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Section 1.0 UNPACKING AND GENERAL INSPECTION

CAUTION: READ ALL SECTIONS OF THIS MANUAL CAREFULLY BEFORE USING THE CO\textsubscript{2}MPACT ENDOSCOPIC INSUFFLATOR\textsuperscript{®} SYSTEM, SUCH THAT OPERATION IS UNDERSTOOD. IF YOU SHOULD HAVE ANY QUESTIONS, PLEASE CONTACT US ENDOSCOPY CUSTOMER SERVICES AT 1-800-769-8226 OR YOUR LOCAL US ENDOSCOPY 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 CO\textsubscript{2}MPACT ENDOSCOPIC INSUFFLATOR\textsuperscript{®} SYSTEM (also referred to in this manual as "unit", or "device", or “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:

CO\textsubscript{2}MPACT ENDOSCOPIC INSUFFLATOR\textsuperscript{®} SYSTEM

Line Cord (see caution below)
Operator’s Manual (English hardcopy)
Quick Reference Guide
Optimum Performance Warning Label
Air Pump Label

Notify US Endoscopy Customer Services immediately if any damage or discrepancies are noted.

Phone: 1-800-769-8226

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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.

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**: CO₂
- **hPa**: Hectapascal

2.1 INDICATION AND CONTRAINDICATIONS

**Indications for Use**: The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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:

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

If the outlet pressure exceeds 375 mmHg, a fixed mechanical pressure relief valve will open.

An audible indicator will sound when the CO₂ gas supply tank pressure is low. Additionally, the Gas Supply Indicator LED light will turn red.

A user-adjustable automatic gas shutoff timer is present, which prevents the device from running continuously. The shutoff timer can be set to 30, 60, or 120 minutes.
Section 3.0 THEORY OF OPERATION

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM operates by administering CO₂ at a selectable flow rate of 2.0 LPM (Low), 2.9 LPM (Medium), or 3.4 LPM (High), nominally. The flow rate is selected by the operator, by using a button found on the front panel to select from Low, Medium, and High. 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. The unit operates in an identical manner to that of the air pump of an endoscopic system.

The user will need to place the system into START mode in order for it to deliver the CO₂ to the endoscopic system. This is done by powering ON the unit, and then depressing the START/STOP button on the front panel of the unit. A green LED light, adjacent to the START/STOP button, will illuminate indicating that the unit is ON and delivering CO₂.

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM has a mechanical Pressure Relief Valve pre-set to 375 mm Hg. This pressure relief valve is active whether the START/STOP button is on or off.
Section 4.0  WARNINGS AND CAUTIONS

This section describes warning and caution information for safe operation of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. 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 intravasion 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 metabolic imbalance related to excessive CO₂ absorption.
- Use only USP “Medical Grade” CO₂.
- Tank designations vary by country. Please check with your local distributor for compatibility.
- 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-US Endoscopy tubing sets will void the warranty and US Endoscopy cannot assume any risk related to the use of non-US Endoscopy products.
- 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, the unit must be grounded. Always connect the power cord to a properly wired grounded hospital grade AC outlet (wall mains outlet).
- To prevent unit contamination, use only US Endoscopy Endoscopic Tubing Sets which include 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 US Endoscopy Endoscopic Tubing Set at the unit’s Output Port.

• The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM can release CO₂ to the surrounding atmosphere in the event of misuse or a fault condition. Use and store the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM in a well-ventilated environment. Additionally, make sure all CO₂ 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM from commercially available CO₂ supply tanks or from a wall source. Please read and carefully follow all Warnings, Cautions and Handling Instructions provided with, and listed on the CO₂ supply tank or wall source that is used with the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. 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.

• Caution: Federal (and Canadian) law restricts this device to sale by or on the order of a licensed medical practitioner.
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.
- To insure electrical grounding reliability, only use a hospital grade UL 498 compliant power cord.
- Electromagnetic interference or other interference may occur in this instrument when it is placed near other devices or RF communications equipment such as cellular phones. If interference occurs, mitigation measures may be necessary, such as reorienting or relocating the CO₂ MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM or shielding the location.
- Do **Not** attempt to use this system until you have completed all the steps in “Assembly Prior to Use” Section 8.0 and “Setting-Up for the Procedure” Section 9.0. 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 US Endoscopy Customer Services at 1-800-769-8226.
### 4.3 SYMBOLS

