**Gradian** Health Systems®

Gradian CCV
User Guide

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## HOW TO GET HELP

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## GENERAL DESCRIPTION OF THE GRADIAN CCV

The Gradian CCV is a *comprehensive care ventilator* that provides reliable mechanical ventilation for critically-ill patients in a hospital or during transport. Its versatile features allow for use in nearly all healthcare environments: it can operate for up to 21 hours without electricity; it connects to multiple oxygen sources; and it automatically compresses and delivers room air as needed. It also comes with a stable rolling cart that easily detaches for bedside or transport use. The Gradian CCV is CE-certified and has been cleared by the U.S. FDA.

**WARNING:** The CCV should not be used on children weighing 5 kg (11 lbs) or less.

**WARNING:** This device should only be operated by qualified personnel under approved medical supervision.

**WARNING:** Use only as directed. Improper usage or unauthorized modification of this product may result in user or patient injury or death.

**WARNING:** Always have an alternate means of ventilation available when using the CCV in case of a mechanical or system problem.

## DEFINITION OF STATEMENTS

The following terminology and statements are important for the operator to understand before consulting the user's guide for the CCV:

**WARNING:** Indicate a possibility of injury to the operator or others.

**CAUTION:** Indicate a possibility of damage to the equipment.

**NOTE: Indicate points of interest for proper operation of the machine.**

# SPECIFICATIONS

## Physical and Electrical
- Size: 34 cm (W) x 13 cm (D) x 35 cm (H), 8.5 kg (without stand)
- ABS casing, ingress protection to IP22
- Reusable silicone breathing circuit (autoclavable up to 134$^o$C)
- Operable between -18$^o$C – 50$^o$C, 5 – 95% RH, non-condensing
- Shock-tested to 100 G-Force, vibration-tested to IEC 60068-2-6
- Internal, sealed lead-acid battery: 7 hour run time
- External, sealed lead-acid battery: 14 hour run time (21 hours total)
- Mains power supply: 110 – 240 VAC, 50/60 Hz, max 1A
- Nurse call or remote alarm system connection, ¼" phone jack

## Gas Supply
- $O_2$ and Air DISS connections for high-pressure cylinders or pipelines
- Barb connections for backup and low-pressure $O_2$ sources (concentrator)
- Internal compressor to entrain and deliver room air

## Ventilation Modes
- 2 programmable Quick Start Presets
- 3 programmable Custom Modes
- (Pressure or Volume) Assist Control
- (Pressure or Volume) SIMV
- CPAP, Bi-PAP (can be programmed in custom modes)

## Control/Settings
- Flow: 5 – 60 LPM ($\geq$ 80 LPM with Pressure Support, CPAP, & demand flows)
- Tidal volume: 40 – 2,000 mL
- Respiratory rate: 0, or 5 – 60 breaths per minute
- Inspiratory time: 0.5 – 2.0 sec
- PEEP/CPAP: 0 – 25 cmH$_2$O
- Pressure Support: 0 – 25 cmH$_2$O
- Breath trigger (sensitivity): -5 to -1 cmH$_2$O
- FiO$_2$: can be set from 21% – 100%

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**NOTE: The FiO$_2$ is not measured, but calculated assuming that the O$_2$ source is 100% pure. If using a concentrator or other source that is less than 100% pure, the delivered FiO$_2$ will be lower than displayed.**

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## Monitoring & Alarms
- Measured parameters: Airway pressure, delivered tidal volume, spontaneous breath count, internal battery level, external battery level
- Calculated parameters: Flow rate, FiO$_2$, I:E ratio
- Alarms for high and low airway pressure, apnea, low air/O$_2$ source, critical battery level, and device malfunction
- Silence/Reset: Silences non-critical alarms for 110 sec

**CAUTION:** To ensure that the CCV performs reliably to specifications, the maintenance schedule detailed in PREVENTATIVE MAINTENANCE must be followed.

# COMPONENTS OF THE CCV

**Portability Features**
Bed hooks, handle, and shoulder strap for convenient use and transportation in any setting

**Ventilator**
Fully automatic, pneumatically-driven ventilator with 7-hour rechargeable internal battery backup

**Internal Compressor**
Capable of delivering room air when other gas sources are not available

**Breathing Circuit**
Durable, reusable, single-limb silicone breathing circuit

**Reservoir**
Allows for use with an oxygen concentrator or flowmeter if pipeline or larger cylinders are not available

**External Battery**
Hot-swappable ruggedized battery providing an additional 14 hours of operating time, for a total of up to 21 hours

**Stand and Base**
Sturdy aluminum frame with a convenient handle and basket, mounted on a no-tip base with 5 durable casters (2 locking)

Power switch

Quick Start
modes

User interface

Carrying handle

Bed hooks

Mounting plate

Internal battery

DISS O$_2$ inlet

High-pressure DISS air inlet

Low-flow O$_2$ inlet

External battery connection

Air entrainment inlet and filter

Casing pressure relief

Fuses

Mains charging port (110-240 VAC)

Exhalation valve port

Patient circuit port

Airway pressure port

Alarm system port

Warranty sticker

Serial number
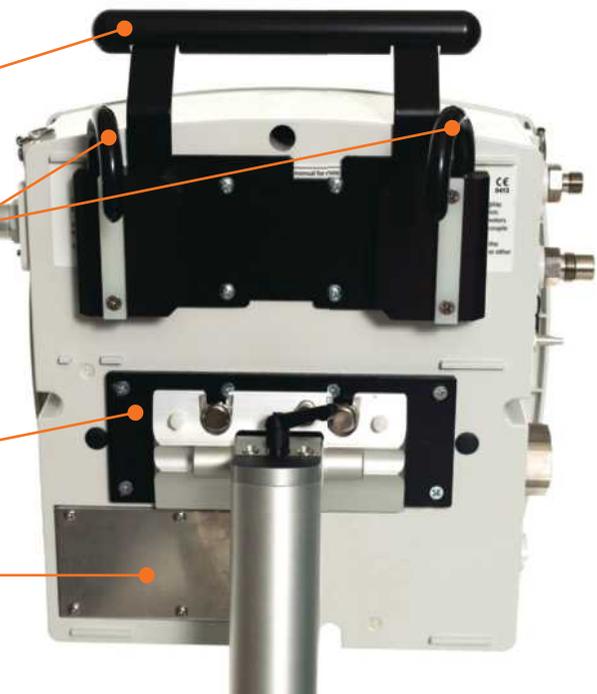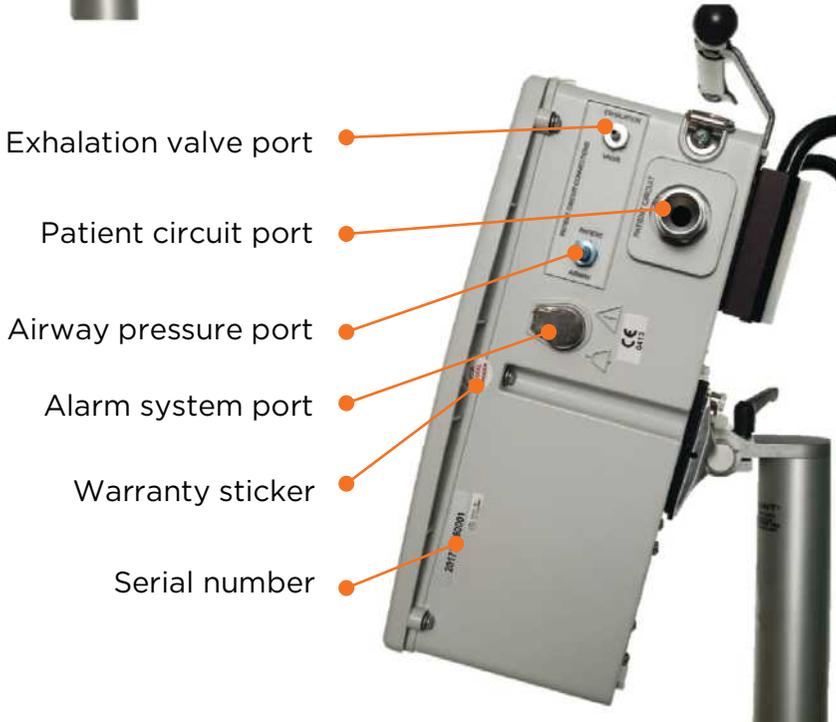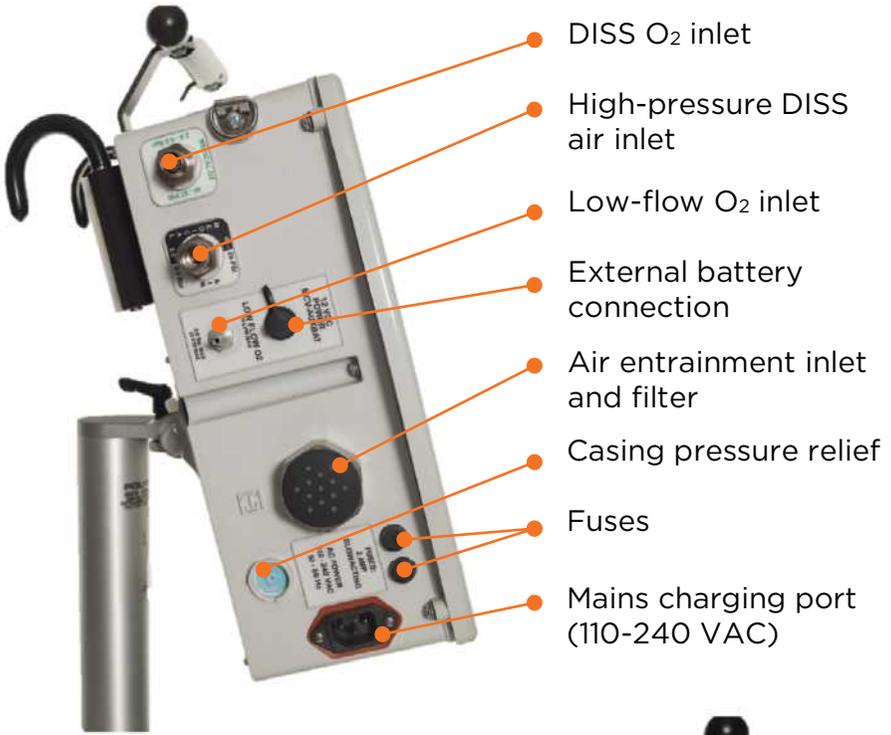
# CHECKLISTS

