Gradian Health Systems Product Note: COVID-19

April 28, 2020



We recognize the enormous pressure the COVID-19 pandemic places on health systems and healthcare providers as they work to provide the best care. Both the <u>Gradian CCV</u> (Comprehensive Care Ventilator) and <u>Gradian UAM</u> (Universal Anaesthesia Machine) offer features pertinent to COVID-19 (and critical care) patient management, particularly in three key areas: 1) mechanical ventilation, 2) oxygen therapy, and 3) patient monitoring.

Gradian CCV

- **Mechanical Ventilation** | The CCV is a fully automatic, standalone ventilator, that is electrically and pneumatically driven with up to 21 hours of rechargeable battery backup.
 - **Modes:** The CCV has **control and support modes**. These include Pressure AC, Volume AC, Pressure SIMV, Volume SIMV, CPAP, and BiPAP (using CPAP mode with Pressure Support).
 - **Oxygen Sources:** The CCV works with high- and low-flow oxygen sources, including pipeline, cylinder, and concentrators. It also has an internal air compressor enabling use of room air to mix with medical grade oxygen, or deliver ventilation if pressurized gas is unavailable.
 - Fraction of Inspired Oxygen (FiO₂): FiO₂ on the CCV can be set in 1% increments between 21% and 100%. However, this is a setting, not a measure. This means the system does not measure the purity of oxygen delivered from an external source.
 - Invasive and Non-invasive: The CCV can be used for both invasive and non-invasive forms of mechanical ventilation.
- Oxygen Therapy | The CCV will only deliver oxygen when connected to an oxygen source.
 - Non-invasive: When used for non-invasive oxygen therapy, the CCV should be used with a CPAP mask to ensure a secure fit on the patient's face and reduced provider risk of airborne contamination.
- **Patient Monitoring** | The CCV comes with a **handheld pulse oximeter**, to measure a patient's oxygen saturation (SpO2).

Gradian UAM

• **Mechanical Ventilation |** The UAM Ventilator (UAMV) is a fully automatic, integrated ventilator, that is electrically driven with 6 hours of rechargeable battery backup. While the UAMV was designed for mechanical ventilation needs during surgery and anesthesia, we recognize some healthcare providers encounter situations where the UAMV is the only mechanical ventilator available to treat critically ill patients. While using the UAMV for intensive care use is considered off-label, the notes below are intended to help healthcare providers assess the utilization of the UAMV in intensive care scenarios if other sources are unavailable.

- Use with the UAM: The UAMV must remain connected to the UAM in order to function. When used strictly for mechanical ventilation without the delivery of anesthesia, the vaporizer top dial should be moved to zero to prevent the delivery of anesthesia gasses. After closing the vaporizer, turn on the UAMV and select the desired mode.
- Modes: The UAMV only has control modes and lacks support modes. It does not have CPAP, BiPAP, or pressure support ventilation. The UAMV cannot recognize a patient's spontaneous breathing.
- Positive End-expiratory Pressure (PEEP): PEEP on the UAMV is a measure, not a setting. This
 means the ventilator cannot be used to set or control pressure in the lungs above atmospheric
 pressure that exists at the end of expiration.
- Oxygen Therapy | The UAM has an inbuilt, 10 liters per minutes (LPM) oxygen concentrator that can be used to deliver up to 95% oxygen. When used strictly for oxygen therapy without the delivery of anesthesia, the vaporizer top dial should be moved to zero to prevent the delivery of anesthesia gasses. After closing the vaporizer, turn on the oxygen concentrator and set the flow meter to the desired LPM.
- **Patient Monitoring** | The UAM comes with a **patient monitor**, to measure a patient's 1) blood pressure (BP), 2) temperature, 3) SpO2, and 4) electrocardiogram (ECG).

Gradian recognizes customers' autonomy in making healthcare decisions and encourages looking to guidance from international, regional, and national professional societies and technical working groups to further guide clinical practice decisions. In all cases, we defer to the assessment, judgment, and discretion of the healthcare professional in charge to determine the best clinical treatment for the patient given the specific context.

We welcome any inquiries and feedback regarding the above, and can be reached by email at **COVID19response@gradianhealth.org** or phone/WhatsApp at **+254-794-764-416.**