# PROTOCO2L TOUCH™

## COLON INSUFFLATOR

**REF 390308**

## Operator's Manual


CE 0086

PHT
DEHP

**Rx Only (USA)**

**NOVEMBER 2015**

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# Section 1.0 UNPACKING AND GENERAL INSPECTION

**CAUTION: READ ALL SECTIONS OF THIS MANUAL CAREFULLY BEFORE USING THE PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, SUCH THAT OPERATION IS UNDERSTOOD. IF YOU SHOULD HAVE ANY QUESTIONS, PLEASE CONTACT BRACCO DIAGNOSTICS INC. PROFESSIONAL SERVICES AT 1-800-631-5245, OR YOUR LOCAL BRACCO DIAGNOSTICS 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 PROTOCO$_2$L TOUCH™ COLON 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:

PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR

Operator's Manual (English Hardcopy)

Quick Reference Guide

Foreign Language Operator Manual and Quick Reference Guide: CD Format

Optimum Performance Warning Label

Line Cord (see CAUTION below)

Notify Bracco Diagnostics Inc. 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 PROTOCO$_2$L TOUCH™ COLON 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

**$CO_2$** Carbon dioxide

**gas** $CO_2$

## 2.1 INDICATION AND CONTRAINDICATIONS

**Indications for Use:** The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR administers and regulates carbon dioxide as a distention media to the colon during CT Colonography (CTC or Virtual Colonoscopy).

**Contraindications for Use:**

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should be used only when colon insufflation is indicated, and should therefore not be used for any other treatments. It should only be used under the direct guidance of a physician experienced in colon insufflation.

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

This product should not be used in patients with known or suspected colonic perforation or toxic megacolon. It should not be used within 6 days of large forceps or “hot” biopsy, or snare polypectomy.

Do not use this product in a colostomy stoma.

Do not use this product following recent rectal surgery or low rectal anastomosis, or when proctitis or other rectal conditions such as inflammatory or neoplastic diseases are suspected.

## 2.2 SAFETY FEATURES

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

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

The electrical pressure relief will occur when 50 mm Hg is reached and sustained for 5 seconds. An audible alert will sound during actuation of the electronic pressure relief at 50 mm Hg. Additionally, the PRESSURE display will turn yellow and flash.

A fixed mechanical pressure relief occurs at 75 mm Hg.

An audible alert will sound when the $CO_2$ gas supply tank pressure is low. Additionally, the Gas Supply icon will change color sequentially, from green (full), to yellow (low) to flashing yellow (empty).

# Section 3.0 INSUFFLATOR THEORY OF OPERATION

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR operates by administering $CO_2$ at a maximum flow rate of 3 LPM, and then monitoring the current colonic pressure. A value for colonic pressure is selected by the operator using the pressure adjustment arrows on the touchscreen. Once started, the colonic pressure will gradually increase and will be displayed in the Pressure field on the screen. The flow of $CO_2$ will gradually decrease when the current pressure approaches the user determined value (adjacent to the Pressure Adjustment arrows on the touchscreen). The colonic pressure has stabilized when the pressure shown on the Pressure Display equals the set pressure and the flow of $CO_2$ will stop. While in the RUN mode, the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR will maintain the selected colonic pressure by continuously monitoring the current colonic pressure and will compensate for a loss in the colonic pressure by allowing additional $CO_2$ to flow until the current pressure is equal again to the user determined colonic pressure setting.

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR has an electronically controlled Pressure Relief Valve at 50 mm Hg and an independent redundant mechanical Pressure Relief Valve pre-set to 75 mm Hg. Both pressure relief safety devices are active whether the Gas Flow is on or off.

# Section 4.0 WARNINGS AND CAUTIONS

This section describes warning and caution information for safe operation of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR. All information in this manual, and particularly in this section, should be read thoroughly and understood before using the device.

## 4.1 WARNINGS

- If pneumoperitoneum (free intra-peritoneal air) is observed, or if colonic perforation is suspected at any time during the use of PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, immediately discontinue use and provide appropriate medical treatment.
- Excessive absorption of $CO_2$ results from either excessive flow rate and/or excessive pressure. The colon can be adequately distended by pressure in the range of 15 to 25 mm Hg. Use of pressure less than or equal to 35 mm Hg will dramatically reduce the likelihood of intravasation of $CO_2$ gas into open vascular channels. Also, adequate respiration helps avoid problems related to $CO_2$.
- Should accidental intravasation of $CO_2$ occur, in rare circumstances, it can result in embolization.
- Interaction between water and $CO_2$ could lead to the formation of carbonic acid, which may cause irritation to directly contacted tissues.
- Use only USP "Medical Grade" $CO_2$. For USP Medical Grade $CO_2$ tanks (cylinders) supplied outside of the USA please note that the tank should be within 430mm to780mm in height to securely fit in the Protocol Accessory Cart, model 6405. The Protocol Accessory Cart is not required for use with the Protocol Touch Insufflator. Tank designations vary by country. Please check with your local distributor for compatibility.
- Using unauthorized, non-Bracco tubing sets will void the warranty and Bracco cannot assume any risk related to the use of non-Bracco 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 line 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 colon insufflation. 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 patient. Diligence on the part of the operator is an essential requirement of overall device safety.
- To avoid the risk of electrical shock, connect the line cord to a properly wired grounding receptacle only.

- To prevent unit contamination and patient cross-contamination, use only Bracco's PROTOCO$_2$L TOUCH™ Administration Set which includes a 0.1 micron hydrophobic filter.
- 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 $CO_2$ absorption.
- 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 insufflation is required, operators should stop the gas flow by promptly disconnecting the PROTOCO$_2$L TOUCH™ Administration Set at the Insufflator Output Port.
- The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR can release $CO_2$ to the surrounding atmosphere in the event of misuse or a fault condition. Use and store the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR in a well ventilated environment. Additionally, make sure all $CO_2$ supply tank connections are correctly installed and free of visible damage. Should an unexplained rapid discharge of $CO_2$ occur, evacuate the immediate area until it has had sufficient time to ventilate.
- High Pressure USP $CO_2$ is supplied to the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR from commercially available $CO_2$ supply tanks. Please read and carefully follow all Warnings, Cautions and Handling Instructions provided with, and listed on these $CO_2$ supply tanks that are used with the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR. Failure to do so can result in Serious Injury or Death.

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- 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.
- No modification of this device is allowed. Repairs and adjustments are to be performed only by Bracco Diagnostics Inc. or authorized service or repair facilities. Unauthorized service, repair, or modifications to the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR will void your warranty.
- Always ensure the placement of the insufflator is positioned so that the plug can easily be removed from the back of the unit.

## 4.2 CAUTIONS

- Prior to use, be sure to read all instructions for use on the PROTOCO$_2$L TOUCH$^{TM}$ Administration Set.
- 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 compatibility, and should not be introduced into the MR exam room.

- Do ***Not*** attempt to use this system until you have completed all the steps in "Assembly Prior to Colon Insufflation" Section 9.0 and "Setting-Up and Performing 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 Bracco Diagnostics Inc. Professional Services at 1-800-631-5245 (USA), 1-609-514-2200.

## 4.3 SYMBOLS

| SYMBOL | DEFINITION | | SYMBOL | DEFINITION |
|---|---|---|---|---|
|  | Type B | |  | Type and Rating of Fusing |
|  | Consult instructions for use | |  | $CO_2$ Gas Input |
|  | Dangerous voltage | |  | $CO_2$ Gas Output to the patient |
|  | Interconnection to ensure all equipment is at the same potential or earth ground. | |  | 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, Bracco UK will be fully responsible for the coordination, logistics, and costs of the WEEE process |

# Section 5.0 DESCRIPTION OF EQUIPMENT

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is indicated for use as a means of providing colonic distention.

## 5.1 SPECIFICATIONS

| | |
|---|---|
| **Size:** | 12" wide x 6" high x 11" deep (± ¼")<br>305 mm x 152 mm x 279 mm |
| **Weight:** | Less than 15 lb. (6.9 kg) |
| **Control Panel:** | Touchscreen with pushbutton icons. Digital pressure and volume readouts. |
| **Gas Flow**: | 0 to 3 LPM (±20%) |
| **Pressure Adjustment:** | 0 to 35 mm Hg operating. (±10 % for values equal or greater than 10 mmHg and ±1 mm hg for value less than 10 mmHg) |
| **Pressure Relief Valve:** | Electronic controlled relief of pressure at 50 mm Hg for 5 seconds. Fixed mechanical pressure relief at 75 mm Hg. Both reliefs are active whether gas flow is on or off for added protection. Audible alert will sound at the time of actuation of the electronic pressure relief at 50 mm Hg. |
| **Operating modes:** | FLOW STOP/RUN |
| **Gas Inlet:** | USP medical grade $CO_2$ supply tank or wall source supply. |

All time specification tolerances are ±10%.