## PRIOR TO EVERY NEW PATIENT
1. Attach a clean breathing circuit and fresh HME to the CCV. Confirm that the valve is assembled correctly.
2. Connect an oxygen source to the CCV's O2 DISS port (high flow), reservoir barb (low flow), or Low Pressure barb (for transport).
3. Check that the gas source is functioning and that a secondary source is available nearby.
4. Turn the CCV on and program the settings appropriate for the patient.
5. Using a watch, count the number of breaths delivered in 1 minute. Confirm that:
    a. The correct number of breaths (the set BPM) have been delivered, $\pm 1$.
    b. The Low Airway Pressure alarm is activated.
6. Occlude the ventilator outlet and confirm that the High Airway Pressure alarm activates and the PIP is nearly the same as the alarm setting.
7. If using a high flow O2 source, set %O2 = 100. If using a low flow O2 source like a concentrator, engage O2 Conserve Mode and increase the %O2 until the red light labeled "% O2 Setting cannot be achieved in O2 Conserve Mode" comes on, then decrease the %O2 by one (1) so that the light goes off again.
8. Repeat steps 5-7.
9. Turn the oxygen source off and wait for the pressure to drop.
10. Confirm that the Low O2 Source alarm light and the main alarm light are on, and that the Low O2 Source alarm sounds.
11. Unplug the CCV from mains power and confirm that the internal battery is sufficiently charged.
12. Press and hold the charge indicator on the external battery and confirm that it is sufficiently charged, and that it is not connected to the CCV.
13. Plug the CCV extension cable back into mains.
14. Turn the O2 source back on.
15. Confirm that the programmed settings are appropriate for the patient and ensure that no alarms are active.

## FOLLOWING EVERY PATIENT
1. Turn off the Gradian CCV.
2. Discard the used HME filter.
3. Ensure that the oxygen hose is attached to the O2 DISS port, and any unused ports are capped.
4. Wipe the unit down with a damp rag containing a mild cleaning solution to remove any residue from the surface.
5. Wipe the unit with a cold disinfecting solution to kill bacteria. Approved cleaning solutions are: Isopropyl Alcohol (70% IPA), Cetylcide (30ml Cetylcide to 3.8 liters H2O), or Bleach (10% Bleach in H2O).
6. Wipe the unit with water to remove any film left by the cold disinfecting solution. Ensure the unit is dry before putting it away.
7. Ensure that the CCV and external battery are both plugged into the CCV extension cable and are charging, and that the external battery is not connected to the CCV.
8. Ensure that gas supplies are turned off.
9. Sterilize the breathing circuit.

## AT EVERY CHANGE OF SHIFT
1. Check the charge level of the internal and external batteries.
2. Ensure that the CCV and external battery are plugged in and charging, and that the external battery is not connected to the CCV.
3. Inspect the exhalation valve to ensure it is assembled and working properly.

# USING THE CCV

## COMPONENTS OF THE CONTROL PANEL

The control panel of the CCV is divided into eight sections. Moving clockwise from the top left:

- **Power** switch and **Quick Start** modes for adults and children to begin ventilation easily with pre-programmed settings
- **Ventilation Settings** where the physician will enter the key respiratory parameters for the patient
- **Alarm Settings** for the pressure limits at which the high and low airway pressure alarms will activate
- **Ventilation Modes**, where the physician will choose between delivery methods
- **Additional Settings** for delivery of manual breaths, oxygen conservation when using a concentrator or emergency cylinder, and keys to change any of the settings on the CCV
- **Battery Parameters** including level and status, confirmation of mains power supply, and connection to external battery
- **Ventilator Alarms** for apnea, out of range airway pressure, circuit leak, and failures in oxygen source or system faults
- **Calculated** and **Measured Parameters** that reflect important information about the ventilation being delivered to the patient
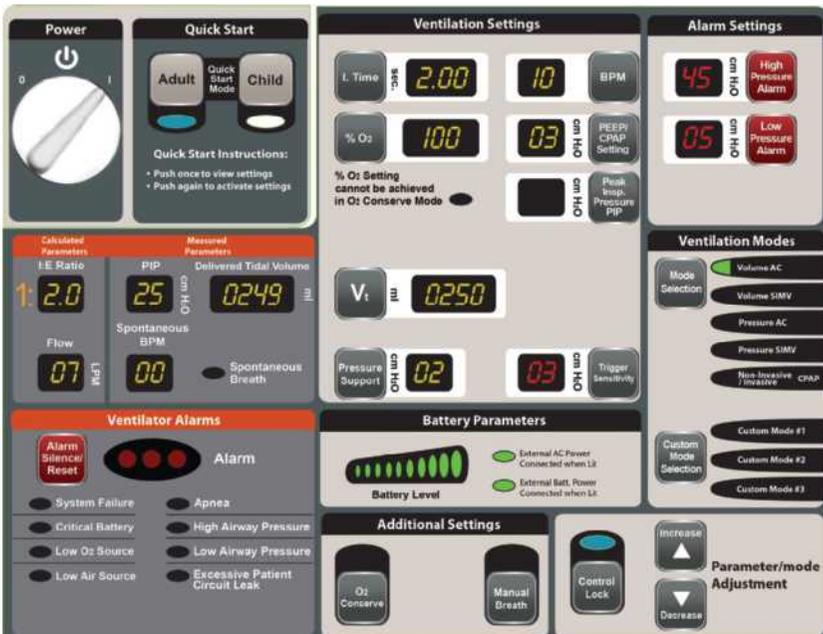
## Startup Panel

The **Power** switch starts the CCV, which will automatically default to the last settings used. The CCV will start ventilation at those prior settings if no other changes are made.

The **Adult** or **Child** Quick Start buttons bring up pre-programmed ventilation modes. Push one of these buttons twice to begin ventilation with the set parameters. The physician may use the factory default or program their own. See **REVISING PROGRAMMABLE MODES.**
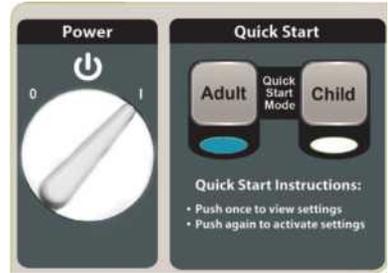
**WARNING:** The CCV should not be used on children weighing 5 kg (11 lbs) or less.

