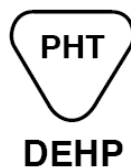
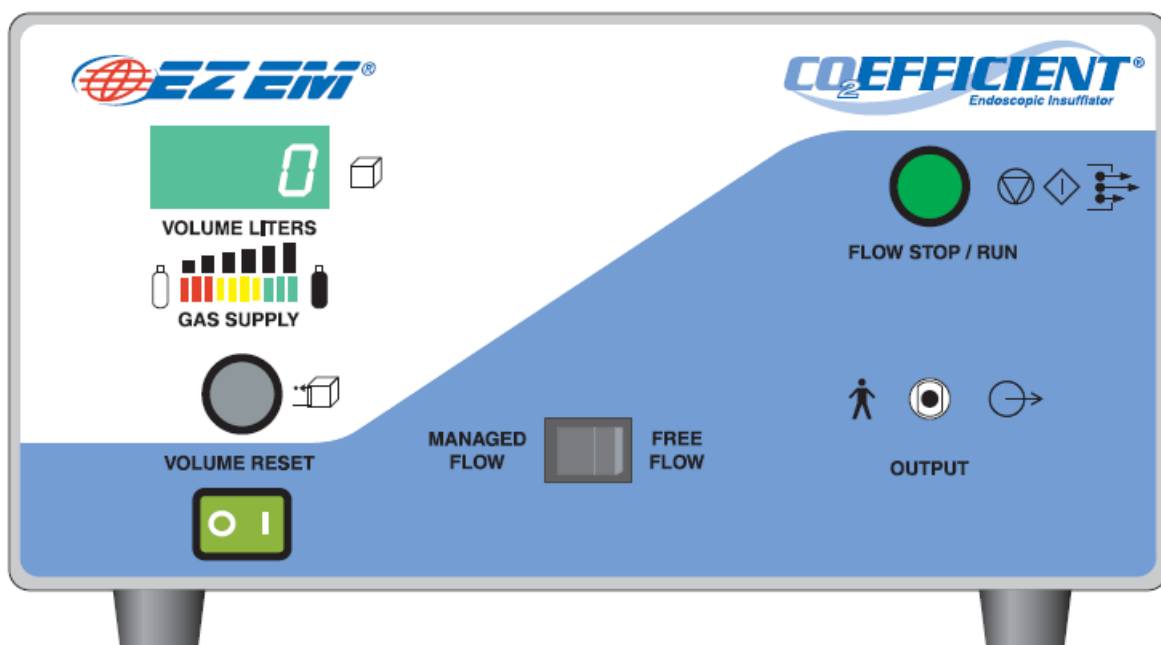




Endoscopic Insufflator

REF 6600

Operator's Manual



Rx Only (USA)

US Patent # 7,806,850 and
US Patent # 8,157,763

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Section 1.0 UNPACKING AND GENERAL INSPECTION

CAUTION: READ ALL SECTIONS OF THIS MANUAL CAREFULLY BEFORE USING THE CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, SUCH THAT OPERATION IS UNDERSTOOD. IF YOU SHOULD HAVE ANY QUESTIONS, PLEASE CONTACT E-Z-EM, INC. CUSTOMER SERVICE AT 1-800-631-5245 (USA), 1-609-514-2200 OR YOUR LOCAL E-Z-EM, INC. REPRESENTATIVE.

Proper care and maintenance are critical for safe operation of sophisticated medical equipment. We recommend careful inspection of all equipment upon receipt and prior to each use as a safeguard against possible injury to patient or operator.

To avoid inadvertent damage, study this manual thoroughly before handling, assembling, testing, using, or cleaning the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR.

Examine the shipping carton and instrument for signs of damage. Any breakage or other apparent damage should be noted, the evidence retained, and the carrier or shipping agency notified.

Verify that the shipping carton contains the items listed below:

CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR

Operator's Manual (English Only)

Quick Reference Guide

Line Cord (mains lead) (see CAUTION below)

High Pressure Hose & Yoke

Foreign Language Disc

Notify Professional Services immediately if any damage or discrepancies are noted.

Phone: 1-800-631-5245 (USA), 1-609-514-2200

CAUTION: The line cord (mains lead) supplied with this unit is designed and approved for use in the USA and Canada only, and should not be used outside these countries. For use outside of the USA and Canada, your Distributor will supply a line cord that is approved for use in your country.

Section 2.0 INTRODUCTION

This manual provides information for the operation of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, (also referred to in this manual as "unit" or "device").

DEFINITIONS

The following list is abbreviations of commonly used terms throughout this manual:

LPM Liter Per Minute (or Liters Per Minute)

mm Hg millimeters of Mercury

gas CO₂

hPa Hundred Pascal

2.1 INDICATION AND CONTRAINDICATIONS

Indications for Use: The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is designed to use CO₂ as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

Contraindications for Use:

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should be used only for an endoscopic procedure when insufflation of the gastrointestinal tract is necessary to support navigation of the endoscope and perform any evaluation procedures through the endoscope, and should therefore not be used for any other treatments. It should only be used under the direct guidance of a physician experienced in Gastrointestinal Endoscopy procedures.

This device is **contraindicated** for hysteroscopic or laparoscopic insufflation, i.e., it must not be used for intrauterine distension.

This device is **contraindicated** for CT Colonography.

2.2 SAFETY FEATURES

The following features help to ensure safe operation of the machine:

FLOW STOP/RUN button: Upon turning power on, gas flow is not initiated until the FLOW STOP/RUN button is pressed.

An initial pressure relief will occur at 375 mm Hg and a redundant pressure relief will occur at 400 mm Hg.

An audible alert will sound when the CO₂ gas supply tank pressure is low.

An audible alert (a single chirp) will sound when the flow of CO₂ is automatically stopped by the device.

Section 3.0 THEORY OF OPERATION

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR operates by administering CO₂ at a maximum flow rate of 3 LPM, and then monitoring the endoscopic pressure. A mode of operation is selected by the operator, by using a switch found on the front panel to select from Free Flow Mode and Managed Flow Mode. It is used to change the rate that the flow is delivered to the endoscopic system. When the switch is set to Free Flow Mode, the unit will deliver CO₂ at a flow rate of 3 liters per minute continuous. The clinician will use the air/water valve on the endoscope and visual feedback of the endoscopic system to manually distend the gastrointestinal tract with CO₂.

When the switch is set to Managed Flow Mode, the system will be delivering CO₂ in a more efficient manner. This mode reduces the amount of CO₂ that is lost through the air/water valve which is normally lost at a rate of 3 liters per minute. When gas is not used in the endoscopic system to insufflate, the unit will operate at the Managed Flow rate of 0.25 to 1.0 liter per minute. This transition to the Managed Flow rate will occur if the unit senses no need for insufflation in a 2 second time period. When gas is needed to insufflate, the unit will deliver CO₂ at a flow rate of 3 liters per minute.