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>DEFINITION</th>
<th>SYMBOL</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Type B</td>
<td>![Symbol]</td>
<td>Type and Rating of Fusing</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Consult instructions for use</td>
<td>![Symbol]</td>
<td>CO₂ Gas Input</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Dangerous voltage</td>
<td>![Symbol]</td>
<td>CO₂ Gas Output to the patient</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Interconnection to ensure all equipment is at the same potential or earth ground.</td>
<td>![Symbol]</td>
<td>This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419). In accordance with European Union WEEE Directive 2002/96/EC, US Endoscopy will be fully responsible for the coordination, logistics, and costs of the WEEE process</td>
</tr>
</tbody>
</table>
Section 5.0 DESCRIPTION OF EQUIPMENT

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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

<table>
<thead>
<tr>
<th>Description</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size:</strong></td>
<td>5.75” wide x 6.5” high x 13.25” deep (± ¼”) 146 mm x 165 mm x 337 mm</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>Less than 14 lb. (6.4 kg)</td>
</tr>
<tr>
<td><strong>Control Panel:</strong></td>
<td>Power switch- Rocker style ON/OFF START/STOP button- Membrane push-button type that starts and stops flow of CO₂ from the unit, with an associated LED for each setting adjacent to the button. FLOW button- Membrane push-button type with Low, Medium, and High settings, with an associated LED for each setting adjacent to the button. TIMER button- Membrane push-button type that selects the amount of time until the flow of gas automatically stops. Can be set to 30 Minutes, 60 Minutes, and 120 Minutes, with an associated LED for each setting adjacent to the button. (All time functions have a tolerance of +/- 10%). Gas Supply Indicator- Tri-color LED that indicates how much gas is remaining in the USP medical grade gas cylinder.</td>
</tr>
<tr>
<td><strong>Gas Flow:</strong></td>
<td>(3) user-selectable settings: 2.0 (1.8-2.3) liters/minute (Low), 2.9 (2.7-3.1) liters/minute (Medium), 3.4 (3.2-3.6) liters/minute (High)</td>
</tr>
<tr>
<td><strong>Operating Pressure:</strong></td>
<td>0 to 375 mm Hg operating range (+0% - 10%).</td>
</tr>
<tr>
<td><strong>Pressure Relief Valve:</strong></td>
<td>Fixed mechanical pressure relief valve at 375 mm Hg (+0% - 10%). The relief valve is active whether gas flow is on or off for added protection.</td>
</tr>
<tr>
<td><strong>Gas Inlet:</strong></td>
<td>USP medical grade CO₂ supply tank or wall source supply.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Description</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gas Input Cylinder Pressure:</strong></td>
<td>43 to 2200 psi</td>
</tr>
<tr>
<td><strong>Gas Input Central Supply Pressure:</strong></td>
<td>50 to 203 psi</td>
</tr>
<tr>
<td><strong>Tubing Set:</strong></td>
<td>Available for use with ≤0.1 micron hydrophobic filter. US Endoscopy supplies tubing sets that include this filter.</td>
</tr>
</tbody>
</table>
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: 75 VA, double fusing with removable power cord.

Standards: UL 60601-1, IEC 60601-1, IEC 60601-1-2, CISPR 11,
EN 60601-1-2, EN55011.

Mains Power Cord: IEC 320 compliant

5.3 UL EQUIPMENT CLASSIFICATION

Underwriter’s Laboratories/CSA Class I Type B applied part, IP31 Enclosure rating

5.4 ENVIRONMENTAL REQUIREMENTS

Operating Temperature: 50° to 104° F (10° to 40° C)

Operating Relative Humidity: 30 to 70% non-condensing

Storage Temperature: 32° to 160° F (0° to 70° C)

Storage Relative Humidity: 30 to 75% non-condensing

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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM may differ slightly from the units shown in the illustrations and photographs.

[1] GAS SUPPLY INDICATOR
Tri-color LED to indicate the relative amount of gas available in a CO₂ supply tank.

[2] FLOW RATE
Membrane type button that selects the rate of flow of CO₂ that is being insufflated from the unit. An associated green LED will illuminate to indicate the flow rate. The Low setting indicates a flow rate of 2.0 Liters/Minute. The Medium setting indicates a flow rate of 2.9 Liters/Minute. The High setting indicates a flow rate of 3.4 Liters/Minute.