## Ventilation Settings

**I. Time** stands for *inspiratory time* and may be set between 0.5 and 2.0 seconds.

**BPM** stands for *breaths per minute* and allows you to set the respiratory rate between 5 and 60 BPM. When a patient is fully spontaneously breathing, the CCV may be used to monitor the patient with the BPM set to 0. This allows the physician to read measured values, and will trigger the Apnea Ventilation Mode if the patient stops breathing (see Automatic Apnea Mode).
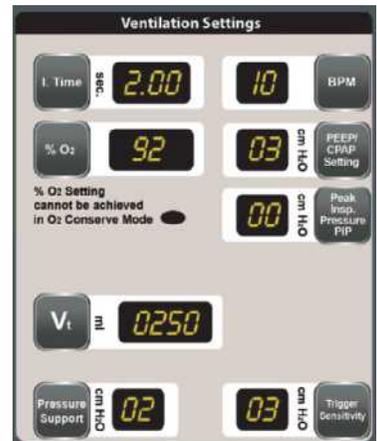
**%O$_2$** is a **setting, not a measured value**, and may be programmed to deliver between 21% (room air) and 100% oxygen. The purpose of the %O$_2$ setting is to mix gas from the oxygen source with air from the compressed air fitting or from room air. The %O$_2$ setting tells the CCV what mix of oxygen and air to use. **It does not tell what the FiO$_2$ is, just what the CCV is using as a target value.**

**NOTE: The CCV assumes the oxygen is pure, i.e. 100% oxygen.** If your facility uses oxygen from an oxygen concentrator plant, the purity is in the range of 92 – 95% if the plant is running optimally. A biomedical technician should check the oxygen level of each cylinder. If the

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available compressed source is known to be less than 99% oxygen, set the $FiO_2$ higher than usual.

For instructions for use of an external oxygen concentrator, see **USING THE CCV WITH A CONCENTRATOR OR FLOWMETER.**

**PEEP/CPAP Setting** *(Positive End Expiratory Pressure)* will hold a set pressure at the end of exhalation to keep the lungs partially inflated and help the exchange of oxygen through the alveoli. The PEEP setting may be used in any mode and set from 0 to 25 cmH2O. This setting also controls the pressure level for CPAP (Continuous Positive Airway Pressure), as described in Continuous Positive Airway Pressure (CPAP)

**PIP** *(Peak Inspiratory Pressure)* In pressure modes PIP may be set from 15 to 55 $cmH_2O$. Measured PIP is reported on the Measured Parameters panel in all modes.

**Vt** is the setting for *tidal volume* and ranges from 40 mL to 2000 mL. In volume modes this is the single breath tidal volume target.

**NOTE: The allowable ranges for I. Time, BPM, and Vt settings are linked together so as not to exceed the CCV's maximum flow rate of 60 LPM in volume modes. For example, if Vt is set at 1000 mL, I. Time will be limited to 1.00 second or more (as 1 L divided by 1/60 minutes is 60 LPM).**

**If the maximum flow has been reached, any attempt to increase the tidal volume will have no effect, and the Vt will remain at its limit. If the maximum flow has been reached and the I. Time is decreased, the Vt will automatically decrease as well to maintain the maximum flow. For example, if the Vt is 1000 mL and the I. Time is 1.00 second, decreasing the I. Time to 0.75 seconds will automatically decrease the Vt to 750 mL. See the table below for details.**

| I. Time (sec) | BPM Range | Vt Range (mL) |
|---|---|---|
| 0.50 | 0, 5 – 60 | 40 – 500 |
| 0.75 | 0, 5 – 45 | 60 – 750 |
| 1.00 | 0, 5 – 30 | 80 - 1000 |
| 1.25 | 0, 5 – 20 | 100 – 1250 |
| 1.50 | 0, 5 – 20 | 125 – 1500 |
| 1.75 | 0, 5 – 20 | 150 – 1750 |
| 2.00 | 0, 5 – 20 | 175 – 2000 |

**Pressure Support** may be added to Volume SIMV, Pressure SIMV, and CPAP modes or used on its own by selecting an SIMV mode and changing the BPM to 0. The ventilator will deliver flow to elevate the airway pressure to the Pressure Support target and maintain it at the target level until the flow required to do so falls below 2 liters per minute. Pressure support ranges from 0 to 25 cmH$_2$O.

When used with CPAP, the Pressure Support feature turns CPAP into a BiPAP ventilation mode. As an example, setting Pressure Support to 15 and CPAP to 10 results in an airway pressure of 15 cmH$_2$O during inhalation and 10 cmH$_2$O during exhalation.

**Trigger Sensitivity** defines the level of effort needed to trigger an assisted breath, or register as a spontaneous breath. It ranges from 1 to 5 cmH$_2$O.

## Alarm Settings



**High Pressure Alarm** sets the maximum allowable airway pressure and is adjustable from 15 to 55 cmH$_2$O. When exceeded, flow halts and the CCV provides both audible and visual alarms.

**Low Pressure Alarm** sets the minimum allowable airway pressure and is adjustable from 5 to 20 cmH$_2$O. It will also trigger audible and visual alarms when pressure falls below the set limit.

## Ventilation Modes



### Volume Control with Assist (Volume AC)
In volume control the ventilator delivers the set tidal volume programmed by the clinician in a cycle determined by the settings for inspiratory time and respiration rate. The flow rate is constant during inspiration and calculated to deliver the set tidal volume during the inspiratory time.
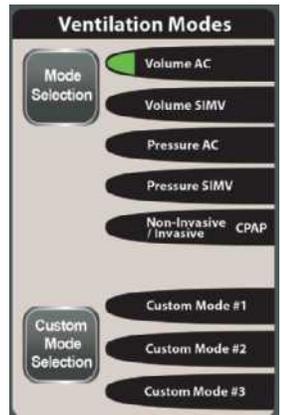
Assist Control means that the ventilator will deliver at minimum the number of breaths entered by the clinician on the BPM setting. If the ventilator detects an effort by the patient to take a breath it will initiate a breath to assist the patient in that spontaneous respiration. The tidal volume will be the same for both patient- and ventilator-triggered breaths.

### Pressure Control with Assist (Pressure AC)
In Pressure Control the ventilator delivers flow to the patient until a set pulmonary pressure is achieved. The flow rate is variable and slows down as the pressure target is approached so that it is not exceeded. The ventilator calculates flow to achieve the target pressure during the predetermined inspiratory time.

Similar to Volume Assist, in this mode the ventilator will react to patient-triggered breathing and ensure that the same pressure is reached for both patient- and ventilator-triggered breaths.

### Volume Synchronized Intermittent Mandatory Ventilation (SIMV)
### Pressure Synchronized Intermittent Mandatory Ventilation (SIMV)
Like Assist Controlled ventilation, SIMV delivers a specific, preset number of breaths to the patient. In SIMV, if a patient initiates a breath in between regularly scheduled machine breaths, the ventilator will not deliver a preset tidal volume or airway pressure. Rather, it allows the patient to draw in as much air as they are able without assistance. The ventilator recognizes this patient-triggered breath and adjusts the timing of the mechanically-delivered breaths, thus synchronizing the pre-set breathing schedule to the variable patient-initiated breaths.

Otherwise, the volume and pressure ventilation modes with SIMV are similar to those with assist.

In addition to the regular settings, the clinician can also use Pressure Support for either volume or pressure SIMV.  When activated, pressure support recognizes the intermittent, patient-triggered breaths and ensures the clinician-defined airway pressure is reached.

### Continuous Positive Airway Pressure (CPAP)
In CPAP the ventilator provides a set level of pressure throughout the respiration cycle.  It will dip for a fraction of a second at the beginning of inspiration and increase slightly for a fraction of a second at the beginning of expiration.  It is used for patients who are spontaneously breathing and keeps the airways continuously open during respiration.

### Bilevel Positive Airway Pressure (BiPAP)
BiPAP is a variant of CPAP that sets a different pressure for inspiration and expiration. It is achieved on the CCV by choosing the CPAP ventilation mode and then setting the Pressure Support option to a higher level. As an example, setting Pressure Support to 15 and CPAP to 10 results in an airway pressure of 15 $cmH_2O$ during inhalation and 10 $cmH_2O$ during exhalation.

## Custom Modes

The CCV includes 3 custom modes which can be programmed by a clinician for quick recall in frequently-encountered scenarios. For information on using and altering these modes, see REVISING PROGRAMMABLE MODES.

## Seamless Transition Between Volume and Pressure Modes

If the clinician changes from a volume-regulated to a pressure-regulated mode of ventilation, the CCV remembers key settings and seamlessly transfers them to the new mode. This provides safety in the transition. When moving from a pressure-regulated mode to a volume-regulated mode, the prior settings for BPM and Inspiratory Time remain the same and the Tidal Volume that has been measured for the last breath in a pressure mode becomes the initial Tidal Volume for the new volume mode.  Likewise, when changing from a volume mode to a pressure mode, the measured Peak Inspiratory Pressure from the most recent breath in the volume mode will become the PIP setting for the first breath in the pressure mode.

