilators.
2. Advanced transport, sub-acute, and home care ventilators that have intensive care features and are capable of treating patients with ARDS.
3. Anesthesia machines. See ECRI Alert S0397: [COVID-19]. Anesthesia units can be repurposed to provide ventilatory support for critically ill patients, as long as precautions are taken.
4. Basic transport, emergency, and home care ventilators.

Non-invasive ventilators with COVID-19

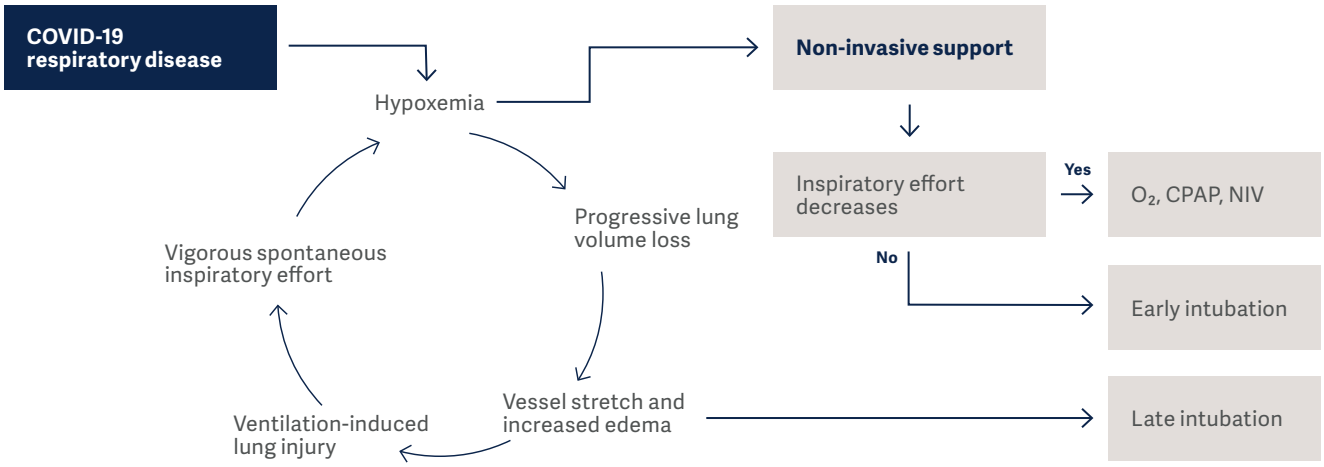
The most common diagnosis[6] in severe COVID-19 patients is severe pneumonia associated with sepsis and ARDS[7]. The latest studies about mechanically-ventilated patients with COVID-19 show that non-invasive ventilators alone will not be sufficient for COVID-19 patients, since these type of ventilation devices are not designed for invasive ventilation of a critically ill, complex patient and most of the COVID-19 patients require invasive ventilation during their ICU stay[8].

Intensive care ventilators with COVID-19

The first step to optimizing mechanical ventilation for patients' conditions and needs in the ICU is to use high performance ventilators[9] such as Getinge Servo-u. The Getinge Servo-u uses built-in sensors, microprocessors, and intelligent software to adequately provide and monitor the target ventilation and automatically adjust the ventilator parameters based upon patients' needs. It is well-known that mechanical ventilation is life saving for patients with respiratory failure, but it can also damage the lungs if the pressures or volumes are not carefully controlled and monitored.

Well-recognized, key opinion leader in mechanical ventilation, Luciano Gattinoni, also focused on the importance of monitoring lung mechanics (e.g., respiratory system compliance, esophageal and transpulmonary pressure) to identify the different phenotypes of COVID-19[10], and individualize the treatment accordingly.

In the figure below, drivers and interrupters of progressive lung injury in COVID-19 infection, are identified.



