



Gradian Health Systems

## Technical Comparison: WHO COVID-19 Specifications for Invasive Ventilators and the Gradian CCV

This document references the [Priority Medical Devices List for the COVID-19 Response and Associated Technical Specifications: Interim Guidance](#), published on Nov. 19, 2020.

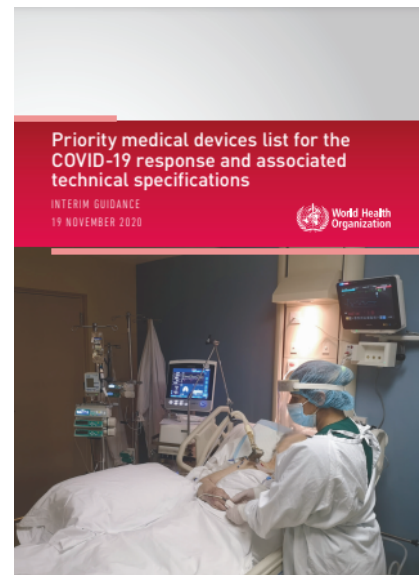
Many of Gradian Health Systems' customers and partners have inquired about how the Gradian Comprehensive Care Ventilator (Gradian CCV) compares with the WHO's specifications for ventilators. This brief provides a summary of how the Gradian CCV compares with WHO specifications for invasive intensive care, transport, and sub-acute care ventilators. A more detailed analysis is available by contacting [info@gradianhealth.org](mailto:info@gradianhealth.org). This brief has been developed by Gradian Health Systems and is not an indication of endorsement by the WHO.

**COVID-19 AND MECHANICAL VENTILATION:** The WHO estimates that 5 percent of all COVID-19 patients will need mechanical ventilation for breathing support. Mechanical ventilation may be invasive—where a tube is inserted into the patient's airway—or non-invasive—where air and oxygen are administered through an interface like a facial or nasal mask.

**WHO VENTILATOR GUIDANCE:** To guide governments and other entities on the procurement of ventilators that meet clinical, infrastructure, and sustainability needs, the WHO has developed and updated the minimum technical specifications for invasive and non-invasive ventilators on their website since the start of the pandemic. The latest version of these specifications were published in the [Priority Medical Devices List for the COVID-19 Response and Associated Technical Specifications: Interim Guidance](#) on Nov. 19, 2020 and include specifications for intensive care, transport, and sub-acute care ventilators.

**THE GRADIAN CCV:** The [Gradian CCV](#) is an innovative, easy-to-use mechanical ventilator that provides respiratory support across the full critical care continuum, via both invasive and non-invasive ventilation. It is built to ventilate critically-ill adult and pediatric (>5kg), and to operate safely despite infrastructure issues such as unstable access to oxygen and power, with up to 21 hours of battery power and the ability to use most oxygen sources, including low-flow oxygen. Each CCV comes standard with installation, technical orientation, multi-day hands-on clinical user training, and a three-year service and parts warranty carried out by local Gradian-certified technicians.

**OVERALL COMPARISON:** Our comparison finds that the Gradian CCV fulfills or exceeds most of the essential specifications across the WHO's three invasive ventilator categories. The Gradian CCV combines the key aspects of specialized ICU ventilators, transport ventilators, and sub-acute care ventilators into one versatile and portable device, enabling use cases that have traditionally required multiple pieces of equipment. The areas where the Gradian CCV's standard package does not meet WHO specifications can be addressed by system upgrades upon request or have been intentionally designed to avoid increased up-front and operating costs, risks to machine durability, or impacts on usability.



## Comparisons by Ventilator Type

### CCV vs. WHO Invasive Ventilators - Intensive Care Unit

According to the WHO, invasive ICU ventilators are:

“designed to provide temporary ventilatory and respiratory assistance to adult and paediatric intensive care patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. The equipment is usually connected to a 50 psi (4 bar/345 kPa) gas supply. Some ventilators have an in-built air compressor and still need an oxygen source. The mixed, heated and humidified gas is delivered to the patient using a double-limb breathing circuit (one for inspiratory and one for expiratory phases). Different parameters can be controlled by the user and displayed on a screen (e.g. fraction of inspired oxygen [FiO<sub>2</sub>], trigger, respiratory rate [RR], positive end-expiratory pressure [PEEP], control modes).”

This definition and associated specifications underscore the importance of versatility and infrastructure-independence. The CCV meets the preferred specifications with its in-built medical air compressor, internal and external backup batteries, and ability to use low-flow oxygen sources. The CCV also includes active humidification and a range of invasive and non-invasive ventilation modes that are important for longer-term care of the critically-ill patients in an ICU setting. While many ICU ventilators utilize touchscreens, the CCV is designed with a much more robust button display which is optimized for readability, with every setting and parameter visible at all times. However, this interface type does not allow for the graphical depictions of certain ventilation parameters relative to time (called waveforms) or each other (called loops), as indicated by the WHO specifications.

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### CCV vs. WHO Invasive Ventilators - Transport

According to the WHO, invasive transport ventilators are:

“designed to provide temporary ventilatory assistance with a full degree of portability (weight and manageability). Battery life is an important consideration - the equipment should have the ability to operate on an external battery for 4 hours. It should also minimize oxygen consumption and operate without any compressed gas source (e.g. by a turbine). It should work when connected to a 35 psi (2.4 bar) or a low-flow oxygen supply. Simplicity of use and low cost are advantages to consider ahead of advanced ventilatory features, including invasive ventilation modes and capabilities.”