**WARNING:** ***Do not allow liquid $CO_2$ to enter the unit. This can be prevented by assuring that the $CO_2$ supply tank is maintained in a vertical position at all times.***

| | |
|---|---|
| **Gas Input Cylinder Pressure**: | 43 to 2200 psi |
| **Gas Input Central Supply Pressure**: | 50 to 203 psi |
| **Patient Set:** | Available for use with 0.1 micron hydrophobic filter.<br>Bracco Diagnostics, Inc. supplies an Administration 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 VA, double fusing with removable line cord |
| **Standards:** | UL 60601-1, IEC 60601-1, IEC 60601-1-2, CISPR 11, EN 60601-1-2, EN55011. |
| **Mains Line Cord :** | IEC 320 compliant |

## 5.3 UL EQUIPMENT CLASSIFICATION

Underwriter's Laboratories/CSA Class I Type B, IP31 Enclosure rating

## 5.4 ENVIRONMENTAL REQUIREMENTS

Not to be used in the presence of flammable gases.

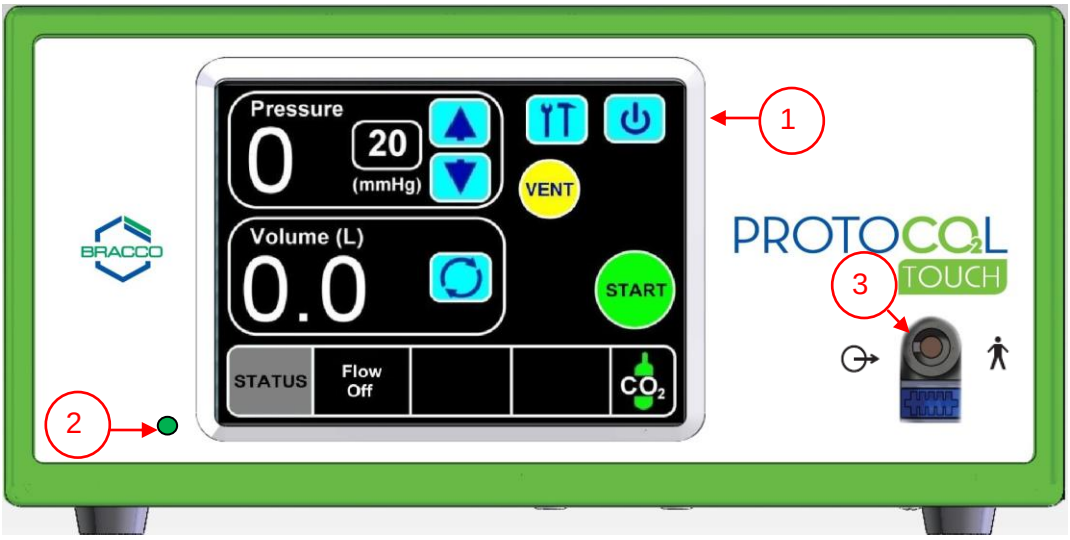
**NOTE:** This unit has not been tested for MR compatibility and should not be introduced into the MR exam room.

## 5.5 DEVICE TERMINOLOGY

This manual contains the following terminology:

- First Target Pressure: This feature can be used to set an intermediate pressure threshold during the procedure. When active, the device will insufflate until the First Target Pressure is reached and then maintain that pressure. A "1st Target Pressure" indicator will flash on the front panel to alert the user that the First Target Pressure has been reached. The user can then check the patient to assure that they are comfortable prior to resuming insufflation. The First Target Pressure can be adjusted in the Pressure Settings Menu.
- Final Target Pressure: The pressure that the device will maintain during a procedure. The Final Target Pressure is the pressure that will be maintained during an initial Scout scan, as well as the prone and supine scans. The final target pressure can be set to a maximum of 35 mmHg. The Final Target Pressure can be adjusted on the Front Panel or in the Pressure Settings Menu.
- Pause Volume: Located in the Gas Volume Menu. The "Pause Volume" is the volume of $CO_2$ at which the device will initially pause at after the START button is pressed. This volume can be set to a minimum of 3 liters up to a maximum of 10 liters in the Main Menu.
- Extension Volume: Located in the Gas Volume Menu. The "Extension Volume" is the volume of additional $CO_2$ that will be insufflated after the initial pause. This volume can be set to a minimum of 1 liter to a maximum of 4 liters. This feature should be used to provide additional insufflation of $CO_2$ during a procedure if optimal distention of the colon has not been obtained prior to insufflation automatically pausing.
- Ready To Scan: If the Ready to Scan feature is active, the device will make a determination of when the patient is ready to be scanned. The device does this through an algorithm that looks at the current pressure vs. set pressure, the stability of the pressure, and the total volume of insufflation. If all three of these criteria are met, a green "Ready To Scan" indicator will begin to flash in the Status Bar.
- Single Patient Only Icon: Located in the Ready to Scan Menu. If the user wants to retain the Ready To Scan setting for one procedure, the user will select the Single Patient icon at the bottom of the screen. The Single Patient option should be selected if the desired settings are for one procedure only. Thereafter, the device will revert back to the previous settings. In this mode, the Ready to Scan Volume will be active for a single procedure.
- Vent: The VENT button actuates the electronic pressure relief valve and relieves pressure in the Administration Set. When pressed, the vent will open and stay open until the pressure reaches zero. Thereafter, the vent will close.
- Resume: The RESUME button will appear on the front panel if the flow of $CO_2$ has stopped during a procedure. If the user wishes to continue insufflation, the green RESUME button should be pushed.
- Extend: The EXTEND button will appear on the front panel as the unit approaches the Pause Volume. If the EXTEND button is pressed, the device will reinitiate the flow for a user set number of liters. The number of liters can be adjusted in the Extension Volume field located in the Gas Volume Menu.

# Section 6.0 FRONT PANEL CONTROLS




**NOTE**: The appearance of your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR may differ slightly from the units shown in the illustrations and photographs.

**[1] LCD Display Screen**

With the rear power switch in the "ON" position, touch screen to turn unit "ON". The LCD screen clearly displays the complete range of treatment choices and settings.

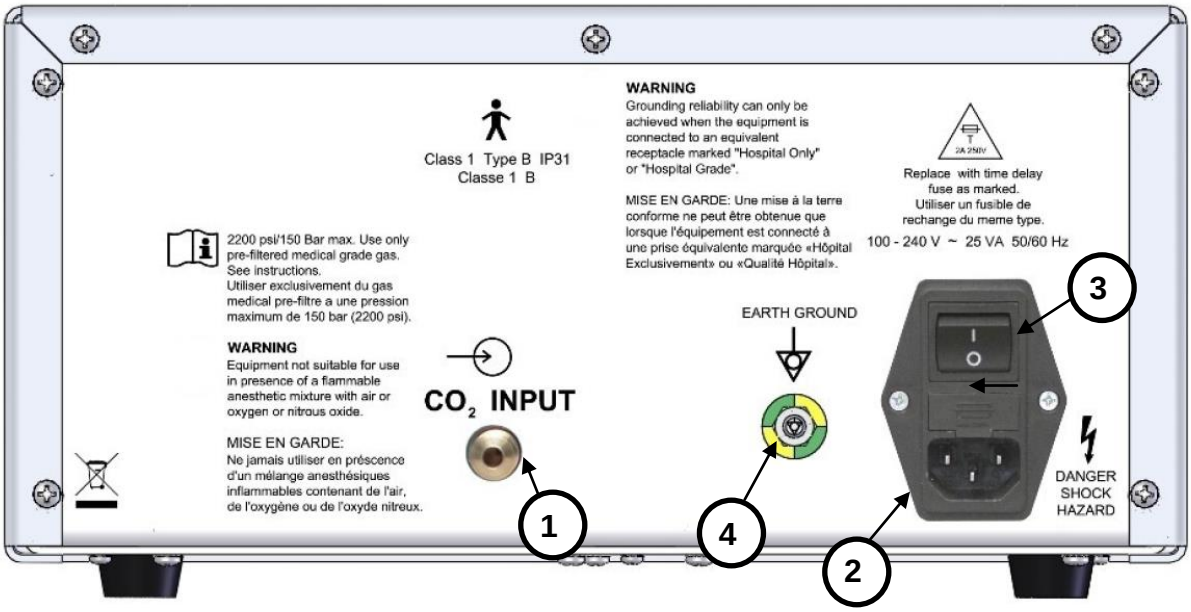
**[2] Front Panel LED Display**

The LED is "Blue" when power is applied, but the unit is "OFF". The LED is Green when the unit is "ON" and the front panel screen is "Active".

**[3] Gas Output Connection**

Allows for connecting a PROTOCO$_2$L TOUCH™ Administration Set to the device through a unique Connector.

# Section 7.0 REAR PANEL CONTROLS




### [1] GAS INPUT PORT

For connecting a $CO_2$ supply tank or wall source.

**WARNING:** ***Do not allow liquid $CO_2$ to enter the unit. This can be prevented by assuring that the $CO_2$ supply tank is maintained in a vertical position at all times.***

### [2] 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. Connection should be to hospital grade receptacles only.

### [3] MAINS POWER SWITCH AND FUSE CONTAINER

Two 2 Amp, 250V / time delay, replaceable fuses are contained within this plastic enclosure.

### [4] COMPENSATOR POST TO EARTH GROUND

This can also be referred to as the Potential Compensator Plug. This connection is used to interconnect other instruments to ensure that they are at the same potential or earth ground.