The user will need to place the system into RUN mode in order for it to deliver the CO₂ to the endoscopic system.

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR has a Pressure Relief Valve set at 375 mm Hg and an independent redundant Pressure Relief Valve pre-set to 400 mm Hg. Both pressure relief safety devices are active whether the FLOW STOP/RUN is on or off.

Section 4.0 WARNINGS AND CAUTIONS

This section describes warning and caution information for safe operation of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. All information in this manual, and particularly in this section, should be read thoroughly and understood before using the device.

4.1 WARNINGS

- Excessive absorption of CO₂ results from over insufflation. The GI Tract can be adequately distended by the physician's modulation of the air/water valve.
- Should accidental intravasation of CO₂ occur, in rare circumstances, it can result in embolization.
- Infusion of CO₂ can result in carbonic acid irritation to directly contacted tissues.
- Idiosyncratic reactions: In patients with sickle cell disease or pulmonary insufficiency, use of these devices may pose increased risks of respiratory acidosis related to excessive CO₂ absorption.
- Use only USP "Medical Grade" CO₂ available in "D" or "E" supply tanks.
- Tubing set is to be changed following standards and guidelines set forth by SGNA and APIC for reprocessing of water bottles used during Gastrointestinal Endoscopy.
- Using unauthorized, non-Bracco brand tubing sets will void the warranty. Bracco cannot assume any risk related to the use of non-Bracco brand product.
- Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Never attempt to service the device when it is connected to a power source. Hazardous voltages inside the device can cause severe electrical shock. Disconnect the power cord before servicing.
- Ensure that all high-pressure gas line connections are secure before opening the gas source(s). Loose connections could separate unexpectedly with great force, causing personal injury.
- This device should be operated only by or under the direct supervision of a licensed physician experienced in Gastrointestinal Endoscopy. The user should be thoroughly familiar with the operation of this device prior to use. Additionally, individuals using this device must be alert and attentive to the operation of the system while it is connected to the endoscopic system. Diligence on the part of the operator is an essential requirement of overall device safety.
- To avoid the risk of electrical shock, connect the power cord to a properly wired grounding receptacle only.
- To prevent unit contamination, use only CO₂ Endoscopic Tubing Set which includes a ≤ 0.1 micron hydrophobic filter.
- Always instruct the patient to immediately notify the operator of any pain experienced during the procedure.

- If an emergency should arise whereby the need to terminate the procedure is required, operators should stop the gas flow by turning off the power to the insufflator and promptly disconnecting the CO₂ Endoscopic Tubing Set at the unit's Output Port.
- The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR can release CO₂ to the surrounding atmosphere in the event of misuse or a fault condition. Use and store the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR in a well ventilated environment. Additionally, make sure all CO₂ supply tank connections are correctly installed and free of visible damage. Should an unexplained rapid discharge of CO₂ occur, evacuate the immediate area until it has had sufficient time to ventilate.
- High Pressure USP CO₂ is supplied to the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR from commercially available CO₂ supply tanks. Please read and carefully follow all Warnings, Cautions and Handling Instructions provided with, and listed on these CO₂ supply tanks that are used with the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. Failure to do so can result in Serious Injury or Death.
- This product contains phthalates which have been perceived as having possible carcinogenic, mutagenic and reproductive risks. However, based on all existing scientific data, the long history of safe use of medical device products containing phthalates, as well as the short duration of contact with this device, there are no known cancer or reproductive risks to humans. Physician discretion is required to ensure that benefits outweigh risks when this device is used in children, elderly and pregnant women.



4.2 CAUTIONS

- Do not allow fluids to enter the device.
- The unit should not be opened except by a qualified service person. Tampering by unqualified persons can damage the unit and void the warranty.
- Verify proper connection of tubing before using the unit.
- This device has not been tested for MR (Magnetic Resonance) compatibility, and should not be introduced into the MR scanner room.
- Do **Not** attempt to use this system until you have completed all the steps in “Assembly Prior to Use” Section 9.0 and “Setting-Up for the Procedure” Section 10.0. If the equipment differs significantly in appearance or operation from the way it is presented in this manual, or you have any doubts what-so-ever concerning its installation or operation, inform Professional Services at 1-800-631-5245 (USA), 1-609-514-2200.

Section 5.0 DESCRIPTION OF EQUIPMENT

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is indicated for use as a means to use CO₂ as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope under direct observation of a physician.

5.1 SPECIFICATIONS

Size:	10" wide x 5.5" high x 10.5" deep. 254 mm x 140 mm x 254 mm
Weight:	Less than 20 lb. (9.0 kg).
Control Panel:	Push-buttons and rocker switch. Digital pressure and volume readouts.
Gas Flow:	0 to 3 LPM.
Operating Pressure:	0 to 350 mm Hg operating.
Pressure Relief Valve:	Relief of pressure at 375 mm Hg A redundant relief of pressure at 400 mm Hg. Both reliefs are active whether gas flow is on or off for added protection.
Operating modes:	Managed Flow, Free Flow, and FLOW STOP/RUN.
Gas Inlet:	"D" or "E" CO ₂ supply tank.

WARNING: *Do not allow liquid CO₂ to enter the unit. This can be prevented by assuring that the CO₂ supply tank is maintained in a vertical position at all times.*

Gas Input Pressure:	75 to 2200 psi, flow to 25 psi.
Tubing Set:	Available for use with ≤0.1 micron hydrophobic filter. E-Z-EM, Inc. supplies a Tubing Set that includes this filter.

5.2 ELECTRICAL REQUIREMENTS

Input Voltage:	100 to 240 VAC nominal line voltage; 50/60 Hz. (line voltage can vary by ±10% from nominal).
Power:	25 watts, double fusing with removable power cord.
Standards:	UL-2601-1; IEC-60601-1; IEC-60601-1-2; EN55011; EN60601-1-2; EN50082-1; EN61000-4-2-3-4-5-6-8-11, EN61000-3-2-3.