[3] FLOW TIMER
Membrane type button that selects the amount of time that elapses before the flow of CO₂ automatically stops. An associated green LED will illuminate to indicate the time setting. The three settings are 30 Minutes, 60 Minutes, and 120 Minutes.

NOTE: The device will default to 60 Minutes when powered on.

[4] FLOW START/STOP
Membrane type button that starts and stops the flow of CO₂. An associated green LED will illuminate to indicate when CO₂ is flowing. The START/STOP button can be depressed at any time to stop the flow of CO₂.

NOTE: Flow cannot be initiated in Wall Source mode if the gas pressure is less than 50 psi. Flow cannot be initiated in Tank mode if the gas pressure is less than 46 psi.

[5] GAS OUTPUT CONNECTION TO ENDOSCOPE
Connector for Tubing Sets.

[6] POWER SWITCH
Turns the power on and off to the unit.
Section 7.0  REAR PANEL CONTROLS

[7] GAS INPUT PORT

For connecting a CO₂ supply tank or wall source.

**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.

[8] GAS SOURCE INDICATOR

This switch allows the user to select from a high pressure CO₂ tank or a central supply source wall connection site.

[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 power cord. Connection should be to hospital grade receptacles only.
Section 8.0 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should be inspected upon receipt and before each use. Damaged equipment should be removed from service and returned to US Endoscopy for repair or replacement. Before each use, perform the procedures and inspections described in Sections 8.1, 8.2, 8.3, and 8.4.

8.1 PREPARATION

1. Install the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM on the Accessory Cart that can be purchased separately, or on a flat surface, away from potential sources of spraying or leaking liquids.

2. Position the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM so that the mains power cord connector can easily be reached.

3. The ideal mounting position is even with or above the height of the water bottle. If the unit is mounted below the water bottle, please use care not to allow water to siphon from the bottle back into the tubing set.

4. Visually inspect the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM for external signs of damage.

8.2 ELECTRICAL CONNECTIONS

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

2. Connect the Power Cord to the AC Power Connection on the back of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.

3. Before connecting the power cord to the hospital grade wall outlet, make sure that the main power switch is off and that the voltage is correct. The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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.
8.3 CONNECTING TO A CO₂ GAS CYLINDER

1. A High Pressure Hose & Yoke (REF 710603) or DIN 477 High Pressure Hose (REF 390513) is required for connecting to a CO₂ gas cylinder. Contact your local sales representative or customer service at 1-800-769-8226 to determine which type of cylinder connection is required in your market.

2. Refer to the Instructions For Use provided with the High Pressure Hose for further information on assembly and connection to a CO₂ cylinder.

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 8.1).

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 “C”, “D”, OR “E” supply tanks.

Tank designations vary by country. Please check with your local distributor for compatibility.

NOTE: Do not use any teflon tape or thread sealing compounds on any connection.
8.4 CONNECTING TO A CO₂ GAS PIPELINE ADAPTER

1. The optional DISS High Pressure Hose (REF 710604) is required for connection to the CO₂ gas pipeline.

2. Attach the 7/16” female connector (see Figure 8.2) on the CO₂ Central Supply Hose to the male CO₂ gas connector on the rear panel of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM and securely tighten it.

3. Connect the DISS connector (see Figure 8.3) on the CO₂ Central Supply Hose to the CO₂ gas pipeline hose and tighten the adapter manually until the position where the connector is stopped.

Figure 8.2  Figure 8.3

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

- Visually inspect the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 9.0  SETTING-UP FOR THE PROCEDURE

#### 9.1 POWER ON AND GAS SUPPLY INDICATOR

1. If the unit is attached to a wall source central gas supply, switch the Gas Supply Indicator on the rear panel to “WALL”. Turn on the source supply. Turn on the Power Switch on the unit. Upon turn on, all lights and indicators will be illuminated for a brief period.

   If a USP Medical Grade gas cylinder is attached to the device, switch the Gas Supply Indicator on the rear panel to “TANK”. Open the valve on the CO$_2$ supply tank approximately 1 turn. Turn on the Power Switch on the unit. Upon turn on, all lights and indicators will be illuminated for a brief period.