## Automatic Apnea Mode

If apnea is detected, the ventilator will operate in Apnea Ventilation Mode. The Apnea ventilation settings automatically default to:

> Ventilation Mode = Pressure AC
> Peak Inspiratory Pressure = 20 cmH$_2$O
> BPM = 10
> Inspiratory Time = 2.00 seconds
> PEEP = 3 cmH$_2$O

The ventilator display will show the apnea settings. The ventilator will revert to the previous settings if the Silence/Reset button is pushed twice or if the patient initiates 2 consecutive spontaneous breaths. One may exit Apnea Ventilation Mode and use other settings by changing the mode in one of the following ways: pushing the Mode Selection button twice, using the Mode Selection button to change the mode, or selecting a stored Quick Start or Custom Mode.

When Apnea Ventilation Mode engages, Control Lock will automatically come on. To change ventilation modes or settings, you must first disable the lock.

## Ventilation Settings by Mode

For each ventilation mode, some settings will be mandatory, some will be optional, and some will not be settable. For example, in volume modes, the PIP will not be controllable. Similarly, in pressure modes, the

PIP can be set but the tidal volume cannot. A full list of how each setting is treated in each mode can be found below:

| Ventilation Mode | Volume Modes | Pressure Modes | CPAP |
|---|---|---|---|
| I. Time | Required | Required | N/A |
| BPM | Required | Required | N/A |
| $\%O_2$ | Required | Required | Required |
| PEEP/CPAP | Optional | Optional | Required |
| PIP | N/A | Required | N/A |
| Vt | Required | N/A | N/A |
| Pressure Support | Optional | Optional | Optional |
| Trigger Sensitivity | Required | Required | Required |
| High Pressure Alarm | Required | Required | Required |
| Low Pressure Alarm | Required | Required | Required |
| $O_2$ Conserve | Optional | Optional | Optional |

## Additional Settings



$O_2$ Conserve is used when an oxygen concentrator is employed as the oxygen source, or when the user wishes to conserve the remaining oxygen in a depleting cylinder. This function limits the amount of oxygen used during inspiration (either through the hose connector or the barbed tree connector) to 10 LPM. See USING THE CCV WITH A CONCENTRATOR OR FLOWMETER for more information.

Manual Breath delivers a single breath at the current ventilator settings in volume and pressure (but not in CPAP) modes.

Control Lock freezes the buttons on the control panel.  When activated, a blue light will illuminate beneath the button. The Alarm Silence/Reset button is still active. Control Lock will automatically come on if Apnea Ventilation Mode is engaged. To change ventilation modes or settings, you must first disable the lock.

Parameter/mode Adjustment arrows are used to adjust settings or choose between programmed Custom Modes. For more information on changing settings and modes see SELECTING SETTINGS AND MODES.

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## Battery Parameters
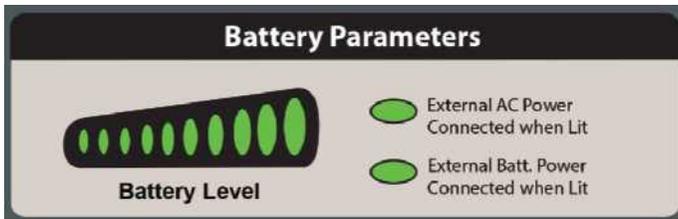


The Battery Level indicator gives an estimate of how much power remains in the battery which is currently in use by the CCV. When the indicators decline to the two leftmost bars, they will turn red and a different battery must be engaged or the CCV must be recharged.

If the battery in use falls to 20 minutes of remaining power, the Critical Battery alarm will activate. It cannot be silenced. A charged battery must be engaged or the CCV must be connected to mains power immediately, or alternative ventilation must be arranged for the patient.

The internal battery can be fully charged in 5 hours if it is not in use, or 10 hours if it is being used to run the CCV while charging. The external battery takes 10 to 20 hours to recharge depending upon whether or not it is being used while it is charging.

When the CCV is connected to active mains power the top indicator light to the right of the battery level will illuminate. When the external battery pack is attached, the bottom indicator light will illuminate.

**NOTE: The CCV has an internal battery and an external battery, but will only charge or use one battery at a time and will not automatically switch between batteries if one is depleted. To keep the batteries fully charged and make sure that a backup is always available, keep the CCV plugged into mains and the external battery plugged into mains, but do not keep the external battery plugged into the CCV. For more information on the internal and external batteries, see CCV BATTERIES.**

## Ventilator Alarms

In alarm conditions, the ventilator will sound an audible tone (>70 dB), illuminate three red lights in a horizontal line, and a single red light next to the label for the specific alarm condition.
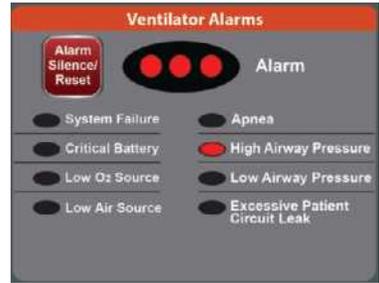


To mute the audible alarm for 110 seconds, press the Alarm Silence/Reset button. The alarm lights will stay on. Any new alarm conditions will also trigger the audible alarm.

The alarm lights stay on until the condition has been resolved *and* the reset button has been pressed.  This means a self-correcting alarm condition will leave a visible record for the clinical provider. To clear the illuminated alarm indicator, press the Alarm Silence/Reset button.

**System Failure Alarm:** Activates if communication between the processors fail. This indicates that the ventilator is not operating or may not be operating per the intended settings. When the processor fails, the alarm sounds and a light will turn on. This alarm may not be silenced.

**WARNING:** Any ventilator with a System Failure Alarm may pose a danger to the patient and must be removed from service immediately.

**Critical Battery Alarm:** Activates when about 20 minutes of battery life remain, clears 10 seconds after adequate power is restored. This alarm may not be silenced. See **CCV BATTERIES** for more information about the CCV battery system.

**Low O$_2$ Source Alarm:** Activates if the oxygen source pressure drops below 2.7 to 2.5 Bar (275 – 255 kPa, 40 – 37 psi). Clears 8 seconds after pressure is restored. The CCV will switch to using the internal compressor, but the displayed %O$_2$ will not change. This alarm does not activate if the %O$_2$ setting is 21% (Air only).

**Low Air Source Alarm:** Activates if the compressed medical air source pressure drops below 2.7 to 2.5 Bar (275 – 255kPa, 40 – 37 psi). Clears 8 seconds after pressure is restored. This alarm does not activate if the %O$_2$ setting is 100% (O$_2$ only). This alarm will not be engaged if using room air (21% O$_2$) via the internal compressor.

**WARNING:** Set Vt may not be delivered when a low gas source alarm is activated.

**Apnea Alarm:** Activates if the ventilator does not detect a spontaneous breath or deliver a machine breath in 20 seconds. The vent will operate in Apnea Ventilation Mode once apnea has been detected.

**High Airway Pressure Alarm:** Activates if the airway pressure rises above the alarm setting (15 – 80 cmH$_2$O, programmable). **The CCV stops flow to the patient when activated**, and clears after the limit has not been exceeded for 25 seconds.

**WARNING:** Preset tidal volumes will not be delivered when the High Airway Pressure Alarm limit is reached. No additional tidal volume will be delivered after the pressure limit is reached.

The CCV also has a mechanical pressure relief which limits the airway pressure to 85 cmH$_2$O or lower. When the airway pressure reaches this limit, the valve will open and gas will be vented to prevent the pressure from increasing. This is a redundant safety measure, as the High Airway Pressure Alarm limits the maximum pressure.

**WARNING:** Preset tidal volumes may not be delivered when the pressure relief setting is reached. Inspiratory times will remain constant, however no additional tidal volume will be delivered after the pressure relief limit is reached.

**Low Airway Pressure Alarm:** Activates if the airway pressure does not go above the set point (5 – 30 cmH$_2$O, programmable) for 12 seconds. Clears when pressure exceeds the set point or if a spontaneous breath is detected.

**Excessive Patient Circuit Leak Alarm:** Activates in pressure modes if on 3 consecutive breaths the pressure fails to reach 75% of the PIP setting and the initial flow is greater than 60 LPM. In CPAP, an Excessive Patient Circuit Leak Alarm will sound if the flow exceeds 10 LPM for more than 5 seconds.