# 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.

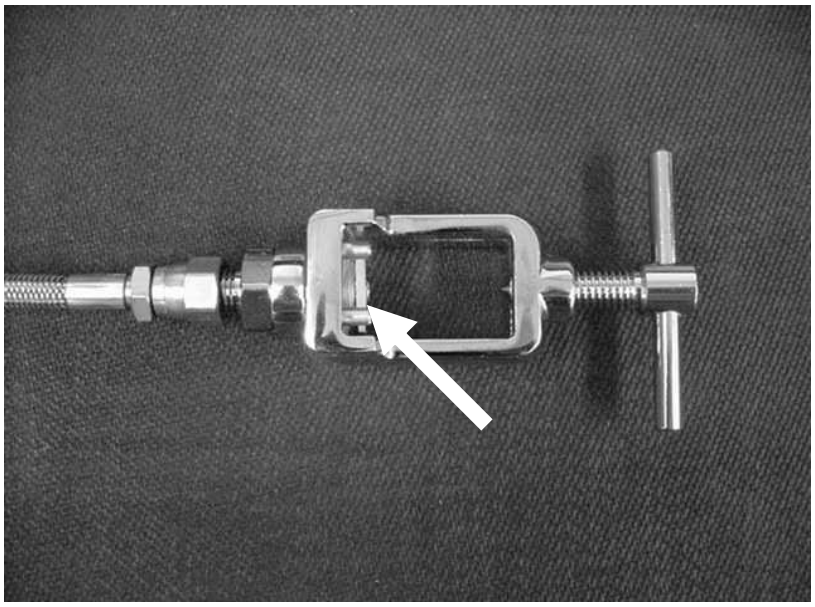


Figure 8.1

**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).

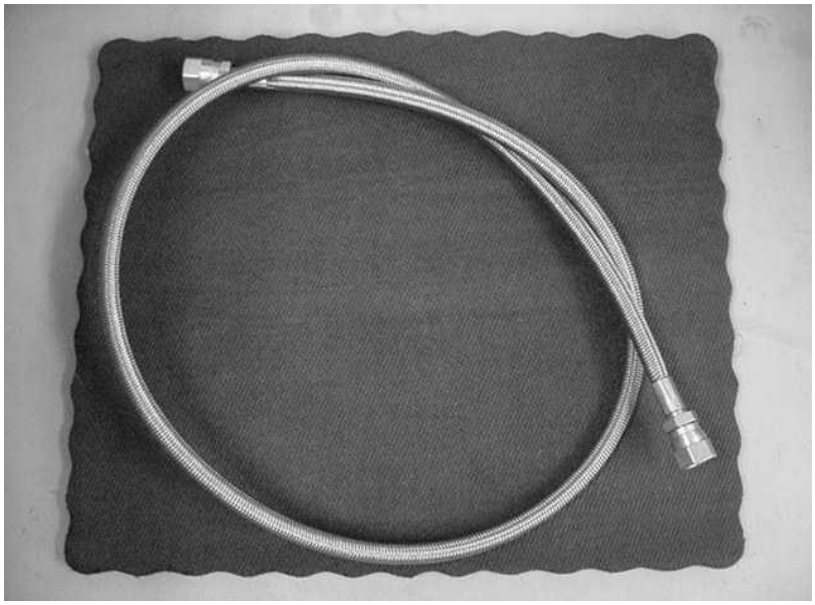


Figure 8.2

# Section 9.0 ASSEMBLY PRIOR TO COLON INSUFFLATION

**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 PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should be inspected upon receipt and before each use. Damaged equipment should be removed from service and returned to Bracco Diagnostics, 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 INSUFFLATOR PREPARATION

1. Install the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR on the Accessory Cart, or on a flat surface, away from potential sources of spraying or leaking liquids.
2. Visually inspect the PROTOCO$_2$L TOUCH™ COLON 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 to the AC Power Connection on the back of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR.
3. Before connecting the line cord to the hospital grade wall outlet, make sure that the main power switch is off and that the voltage is correct. The PROTOCO$_2$L TOUCH™ COLON 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 CONNECTING TO A $CO_2$ GAS CYLINDER

1. If not already connected, assemble the High Pressure Hose and Yoke using a 9/16″ Open-End wrench on the hose fitting and a ¾″ 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 $CO_2$ supply tank (Tank not provided with system), as shown in Figure 9.2.

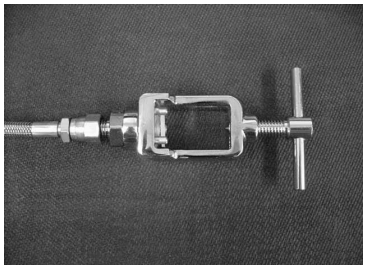


Figure 9.1

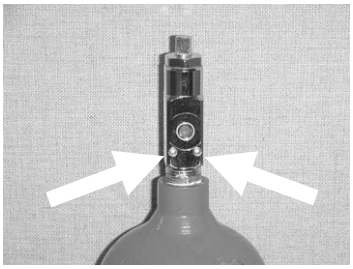


Figure 9.2

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 $CO_2$ 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-end/adjustable wrench, on the valve stem as shown in Figure 9.4

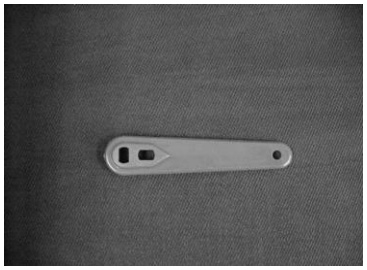


Figure 9.3

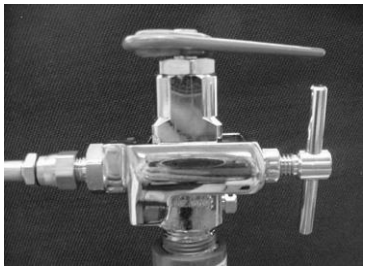


Figure 9.4

3. Remove cap from the $CO_2$ Input port on back of Insufflator. Tighten the other end of the High-Pressure Hose to the $CO_2$ Input port on the back of the Unit using a 9/16″ Open-Ended wrench (see Figure 9.5).

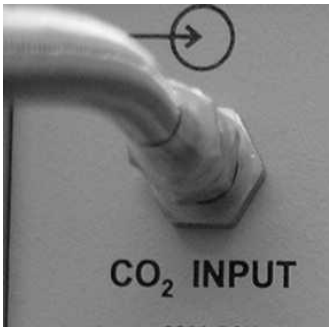



Figure 9.5

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

**WARNING:** ***Do not allow liquid $CO_2$ to enter the unit. This can be prevented by assuring that the $CO_2$ supply tank is maintained in a vertical upright position at all times.***

- ***USE ONLY MEDICAL GRADE $CO_2$ SIZE "D" OR "E" supply tanks. For USP Medical Grade $CO_2$ tanks (cylinders) supplied outside of the USA please note that the tank should be within 430mm to780mm in height to securely fit in the Protocol Accessory Cart, model 6405. The Protocol Accessory Cart is not required for use with the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR.***

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

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

  - Visually inspect the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR for external signs of damage.
  - Inspect the electrical connections. Do not use if inspection reveals damage.
  - Before connecting the line cord to the wall outlet, make sure the main power switch is off and that the voltage is correct. Inspect the connection to the $CO_2$ supply tank, to assure it is intact and tight.

  NOTE: To assure maximum life of $CO_2$ supply tank, always close $CO_2$ tank from the post valve when not in use.

## 9.4 CONNECTING TO A $CO_2$ GAS PIPELINE ADAPTER

1. The optional DISS High Pressure Hose (REF 710604) is required for connection to the $CO_2$ gas pipeline.
2. Attach the 7/16" female connector (see Figure 9.6) on the $CO_2$ Central Supply Hose to the male $CO_2$ gas connector on the rear panel of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR and securely tighten it.
3. Connect the DISS connector (see Figure 9.7) on the $CO_2$ Central Supply Hose to the $CO_2$ gas pipeline hose and tighten the adapter manually until the position where the connector is stopped.

Figure 9.6

Figure 9.7

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

- Visually inspect the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR for external signs of damage.
- Inspect the electrical connections. Do not use if inspection reveals damage.
- Before connecting the line cord to the wall outlet, make sure the main power switch is off and that the voltage is correct. Inspect the connection to the $CO_2$ gas pipeline adaptor, to assure it is intact and tight.