5.3 UL EQUIPMENT CLASSIFICATION

Underwriter's Laboratories/CSA Class I Type B

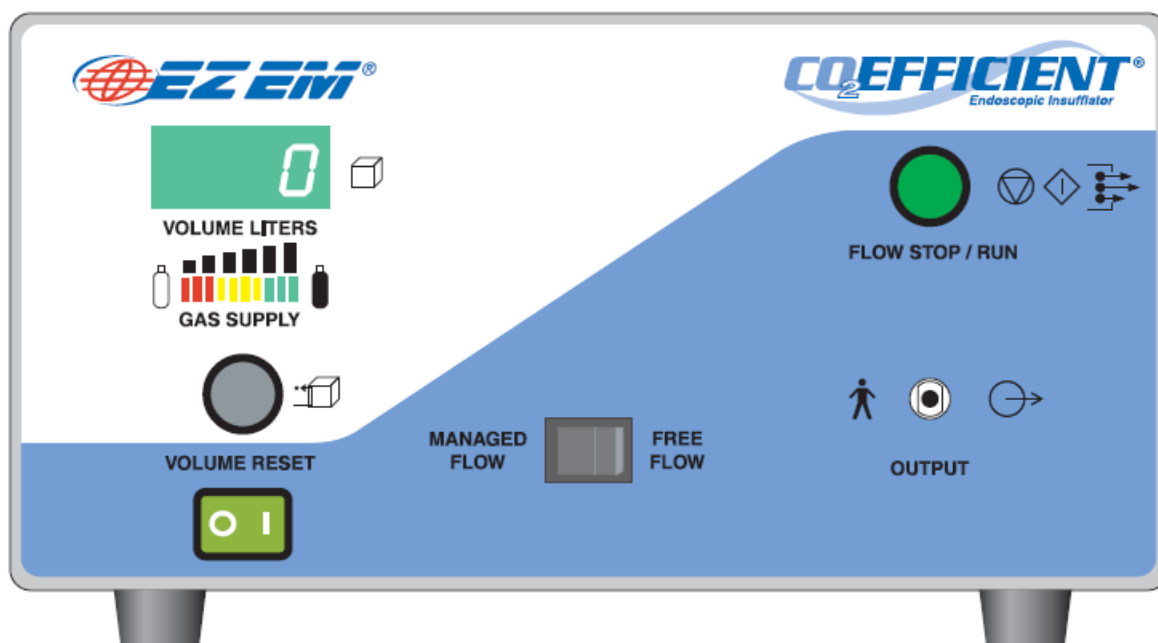
5.4 ENVIRONMENTAL REQUIREMENTS

Operating Temperature:	50° to 104° F (10° to 40° C)
Operating Relative Humidity:	30 to 70% non-condensing
Operating Pressure:	700 to 1060 hPascal 20.7 to 31.3 (inches of Mercury)
Storage Temperature:	32° to 160° F (0° to 70° C)
Storage Relative Humidity:	20 to 90% non-condensing
Storage Pressure:	500 to 1060 hPascal 14.8 to 31.3 (inches of Mercury)

Not to be used in the presence of flammable gases.

NOTE: This unit has not been tested for MR compatibility and should not be introduced into the MR exam room.

Section 6.0 FRONT PANEL CONTROLS



NOTE: The appearance of your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR may differ slightly from the units shown in the illustrations and photographs. (Example: buttons may be round or square).

[1] GAS SUPPLY INDICATOR

Three colors of LED's to indicate the relative amount of gas available in a "D" or "E" CO₂ supply tank.

[2] VOLUME LITERS DISPLAY

Indicates the total amount of gas used since last reset.

[3] VOLUME RESET

Clears the volume display to zero.

[4] FLOW STOP/RUN

Depression starts flow and button will illuminate. CO₂ will flow in one of two modes set by the switch. The pressure response characteristics at which CO₂ is delivered to distend the gastrointestinal tract is a function of the clinician and how this clinician uses CO₂ to distend the gastrointestinal tract during a procedure. In Managed Flow Mode, the control system will automatically transition between the high flow rate and low flow rate as required during the procedure to compensate for external variables.

To prevent wasting gas in the Free Flow mode, when the FLOW STOP/RUN button is pressed initially and after 150 Liters of CO₂ is continuously delivered, the unit automatically returns to STOP mode. An audible alert, in the form of a single chirp, will sound when the unit automatically returns to STOP mode. Thereafter, subsequent presses of the FLOW STOP/RUN button will resume the

delivery of CO₂ for an additional 150 Liters before automatically returning to STOP mode. To prevent wasting gas in the Managed Flow mode, when the FLOW STOP/RUN button is pressed initially and no changes in pressure have been detected for 10 minutes, the unit automatically returns to STOP mode. An audible alert, in the form of a single chirp, will sound when the unit automatically returns to STOP mode. However, you can stop the flow using the FLOW STOP/RUN button while the unit is in RUN mode, as evidenced by the illuminated FLOW STOP/RUN button.

The user can always depress the FLOW STOP/RUN button during any of these volume increments to stop delivery of CO₂.

NOTE: Flow cannot be initiated if gas bottle pressure is less than 25 psi.

[5] FLOW MODE SELECTION SWITCH

The unit operates in one of two modes.

When the switch is set Free Flow Mode, the unit will deliver CO₂ at a flow rate of 3 liters per minute continuous. The clinician will use the air/water valve on the endoscope and visual feedback of the endoscopic system to manually distend the gastrointestinal tract with CO₂.

When the switch is set to Managed Flow Mode, the system will be delivering CO₂ in an more efficient manner. This mode reduces the amount of CO₂ that is lost through the air/water valve which is normally lost at a rate of 3 liters per minute. When gas is not used in the endoscopic system to insufflate, the unit will operate at the Managed Flow rate of 0.25 to 1.0 liter per minute. This transition to the Managed Flow rate will occur if the unit senses no need for insufflation in a 2 second time period. When gas is needed to insufflate, the unit will deliver CO₂ at a flow rate of 3 liters per minute.

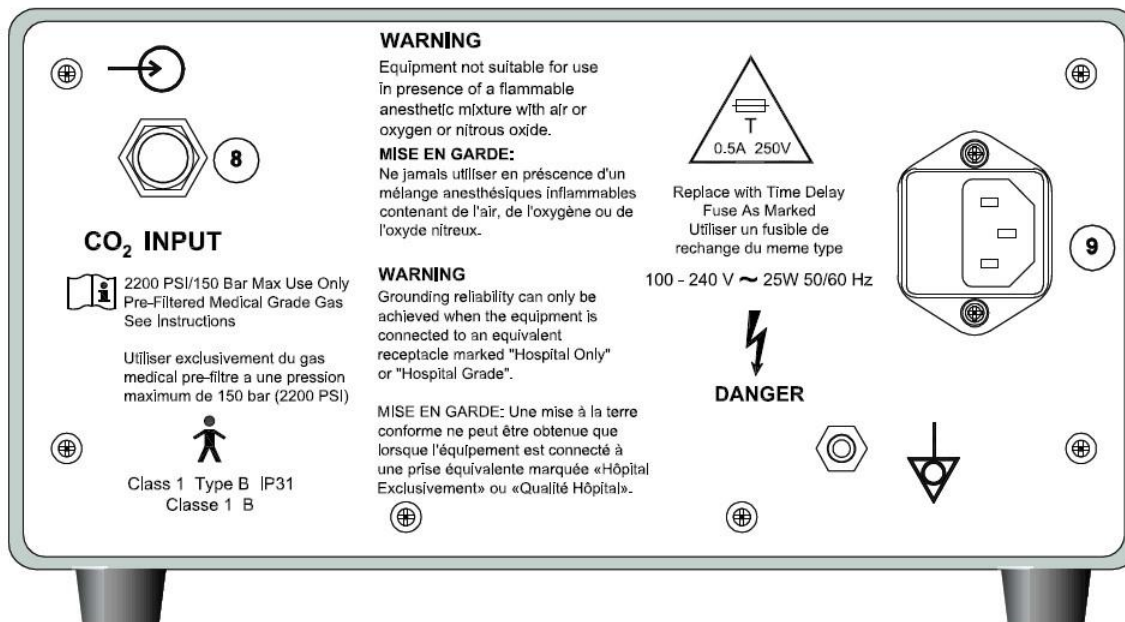
[6] GAS OUTPUT CONNECTION TO ENDOSCOPE

Connector for Tubing Set.