## Ventilation Parameters

This panel shows five parameters which are calculated or measured and displayed by the CCV. These are updated in real time, breath to breath. Measurements include the following:



**I:E Ratio** is the ratio of inspiration time to expiration time. The ratio is always expressed as 1:Y where Y is the expiration value. Thus, when the illuminated display shows 2.0, the I:E ratio is 1:2, and the expiration time is twice as long as the inspiration time. The ratio is determined by the clinician's choice of inspiration time and respiratory rate.

**Flow** is the flow rate in liters per minute delivered **during inspiration** in Volume AC and Volume SIMV. It is not the same as minute volume.

**PIP** shows the airway pressure measured in the patient circuit near the connection to the endotracheal tube or mask. This value will change during the course of a breath, and the maximum value achieved during the breath (the Peak Inspiratory Pressure) will be displayed for half a second at the end of the breath.

**Delivered Tidal Volume** is measured in the CCV and represents the volume of oxygen and air that entered the patient circuit during the breath.

**Spontaneous BPM** is the number of spontaneous breaths taken in the last minute based on the trigger sensitivity set by the clinician.

Each time a patient takes a spontaneous breath, the green indicator light will flash and the breath will be added to the running one-minute total.

## SELECTING SETTINGS AND MODES

When the CCV is turned on, it will recall the settings which were in use when it was last turned off, and will begin ventilation using those parameters.  The clinician may manually change individual settings or select a pre-programmed mode using the Quick Start or Custom Modes.

### Changing Settings

The CCV requires two-step verification every time a setting is changed. This guards against accidentally changing a ventilation parameter. To change any of the settings on the CCV:

1) Make sure the Control Lock is not activated. When it is on, a blue light illuminates above it. Control Lock may be used to provide additional protection against accidentally changing any setting.

2) Press the button for the setting which is to be changed, the displayed value next to it will start blinking.

3) Press the Increase or Decrease arrow keys to change the setting. To make changes in larger steps, hold the Alarm Silence/Reset button down while pressing the Increase or Decrease arrow buttons.  For example, this will change $\%O_2$ in increments of 10% rather than 1%.

4) Press the button for the setting you are changing again. The displayed value will stop blinking and the new setting will be active.

**NOTE: If using a Custom Mode or Quick Start Mode and any of the ventilation settings are changed, the light next to that mode will go off to indicate that the exact settings of that mode are no longer being used. Any changes made to the settings will not be saved to that mode. To revise the settings saved under a programmable mode, see REVISING PROGRAMMABLE MODES.**

### Changing Between Modes

1) Make sure the Control Lock is not activated.  When it is on, a blue light illuminates above it.  Control Lock may be used to provide additional protection against accidentally changing any setting.

2) Press the Mode Selection button, and the green light next to the currently selected ventilation mode will start blinking.

3) Press the Increase or Decrease arrow keys to move the blinking light to the ventilation mode to be selected.

4) Press the Mode Selection button again.  The green light will stop blinking and the new mode will be active.

## Selecting a Quick Start Mode

1) Make sure the Control Lock is not activated. When it is on, a blue light illuminates above it.  Control Lock may be used to provide additional protection against accidentally changing any setting.

2) Push one of the Quick Start buttons (Adult or Child). The light below the button will blink and the stored settings will be displayed.

3) Push the button a second time and these settings will be activated. If the button is not pushed a second time within 10 seconds, the displayed settings will revert back to the current ventilator settings and the process must be started over.

## Selecting a Custom Mode

1) Make sure the Control Lock is not activated. When it is on, a blue light illuminates above it. Control Lock may be used to provide additional protection against accidentally changing any setting.

2) Press the Custom Mode Selection button, and the green light next to the currently selected ventilation mode will start blinking.

3) Press the Increase or Decrease arrow keys to move the blinking light to the pre-programmed custom ventilation mode to be selected.

4) Press the Custom Mode Selection button again. The green light will stop blinking and the new mode will be active.

## REVISING PROGRAMMABLE MODES

The CCV has five programmable modes, 2 Quick Start modes and 3 Custom Modes. Each of these comes with standard settings which **must be confirmed or amended by a physician prior to use**. This initialization should be performed by the technician installing the CCV under the supervision of a physician, and if it is not, the Custom Modes cannot be used. The factory settings for the Custom Modes are:

| Mode | Adult Quick Start | Child Quick Start | Custom Mode (#1-3) |
|---|---|---|---|
| Ventilation Mode: | Pressure AC | Pressure AC | Volume AC |
| BPM: | 10 | 15 | 12 |
| I. Time: | 2 sec | 1 sec | 1 sec |
| %$O_2$: | 100% | 100% | 100% |
| PIP: | 15 cmH$_2$O | 15 cmH$_2$O | n/a |
| Vt: | n/a | n/a | 500 mL |
| PEEP: | 3 cmH$_2$O | 3 cmH$_2$O | 0 cmH$_2$O |
| Low Pressure Alarm: | 10 cmH$_2$O | 10 cmH$_2$O | 10 cmH$_2$O |
| High Pressure Alarm: | 30 cmH$_2$O | 30 cmH$_2$O | 30 cmH$_2$O |
| Trigger Sensitivity: | 2 cmH$_2$O | 2 cmH$_2$O | 2 cmH$_2$O |

**WARNING:** Do not initialize Custom Modes while the CCV is in use on a patient.

Once the custom modes have been initialized, they can be changed at any time by a physician using the following procedures. To abort the process of changing a custom mode, either press the Alarm Silence/Reset button or turn the CCV off and on again. The changes made will not be saved.

### Revising a Quick Start Mode

1) Make sure the Control Lock is not activated. When it is on, a blue light illuminates above it. Control Lock may be used to provide additional protection against accidentally changing any setting.

2) Enter the mode to be amended by pressing the button for either the Adult or Child Quick Start mode twice.

3) Once that mode has been selected, hold the same button for 3 seconds until the light below the active button begins to flash rapidly.

4) Revise any settings as desired, using the Parameter/mode Adjustment arrows.

5) To store the altered settings press and hold the button of the mode being edited (Adult or Child) for 3 seconds, until the ventilator beeps. The ventilator will be operating with the stored settings.

Note that for CPAP and BIPAP, because the CCV is operating, it will go into Apnea Ventilation Mode in 20 seconds. If the adjustment is taking longer than that, breathe with the circuit to trigger a spontaneous breath. In Pressure Control and Volume Control the use of a test lung is recommended to prevent alarms from activating.

## Revising a Custom Mode

1) Make sure the Control Lock is not activated. When it is on, a blue light illuminates above it.  Control Lock may be used to provide additional protection against accidentally changing any setting.

2) Push the Custom Mode Selection button and use the Parameter/mode Adjustment arrows to move the blinking light to the custom mode to be revised.

3) Push the Custom Mode Selection button again to begin using that mode. The blinking light will become solid.

4) Push and hold the Custom Mode Selection button for 3 seconds. The light by the selected custom mode will now flash rapidly.

5) Revise any settings as desired, using the Parameter/mode Adjustment arrows.

6) To store the revised settings, press and hold the Custom Mode Selection button first and then the Mode Selection button. The ventilator will sound a short beep to indicate that the Custom Mode has been saved.

## GAS CONNECTIONS

**CAUTION:** In order to provide optimal performance, check all gas supplies to assure that only medical grade gas is used.

### Oxygen Sources

The CCV can operate with 4 different sources of oxygen:

1) Pipeline
2) Cylinder (with regulator or flowmeter)
3) Oxygen concentrator
4) Medical or room air

At least two sources of high-concentration (above 21%) oxygen should be kept ready and available at all times in case a source is depleted or becomes unusable for any reason.

**WARNING:** The CCV operates with medical gases under pressure, including oxygen. Do not use this device while smoking or near open flames. Do not use this device or operate near flammable materials, including anesthetics.

### Oxygen Hose

The CCV comes with a green high-pressure oxygen hose, which connects to the Diameter Index Safety System (DISS) port on the CCV. DISS is a secure, threaded fitting which guarantees a safe connection even at high pressures. The DISS system uses connectors of different sizes so that gases cannot be connected to incorrect ports; a DISS air hose cannot be connected to an oxygen DISS fitting. This hose should always remain connected to the CCV.

## Connecting to Oxygen Sources

The CCV has three ports for source oxygen: the DISS port, reservoir barb, and low pressure barb. In general, the following rules should be observed:

- Sources delivering **10+ LPM** may be connected directly to the DISS port.
- Sources delivering **less than 10 LPM** should be connected via the reservoir.
- The low pressure barb should be used **only during transport.**

## High Flow Sources

Any source capable of delivering over 10 LPM of oxygen may be connected directly to the DISS port on the CCV via the green oxygen hose, provided the source is regulated to below the maximum allowable pressure (6 Bar or 87 psi). The green hose can be attached directly to a cylinder regulator or, using the provided adapter, to a pipeline system.