# Section 10.0 SETTING-UP AND PERFORMING THE PROCEDURE

## 10.1 POWER ON

1. Open the valve on the $CO_2$ supply tank approximately 1 turn.

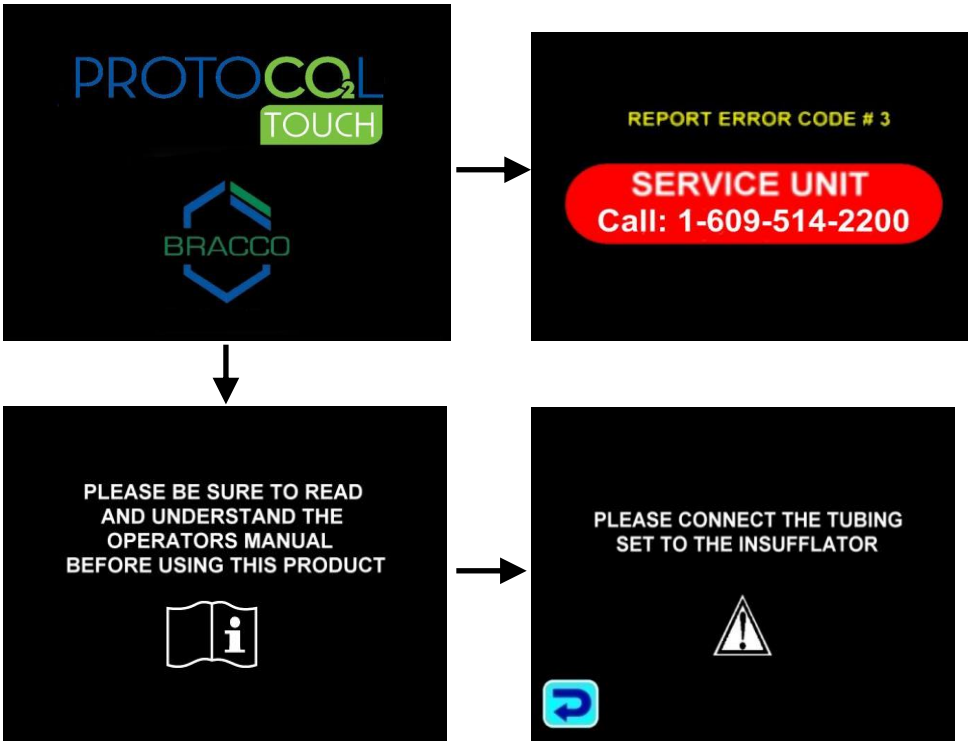
   Turn on the Power Switch located on the rear panel. The first screen to appear on the initial start-up is the main title screen. This screen will remain in view for approximately 5 seconds while the unit completes a self-diagnostic check. If a problem is discovered during the self-diagnostic check, the SERVICE UNIT screen will appear. An error code number that corresponds to a specific problem will be displayed. This problem information will need to be described to Bracco Diagnostics Inc., Professional Services and be sent in for service.

2. Note: If the unit is powered on and the touchscreen is not contacted for 30 minutes, the display will automatically go into Standby Mode. If the LED on the front panel is illuminated but the touchscreen is blank, the user can touch the screen to activate the device from Standby Mode.

3. Note: A complete list of all possible error messages can be found in Section 10.13.

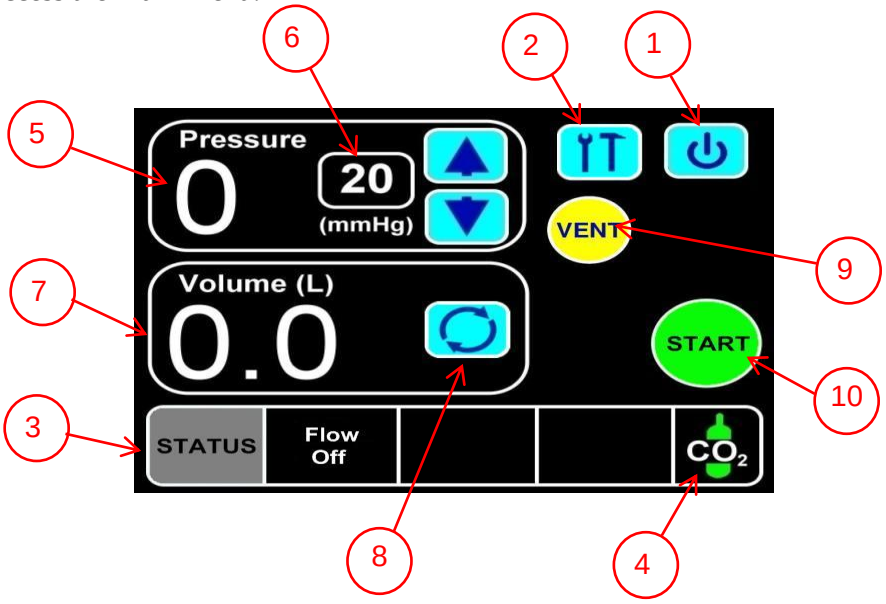
4. If a Bracco Diagnostics Administration Set is not connected to the unit, a Warning Message will appear. The device will not insufflate if a Protocol Touch Administration Set is not attached.

   Note: The device Operating Screen can be accessed by pressing the Back icon that appears.



## 10.2 GETTING STARTED, OPERATING SCREEN

The Operating Screen is the first screen to appear after start up and self-diagnostic check is complete. The user is able to start a procedure from this screen, as well as access the Main Menu.




**[1] POWER OFF ICON**

To POWER OFF the LED display, press and hold the POWER OFF ICON for at least 1 second. This will turn the LED display off. To power the LED display on, press anywhere on the display.

**[2] MAIN MENU ICON**

To enter the MAIN MENU, press MAIN MENU ICON. See Section 10.3 for using the Main Menu.

**[3] STATUS BAR**

The Status Bar displays the current status of the device. Within the Status Bar, the state of Flow, Ready-To-Scan, Vent, First Target Pressure, and Gas Supply is displayed.

**[4] GAS SUPPLY INDICATOR**

The Gas Supply Indicator displays the current status of the Gas Supply Source that is attached to the device by changing color. The color is a guide that can be used to determine whether there is sufficient gas in a "D/E" $CO_2$ supply tank (CYLINDER) or central gas (WALL) supply, as indicated below:

**In Cylinder Mode:**

| **Gas Supply Icon** | **Available $CO_2$ Gas** |
|---|---|
| Green | Tank Pressure is greater than 175 PSI in gas cylinder |
| Yellow | Tank Pressure is 75 to 175 PSI in gas cylinder |
| Flashing Yellow Change Tank! | Tank Pressure is less than75 PSI in gas cylinder. |

- **NOTE:** If $CO_2$ supply tank pressure is less than 75 PSI (flashing yellow), flow cannot be initiated. For USP Medical Grade $CO_2$ tanks (cylinders) supplied outside of the USA please note that the tank should be within 430mm to780mm in height to securely fit in the Protocol Accessory Cart, model 6405. The Protocol Accessory Cart is not required for use with the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR.

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

**In Wall Mode:**

| **LED Color** | **Available $CO_2$ Gas** |
|---|---|
| Green | Central Wall Supply is greater than 30 psi. |
| Flashing Yellow | Central Wall Supply is less than 30 psi. Flow cannot be initiated in this state. |

**[5] CURRENT PRESSURE DISPLAY**

The Current Pressure Display shows the current pressure within the system.

**[6] FINAL TARGET PRESSURE SETTING**

The Final Target Pressure Setting is the pressure that the device will maintain during a procedure. This setting can be adjusted by using the adjacent Up and Down Arrows. In addition, the user can enter the Main Menu (See Section 10.3) to adjust the Pressure Setting.

**[7] VOLUME DISPLAY**

The Volume Display indicates the total amount of gas used.

**[8] VOLUME RESET ICON**

The Volume Reset Icon clears the volume display to zero. Pressing the icon will also reset the device so that a new procedure can begin.

**[9] VENT**

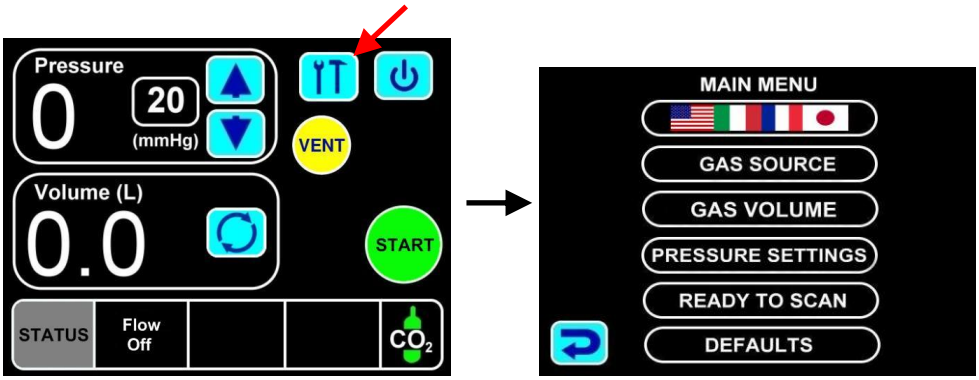
The VENT button actuates the electronic pressure relief valve and relieves pressure in the Administration Set. When pressed, the vent will open and stay open until the pressure reaches zero. Thereafter, the vent will close.

**[10] START**

The START button starts the flow of $CO_2$ to initiate insufflation.

## 10.3 GETTING STARTED, MENU SETTINGS

1. In the Operating Screen, the user may wish to make adjustments to the PROTOCO$_2$L TOUCH™ settings. This can be done by touching the MAIN MENU ICON located at the top of the screen. This will bring the user to the MAIN MENU screen.