[7] POWER SWITCH

Turns the power on and off to the unit.

Section 7.0 REAR PANEL CONTROLS



[8] GAS INPUT PORT

For connecting a “D” or “E” supply tank using the High Pressure Hose and Yoke assembly provided.

WARNING: *Do not allow liquid CO₂ to enter the unit. This can be prevented by assuring that the CO₂ supply tank is maintained in a vertical position at all times.*

[9] AC POWER CONNECTION

Universal AC line input device – nominal AC line voltage 100 to 240 VAC frequency 50/60 Hz. The AC line voltage should not drop below 90 VAC or exceed 264 VAC. There are no switches or other AC line configuration requirements.

The line cord (mains lead) supplied with this unit is designed and approved for use in the USA and Canada only, and should not be used outside these countries. For use outside of the USA and Canada, your Distributor will supply a line cord that is approved for use in your country.

AC input is with a standard hospital grade line cord (mains lead). Connection should be to hospital grade receptacles only.

Section 8.0 HIGH PRESSURE HOSE AND YOKE ASSEMBLY

The assembly consists of the YOKE as shown in Figure 8.1 and the HIGH PRESSURE HOSE as shown in Figure 8.2.

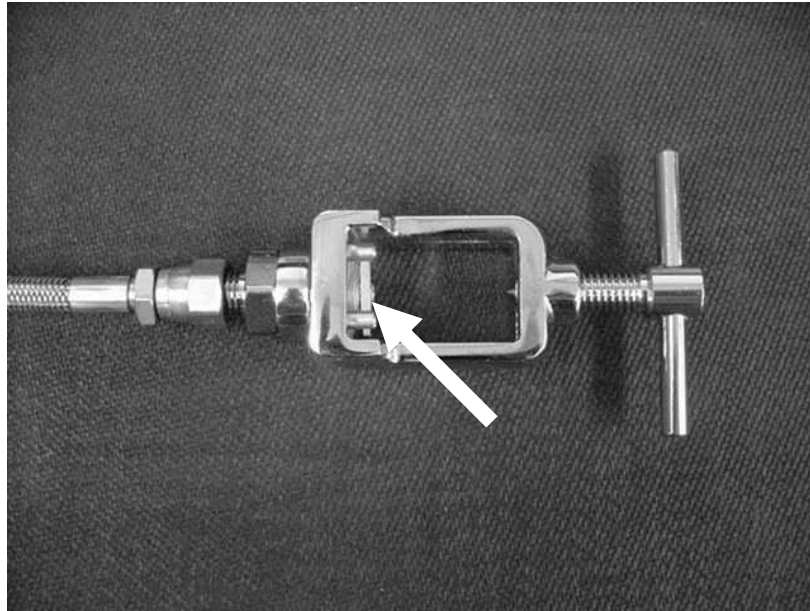


Figure 8.1

NOTE: Before proceeding to the next step, check for the presence of the plastic gasket on the inside of the yoke (arrow on Figure 8.1).

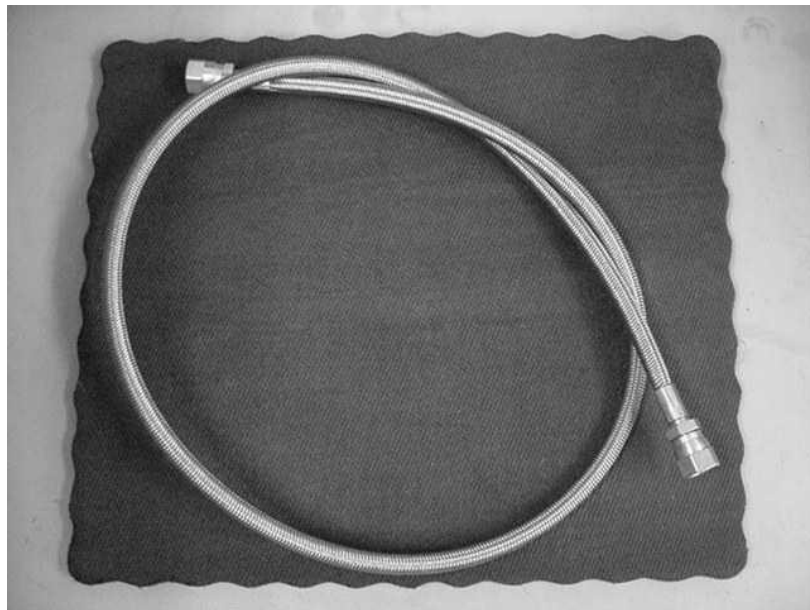


Figure 8.2

Section 9.0 ASSEMBLY PRIOR TO USE

IMPORTANT

If at any time the unit performs erratically or provides otherwise abnormal operation, remove the unit from service and have it inspected or repaired.

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should be inspected upon receipt and before each use. Damaged equipment should be removed from service and returned to E-Z-EM, Inc. for repair or replacement. Before each use, perform the procedures and inspections described in Sections 9.1, 9.2 and 9.3

9.1 PREPARATION

1. Install the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR on the Accessory Cart that can be purchased separately, or on a flat surface, away from potential sources of spraying or leaking liquids.
2. Visually inspect the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR for external signs of damage.

9.2 ELECTRICAL CONNECTIONS

1. Inspect the electrical connections. Do not use if inspection reveals any damage.
2. Connect the line cord (mains lead) to the AC Power Connection on the back of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR.
3. Before connecting the line cord (mains lead) to the hospital grade wall outlet, make sure that the main power switch is off and that the voltage is correct. The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR has a universal AC line input device, the nominal AC line voltage is 100 to 240 VAC and the AC line frequency is 50/60 Hz. The AC line voltage should not drop below 90 VAC or exceed 264 VAC. There are no switches or other AC line configuration requirements.

9.3 CO₂ HOSE CONNECTIONS

1. If not already connected, assemble the High Pressure Hose and Yoke using a 9/16" open-ended wrench on the hose fitting and a 3/4" open-ended wrench on the yoke's hexagonal shaped surface. The complete Hose-Yoke assembly is shown in Figure 9.1. Identify the post valve yoke positioning holes on the CO₂ supply tank (tank not provided with system), as shown in Figure 9.2.