2. The GAS SUPPLY INDICATOR LED illuminates red, yellow, or green. The color coding is a guide to determine whether there is sufficient gas in a supply tank to finish a procedure, as indicated below:

   **In Tank Mode**

<table>
<thead>
<tr>
<th><strong>LED Color</strong></th>
<th><strong>Available CO$_2$ Gas</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>Tank Pressure is greater than 280 psi</td>
</tr>
<tr>
<td>Yellow</td>
<td>Tank Pressure is between 143-280 psi</td>
</tr>
<tr>
<td>Red</td>
<td>Tank Pressure is less than 143 psi. Change tank!</td>
</tr>
</tbody>
</table>

   **NOTE:** If CO$_2$ supply tank pressure is less than 46 psi (red), flow cannot be initiated. Flow cannot be initiated in Tank mode if the gas pressure is less than 46 psi.

   **In Wall Mode**

<table>
<thead>
<tr>
<th><strong>LED Color</strong></th>
<th><strong>Available CO$_2$ Gas</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>Central Wall Supply is greater than 30 psi.</td>
</tr>
<tr>
<td>Red</td>
<td>Central Wall Supply is less than 30 psi. Flow cannot be initiated in this state.</td>
</tr>
</tbody>
</table>
9.2 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 START/STOP button. When pressed, the adjacent LED light will illuminate green, and gas may be heard exiting from the unit. If gas does not begin flowing, verify that the CO₂ cylinder valve is in the open position (see Section 9.1, Power On and Gas Supply Indicator, above).

3. To prevent wasting gas, when the START/STOP button is pressed initially, an internal timer will start. Depending on the TIMER setting selection, the flow of CO₂ will automatically stop after 30 minutes, 60 minutes, or 120 minutes. The TIMER can be pre-selected by the user depending on the anticipated length of the procedure. After the pre-selected time has elapsed, the unit automatically returns to STOP mode. Thereafter, subsequent presses of the START/STOP button will resume the delivery of CO₂ for an additional 30, 60, or 120 minutes, depending on the pre-selected time. However, the flow can be stopped at any time using the START/STOP button.

   NOTE: The device will default to 60 Minutes when powered on.

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.

9.3 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 US Endoscopy manufactured high flow tubing sets, 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.
9.4 CONNECTION TO ENDOSCOPIC SYSTEM

The Tubing Sets connect 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 9.1 CO$_2$ Adaptor for Pentax Endoscope

Figure 9.2 Example Olympus Water bottle with CO$_2$ Connection MAJ-902

*PENTAX®* is the registered trademark of Hoya Corporation. *Olympus®* is the registered trademark of Olympus Corporation.
9.5 SYSTEM SET-UP

The following operational sequence describes the system set-up for both the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM and Tubing Set:

i) Make sure the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is powered up with no Tubing Set in place.

ii) Make sure the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is in STOP mode. The green LED will not be illuminated.

iii) Remove the Tubing Set from its packaging.

iv) Connect Tubing Set fitting to the endoscopic system.

v) Connect the Tubing Set fitting to CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.

vi) Select a flow rate of Low, Medium, or High using the FLOW button.

vii) Select a shut off time of 30, 60, or 120 Minutes using the TIMER button.

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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM by pressing the START/STOP button.

xi) 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 promptly disconnecting the Tubing Set at the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM Output port.
9.6 TERMINATING GAS FLOW & SHUT-DOWN PROCEDURES

1. Upon completion of the diagnostic procedure, press the START/STOP button if in START mode.

2. Discard the entire US Endoscopy Endoscopic Tubing Set daily 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 cylinder valve be fully closed when not in use.
Section 10.0 DECONTAMINATION, CLEANING AND STORAGE

Prior to disinfecting the CO2MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM, ensure the power is turned off and the electrical cord is unplugged. To disinfect the CO2MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 CO2MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. Do not spray fluids directly onto the unit or allow fluids to enter the unit. Dry all components thoroughly. Do not sterilize or autoclave this unit.

For general cleaning, the CO2MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM can be wiped down with a damp cloth and mild soap.

The CO2MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should be covered and stored in a cool dry location. Care should be taken to avoid rough handling, jarring, or dropping the unit.
Section 11.0 REPAIR

There are no user adjustments inside the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM case. Repairs and adjustments are to be performed only by US Endoscopy or authorized service or repair facilities. Unauthorized service, repair, or modifications to the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM will void your warranty.