2. Six selections will appear in the Main Menu. They are:

    1. Language
    2. Gas Source
    3. Gas Volume
    4. Pressure Settings
    5. Ready to Scan
    6. Defaults

    The user can select the choices that best suits the needs of each procedure room or physician.

    Note: Press the Back button icon on the lower left corner of the screen to return to the Operating Screen.

**LANGUAGE:**

Select from:

| | | | |
|---|---|---|---|
| **ENGLISH** | **SPANISH** | **FRENCH** | **GERMAN** |
| **ITALIAN** | **PORTUGUESE** | **SWEDISH** | **FINNISH** |
| **NORWEGIAN** | **DANISH** | **GREEK** | **TURKISH** |
| **DUTCH** | **KOREAN** | **JAPANESE** | **CZECH** |
| **POLISH** | | | |

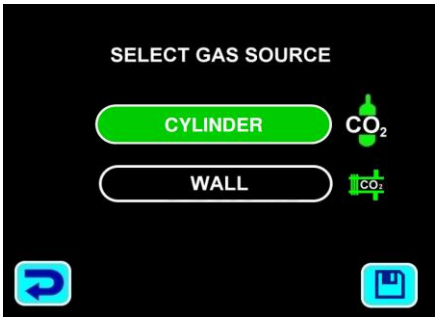
Press the "Save" icon in the lower right corner of the screen to store the selected language.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.


**GAS SOURCE:**

Select from "CYLINDER" or "WALL". Press the Save icon in the lower right corner of the screen to store the selection.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.



**GAS VOLUME:**

The user can adjust the initial "Pause Volume" and the "Extension Volume" from this menu pressing the Up and Down arrows on the screen.

The "Pause Volume" is the volume of $CO_2$ at which the device will initially pause at after the START button is pressed. This volume can be set to a minimum of 3 liters up to a maximum of 10 liters.

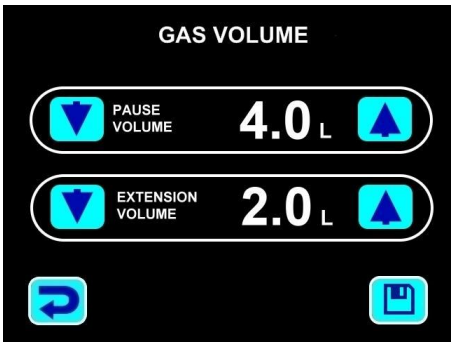
Note: The default Pause Volume is 4 liters.

The "Extension Volume" is the volume of additional $CO_2$ that will be insufflated after the initial pause. This volume can be set to a minimum of 1 liter to a maximum of 4 liters. This feature should be used to provide additional insufflation of $CO_2$ during a procedure if optimal distention of the colon has not been obtained prior to insufflation automatically pausing.

Note: The default Extension Volume is 2 liters.

Press the Save icon in the lower right corner of the screen to store the selection.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.



**PRESSURE SETTING:**

The user can activate an adjustable First Target Pressure that the device will reach during initial insufflation by using the Up and Down Arrows. When activated, the First Target Pressure can be adjusted by pressing the Up and Down arrows inside of the First Target Pressure field.

The First Target Pressure can be used to set an intermediate pressure threshold during the procedure. When active, the device will insufflate until the First Target Pressure is reached and then maintain that pressure. A "1st Target Pressure" indicator will flash on the front panel to alert the user that the First Target Pressure has been reached. The user can then check the patient to assure that they are comfortable prior to resuming insufflation.

Note: The First Target Pressure will be maintained at the set pressure until the "Resume" button is pressed in the Main Operating Screen. The Final Target Pressure will not be reached until the user presses the "RESUME" button on the front panel.

The user can adjust the Final Target Pressure that the device will reach after the First Target Pressure has been reached. The user can adjust the Final Target Pressure by pressing the Up and Down arrows inside of the Final Target Pressure field.

The Final Target Pressure will be maintained by the device until the "STOP" button is pressed in the Main Operating Screen.

Note: The default First Target Pressure is 15 mm Hg. The default Final Target Pressure is 20 mm Hg.

Press the Save icon in the lower right corner of the screen to store the selection.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.

## READY TO SCAN SETTINGS:

If the READY TO SCAN feature is active, the device will make a determination of when the patient is ready to be scanned. The device does this through an algorithm that looks at the current pressure vs. set pressure, the stability of the pressure, and the total volume of insufflation. If all three of these criteria are met, a green "Ready To Scan" indicator will begin to flash in the Status Bar. To adjust the READY TO SCAN feature in the Main Menu, see Section 10.3.

WARNING: Ready To Scan is not intended to supersede the judgment of the Technologist or Radiologist during a procedure. This feature is a suggested indicator of when scanning should take place. Other factors could influence the decision to begin a scan, such as those listed in Section 10.10. The Technologist or Radiologist should always rely on their experience, training, and institution's policies when determining if the patient is ready to scan or not.

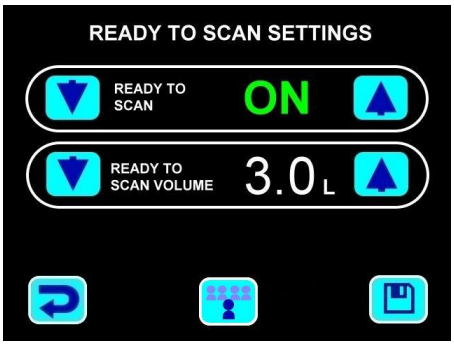
The user can activate or de-activate the READY TO SCAN feature during a procedure. This is done by pressing the Up and Down arrows.

When activated, the user can then select the Gas Volume in which the Ready to Scan will activate at by pressing the Up and Down arrows in the READY TO SCAN VOLUME field. The range is from 2 - 5 Liters, in increments of 0.1 Liters.
Note: The default READY TO SCAN VOLUME is 3.0 Liters.

The Selected Volume can either be set for one patient only or for all patients. If the user wants to retain the setting for one procedure, the user will select the Single Patient icon at the bottom of the screen. The Single Patient option should be selected if the desired settings are for one procedure only. Thereafter, the device will revert back to the previous settings. In this mode, the Ready to Scan Volume will be active for a single procedure.

Press the Save icon in the lower right corner of the screen to store the selection.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.



## DEFAULTS:

The user can reset the device to the factory default settings. The user can do this by touching the Reset button. Once selected, the user touches Reset Icon to activate the Reset and return to the Main Menu. If the user does not want to activate the Reset, the Return button can be touched to return to the Main Menu.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.

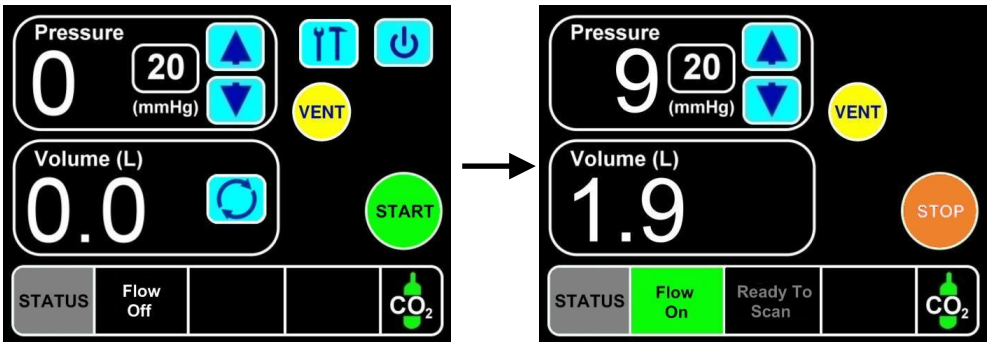
## 10.4 PREPARATION TEST

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 LCD touchscreen display is on.

**NOTE:** If the output pressure is negative or in an alert state, the Pressure Display will indicate the actual pressure.