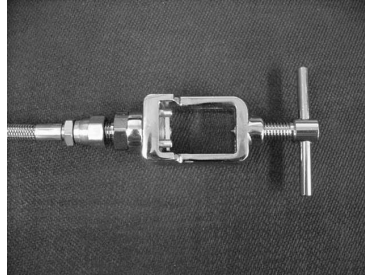


Figure 9.1

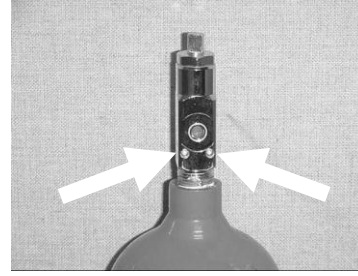


Figure 9.2

2. Slide the Hose-Yoke assembly over the top of the post valve and align the two positioning pins from the yoke with the two locating holes from the CO₂ supply tank post valve. Insert the pins into the locating holes and tighten the yoke on the post valve with the T-handle provided with the yoke. Place the valve wrench included with cart (see Figure 9.3), or equivalent open-ended wrench, on the valve stem as shown in Figure 9.4



Figure 9.3

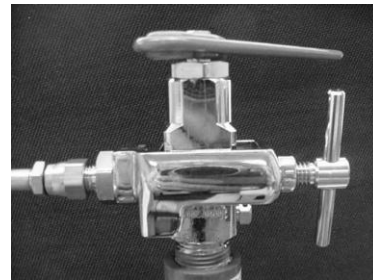


Figure 9.4

3. Remove cap from the CO₂ Input port on back of the unit. Tighten the other end of the High-Pressure Hose to the CO₂ Input port on the back of the unit using a 9/16" open-ended wrench (see Figure 9.5).



Figure 9.5

NOTE: Do not use any teflon tape or thread sealing compounds on any connection.

WARNING: *Do not allow liquid CO₂ to enter the unit. This can be prevented by assuring that the CO₂ supply tank is maintained in a vertical upright position at all times.*

USE ONLY MEDICAL GRADE CO₂ SIZE “D” OR “E” supply tanks.

Before each use the following procedures or inspections should be performed:

Visually inspect the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR for external signs of damage.

Inspect the electrical connections. Do not use if inspection reveals damage.

Before connecting the power cord to the wall outlet, make sure the main power switch is off and that the voltage is correct.

Inspect the connection to the CO₂ supply tank, to assure it is intact and tight.

Section 10.0 SETTING-UP FOR THE PROCEDURE

10.1 POWER ON AND GAS SUPPLY INDICATOR

1. Open the valve on the CO₂ supply tank approximately 1 turn. Turn on the Power Switch. Upon turn on, all lights and indicators will be illuminated for a brief period.
2. The Gas Supply indicator should display red-yellow-green bars. The color coding in the bar graph is a guide to determine whether there is sufficient gas in a “D” or “E” CO₂ supply tank to finish a procedure, as indicated below:

<u>Lights</u>	<u>Available CO₂ Gas</u>
Green	Tank is Full.
Yellow	Tank is Getting Low.
Red	Tank is Low. Change Tank!

10.2 PREPARATION TEST

There is always the possibility that delicate equipment can be damaged in transportation or storage. Therefore it is important to verify proper operation of the unit before use.

1. After power is applied to the unit, verify that the front panel lights are enabled.
2. To verify that flow control is functioning properly, depress the FLOW STOP/RUN button. When pressed, the light in the switch should light, and gas may be heard exiting from the unit. If gas does not begin flowing, verify that the CO₂ supply tank valve is in the open position (see section 10.1, *Power On and Gas Supply Indicator*).
3. To prevent wasting gas in the Free Flow mode, when the FLOW STOP/RUN button is pressed initially and after 150 Liters of CO₂ is continuously delivered, the unit automatically returns to STOP mode. Thereafter, subsequent presses of the FLOW STOP/RUN button will resume the delivery of CO₂ for an additional 150 Liters before automatically returning to STOP mode. To prevent wasting gas in the Managed Flow mode, when the FLOW STOP/RUN button is pressed initially and no changes in pressure have been detected for 10 minutes, the unit automatically returns to STOP mode. However, you can stop the flow using the FLOW STOP/RUN button while the unit is in RUN mode, as evidenced by the illuminated FLOW STOP/RUN button.
4. If the unit does not perform properly, do not use. Inspect the unit using the Troubleshooting Guide (Section 13.0) before returning for service.

10.3 TUBING SET CONNECTION

Insert the connector on the Tubing Set to the Gas Output connection on the unit's front panel. It is important to use only Bracco manufactured high flow tubing labeled as Bracco CO₂ Endoscopic Tubing Set (that includes a ≤ 0.1 micron hydrophobic filter) designed to provide optimum performance. Always inspect every Tubing Set to make sure there are no signs of damage. If such a condition exists, do not use the Tubing Set. See Tubing Set instructions for use.

10.4 SETTING MODE OF OPERATION

To set the mode of operation, use the rocker switch on the front panel to select between Managed Flow and Free Flow.

10.5 RESET CO₂ VOLUME

Assure that the Volume Liters Display reads zero prior to starting the procedure. To reset the Volume Liters Display, press the Volume Reset button.

NOTE: Do not press Volume Reset button once procedure has started.

10.6 CONNECTION TO ENDOSCOPIC SYSTEM

The Tubing Set connects into the air/water line of the endoscopic system. Depending on the Endoscope manufacturer there are different connections to the air/water supply line. Each connection has a Luer adaptor and some examples are provided below.



Figure 10.1 CO₂ Adaptor for Pentax Endoscope



Figure 10.2 Example Olympus Water bottle with CO₂ Connection MAJ-902

*Pentax Medical Group is a Division of Pentax of America, Inc.
Olympus America is a Division of Olympus Corporation.*

10.7 SYSTEM SET-UP

The following operational sequence describes the system set-up for both the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR and Tubing Set:

- i) Make sure the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is powered up with no Tubing Set in place.
- ii) Make sure the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is in STOP mode.
- iii) Use the Flow Mode Selection Switch to set the desired mode for the system.
- iv) As required, zero the volume display using the Volume Reset button.
- v) Remove the Tubing Set from its packaging.

- vi) Connect Tubing Set Luer fitting to the endoscopic system.
- vii) Connect the Tubing Set fitting to CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR.
- viii) Start the endoscopic system by turning on the necessary light and video equipment.
- ix) Verify that the air supply from the endoscopic system is turned off.
- x) Start CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR by pressing the FLOW STOP/RUN button.
- xi) Monitor the unit's volume indicator during procedure
- xii) Stop the unit at conclusion of procedure.

NOTE: *If an emergency should arise whereby there is a need to terminate the procedure, the operator should stop the CO₂ gas flow by turning off the power to the insufflator and promptly disconnecting the Tubing Set at the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR Output port.*

10.8 CO₂ VOLUME DISPLAY

The Digital Volume Display reads the total volume of CO₂ passing from the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR to the patient. The digital display indicates the volume of CO₂ delivered in Liters and tenths of Liters and has a range of 0 to 999 Liters.