*If repairs become necessary call US Endoscopy 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, US Endoscopy 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:

US Endoscopy
5976 Heisley Road
Mentor, Ohio 44060 USA

*PRODUCTS MAY NOT BE RETURNED TO US ENDOSCOPY UNLESS US ENDOSCOPY HAS PROVIDED AN RA NUMBER TO THE PURCHASER. ALL PRODUCTS BEING RETURNED TO US ENDOSCOPY 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 Mains or Power line cord that is used to provide power to your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. If it is worn, frayed or damaged, replace it immediately with an equivalent IEC 60601-1 Rated (Medical Grade) line cord possessing a grounded IEC-320 plug. **Warning: Do not use or replace with a commercially rated line cord.**

2. Visually inspect the high-pressure hose between the CO₂ supply source and the rear panel of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. If it is worn, frayed, kinked or damaged, call US Endoscopy immediately to obtain a replacement. Confirm it is attached to a D or E sized medical grade cylinder and the rear panel switch is set to “Tank” mode. For central supply connections confirm switch is in “Wall” mode and make sure CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is connected to wall supply using the DISS High Pressure hose.

3. Verify that the power rocker switch on the front panel is seated properly, undamaged, exhibits no evidence of fluid/dirt infiltration, and functions properly. Plug in the power cord, 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM compatible tubing set to the
outlet port on the front panel. Place the capped end of the tubing set into a sterile water bottle that is 1/2 filled. Power on the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.

a. Verify the unit insufflates CO₂ by pressing the START button on the screen. The green LED next to the start/stop button will illuminate. CO₂ will begin to exit the tubing set causing the water to bubble.

b. Confirm flow can be adjusted by depressing the Flow button and verifying the LED cycles from high (default) to low to medium and back to high again. The flow intensity can be verified by visually observing changes in the amount of bubbles produced. Once confirmed, press the Start/Stop button again to stop the flow. Confirm flow stops.

c. Confirm the 30/60/120 minute shut off by powering on the unit and depressing the Timer front panel switch. It should rotate through the 60 (default), then 120, and then 30 minute settings. If further testing is desired move unit to a well-ventilated room. With the free end of the tubing set immersed in sterile water, set unit to desired test position and start flow. Monitor time lapse with a timer. Approximately two minutes prior to each time expiration you will hear an audible tone (double beep) intended to alert the user. In addition, the selected timer setting (30, 60 or 120 minutes) will begin to flash. If the flow is not depressed during the two minute warning time, insufflation will stop and an audible tone (double beep) will be heard after the 30, 60, 120 minutes have passed. In addition, the front panel lights will begin to flash. Turn the unit off, then on again to reset the unit. Allow 30-60 minutes between each test to ensure adequate room ventilation.

5. 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 design 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. At conclusion of testing power off unit, shut off CO₂ supply and unplug unit.

   i. If you are unable to perform this inspection, the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM can be sent to US Endoscopy.

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 Mains or Power line cord
   - □ Pass
   - □ Fail

2. High Pressure Hose Inspection
   - □ Pass
   - □ Fail

3. Front Panel Rocker Switch Inspection
   - □ Pass
   - □ Fail

4a. Inspection of CO₂ Insufflation
   - □ Pass
   - □ Fail

4b. L/M/H Flow settings
   - □ Pass
   - □ Fail

4c. 30/60/120 Timer settings
   - □ 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is suspect as a result of these inspection steps, please call US Endoscopy Customer Services to make arrangements for repair.

Tested By: ___________________________  Test Date: _______________________

Unit Serial Number: #__________________

Located on bottom of unit
11.2 CUSTOMER SERVICES AND ORDERING INFORMATION

Phone: 1-800-769-8226

11.3 WARRANTY

Your new CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is warranted against all defects in materials and workmanship for 12 months from the date of purchase.

This warranty shall not apply to any CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM which:

- Has been repaired by anyone other than an authorized US Endoscopy representative.
- Has been altered in any way so as to, in the judgment of US Endoscopy, 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 US Endoscopy. There are no warranties that extend beyond the description on the face hereof.

11.4 CERTIFICATION OF NON-CONTAMINATION

- All products being returned to US Endoscopy must be accompanied by a Certificate of Non-Contamination.
- Products that have become contaminated in any way shall not be returned to US Endoscopy unless special written permission has been granted by US Endoscopy. 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 US Endoscopy 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.: 710300

Description: CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM

SERIAL No.: __________________ RA. No.: __________________

The above person hereby certifies that the above described product being returned to US Endoscopy 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM, ensure the power is turned off and the electrical cord is unplugged. To disinfect the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM. Do not spray fluids directly onto the unit or allow fluids to enter the unit. Dry all components thoroughly. Do not sterilize or autoclave this unit.

