

Co2mmander® ELITE

Medical Gas Delivery System

INSTRUCTIONS FOR USE



Manufactured by PMDA, LLC.
5235 #11 Ramsey Way
Fort Myers , FL 33907

Indications for Use

The CO₂mmander® ELITE is intended to provide a portable, safe, convenient source of carbon dioxide gas to health care professionals in hospital or medical office settings where small volumes of CO₂ are needed. The device is intended for general use by physicians and is not intended to be marketed for any specific treatment or medical purpose."

Specific uses of this device for particular indication are ultimately the responsibility of the physician, but note that the sale and use of this product is limited to, and on the order of, a physician.

****CARTRIDGES SOLD SEPERATELY**

- 1) Read, understand, and follow all safety and operating instructions before the Device is operated.
- 2) The safety and operating instructions should be retained for future reference.
- 3) All warnings on the device and operating instructions should be followed.
- 4) Cleaning: The device should not be immersed in water or any other liquid. Use only a damp cloth or alcohol pad for cleaning the exterior of the device.
- 5) Stabilization: Do not place the device on an unstable cart, stand, bracket or table. The device may fall, causing serious personal injury and damage to the device.
- 6) Ventilation: This device should be situated so that its location or position does not interfere with its proper ventilation. Some condensation may form as the CO₂ gas is expressed.
- 7) Heat: Never put the device in direct sunlight in an unventilated area. The device should be away from heat sources such as radiators, heat registers, or other equipment that produces heat.
- 8) Storage: Store Device and Cartridges in Room Temperature.

WARNINGS

- 1) DO NOT CONNECT THIS DEVICE TO A HUMAN BODY.
- 2) If the device is left unused for long periods of time, turn the device to OFF.
- 3) Do not attempt to service the device yourself. Removing the cover will void the warranty. Refer all servicing to authorized service personnel.
- 4) Never use any CO₂ cartridge in the device that is not recommended by the manufacturer of the device. Do not use any cartridge that is not medical-grade CO₂ as it can contain oils not satisfactory for medical need.
- 5) NEVER fill a reservoir to capacity as this may cause a "compression" of the CO₂ gas resulting in an inaccurate measurement.

- 6) The device is not intended to measure quantitatively a physiological or anatomical parameter or a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body.
- 7) The user should not attempt to service the device beyond that described in the operating instructions. All other servicing should be referred to qualified service personnel. The device should be serviced by qualified service personnel when:
 - A. The device has been accidentally immersed in liquid, or
 - B. The device does not appear to operate normally or exhibits a marked change in performance, or
 - C. The device has been dropped, or the enclosure damaged.
- 8) NEVER point the terminating end of the tubing, or the reservoir that it attaches to, toward your face or toward any other person while activating the CO₂.
- 9) Always point the Cartridge at the floor when removing. Cartridges can become a projectile if gas remains upon removal.

Potential Complications

- None Known

Instruments Required

- Safety Eyewear
- AngiAssist™ Medical Gas Management and Delivery System
- Compatible gas filter
- Medical-Grade CO₂ Cartridge - These cartridges must be threaded for use in the CO₂mmander® ELITE

Positioning of the Co2mmander® ELITE

- CO₂mmander® ELITE should be used only in an upright, or horizontal position with the Cartridge downward. Never hang, or dangle the CO₂mmander® ELITE in an upside-down

position allowing the liquid in the Cartridge to drain into the Device.

Specifications:

Service: Compatible Medical gases. Please check with manufacturer for a complete list.

Process Connection Incoming Tubing: 1/8" OD Tubing 36" long PVC Tubing with One Way Valve and Female Luer Fitting

Accuracy: The graduation marks on the Gauge are approximate; accurate within +/-5%.



Instructions for Use of the CO₂mmander® ELITE

Before loading, or reloading, the CO₂mmander® ELITE with a cartridge, the Adjustment Knob should be turned until it stops at the OFF indication. This is referred to as **disengaging** the device.



After the cartridge has been loaded, the Adjustment Knob can then be slowly screwed in a clockwise direction until the Pressure Indicator reads the desired amount of flow of the CO₂. This is known as **engaging, or turning ON**, the device.

For best results, adjust until the pressure on the Pressure Indicator reads between 8-10PSI. ****NOTE** Caution should be taken when Pressure Gauge reads over 20PSI.