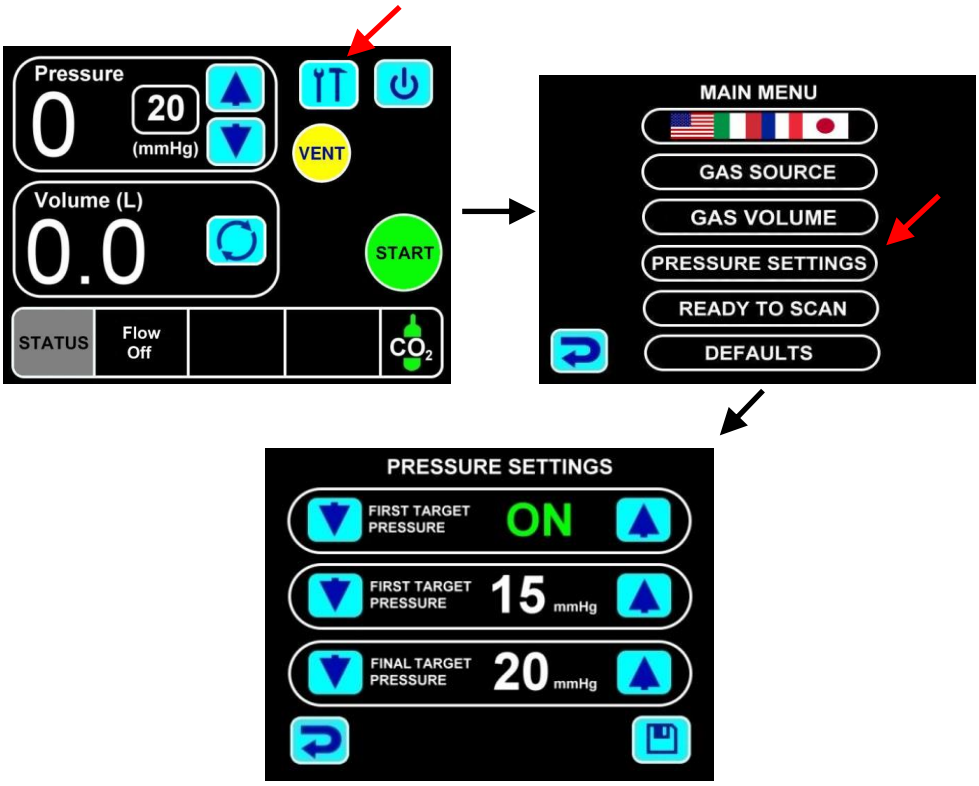
2. To verify that flow control is functioning properly, depress the green START button. When pressed, the "FLOW ON" icon in the bottom status bar will display, and gas may be heard exiting from the unit. If gas does not begin flowing, verify that the $CO_2$ supply tank valve is in the open position (see Section 10.1, Power On, and Section 10.2 Gas Supply Indicator, above).




3. When the START button is pressed initially, $CO_2$ will begin to be delivered and the unit will automatically return to STOP mode after a user adjustable amount of $CO_2$ has been insufflated. The factory default is 4 liters. Thereafter, pressing the green RESUME button will resume the delivery of $CO_2$ before automatically returning to STOP mode after a user adjustable amount of $CO_2$ has been insufflated. The factory default is 2 liters. However, you can stop the flow by pressing the STOP button while the unit is flowing.
4. If the unit does not perform properly, do not use. Inspect the unit using the Troubleshooting guide (Section 14.0) before returning for service.

## 10.5 SETTING PATIENT PRESSURE

The Patient Pressure can be set in several ways. The first way is to navigate to the MAIN MENU. To do this, press the MAIN MENU ICON on the top right area of the Operating Screen. In the MAIN MENU press the "PRESSURE SETTING" button.




The user can activate an adjustable First Target Pressure that the device will reach during initial insufflation by using the Up and Down Arrows. When activated, the First Target Pressure can be adjusted by pressing the Up and Down arrows inside of the First Target Pressure field.

The First Target Pressure can be used to set an intermediate pressure threshold during the procedure. When active, the device will insufflate until the First Target Pressure is reached and then maintain that pressure. A "1st Target Pressure" indicator will flash on the front panel to alert the user that the First Target Pressure has been reached. The user can then check the patient to assure that they are comfortable prior to resuming insufflation.

Note: The First Target Pressure will be maintained at the set pressure until the "Resume" button is pressed in the Main Operating Screen. The Final Target Pressure will not be reached until the user presses the "RESUME" button on the front panel.

The user can adjust the Final Target Pressure that the device will reach after the First Target Pressure has been reached. The user can adjust the Final Target Pressure by pressing the Up and Down arrows inside of the Final Target Pressure field.

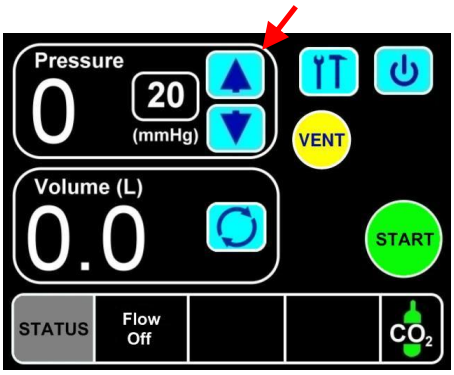
The Final Target Pressure will be maintained by the device until the "STOP" button is pressed in the Main Operating Screen.

Note: The default First Target Pressure is 15 mm Hg. The default Final Target Pressure is 20 mm Hg.

Press the Save icon in the lower right corner of the screen to store the selection.

Note: Press the Back icon on the lower left corner of the screen to exit this menu and return to the Main Menu.

To adjust the Final Target Pressure from the Operating Screen, press the Up and Down Arrows in the PRESSURE field to set the desired pressure.

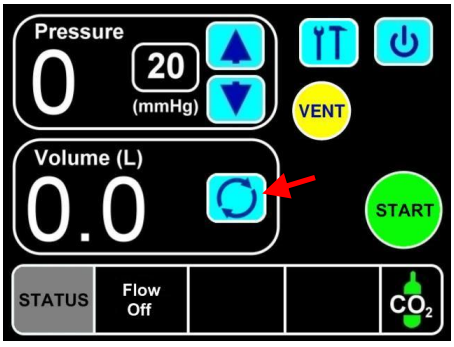



An initial insufflation pressure of 20 mm Hg is recommended. If necessary, the pressure may be increased up to 35 mm Hg during the procedure to obtain adequate distention.

## 10.6 RESET $CO_2$ VOLUME

Assure that the Volume Display reads zero prior to beginning insufflation. To reset the Volume Liters Display, press the Volume Reset button in the Operating Screen.

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



## 10.7 PATIENT CONNECTION FOR INSUFFLATION

Place the patient in the lateral decubitus position, and insert the Administration Set into the patient, following the instructions included with the Administration Set.

It is important to use only Bracco Diagnostics, Inc. manufactured high flow tubing with a 0.1 micron hydrophobic filter and unique Connector. The 0.1 micron hydrophobic filter prevents cross contamination of the patient and PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR. Bracco Diagnostics, Inc. manufactures an Administration Set (that includes the filter and unique Connector) designed to provide optimum insufflator performance. The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR will not insufflate with an Administration Set that does not include the unique Connector. Always inspect every Administration Set to make sure there are no signs of damage. If such a condition exists, do not use the Administration Set. See Administration Set instructions for use.

The use of unauthorized administration sets may cause damage of your insufflator and result in voiding your warranty.

## 10.8 ADMINISTRATION SET CONNECTION FOR INITIAL INSUFFLATION

Insert the unique Connector on the Administration Set to the Gas Output connection on the insufflator's Front panel.

## 10.9 PATIENT INSUFFLATION

1. Begin insufflation in the lateral decubitus position by pressing the green START button to initiate gas flow. Gently roll the patient into the supine position. Allow the pressure and volume to stabilize.

2. Within approximately 1 to 3 minutes, the volume will stabilize between 2 and 3 L, and the pressure will stabilize at the set-point. If after 3 to 5 minutes, the actual volume stabilizes at less than 2 Liters, the pressure remains less than the set-point, or the volume fails to stabilize, see Section 10.10, OBSERVATIONS DURING INSUFFLATION.

Note: If the volume reaches the set PAUSE VOLUME at any point during the procedure, the flow of $CO_2$ will automatically pause. The PAUSE VOLUME can be adjusted in the Main Menu (See Section 10.3). The default Pause Volume is 4 Liters. This will be evident by the orange "Flow Paused" indicator in the Status Bar and the green "EXTEND" button appearing on Operating Screen. The PAUSE VOLUME can be adjusted in the Main Menu (See Section 10.3). Pressing the EXTEND button will reinitiate the flow for a user set number of liters. The VOLUME EXTENSION can be adjusted in the Main Menu (See Section 10.3). The default Volume Extension is 2 Liters. Each subsequent restarting of the flow will reinstate the flow for an additional user set number of liters. The Volume Extension should be used if additional insufflation is needed to obtain optimal distention of the colon.

3. If the READY TO SCAN feature is active, the device will make a determination of when the patient is ready to be scanned. The device does this through an algorithm that looks at the current pressure vs. set pressure, the stability of the pressure, and the total volume of insufflation. If all three of these criteria are met, a green "Ready To Scan" indicator will begin to flash in the Status Bar. To adjust the READY TO SCAN feature in the Main Menu, see Section 10.3.

WARNING: Ready To Scan is <u>not</u> intended to supersede the judgement of the Technologist or Radiologist during a procedure. This feature is a suggested indicator of when scanning should take place. Other factors could influence the decision to begin a scan, such as those listed in Section 10.10. The Technologist or Radiologist should always rely on their experience, training, and institution's policies when determining if the patient is ready to scan or not.

4. Take the scout image. Evaluate the quality of insufflation. If insufflation is insufficient, see Section 10.10, OBSERVATIONS DURING INSUFFLATION .