With its extended battery life, built-in portability features, compact size, and exceptional robustness, the CCV is an excellent solution for transport ventilation within or between facilities. To allow for easy transition from transport to bedside care, the CCV comes with bed hooks and a shoulder strap as well as a mobile workstation with active humidifier and oxygen reservoir, reducing the need for multiple unit-specialized ventilators and avoiding any interruptions to patient care.

## CCV vs. WHO Invasive Ventilators - Sub-Acute Care

According to the WHO, invasive sub-acute care ventilators are:

“designed to provide mainly non-invasive ventilation, but in case of an emergency, it can also provide temporary invasive ventilation to patients who cannot breathe on their own or who require assistance to maintain adequate ventilation. The equipment should be capable of operating on an external battery for an extended period and minimize oxygen consumption. It should work when connected to a 35 psi (2.4 bar) or a low-flow oxygen supply. Simplicity of use and low cost are advantages to consider ahead of advanced ventilatory features.”

The CCV's versatility and ease of use make it well-suited to support patients at any point on the continuum of treatment and recovery. This includes the sub-acute level, in care environments such as high-dependency units, where the CCV's capabilities and ventilation modes exceed what is generally required by this level of care, but provide peace of mind and the ability to transition seamlessly to other care contexts. The CCV's in-built compressor to entrain room air when needed and its long battery life enable it to be used in any setting for temporary respiratory support, inter-hospital transport, or longer-term care as needed.

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## CCV Service Warranty and Training Package

All Gradian products come with installation, product and clinical refresher training, and a three-year service warranty carried out by Gradian-certified local technicians. Our robust warranty covers annual maintenance, on-demand repairs, spare parts, and 24/7 remote support. In addition, our trainings help healthcare providers operate Gradian equipment with confidence and serve as a platform to strengthen existing clinical skills across the anesthesia and critical care spectrum. Trainings can be taken in-person (at a trainee's facility or in a centralized location with other trainees), remotely through instructor-led online trainings, or independently through our self-guided offerings at our [Gradian Training Resource Center](#).

For a more detailed analysis or to request a quote, contact Gradian Health Systems:

[www.gradianhealth.org/gradianccv/](http://www.gradianhealth.org/gradianccv/)  
[info@gradianhealth.org](mailto:info@gradianhealth.org)

## Gradian CCV & WHO Specifications for Invasive Ventilators: Comparison of Key Specifications

Specification	Gradian CCV	WHO Intensive Care	WHO Transport	WHO Sub-acute Care
Battery life	21 hours total	1 hour	4 hours	4 hours
Min. O <sub>2</sub> source pressure	7+ psi	20+ psi preferred	Low-flow preferred	20+ psi preferred
In-built air compressor	Yes	Preferred	Yes	Yes
Oxygen conserve mode	Yes	No	Preferred	Preferred
Graphical displays	None (only numerical)	Loops & waveforms	Waveforms	Waveforms
Water & dust protection	IP22	IP21	IP21	IP21
Portability features	Cart, handle, hooks, strap	Cart	None	Cart (optional)
Tidal volume	40-2000 mL	20-1500 mL	20-1000 mL preferred	50-1000 mL preferred
Ventilation modes	Assist control (Pressure & Volume), SIMV (Pressure & Volume) with Pressure support, CPAP, BiPAP.	Pressure control, Volume control, Pressure support, CPAP or BiPAP.  Preferred: SIMV, PRVC.	Pressure control, Volume control, CPAP or BiPAP.  Preferred: SIMV, PRVC, Pressure support.	Pressure or Volume control, Pressure support, NIV.  Preferred: SIMV, PRVC.
Controlled parameters	%O <sub>2</sub> (21% - 100%), Tidal volume, Inspiratory pressure, Insp. time, RR, PEEP, Pressure support, Peak pressure limit, Trigger sensitivity.	FiO <sub>2</sub> (21% - 100%), Tidal volume, Inspiratory pressure, I:E ratio, RR, PEEP, Peak pressure limit.	FiO <sub>2</sub> (40% - 97%), Tidal volume, Inspiratory pressure, I:E ratio, RR.	FiO <sub>2</sub> (21% - 100%), Tidal volume, Inspiratory pressure, I:E ratio, RR, PEEP.
Monitored parameters	Airway pressure (peak and PEEP), Tidal volume (delivered), I:E ratio (calculated), RR (spontaneous and mechanical).	FiO <sub>2</sub> , Airway pressures (peak, plateau, mean, and PEEP), Tidal volume (exp. and insp. preferred), Minute volume (insp. and exp.), I:E ratio, RR (spont. and mechanical).	FiO <sub>2</sub> , Airway pressures (peak and PEEP), Tidal volume (exp.), Minute volume (exp.), I:E ratio, Insp. time, RR, Spont. ventilation, Leak, Air and/or oxygen pressure, Gas available.	FiO <sub>2</sub> , Airway pressures (peak, mean, PEEP), Tidal volume (exp.), Minute volume (exp.), I:E ratio, Insp. and exp. times, RR, Spont. ventilation, Leak, Air and oxygen pressure, Spont. minute volume (preferred).
Active humidifier	Yes	Yes	No	Yes
EtCO <sub>2</sub>	Optional	Yes	Preferred	Preferred
Breathing circuits	Single-limb	Double-limb	Double-limb	Single- & double-limb
Warranty	3 years, parts & service	2 years	2 years	2 years