10.9 TERMINATING GAS FLOW & SHUT-DOWN PROCEDURES

1. Upon completion of the diagnostic procedure, press the FLOW STOP/RUN button if in RUN mode.
2. Discard the entire CO₂ Endoscopic Tubing Set according to standards and guidelines set forth by SGNA and APIC for reprocessing of water bottles used during Gastrointestinal Endoscopy.
3. Turn power off and disconnect the power cord from power outlet.
4. It is recommended that the CO₂ supply tank valve be fully closed when not in use.

Section 11.0 DECONTAMINATION, CLEANING AND STORAGE

Prior to disinfecting the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, ensure the power is turned off and the line cord (mains lead) is unplugged. To disinfect the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR wipe down with an intermediate-level disinfectant (corrosive disinfectants, such as bleach, are not recommended since they may damage the equipment) in accordance with the manufacturer's directions. Do not use abrasive or sharp-edged devices when disinfecting the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. Do not allow fluids to enter the unit. Dry all components thoroughly. Do not sterilize or autoclave this unit.

For general cleaning, the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR can be wiped down with a damp cloth and mild soap.

The E-Z-EM, Inc. CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should be covered and stored in a cool dry location. Care should be taken to avoid rough handling, jarring, or dropping the unit.

There are no user adjustments inside the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR case. Repairs and adjustments are to be performed only by Bracco or authorized service or repair facilities. Unauthorized service, repair, or modifications to the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR will void your warranty.

*If repairs become necessary call E-Z-EM prior to returning the device, and request an RA (Return Authorization) number.

Warranty repairs will be made without charge. All other repairs will be made on a time and material basis. If requested, E-Z-EM will provide an estimate of the repair cost and the time for the repair before any work is done. Repair items should be carefully repackaged and returned, post paid, to:

E-Z-EM INC.
532 Broadhollow Rd.
Suite 126
Melville, NY 11747 USA

***PRODUCTS MAY NOT BE RETURNED TO E-Z-EM UNLESS E-Z-EM. HAS PROVIDED AN RA NUMBER TO THE PURCHASER. ALL PRODUCTS BEING RETURNED TO BRACCO MUST BE ACCOMPANIED BY A CERTIFICATE OF NON-CONTAMINATION.**

11.1 MAINTENANCE CHECKS

As with any precision instrument, periodic inspection of the unit on an annual basis is recommended, or on a more frequent basis if conditions require.

It is recommended that the following inspection be conducted on at least an annual basis and recorded on the following page. Prior to recording, a copy of the page should be made so that future inspection results can be recorded.

1. Visually inspect the line cord (mains lead) that is used to provide power to your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. If it is worn, frayed or damaged, replace it immediately with an equivalent IEC 60601-1 Rated (Medical Grade) line cord (mains lead) possessing a grounded IEC-320 plug. **Warning: Do not use or replace with a commercially rated line cord (mains lead).**
2. Visually inspect the high-pressure hose between the CO₂ supply source and the rear panel of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. If it is worn, frayed, kinked or damaged, call E-Z-EM immediately to obtain a replacement. Confirm hose is firmly attached to unit and a “D” or “E” sized medical grade CO₂ tank.
3. Verify that the power rocker switch on the front panel is seated properly, undamaged, exhibits no evidence of fluid/dirt infiltration. Plug in the line cord (mains lead), ensure the power switch is on the “I” position and check if unit’s front display lights up.
4. Connect the device to a CO₂ supply source and attach a CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR compatible tubing set to the outlet port on the front panel. Switch unit to Free Flow mode using front panel rocker switch. Open CO₂ tank. Confirm CO₂ gas supply gauge on front panel illuminates fully. When testing with the disposable water bottle tubing set, place the capped end of the tubing set into a sterile water bottle that is 1/2 filled. Place the free end (the end that normally connects to the endoscope) in a cup of sterile water. When testing with a 710304 (aka 6601) Tubing Set, place the free end (the end that normally connects to a reusable CO₂ water bottle or Pentax adapter) into a cup of sterile water. Power on the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR.
 - a. Verify the unit insufflates CO₂ by pressing the FLOW STOP/RUN button. The green lamp will illuminate. CO₂ will begin to exit the tubing set causing the water to bubble.
 - b. Switch flow mode to Managed Flow mode on the front panel and confirm CO₂ exits the tubing set and causes the water to bubble. *It will bubble with less intensity than it does in Free Flow mode.*
5. Turn unit off. Unplug Tubing Set and visually inspect the metal gas outlet connection on the front panel for damage or fluid invasion.
6. Using an Electrical Safety Analyzer designed for measuring leakage current for medical equipment (e.g. Fluke, Dynatech Nevada, Biotech, etc.), measure the earth leakage current. Verify that this is less than 300 microamperes for the Class 1, Type B rating, as indicated on the rear panel of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. At conclusion of testing, power off unit, shut-off CO₂ supply and unplug unit.
 - i. If you are unable to perform this inspection, the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR can be sent to Bracco Diagnostics Inc.
7. Refer to the Troubleshooting Guide in the back of this Operator’s Manual.

MAINTENANCE CHECKLIST

Refer to Section 11.1 of this Operator's Manual for instructions on how to perform each item in the checklist below:

- | | | |
|---|-------------------------------|-------------------------------|
| 1. Inspection of line cord (mains lead) | ☐ Pass | ☐ Fail |
| 2. High Pressure Hose Inspection | ☐ Pass | ☐ Fail |
| 3. Front Panel Rocker Switch Inspection | ☐ Pass | ☐ Fail |
| 4. Inspection of CO ₂ Insufflation | ☐ Pass | ☐ Fail |
| 5. Visual Inspection of Gas Outlet Connection | ☐ Pass | ☐ Fail |
| 6. Inspection of Earth Leakage Current | ☐ Pass | ☐ Fail |
| Actual Reading _____ | | |

If for any reason, the integrity of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is suspect as a result of these inspection steps, please call Customer Service to make arrangements for repair.

Tested By: _____ Test Date: _____

Unit Serial Number: # _____

Located on bottom of unit

11.2 PROFESSIONAL SERVICES AND ORDERING INFORMATION

Phone: 1-800-631-5245 (USA), 1-609-514-2200

11.3 WARRANTY

Your new CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is warrantied against all defects in materials and workmanship for 12 months from the date of purchase.

This warranty shall not apply to any CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR which:

- Has been repaired by anyone other than an authorized E-Z-EM representative.
- Has been altered in any way so as to, in the judgment of E-Z-EM, affect its function.
- Has been subject to misuse, negligence, or accident, including damage caused by contact with patient effluent or other substances.

This warranty does not cover routine cosmetic wear and tear on the system, including scratching and marring of this device.