**WARNING:** Verify that there are no noticeable leaks after connection to the 3.4 Bar (344 kPa) (50 psi) Medical $O_2$ or Medical Air source.

## Low Flow Sources

The reservoir should be employed whenever the oxygen source to be used delivers less than 10 LPM, such as a flowmeter or concentrator. While the barb allows for connection to any oxygen source using generic silicone tubing, the reservoir barb should only be used with high-pressure sources in emergency cases as increased pressure could cause the hose to become disconnected from the barb, posing a danger to those nearby.

**NOTE: In order to use the reservoir barb, the provided oxygen hose must be connected between the reservoir outlet and the CCV's DISS port. See USING THE CCV WITH A CONCENTRATOR OR FLOWMETER for more information.**

## Low Flow Barb

The Low Flow O2 barb should be used only if no high flow source is available and the reservoir cannot be used, such as during transport when the CCV is not attached to the stand. Like the reservoir barb, the Low Flow barb is **not** a secure connection for high-pressure sources, and may only be used when the source pressure is below 0.7 Bar (10 psi) and for flows of 10 LPM or less. Any higher pressure or flow could lead to the hose being blown off of the barb.

**WARNING:** When using a barbed connection, always use an appropriate external regulator to lower the source pressure to the below a safe level.

## Air Sources

The CCV has two ports for source air: the high-pressure DISS port and the filtered compressor inlet. Unless compressed medical-grade air is readily available via cylinder or a pipeline system, the internal compressor should be used as a reliable source of compressed air. The inlet port includes a filter which prevents dust and other matter from being sucked into the CCV. This filter should be checked every three months and replaced if dirty (see PREVENTATIVE MAINTENANCE).

## BREATHING CIRCUIT

## Components and Function

The CCV comes with two durable, reusable single limb silicone breathing circuits. Each circuit is composed of a main limb, control line, pressure line, exhalation valve, and Heat/Moisture Exchange (HME) filter. The circuit must be assembled correctly in order to function.

**WARNING:** Do not use unapproved circuits, as loss of performance may result.

### Main Limb, Control and Pressure Lines
The breathing limb, pressure line (green) and control line (clear) are all made of durable silicone. They are critical for the function of the ventilator, and must be replaced if damaged.

The main limb is the conduit through which fresh gas is delivered to the patient from the ventilator. The pressure line is used to measure the patient's airway pressure. It must be connected to the blue port on the CCV marked PATIENT AIRWAY. The control line is used to control when the patient is allowed to exhale. It must be connected to the silver port on the CCV marked EXHALATION VALVE.

**NOTE: The breathing circuit should never be used to pull the CCV.**

### Exhalation Valve
The exhalation valve consists of a plastic main body, silicone disc, top cover, and securing ring as shown below. Together, these components form an airtight seal and ensure that gas is directed the correct way during each part of ventilation.
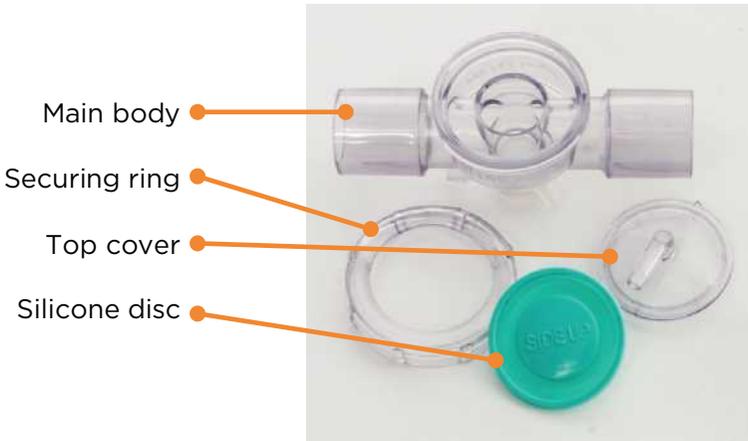


During inspiration, fresh gas flows into the main body of the valve. At the same time, gas from the control line presses down on top of the silicone disc, which seals off exhaust holes in the side of the main valve body. The fresh gas for ventilation flows directly through the main body and to the patient. The pressure line at the bottom of the valve allows the ventilator to measure the patient's airway pressure.

During exhalation, the control line releases the pressure on top of the silicone disc, allowing it to lift up and expose the exhaust holes on the side of the main body. The gas exhaled by the patient is free to exit these exhaust holes and enter the room. The cycle, illustrated below, repeats as the next breath begins.

Inhalation | Exhalation
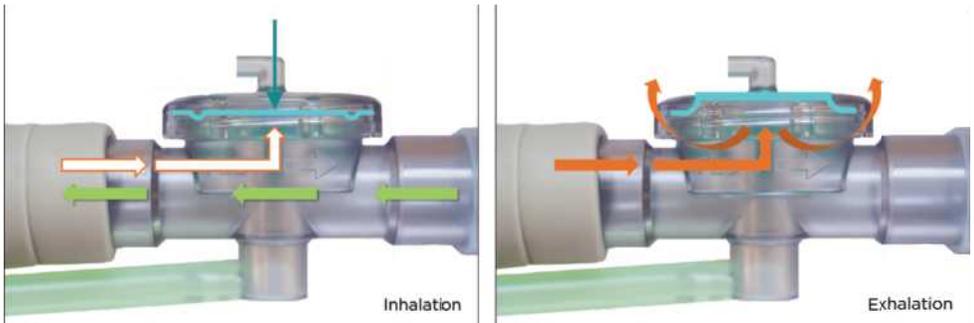
In order for the valve to function correctly, all parts must be assembled carefully and correctly. To make sure that the valve is correctly assembled, verify that:

1)  The side of the silicone disc which says "SIDE UP" is facing up. If it is not, the valve will leak.

2)  The control line port is facing straight back towards the ventilator, and the locating features on the top cover and main body (shown circled below) are correctly aligned. If they are not, the valve may be broken when the securing ring is tightened, and will leak.



3)  The securing ring is threaded on straight and is not overtightened.

4)  The sampling port on the bottom of the valve is plugged.
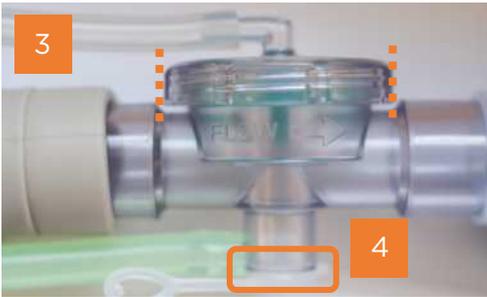
5) The pressure and control lines are attached correctly, with the pressure line (green) connecting the bottom of the valve to the blue port on the CCV marked PATIENT AIRWAY and the control line (clear) connecting the top of the valve to the silver port on the CCV marked EXHALATION VALVE. Connecting these tubes improperly will prevent the ventilator from functioning and will cause errors.

## HME Filter

When receiving mechanical ventilation, a patient is at risk for ventilator-associated pneumonia (VAP). Keeping the gas delivered to the patient warm and humid can help reduce this risk.

Some ventilators use active humidifiers, but these often fail due to lack of diligent maintenance or the availability of distilled water. The CCV is designed to work with disposable Heat/Moisture Exchanger (HME) filters, which trap the heat and moisture in a patient's exhaled breath and use it to warm and humidify the gas inhaled in the next breath. They also serve as bacterial filters to prevent bacteria from the patient from entering the breathing circuit. The HME should be placed between the control valve and the patient as shown below.

When using the CCV with a patient who poses an increased risk for fluid buildup in the patient circuit, or for added protection against machine contamination, an HME may also be placed on the Patient Circuit port to protect the CCV.

**WARNING:** HMEs are not reusable. They should be replaced at least every 4-6 hours for patients receiving ventilation and must be replaced between patients to prevent cross-contamination.

### Dead Space and Resistance

Components of the breathing circuit that contain volume may introduce mechanical dead space (gas which is not delivered to the patient) into the ventilation system.  Too large of an apparatus dead space can affect the oxygen and other gas levels delivered to the patient. The addition of accessories may impact the dead space and must be considered when configuring a breathing circuit.

This is particularly important when ventilating pediatric patients, as increases in dead space will increase the work of breathing. For pediatric patients, small increases in apparatus dead space lead to large increases in the ratio between dead space and tidal volume. This can lead to hypercapnia, requiring a larger minute ventilation to clear excess $CO_2$. When possible, accessories with lower amounts of dead space should be used for pediatric patients.