Symbol	Used For
	Caution, consult accompanying documents
	Consult instructions for use
	Manufacturer
	Does not contain Natural Rubber Latex

WARNINGS and PRECAUTIONS



Once you have set the pressure of the Device you can now connect the desired reservoir to the Luer Lock Attachment. Now, depress the Activator Button and the CO₂ will begin to flow from

Luer Fitting to your Reservoir. By removing your finger from the Activator Button the gas flow will stop. Press the Activator Button in a pulsing manner to fill your reservoir.

The Pressure Indicator will clearly display the pressure and rate at which the gas is being expressed. If you are using a syringe for your reservoir, please be sure that the air pressure is regulated to 8-10PSI, so as not to pop the plunger out of the syringe.

NOTE*** Do not remove the cartridge until it has been expended. The CO₂mmander® ELITE will hold the unused gas within the cartridge while not in use, if the Adjustment Knob is to the OFF position.

Once the CO₂ cartridge has been expended, allow the cartridge to return to room temperature, or protect the hand with a towel or mitt, as the cartridges can become very cold. Carefully and SLOWLY unscrew the used cartridge and dispose of, or recycle. If there is any CO₂ left within the cartridge you may hear a bursting sound as the additional air is expressed from the port of the CO₂mmander® ELITE. This is normal and will not harm you.

Warranty

PMDA, LLC. Limited Warranty Statement

PMDA, LLC warrants to the original purchaser that its products will be free from defects in material and workmanship for a period of 2 years, following date of purchase. In no instance shall PMDA, LLC liability exceed the amount of the original purchase price.

PMDA, LLC products which fail within the warranty period due to defects in material or workmanship, will be repaired or replaced, at PMDA, LLC's option, without charge to purchaser, when returned with proof of purchase to PMDA, LLC transportation prepaid.

This warranty does not cover failure of parts or components due to normal wear, or damage, or wear which in the judgment of Portable Medical Devices, Inc. arises from misuse, abrasion, corrosion, negligence, accident, substitution of non-Portable Medical Devices parts, faulty installation or tampering. This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state.

IMPLIED WARRANTIES INCLUDE THAT OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY LIMITED TO THE DURATION OF THIS WARRANTY. PMDA, LLC. AND/OR SELLER DISCLAIMS ANY LIABILITY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

Some states/provinces do not allow limitations on how long an implied warranty lasts, or the exclusion or limitation of special, incidental or consequential damages, so these limitations and exclusions may not apply to you. This warranty gives you specific legal rights. You may also have other rights which vary from state/province to state/province.

This is PMDA/Portable Medical Devices, Inc.'s exclusive written warranty. To obtain warranty service, contact PMDA, LLC. through your Dealer, or the company website www.CO2mmander.com or by contacting the PMDA, LLC Customer Service Department by calling 1-239-731-6200 from within the USA.

IMPORTANT NOTE*** Removing the Tamper Proof Screws will void any and all warranty of the device.**



Item Key	Part Description
A	Adjustment Knob
B	Gauge
C	Luer Lock Attachment
D	Cartridge Port
E	Activator Button
F	Serial Number

Troubleshooting

- If the CO₂mmander® ELITE fails to deliver the CO₂, please use the following troubleshooting options:
- Check your Tubing Attachment to ensure that the connections are secure.
- Be sure that you are using a fresh CO₂ cartridge and that the air has not been totally expressed from the cartridge.

- Be sure that the CO₂ cartridge is screwed in tightly enough to puncture the cartridge and start the flow of gas.
- If you hear a continuous leaking of gas after the initial puncture and have not depressed the Activation Button, do not use the unit and contact us immediately for service.
- Check the tubing for any crimping or blockage.
- If, after following these troubleshooting options, your device still fails to deliver CO₂, you may contact the dealer from which you purchased the device; or contact PMDA, LLC directly.
- In the unlikely event that the device does not deliver CO₂, we recommend that you have a backup device, or a CO₂ source available for a patient.
- **To obtain warranty service, contact PMDA, LLC. through your Dealer, or the company website www.CO2mmander.com or by contacting the PMDA, LLC Customer Service Department by calling 1-239-731-6200 from within the USA.**