This warranty is in lieu of all other warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness for a particular use, and of all other obligations or liabilities on the part of E-Z-EM. There are no warranties that extend beyond the description on the face hereof.

11.4 CERTIFICATION OF NON-CONTAMINATION

- All products being returned to E-Z-EM, Inc. must be accompanied by a Certificate of Non-Contamination.
- Products that have become contaminated in any way shall **not** be returned to E-Z-EM Inc., unless special written permission has been granted by E-Z-EM, Inc. Otherwise, a Certificate of Non-Contamination shall be provided with returned products that have been reportedly decontaminated.
- In other special cases certification of Proper Handling for Bio-Hazardous Material must be sent to E-Z-EM, Inc. for pre-approval before such material can be returned.

Section 12.0 CERTIFICATE OF NON-CONTAMINATION



Customer Name: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Contact Name: _____

Authorized Signature: _____

Telephone # and E-mail: _____

Product Model No.: _____

Description: _____

SERIAL No.: _____ RA. No.: _____

The above person hereby certifies that the above described product being returned to E-Z-EM, Inc., has been inspected and contains no foreign material or fluids and is not contaminated with any bio-hazardous matter or any other material that may cause or contribute to any illness or personal injury of any kind.

Prior to disinfecting the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, ensure the power is turned off and the electrical cord is unplugged. To disinfect the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR wipe down with an intermediate-level disinfectant (corrosive disinfectants, such as bleach, are not recommended since they may damage the equipment) in accordance with the manufacturer's directions. Do not use abrasive or sharp-edged devices when disinfecting the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. Do not allow fluids to enter the unit. Dry all components thoroughly. Do not sterilize or autoclave this unit.

Prior to returning any product to E-Z-EM, Inc. complete this Certificate of Non-Contamination Form, and send/fax to E-Z-EM, Inc. Quality department at 1-631-847-3904.

Section 13.0 TROUBLESHOOTING GUIDE

Make sure that you have read and understand the prior sections of this operator's manual that provide normal operating instructions for your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, including the **WARNINGS AND CAUTIONS** Section, 4.0. Before making arrangements with E-Z-EM, Inc. Customer Service to send your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR unit back to the factory for service, we ask that you take a few minutes to review the following information in this guide while simultaneously examining your unit.

Please be advised that the appearance of your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR may differ slightly from the units shown in the following photographs. (Example: buttons may be round or square).

The Field Checkout steps listed here pertain to common operating conditions and possible malfunctions. Review this information and refer to it when communicating with your E-Z-EM, Inc. Customer Service Representative. This will enable us to identify the best course of action to meet your service needs.

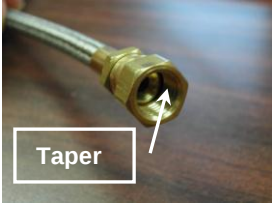
Should you need further assistance with this guide, see your supervisor, or contact E-Z-EM, Inc. Customer Service at 1-800-631-5245 (USA), 1-609-514-2200.

Condition	Possible Causes	Field Checkout
<i>My CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR does not power-up at all.</i> What should I do?	No power at wall outlet. Blown fuse.	Check CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR in wall outlet known to be operational. Remove power cord from rear panel of CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR and use a small screwdriver to open fuse holder.  Pull fuse holder down and examine fuses.  If blown, replace with 0.5-Amp 250-Volt Time-Delay Fuses.

Condition	Possible Causes	Field Checkout
<i>My CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR does not power-up at all.</i> What should I do?	Front panel rocker power switch is “off”.	With unit plugged into wall outlet, activate Power Switch to the ON or (1) position. Upon completing its Power-up sequence, the front panel should appear as follows: The image shows the front panel of the CO₂EFFICIENT INSUFFLATOR. It features a digital display showing '0.0', a 'GAS SUPPLY' indicator, a 'VOLUME RESET' button, and a 'POWER SWITCH' (rocker switch) which is illuminated. The panel also has 'MANAGED FLOW' and 'FREE FLOW' settings, and an 'OUTPUT' port. A white box with an arrow points to the 'POWER SWITCH' and is labeled 'Power Switch'. The power switch should be illuminated with the VOLUME LITERS display will indicate “0”. Additionally, the GAS SUPPLY Indicator should also be illuminated and indicate the current amount of CO₂ in the supply tank. The above display indicates that the unit has correctly powered-up. Should the unit continue to fail to power-up, or if the front panel does not appear as shown above after power-up, you will need to contact Professional Services.

Condition	Possible Causes	Field Checkout
<i>My CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR does not deliver CO₂.</i> What could be the problem?	Empty CO₂ supply tank or valve closed.	After successfully powering-up your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, examine the GAS SUPPLY Indicator on the front panel. Make sure that the tank valve for the CO₂ supply tank is open. Your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should sense the pressure from the CO₂ supply tank and the GAS SUPPLY Indicator should illuminate as follows: 3 red, 4 yellow and 3 green. If during power-up or operation of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR, the CO₂ in the supply tank is depleted, the illuminated GAS SUPPLY Indicator segments extinguish themselves from the full reading. Once the GAS SUPPLY Indicator shows 3 red segments, the unit will periodically beep and no longer deliver CO₂. If this occurs, reconnect the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR to a full CO₂ supply tank to continue operation. Should the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR's CO₂ Supply display fail to indicate full after verifying the CO₂ supply tank is full and the tank valve is open, you will need to contact Professional Services.

Condition	Possible Causes	Field Checkout
<i>My CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR does not deliver CO₂.</i> What could be the problem?	CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR flow rate incorrect.	To check the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR's ability to deliver CO₂ to the patient, follow these verification steps: After powering-up and making sure that your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is connected to the CO₂ supply tank, depress the VOLUME RESET button, zero will appear in the VOLUME LITERS display.  Set the mode selector switch to FREE FLOW. Disconnect the Tubing Set if connected. Press the FLOW STOP/RUN button to start.  Using a wrist watch with a second hand or a stop watch, allow the unit to deliver 3.0 liters of CO₂. The unit should reach this volume between 50 and 70 seconds. During this time interval, place your finger near the Gas Output. You should feel CO₂ exiting from the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. 

Condition	Possible Causes	Field Checkout
<i>My CO₂ supply tank is prematurely emptying.</i> What could be the problem?	Valve on CO₂ supply tank left open all of the time. High Pressure Hose from CO₂ supply tank is not installed properly.	We recommend attaching your CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR accessory to either “D” or “E” size CO₂ supply tank. For days when the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is scheduled for continuous use, the CO₂ supply tank valve should be opened at the start of the shift and closed at the end of the shift. The pneumatic design of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is not intended to provide a full time gas seal from the CO₂ supply tank while the device is not being used or in storage. Should the CO₂ supply tank valve inadvertently be left open, there is a high likelihood that the CO₂ supply tank contents will gradually empty over several days. If after opening and closing the CO₂ supply tank valve with your procedure schedule, you still encounter problems with CO₂ supply tank prematurely emptying, there is the possibility that the High Pressure Hose from the CO₂ supply tank to the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR unit is leaking. Please inspect the High Pressure Hose in accordance with the following procedure: Close valve on CO₂ tank. Using an adjustable or open-ended ¾" wrench, detach the High Pressure Hose from CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR’s rear panel. Inspect the tapered surface of the free standing nipple on the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR and the interior of the High Pressure Hose. This is the sealing surface. Verify that it is free of any debris or contaminant. Also, verify that the surface is smooth and free of any nicks or distortion.   Repeat this inspection procedure at the identical tapered gas connection at the CO₂ supply tank valve yoke.