## Breathing Circuit Care

While the components of the breathing circuit are robust and durable, care should be taken to prevent any damage in order to prolong their usable life. Components of the circuit should never be used to drag the CCV on its rolling stand. The circuit should not be allowed to touch the floor, as this poses a danger of contamination and a risk for physical damage.

**WARNING:** Ventilator patient circuits may become contaminated during use. To prevent cross contamination do not reuse patient circuits without proper disinfecting. Never reuse a "single patient use" ventilation circuit.

For approved cleaning methods, see **CLEANING AND STERILIZATION.**

## USING THE CCV WITH A CONCENTRATOR OR FLOWMETER

The CCV may be used with a low flow source such as an oxygen concentrator or flowmeter, provided the source can maintain an output pressure of **at least 0.7 Bar (10 psi)**. To use a low flow source the CCV must be configured to utilize the oxygen reservoir, and O$_2$ Conserve Mode must be engaged.

### CCV Reservoir

Because the flow rate of a concentrator or flowmeter is generally lower than the flow rate required by the patient during inspiration, a low flow source alone would not be able to act as a usable oxygen source because it could not keep up with patient demand and would consistently cause a Low Oxygen Source alarm.

To resolve this, the CCV utilizes a reservoir which stores sufficient gas to allow the patient to take a full breath, allowing a concentrator or flowmeter to be used. Gas from the reservoir is used during inspiration (at any flow rate required by the ventilation settings), and the reservoir is refilled by the oxygen source during exhalation.

**NOTE: The CCV reservoir is not an emergency supply of gas and will not hold sufficient volume to ventilate a patient for any significant period of time beyond a single breath.**

The CCV reservoir is a simple tank mounted to the bottom of the stand basket. The reservoir has two ports on the left side (while facing the machine): a hose barb inlet threaded fitting outlet to be connected to the CCV's DISS port via the provided hose. When not in use, both ports should be plugged, the inlet by leaving the provided flexible silicone hose attached for quick access, and the outlet by the provided red plastic cap. Keeping the ports plugged will prevent any cleaning fluid from entering the reservoir, which would then pose a danger to the patient as fumes or vapors could be inhaled.

## O₂ Conserve Mode

In order to use a low-pressure oxygen source without causing a Low Oxygen Source alarm, $O_2$ Conserve mode must be enabled on the CCV. This mode allows the CCV to use an oxygen source below 2.8 Bar (40 psi), and also limits the allowable flow of oxygen during inspiration to 10 LPM. It should be engaged when attempting to make a cylinder last longer, or whenever a low-pressure oxygen source is used.

To enable $O_2$ Conserve mode, connect an oxygen source and ensure that Control Lock is not engaged. Press the $O_2$ Conserve button in the Additional Settings panel of the CCV interface. The green light will come on when $O_2$ Conserve mode is engaged.
If the ventilation settings are changed such that more than 10 LPM of oxygen is used while in $O_2$ Conserve mode, the red alarm light will turn on in the Ventilation Settings panel next to the message **"%O₂ Setting cannot be achieved in O₂ Conserve Mode."**

If this light comes on, the CCV is outputting a lower oxygen concentration than the displayed setting. **Immediately alter the settings until the light goes back off**. This can be done by:

     a. Decreasing the %O₂,
     b. Decreasing the Vt, or
     c. Increasing the I. Time.

**Until the red warning light goes off again, the %O₂ value will not reflect the oxygen concentration that is being delivered to the patient.**

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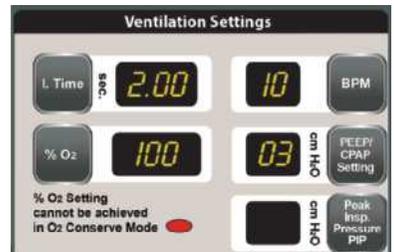
## Low Flow Source Setup Procedure

To use a concentrator or flowmeter as the CCV's oxygen source, the following steps must be performed:

1) Turn the CCV off.

2) Ensure that the $O_2$ hose is securely connected to the DISS port on the CCV and the outlet port on reservoir.

3) Connect the low flow oxygen source to the reservoir inlet barb hose fitting.

4) Turn the source on and check for leaks.

5) Lower the %$O_2$ setting to 21% and set the other ventilation parameters as desired.

6) Ensure that Control Lock is not engaged and press $O_2$ Conserve, noting that the green light above the $O_2$ Conserve button turns on.

7) Increase the %$O_2$ setting until the red alarm light next to the message "%$O_2$ Setting cannot be achieved in $O_2$ Conserve Mode" is illuminated.

8) Alter the settings to lower oxygen usage until the red alarm light goes off.

## CLEANING AND STERILIZATION

In order to prevent the spread of communicable diseases, it is critical that the CCV and breathing circuit be disinfected between patients, as well as at the beginning and end of each day.

**WARNING:** Cleaning procedures should be performed in an environment free of oil and petroleum based products.

### CCV UNIT

To disinfect the CCV ventilator unit, perform the following steps:

1) Wipe the unit down with a damp rag containing a mild cleaning solution to remove any residue from the surface

2) Wipe the unit down with isopropyl alcohol or a cold disinfecting solution to kill bacteria. Approved cleaning solutions are:
   a) **Bleach:** 10% Bleach in $H_2O$
   b) **Isopropyl Alcohol:** 70% IPA
   c) **Cetylcide:** 30 mL Cetylcide to 3.8 liters $H_2O$

3) The unit should then be wiped down with water to remove any film left by the cold disinfecting solution

4) Make sure the unit is dry before putting the unit away

### BREATHING CIRCUIT

The following methods are approved for disinfection of the CCV reusable silicone breathing circuit. While other compatible breathing circuits may be used with the CCV, manufacturers' instructions must be understood and followed. Single-use accessories should never be reused or reprocessed, as loss of performance may occur.

1) Autoclave sterilization, either for 15 minutes at 1 Bar (15 psi) and 121$^o$C or for 5 minutes at 1.4 Bar (20 psi) and 134$^o$C.
2) Hot-water disinfection by immersion in water of at least 70$^o$C for 30 minutes.
3) Chemical disinfection using only chemicals approved by the manufacturer. If employing chemical disinfection, wash the breathing circuit thoroughly in distilled or fresh water afterwards.

**WARNING:** Do not attempt to clean and re-use single patient ventilation circuits, as loss of performance may occur.

# CCV BATTERIES

## INTERNAL AND EXTERNAL BATTERIES

**CAUTION:** Use only the MCV-AUXBAT external battery pack, damage to the ventilator may occur with a non-approved battery pack.

The CCV has an internal and external battery, but **will only charge or use one** at a time. If the external battery is connected, it will be used and the internal battery will be ignored. If the battery in use is depleted the user must engage another charged battery, as the CCV will not automatically switch between batteries. For example, if the external battery is plugged into the CCV and the Critical Battery alarm sounds, the external battery must be unplugged in order for the internal battery to be used.

**WARNING:** The auxiliary power connection is keyed. Make sure that connectors are properly aligned before insertion, do not force. Damage to the ventilator may occur making the ventilator unavailable for use.

To keep the batteries fully charged and make sure that a backup is always available, it is recommended that the CCV be plugged into mains power at all times to charge the internal battery, and that the external battery be plugged into mains separately and **not** connected to the CCV.

When plugged into the CCV, the external battery **cannot** be charged by connecting it to mains. If the external battery is connected to the CCV and the CCV is connected to mains, the external battery will be used and will charge. If the external battery is connected to the CCV and the external battery is also connected to mains but the CCV is not plugged into mains, the battery will be used but **will not charge**.

**If at any point the CCV shows a Critical Battery alarm, follow these steps:**

1) Plug the CCV into mains power. If it is already plugged in, find another functional mains outlet and wait 10 seconds for the alarm to clear.
2) If mains power is not available, connect the external battery into the CCV and wait 10 seconds for the alarm to clear.
3) If the external battery is depleted, unplug it from the CCV to engage the internal battery.

## BATTERY CARE

To maintain optimum battery life, both batteries should be plugged into mains at all times, even when not in use. If this is not possible, the batteries should be fully charged once a week. Failure to do so will degrade the capacity of the battery, resulting in a decreased battery life.

If the internal battery does not recharge fully after being plugged into mains for 7 hours, all the lights on the battery indicator will blink to indicate that the battery does not have full capacity and should be replaced.

If a battery has been allowed to run completely dead (the units stops operating) there will be permanent damage to the battery, reducing battery life. Any battery which has been run until the unit stops operating should be replaced. The lead acid cells of the internal and external batteries should be replaced every 3 years as part of normal planned maintenance to ensure continued performance.