5. Begin supine CT scan.

6. Following the supine scan, roll the patient to the prone position. Immediately take the scout image.

7. Begin prone CT scan.

## 10.10 OBSERVATIONS DURING INSUFFLATION

1. **Patient Discomfort:** Occasionally, the patient may feel some abdominal discomfort during the initial stages of insufflation, which is primarily due to the distention of the colon. To minimize patient discomfort, the following steps may be taken:

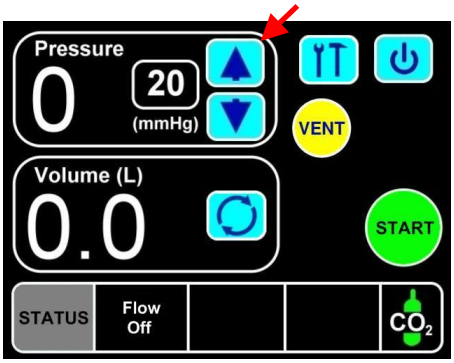
    a. Instruct the patient to breathe through his/her mouth.

    b. Instruct the patient to relax his/her abdominal muscles during the procedure.

    c. If the unit has begun insufflation, the flow of $CO_2$ may be paused by pressing the orange STOP button to allow time for the colon to relax. Once the patient is comfortable, the flow can be re-started by pressing the green START button.

    d. For patients who require more gradual insufflation, the FIRST TARGET PRESSURE setting can be activated to create an intermediate target pressure prior to reaching the FINAL TARGET PRESSURE. To set a FIRST TARGET PRESSURE, see Section 10.3.

    e. If the user does not wish to activate the FIRST TARGET PRESSURE, the pressure of $CO_2$ may be lowered (15 to 20 mm Hg) by using the Up and Down arrows adjacent within the Pressure field on the Operating Screen to allow for a more gradual distention of the colon. When the patient is comfortable, the pressure should be slowly raised to 20-25 mm Hg.



2. **Insufficient Distention:** It is not uncommon for some colonic segments to appear inadequately distended in either the prone or supine positions. In particular, inadequate distention of the transverse colon may occur in heavier patients in the prone position. To improve distention:
    a. Check to make sure that the flow of $CO_2$ has not paused (i.e. that the green "Flow On" indicator is showing in the Status Bar).
    b. Check the Administration Set tubing for kinks, closed clamps, excessive colonic fluid, or anything that could block the flow of $CO_2$ into the patient.
    c. Remind the patient to breathe orally.
    d. Instruct the patient to relax his/her abdominal muscles.
    e. It may be necessary, particularly for heavier patients, to use pillows or foam positioning blocks underneath a patient's sternum and/or pelvis to improve colonic distention while in the prone position. By elevating these portions of a patient's anatomy, the abdominal cavity should distend more freely and redistribute the patient's weight on the CT table.
    f. If necessary, additional $CO_2$ may be added by pressing the green EXTEND button.
    g. The FINAL TARGET PRESSURE can be increased up to a maximum of 35 mm Hg. The pressure should only be adjusted to this amount if some colonic segments are not adequately distended.
3. **Lower than expected volume of $CO_2$ :** A stabilized volume of less than 2 Liters of $CO_2$ in the initial scanning position is generally an indication of incomplete distention of one or more colonic segments. If this occurs, perform the following steps:
    a. Roll the patient onto either side to redistribute the $CO_2$ in the colon.
    b. Raise the pressure to between 25 - 35 mm Hg.
    c. A drop in the pressure as indicated on the pressure display on the screen will indicate the opening of the segment in question, and will be accompanied by an increase in the volume of $CO_2$.
    d. Continue with the rolling maneuver until the volume reaches at least 2 Liters.

4. **Higher than expected volume of $CO_2$:** If the volume becomes greater than 4 Liters without reaching the target pressure, one of the following conditions may be present. A scout image should be taken immediately to evaluate.
    a. **Pneumoperitoneum –** If free intra-peritoneal air is observed, or if colonic perforation is suspected, immediately discontinue insufflation by disconnecting the administration set from the insufflator. Provide appropriate medical attention.
    b. **Small bowel reflux –** If reflux is evident and distention is acceptable, proceed with study. If additional $CO_2$ is required, it may be added by pressing the green EXTEND button, under the supervision of a physician. If small bowel reflux is observed, completing the study as quickly as possible will help to minimize the reflux.
    c. **Leakage around rectal tube –** If the colon is not fully distended, and no small bowel reflux is evident, it may be due to leakage around the rectal tube. If not already inflated, the physician should consider inflating the rectal balloon on the rectal tube. In addition, ask the patient to squeeze his/her muscles to retain the rectal tube. If additional $CO_2$ is required, it may be added by pressing the green EXTEND button.

**NOTE:** ***If an emergency should arise whereby there is a need to terminate insufflation, the operator should stop the $CO_2$ gas flow by promptly disconnecting the Administration Set at the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR Output port.***

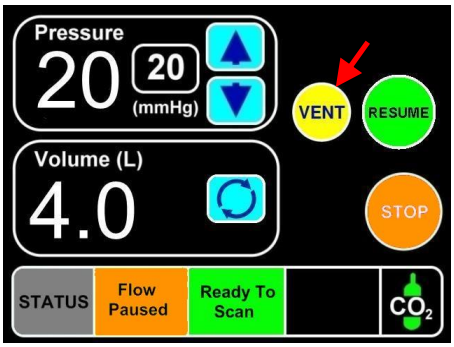
## 10.11 $CO_2$ VOLUME DISPLAY

The Digital Volume Display reads the total volume of $CO_2$ passing from the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR to the patient. The digital display indicates the volume of $CO_2$ delivered in Liters and tenths of Liters and has a range of 0 to 99.9 Liters.

**NOTE:** When insufflating $CO_2$, the unit will maintain the set pressure in the colon even if there is no apparent flow. The unit must be left on until the procedure is completed.

## 10.12 TERMINATING GAS FLOW & SHUT-DOWN PROCEDURES

1. Upon completion of the diagnostic procedure, disconnect PROTOCO$_2$L TOUCH™ Administration Set from the unit at the Output port and press the orange STOP button. Allow colon to deflate through the PROTOCO$_2$L TOUCH™ Administration Set or by pressing the yellow "VENT" button in the Operating Screen. When the VENT button is pressed, the Electronic Pressure Relief Valve opens and remains open until the pressure reaches 0 mm Hg in the system.




2. Deflate retention cuff, clamp administration set to prevent spillage of colonic fluids and remove tip. Discard the entire PROTOCO$_2$L TOUCH™ Administration Set in accordance with all National, State and Local regulations. **Administration Sets are intended for single-use only. Reuse of the administration set carries an increased risk of cross-contamination.**
3. Turn power off and disconnect the line cord from power outlet.
4. It is recommended that the $CO_2$ supply tank valve be fully closed when not in use.

## 10.13 ERROR CODES

If a problem is discovered during the self-diagnostic check, the SERVICE UNIT screen will appear.


An error code number that corresponds to a specific problem will be displayed. The list of all error codes is shown below. This problem information will need to be described to Bracco Diagnostics Inc., Professional Services and be sent in for service.

| ERROR CODE NUMBER | ERROR DESCRIPTION |
|---|---|
| 1 – 3 | Internal Memory Error |
| 4 – 7, 14 | Communication Error |
| 8 | External Memory Error |
| 9 | Digital Valve Error |
| 10 | Proportional Valve Error |
| 11 | Pressure Relief Valve Error |
| 12 | Pressure Sensor Error |
| 13 | Flow Sensor Error |
| 15 | Power Supply Error |
| 16 | Noise Error |

# Section 11.0 DECONTAMINATION, CLEANING AND STORAGE

Prior to disinfecting the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, ensure the power is turned off and the electrical cord is unplugged. To disinfect the PROTOCO$_2$L TOUCH™ COLON 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 PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR. Do not allow fluids to enter the unit. Dry all components thoroughly. Do not sterilize or autoclave this unit.

For general cleaning, the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR can be wiped down with a damp cloth and mild soap.

The Bracco Diagnostics Inc. PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should be covered and stored in a cool dry location. Care should be taken to avoid rough handling, jarring, or dropping the unit.

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is labeled as Electrical and Electronic Equipment in accordance with 2002/96/EC. It should not be disposed of in unsorted municipal waste. The unit must be decontaminated prior to disposal. This insufflator should be disposed of in accordance with local environmental regulations.

# Section 12.0 REPAIR AND MAINTENANCE CHECKS

## 12.1 REPAIR

There are no user adjustments inside the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR cabinet. Repairs and adjustments are to be performed only by Bracco Diagnostics Inc. or authorized service or repair facilities. Unauthorized service, repair, or modifications to the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR will void your warranty.

If repairs become necessary call Bracco Diagnostics Inc. prior to returning the device, and request return authorization.

Warranty repairs will be made without charge. All other repairs will be made on a time and material basis. If requested, Bracco Diagnostics Inc. will provide an estimate of the repair cost and the time for the repair before any work is done. For customers within the US, repair items, (including line cord, Yoke and High Pressure Hose) should be carefully repackaged and returned, post paid, to:

Bracco Diagnostics Inc.
155 Pinelawn Road
Suite 230N
Melville, NY 11747
Attention: Quality Assurance

For customers outside of the US, please call Customer Service for instructions on returning your unit for service.