Condition	Possible Causes	Field Checkout
“CONTINUED” <i>My CO₂ supply tank is prematurely emptying.</i> What could be the problem?	High Pressure Hose from CO₂ supply tank is not installed properly.	Inspect the CO₂ supply tank yoke and verify that the plastic disc that creates the gas seal at the CO₂ supply tank valve is in-place and free from defect. After verifying all High Pressure Hose sealing surfaces are clean and free of defect; reconnect the High Pressure Hose to the CO₂ supply tank yoke and CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR. Use an adjustable or opened-ended ¾" wrench to tighten securely. <u>DO NOT USE ANY TEFLON TAPE OR THREAD SEALING COMPOUNDS.</u> Reconnect the yoke to the CO₂ supply tank valve making sure that the plastic sealing disc is in place. Open the CO₂ supply tank valve. If CO₂ continues to prematurely empty or should you hear CO₂ escaping from any of these connections or the High Pressure Hose itself, contact Professional Services.

Section 14.0 EMC TABLES

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR has been tested by Underwriters Laboratory to the following electromagnetic compatibility standards:

Table 1 Guidance and manufacturer's declaration – electromagnetic emissions		
The CO ₂ EFFICIENT ENDOSCOPIC INSUFFLATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the CO ₂ EFFICIENT ENDOSCOPIC INSUFFLATOR should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
CISPR 11 RF Emissions	Group 1	The unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
CISPR 11 RF Emissions	Class A	
IEC 61000-3-2 Harmonic Emissions	Class A	
IEC 61000-3-3 Voltage fluctuations / flicker emissions	Complies	

Table 2 Guidance and manufacturer's declaration – electromagnetic immunity			
The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
IEC 61000-4-2 Electrostatic discharge (ESD)	+/-6 KV contact +/-8 KV air	+/-6 KV contact +/-8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
IEC 61000-4-4 Electrical fast transient burst	+/-2 KV for power supply lines +/-1 KV for input/output lines	+/-2 KV for power supply lines +/-1 KV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 Surge	+/-1 KV differential mode +/-2 KV common mode	+/-1 KV differential Mode +/-2 KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-11 Voltage dips, short interruptions and voltage variations on power supply input lines	<5 % U_t (>95 % dip in U_t) for 0.5 cycle 40 % U_t (60 % dip in U_t) for 5 cycles 70 % U_t (30% dip in U_t) for 25 cycles <5 % U_t (>95 % dip in U_t) for 5 sec	<5 % U_t (>95 % dip in U_t) for 0.5 cycle 40 % U_t (60 % dip in U_t) for 5 cycles 70 % U_t (30% dip in U_t) for 25 cycles <5 % U_t (>95 % dip in U_t) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CO ₂ EFFICIENT ENDOSCOPIC INSUFFLATOR requires continued operation during power mains interruptions, it is recommended that the CO ₂ EFFICIENT ENDOSCOPIC INSUFFLATOR be powered from an uninterruptible power supply or battery.
IEC 61000-4-8 Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_t is the A.C. mains voltage prior to application of the test level.			

Table 3
Guidance and manufacturer's declaration – electromagnetic immunity

The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CO ₂ EFFICIENT ENDOSCOPIC INSUFFLATOR, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is used exceeds the applicable RF compliance level above, the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table 4
Recommended separation distances between Portable and mobile RF communications equipment and the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR

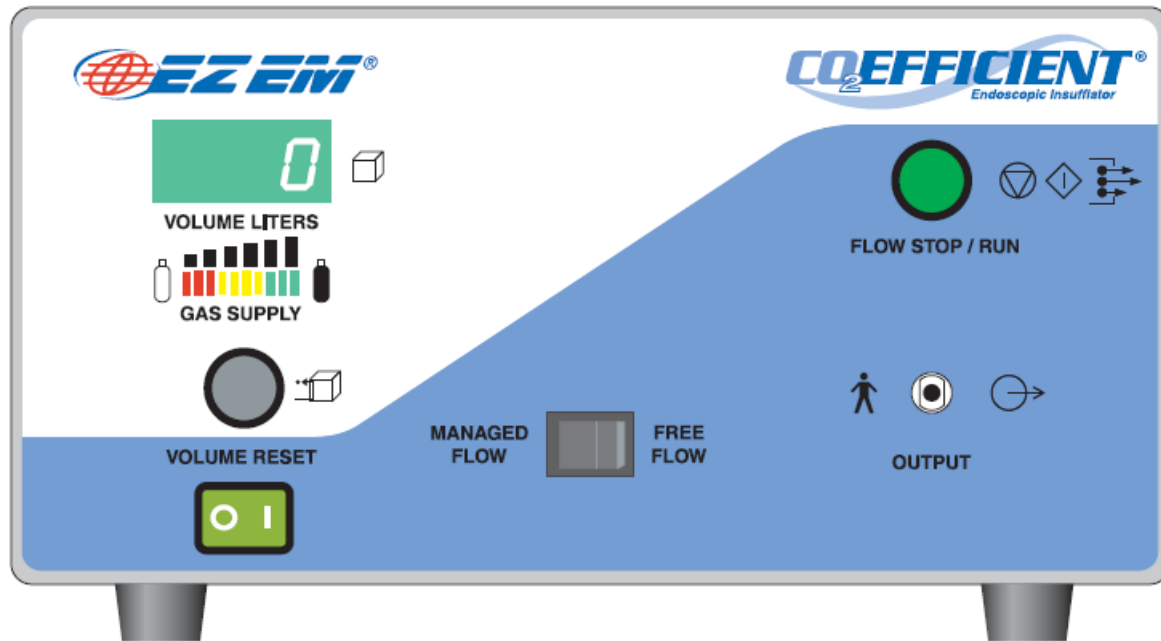
The CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CO₂EFFICIENT ENDOSCOPIC INSUFFLATOR as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter		
Read maximum output power of transmitter	M		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	$d = 1,2 \sqrt{P}$	$d = 1,2 \sqrt{P}$	$d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



Manufactured for E-Z-EM, Inc.
a subsidiary of Bracco Diagnostics Inc.
259 Prospect Plains Road
Monroe Township, NJ 08831 USA
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00800L rev. 07/14