## PREVENTATIVE MAINTENANCE

In order to ensure patient and user safety and to achieve the longest possible usable lifetime of the CCV, regular maintenance is required by users and Gradian-certified technicians.

## USER MAINTENANCE

### General Care

While designed to be very rugged and robust, the CCV is a sophisticated medical instrument and should be treated with care. The following are best practices which should always be observed:
- Do not pull the CCV by the breathing circuit or high pressure hose
- Keep all components off the ground to avoid damage and contamination
- Unlock the 2 locking casters before attempting to roll the CCV stand
- Keep unused ports capped with the provided plastic protective caps
- Keep unused cables and tubes wrapped neatly and securely around the cable management features on the stand baskets

## Disinfection

The CCV and breathing circuit must be cleaned before and after each use. For instructions and appropriate cleaning methods, see CLEANING AND STERILIZATION.

HME filters should be discarded between patients to avoid cross-contamination.

## Filter Replacement

The CCV contains a particle filter located inside the room air inlet on the side of the unit. This filter removes dust and other particles from the ambient air drawn in by the compressor. This filter should be checked **every 3 months** on CCVs in regular use, and changed if visibly dirty.



To replace the filter, remove the protective screen by prying it off with fingernails or a dull flat tool. Discard the filter, insert a fresh one, and replace the protective screen.

## Battery Care

To prolong battery life, keep the internal and external batteries plugged into mains at all times. Do not allow a battery to run the ventilator until fully depleted (the ventilator stops working), as this will reduce the battery life. Batteries should be replaced every 3 years to ensure continued performance. See CCV BATTERIES for more information.

## GRADIAN-CERTIFIED TECHNICIAN MAINTENANCE

In order to ensure patient and provider safety, a technician certified by Gradian to work on the CCV will perform scheduled annual maintenance during the warranty period. This work should not be attempted by anyone not certified by Gradian.

## Yearly

Each year, the technician will use a specialized piece of equipment to test the calibration of the CCV and ensure that it is operating correctly. They will be able to recalibrate the machine if necessary, and address any other repair needs at that time. The technician will also replace the air inlet filter, and bring 2 more filters to be used in the coming year as described above.

## Year 3

In addition to the yearly maintenance activities described above, during the third maintenance visit the technician will replace the internal and external batteries in order to address the deterioration of battery life which will occur naturally over time.

## Year 6

After the sixth year of use, the CCV requires comprehensive maintenance in order to ensure proper function and safety. This includes replacement of the batteries, compressor, flow sensors, plastic tubing and fittings, and all seals in the ventilator, as well as calibration and performance testing. This major service means that the internal components of the machine will operate just as when the CCV was fresh from the factory, and will allow for years of use to come. Contact your Gradian representative for information and to schedule this comprehensive maintenance.

## WARRANTY

The CCV comes with Gradian's standard **3-year warranty**, which covers:

- Remote support, available 24/7 via phone, email, or WhatsApp
- Yearly preventive maintenance
- Repairs of non-consumable parts due to manufacturing defects

The warranty may be voided if its terms are violated, including:

- If any service is attempted by someone not properly certified by Gradian
- Damage is caused poor care, accident, or improper use

For more information, reference the full warranty available at **www.gradianhealth.org**.

# SYMBOLS & TECHNICAL SPECIFICATIONS

**Gas Inputs:** 280 kPa (40.6 psi) to 600 kPa (87 psi), via Oxygen DISS and Air DISS 69 kPa (10 psi) to 275 kPa (40 psi), via Oxygen DISS ($O_2$ Conserve Mode) 0 kPa (0 psi) to 69 kPa (10 psi), via 1/8" Barb

**Gas Outputs:** ISO 5356, 22mm

**Gas Flow:** 5 to 60 LPM in volume modes and peak flows > 80 LPM in pressure modes, CPAP and demand flows.

**Electrical Rating:**
- Operating Voltage: 12 VDC, 5.0 Amp max current draw
- Input Voltage AC: 110-240 VAC, 50/60 Hz <1 Amp max current draw (55 watts)
- Input Voltage DC: 11 – 15 VDC, 5.0 Amp max current draw
- Fuses: 2 Amp slow acting, 250 VAC rating

**WARNING:** Use only a 12 VDC HC1221W battery or equivalent for the internal battery. Improper function or damage may occur with the wrong battery.

**WARNING:** Use only the specified fuse. Improper fuse rating may result in damage to the ventilator or electrical shock to the user.

**WARNING:** Grounding reliability can only be achieved when the equipment is connected to a hospital grade receptacle.

**WARNING:** The CCV is not MRI compatible.

**Inspiratory Time:** 0.5 to 2.0 seconds in increments of 0.25 seconds, accuracy: ±10%

**Breaths Per Minute:** Range dependent on ventilation settings, accuracy: ±10%

**$O_2$ Blending Capability:** 21% to 100% $O_2$ in 1% increments, accuracy: ±12%

**CPAP/PEEP Range:** 0 to 25 $cmH_2O$, Inadvertent PEEP <2 $cmH_2O$

**PIP (setting):** 15 to 55 $cmH_2O$, accuracy: ±2 $cmH_2O$ or 10% (whichever is greater)

**Tidal Volume:** Range dependent on ventilation settings, accuracy: ±10% with 100% Oxygen or 100% Air (±12% below -9°C), ±12% for blended gases (±14% below -9°C)

**High Airway Alarm:** Adjustable 15 – 80 cmH$_2$O, accuracy: ±5% or ±1 cmH$_2$O, whichever is greater

**Safety Pressure Relief:** Fixed at 88 cmH$_2$O, accuracy: ±10% cmH$_2$O

**External Alarm Connection:** ¼" Phono style jack, normally open switch that will close when an alarm occurs. Max 0.5 Amp at 125 VAC or 1 Amp at 30VDC signal. Minimum signal 1 mAmp @ 5 volts.

**WARNING:** Use only insulated connectors for the external alarm connection. The use of non-insulated connectors will result in a shock hazard if using high voltages.

**Airway Pressure:** 0 – 99 cmH$_2$O, accuracy: ±5% or ±1 cmH$_2$O (whichever is greater)

**Internal Battery Life:** Run time at 21°C (70±5°F), BPM = 10, and Vt = 600 mL
- 100% O$_2$: 7.5 hours (Approx 5 hours at 0°F (-18°C))
- 100% Air: 7.5 hours (Approx 5 hours at 0°F (-18°C))
- 21% (Air Compressor): 7 hours (Approx 4 hours at 0°F (-18°C))

**Oxygen Inlet Filter:** 65 micron sintered bronze

**Burst Pressure:** 145 psi (1000kPa) minimum through oxygen inlet

**Storage Conditions:** -40 – 60°C (-40 – 140°F), 10% - 95% RH non-condensing

**Shipping Conditions:** -40 – 60°C (-40 – 140°F), 5% - 95% RH non-condensing

**Sound Level:** tested per ISO 80601-2-12
- < 40 dBA with compressed gas
- < 50 dBA with internal compressor and flows less than 36 LPM
- < 55 dBA max sound level while using internal compressor

**NOTE: Maintenance schedules must be followed to ensure the product can reliably meet specifications.**

## Symbols:

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
|  | Degree of protection against shock: Type BF |  | Off / On |
|  | Caution, consult accompanying documents |  | External Alarm |
|  10% - 95% Non-Condensing | Relative Humidity Range |  | Do Not Occlude |
|  | Temperature Range |  | Shock Hazard |

## APPLICABLE STANDARDS

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/ECN (EN 55011 and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Consult the manufacturer or field service technician for help

The CCV is intended to provide emergency respiratory support for children and adults. The product is intended to meet the following safety and performance standards:

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## Performance and Safety Requirements
- ASTM F920 – Performance and Safety Requirements for Resuscitators Intended for Use with Humans
- ISO 10651-3 Lung Ventilators for Medical Use

## Electrical Safety Requirements
- IEC 60601-1

## Electromagnetic Compatibility
- IEC 60601-1,-2

## Biocompatibility Requirements
- ISO 10993 – Biocompatibility Tests – Part 1, 10, 11

## Transport and Storage Requirements
- IEC 60068-2-27 – Shock
- IEC 60068-2-6 – Sinusoidal Vibration
- IEC 60068-2-31 – Rough Handling Shocks
- IEC 60068-2-64 – Random Broadband Shocks

The above listing of standards is not intended to be a complete listing of standards reviewed and tested during the development of this product. It may also not reflect latest versions as standards change. Gradian Health Systems regularly reviews the standards and updates the products to ensure compliance as necessary.

For the latest revision of the instruction manual in all available languages, please refer to the company website at www.gradianhealth.org.

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