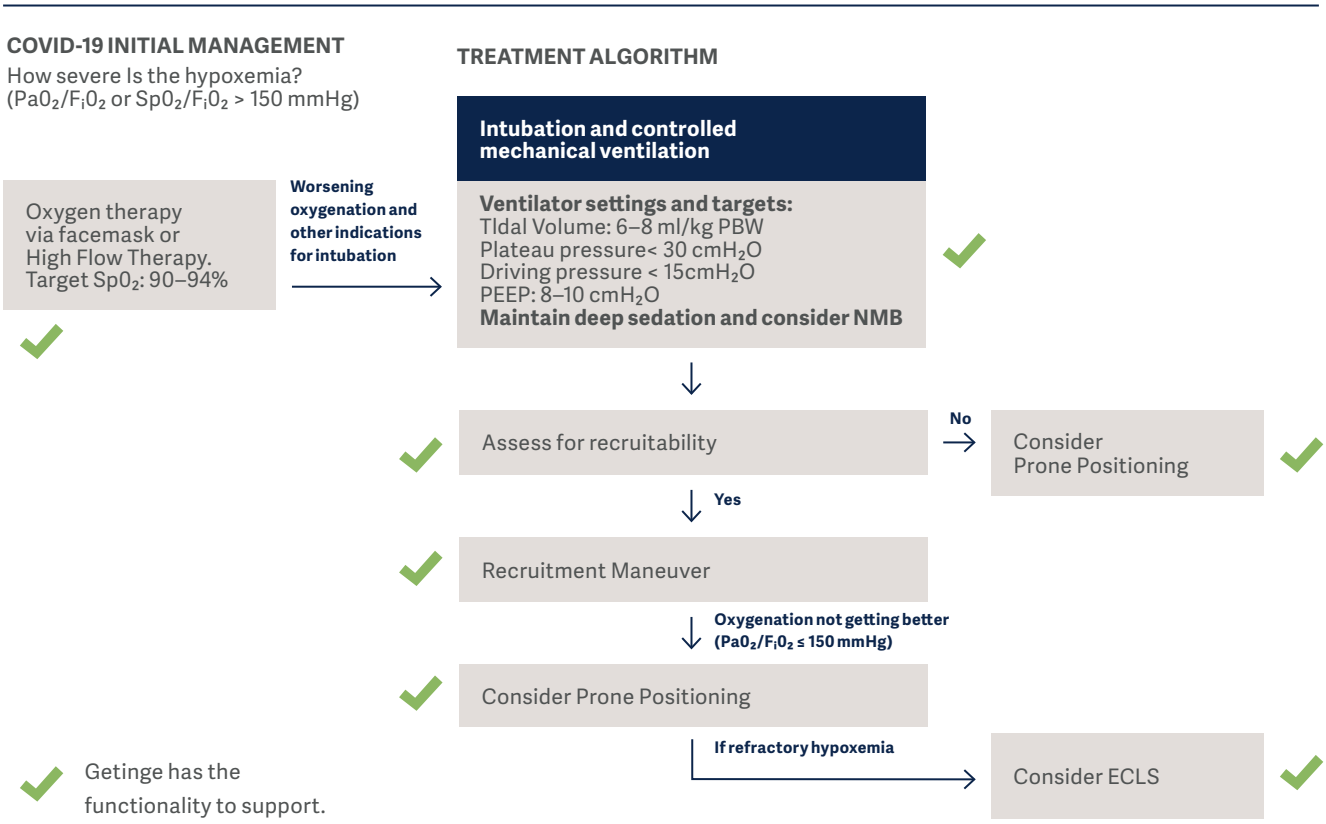
Adapted from Marini JJ, Gattinoni L. Management of COVID-19 respiratory distress. JAMA. doi:10.1001/jama.2020.6825

It is vital to know that the clinical presentation of COVID-19 patients can change over time, and monitoring of esophageal pressure swings is of extreme importance in these patients to detect risk of lung injury[10]. In their interim guidance document[11], WHO also strongly recommends implementing lung protective ventilation strategies for the management of critical COVID-19. Therefore, intensive care ventilators play a critical role during the COVID-19 pandemic since they:

- Can support clinicians in every phase of COVID-19, from non-invasive (NIV) to invasive ventilation modes if the patient's condition worsens. Clinicians do not have to triage the ventilation devices at their disposal, matching the device capabilities with the severity of the patient illness due to ventilator shortages.
- Can generate the precise gas delivery needed to treat patients with ARDS (acute lung injury).
- Are able to adequately provide and monitor the target ventilation, and automatically adjust the ventilatory parameters, based on the patient's needs in order to protect the lungs and prevent lung injury.
- Offer advanced monitoring tools such as P0.1, Edi, ΔPes, PL, and transpulmonary pressure monitoring, which allows the clinician to understand the effects of mechanical ventilation in real time and adjust the ventilatory parameters on the basis of the patient's condition and needs.
- Provide early alerts and alarms to warn clinicians of a potentially harmful situation, or if the patient becomes distressed or even crashes. Please note that the alarm capabilities for emergency, transport, and home care ventilators can be very limited[4].
- Ability to deliver collaborative therapy – offer nebulized drugs through a closed circuit state-of-the art nebulizer system.
- Ability to remove the user interface, keep it outside the room in order to reduce exposure and the use of PPE.
- Have the advanced weaning modalities, which will help the patient liberate from mechanical ventilation faster.

Getinge's Servo ventilators support clinicians with advanced lung protective tools – which helps to identify injurious ventilation and to diagnose clinical problems.

In the flowchart below, the clinical guidelines for COVID-19, which has been developed by representatives of the University of Toronto Interdepartmental Division of Critical Care Medicine, are demonstrated[12]. Using these guidelines we are able to show where Getinge can support or offers a solution.



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Appendix - Classification of ventilators

- **Intensive care ventilators:** Ventilators designed for use in the ICU.
- **Home care ventilators:** Ventilators used for long-term ventilation in the patient's home environment.
- **Sub-acute ventilators:** Ventilators that are desingned for use outside of the ICU, through either non-invasive ventilation, or ventilation of stable patients. This includes step-down wards, general wards, and skilled nursing facilities.
- **Emergency & Transport ventilators:** Ventilators used in emergency situations both within the hospital and externally (mainly for short term).

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