Prior to returning any product to US Endoscopy complete this Certificate of Non-Contamination Form, and send/fax to US Endoscopy Quality department at 1-800-769-8226.
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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM, including the warnings and cautions section. Before making arrangements with US Endoscopy Customer Services to send your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 US Endoscopy Customer Services 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 contact US Endoscopy Customer Services at 1-800-769-8226.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Possible Causes</th>
<th>Field Checkout</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>My CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM does not power-up at all.</strong></td>
<td>No power at wall outlet.</td>
<td>Check CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM in wall outlet known to be operational.</td>
</tr>
<tr>
<td>What should I do?</td>
<td>Blown fuse.</td>
<td>Remove power cord from rear panel of CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM and use a small screwdriver to open fuse holder.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pull fuse holder down and examine fuses.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If blown, replace with 2.0-Amp 250-Volt Time-Delay Fuses.</td>
</tr>
<tr>
<td>Condition</td>
<td>Possible Causes</td>
<td>Field Checkout</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><em>My CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM does not power-up at all.</em></td>
<td>Front panel rocker power switch is “off”.</td>
<td>With unit plugged into wall outlet, activate Power Switch to the ON or (1) position.</td>
</tr>
<tr>
<td>What should I do?</td>
<td></td>
<td>Upon completing its Power-up sequence, the front panel should appear as follows:</td>
</tr>
<tr>
<td></td>
<td></td>
<td><img src="image.png" alt="Image" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Gas Supply Indicator LED should be illuminated and indicate the current amount of CO₂ in the supply tank. The FLOW should be pre-selected to High, as indicated by a green LED. The TIMER should be pre-selected to 60 minutes, as indicated by a green LED. The above display indicates that the unit has correctly powered-up.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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 US Endoscopy Customer Services.</td>
</tr>
</tbody>
</table>
**Condition**  
*My CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM does not deliver CO₂.*  
What could be the problem?

<table>
<thead>
<tr>
<th>Possible Causes</th>
<th>Field Checkout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empty CO₂ supply tank or valve closed.</td>
<td>After successfully Powering-up your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM examine the Gas Supply Indicator on the front panel. Make sure that the CO₂ cylinder valve is open. Your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should sense the pressure from the CO₂ supply tank and the Gas Supply Indicator should illuminate as shown:</td>
</tr>
</tbody>
</table>

![Image of CO₂ gas supply indicator illuminated](image)

If during Power-up or operation of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM, the CO₂ in the supply tank is depleted, the GAS SUPPLY INDICATOR LED will display red. The unit will no longer deliver CO₂.

![Image of CO₂ gas supply indicator red](image)

If this occurs, reconnect the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM to a full CO₂ supply tank to continue operation. Should the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 US Endoscopy Customer Services. |
<table>
<thead>
<tr>
<th>Condition</th>
<th>Possible Causes</th>
<th>Field Checkout</th>
</tr>
</thead>
<tbody>
<tr>
<td>My CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM does not deliver CO₂.</td>
<td>CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM flow rate incorrect.</td>
<td>To check the ability of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM to deliver CO₂ to the patient, follow these verification steps:</td>
</tr>
<tr>
<td>What could be the problem?</td>
<td></td>
<td>After Powering-up and making sure that your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is connected to the CO₂ supply tank, depress the START/STOP button to start the flow of CO₂.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Place your finger near the Gas OUTPUT. You should feel CO₂ exiting from the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>As a second test, connect the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM to the endoscope system using a tubing set. Power up the endoscope. Be sure to turn off the endoscope air pump before turning on the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After Powering-up and making sure that your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is connected to the CO₂ supply tank, depress the START/STOP button to start the flow of CO₂.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fill a cup or small container with sterile water. Insert the tip of the endoscope into the cup or container. Place your finger on the endoscope air/water valve to initiate the flow of CO₂ through the endoscope.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Verify that gas bubbles are exiting the tip of the endoscope into the water.</td>
</tr>
<tr>
<td>Condition</td>
<td>Possible Causes</td>
<td>Field Checkout</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>My CO₂ cylinder is prematurely emptying.</strong></td>
<td>The valve on the CO₂ cylinder left open all of the time.</td>
<td>We recommend attaching your CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM to C, D, or E size CO₂ cylinders. For days when the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is scheduled for continuous use, the CO₂ cylinder valve should be opened at the start of the shift and closed at the end of the shift. The pneumatic design of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is not intended to provide a full time gas seal from the CO₂ cylinder while the device is not being used or in storage. Should the CO₂ cylinder valve inadvertently be left open, there is a high likelihood that the CO₂ cylinder contents will gradually empty over several days.</td>
</tr>
<tr>
<td></td>
<td>High Pressure Hose from CO₂ cylinder is not installed properly.</td>
<td>If after opening and closing the CO₂ cylinder valve with your procedure schedule, you still encounter problems with the CO₂ cylinder prematurely emptying, there is the possibility that the High Pressure Hose from the CO₂ cylinder to the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM rear panel. Inspect the tapered surface of the free standing nipple on the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM 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 cylinder valve Yoke.</td>
</tr>
<tr>
<td>Condition</td>
<td>Possible Causes</td>
<td>Field Checkout</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>“CONTINUED”</td>
<td>High Pressure Hose from CO\textsubscript{2} cylinder is not installed properly.</td>
<td>Inspect the CO\textsubscript{2} cylinder Yoke and verify that the plastic disc that creates the gas seal at the CO\textsubscript{2} cylinder valve is in-place and free from defect.</td>
</tr>
<tr>
<td>My CO\textsubscript{2} cylinder is prematurely emptying.</td>
<td></td>
<td>After verifying all High Pressure Hose sealing surfaces are clean and free of defect; reconnect the High Pressure Hose to the CO\textsubscript{2} supply tank Yoke and CO\textsubscript{2}MPACT ENDOSCOPIC INSUFFLATOR\textsuperscript{®} SYSTEM. Use an adjustable or Opened Ended ¾&quot; wrench to tighten securely. DO NOT USE ANY TEFLOW TAPE OR THREAD SEALING COMPOUNDS. Reconnect the Yoke to the CO\textsubscript{2} cylinder valve making sure that the plastic sealing disk is in place. Open the CO\textsubscript{2} supply tank valve. If CO\textsubscript{2} continues to prematurely empty or should you hear CO\textsubscript{2} escaping from any of these connections or the High Pressure Hose itself, contact US Endoscopy Customer Services.</td>
</tr>
</tbody>
</table>
Section 14.0  EMC TABLES

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM has been tested by Underwriters Laboratory to the following electro-magnetic compatibility standards:

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>CISPR 11 RF Emissions</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>CISPR 11 RF Emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2 Harmonic Emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3 Voltage fluctuations / flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
Table 2
Guidance and manufacturer’s declaration – electromagnetic immunity

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-2 Electrostatic discharge (ESD)</td>
<td>+/-8 KV contact</td>
<td>+/-8 KV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-4 Electrical fast transient burst</td>
<td>+/-2 KV, +/-4 KV, +/-8 KV, +/-15 KV air</td>
<td>+/-2 KV, +/-4 KV, +/-8 KV, +/-15 KV air</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5 Surge</td>
<td>+/-0.5 KV, +/-1 KV differential mode</td>
<td>+/-0.5 KV, +/-1 KV differential Mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11 Voltage dips</td>
<td>0 % Ut (&gt;95 % dip in Ut) for 0.5 cycle</td>
<td>0 % Ut (&gt;95 % dip in Ut) for 1 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM requires continued operation during power mains interruptions, it is recommended that the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM be powered from an uninterruptible power supply or battery.</td>
</tr>
<tr>
<td>Short interruptions and voltage variations on power supply input lines</td>
<td>70 % Ut (30% dip in Ut) for 25 cycles</td>
<td>70 % Ut (30% dip in Ut) for 25 cycles</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8 Power frequency (50/60 Hz) magnetic field</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note: Ut is the A.C. mains voltage prior to application of the test level.
Table 3
Guidance and manufacturer’s declaration – electromagnetic immunity

The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-6 Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-3 Radiated RF</td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
<td>3 V/m</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
</tbody>
</table>

Recommended separation distance

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:

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 CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is used exceeds the applicable RF compliance level above, the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM as recommended below, according to the maximum output power of the communications equipment.

### Table 4
Recommended separation distances between Portable and mobile RF communications equipment and the CO₂MPACT ENDOSCOPIC INSUFFLATOR® SYSTEM

<table>
<thead>
<tr>
<th>Read maximum output power of transmitter</th>
<th>Separation distance according to frequency of transmitter</th>
<th>M</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>W</td>
<td>$d = 1.2 \sqrt{P}$</td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

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.