***PRODUCTS MAY NOT BE RETURNED TO BRACCO DIAGNOSTICS, INC. WITHOUT PRE-APPROVAL.**

## 12.2 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.

- Visually inspect the Mains or line cord that is used to provide power to your PROTOCO$_2$L TOUCH™. 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.**
- Open the fuse holder in the power entry module mounted to the rear panel of the PROTOCO$_2$L TOUCH™. Verify that the fuses are correctly typed and rated as printed on the rear panel.
- Visually inspect the high-pressure hose between the $CO_2$ supply source and the rear panel of the PROTOCO$_2$L TOUCH™ unit. If it is worn, frayed, kinked or damaged, call Bracco Diagnostics Inc. immediately to obtain a replacement.
- Verify that the power rocker switch on the rear panel is seated properly, undamaged, exhibits no evidence of fluid/dirt infiltration, and functions properly.
- Connect the device to a $CO_2$ supply source and attach a PROTOCO$_2$L TOUCH Administration Set to the outlet port on the front panel. Power on the PROTOCO$_2$L TOUCH™ unit.
    - Verify the unit insufflates $CO_2$ by pressing the green START button on the screen. The green "Flow On" will appear in the Status Bar. The volume of $CO_2$ exiting the gas outlet port will begin to increase, as shown in the Volume Field on the front panel. When done, press the orange STOP button on the screen.
    - Verify that the pressure adjustment controls in the Pressure Field properly adjust the Set Pressure from a range of 0 – 35 mm Hg.
    - Verify that the screen can be powered off by pressing and holding the Power Off icon in the upper right corner of the screen for at least two seconds.
- Visually inspect the pneumatic gas outlet connection on the front panel for damage or fluid invasion.
- Refer to the Troubleshooting Guide in the back of this Operator's Manual. Verify insufflation and venting performance in accordance with the specified instructions related to $CO_2$ delivery pressure and flow rate.
- 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 PROTOCO$_2$L TOUCH™ unit.

If you are unable to perform this inspection, the PROTOCO$_2$L TOUCH™ unit can be sent to Bracco Diagnostics Inc.

# MAINTENANCE CHECKLIST

Refer to Section 12.2 of this Operator's Manual for instructions on how to perform each item in the checklist below:

| | | |
|---|---|---|
| Inspection of Mains or line cord | Pass ☐ | Fail ☐ |
| Fuse Inspection | Pass ☐ | Fail ☐ |
| High Pressure Hose Inspection | Pass ☐ | Fail ☐ |
| Rear Panel Rocker Switch Inspection | Pass ☐ | Fail ☐ |
| Inspection of $CO_2$ Insufflation | Pass ☐ | Fail ☐ |
| Inspection of Pressure Adjustment | Pass ☐ | Fail ☐ |
| Inspection of Power Off Function on Screen | Pass ☐ | Fail ☐ |
| Visual Inspection of Gas Outlet Connection | Pass ☐ | Fail ☐ |
| Inspection of Insufflation and Venting Performance | Pass ☐ | Fail ☐ |
| Inspection of Earth Leakage Current | Pass ☐ | Fail ☐ |

If for any reason, the integrity of the PROTOCO$_2$L TOUCH™ unit is suspect as a result of these inspection steps, please call Bracco Diagnostics Inc. Customer Service to make arrangements for repair.

Tested By: _____ Test Date: _____

Unit Serial Number: _____

## 12.3 PROFESSIONAL SERVICES AND ORDERING INFORMATION

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

## 12.4 WARRANTY

Your new PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is warranted against all defects in materials and workmanship for 12 months from the date of purchase.

This warranty shall not apply to any PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR which:

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

## 12.5 CERTIFICATION OF NON-CONTAMINATION

- All products being returned to Bracco Diagnostics Inc. must be accompanied by a Certificate of Non-Contamination.
- Products that have become contaminated in any way shall ***not*** be returned to Bracco Diagnostics Inc., unless special written permission has been granted by Bracco Diagnostics 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 Bracco Diagnostics Inc. for pre-approval before such material can be returned.

# Section 13.0 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 Bracco Diagnostics, 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 PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, ensure the power is turned off and the electrical cord is unplugged. To disinfect the PROTOCO$_2$L TOUCH™ COLON 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 PROTOCO$_2$L TOUCH™ COLON 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 Bracco Diagnostics, Inc. complete this Certificate of Non-Contamination Form, and send/fax to Bracco Diagnostics, Inc. Quality department at 1-631-847-3904.

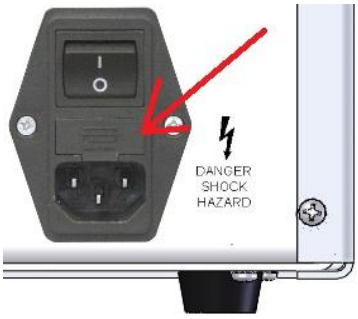
# Section 14.0 TROUBLESHOOTING GUIDE

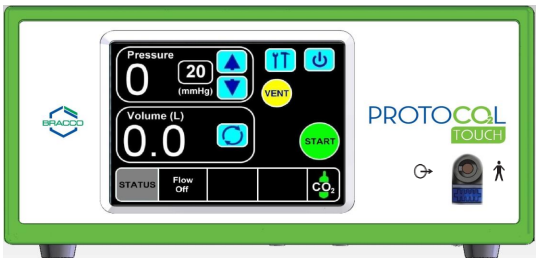
Make sure that you have read and understand the prior sections of this operator's manual that provide normal operating instructions for your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, including the warnings and cautions section. Before making arrangements with Bracco Diagnostics, Inc. Professional Services to send your PROTOCO$_2$L TOUCH™ COLON 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.

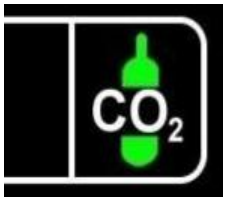
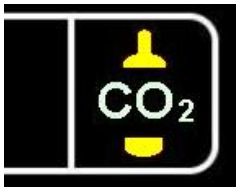
Please be advised that the appearance of your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR may differ slightly from the units shown in the following photographs. (Example: buttons may be round or square).

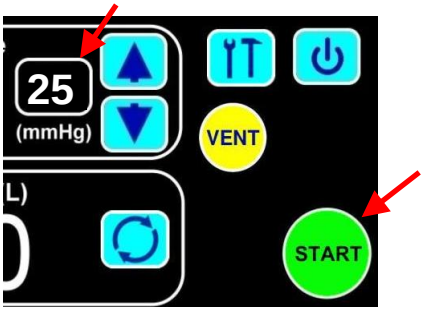
The Field Checkout steps listed here pertain to common operating conditions and possible malfunctions. Review this information and refer to it when communicating with your Bracco Diagnostics, Inc. Professional Services Representative. This will enable us to identify the best course of action to meet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

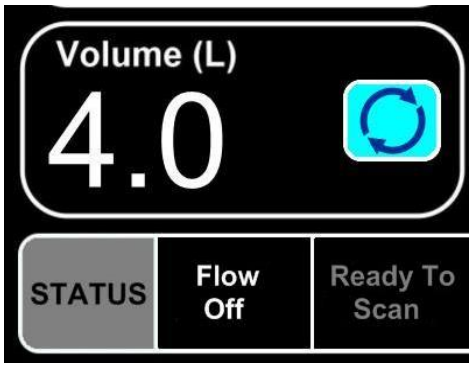
Should you need further assistance with this guide, see your supervisor, or contact Bracco Diagnostics, Inc., Professional Services at 1-800-631-5245 (USA), 1-609-514-2200.

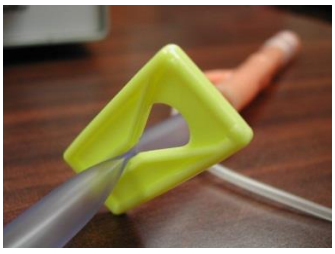
| Condition | Possible Causes | Field Checkout |
|---|---|---|
| ***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR does not Power-up at all.*** | No power at wall outlet | Check PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR in wall outlet known to be operational. |
| What should I do? | Blown fuse | Remove line cord from rear panel of PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR and use a small screwdriver to open fuse holder.<br>Pull fuse holder down and examine fuses.<br>  <br>If blown, replace with 2-Amp 250-Volt Time-Delay Fuses. |

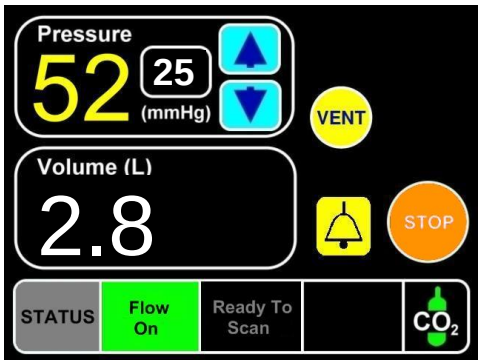
| Condition | Possible Causes | Field Checkout |
|---|---|---|
| ***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR does not Power-up at all.***<br><br>What should I do? | **Rear** panel rocker switch "off" | With unit plugged into wall outlet, activate Power Switch to the ON or (1) position.<br><br>Upon completing its Power-up sequence, the front panel should appear as follows:<br><br>  <br><br>The power switch should be illuminated with the VOLUME LITERS and PRESSURE displays both Indicating "0". Additionally, the GAS SUPPLY Indicator should also be illuminated and indicate the current amount of $CO_2$ in the supply tank. The above display indicates that the unit has correctly Powered-up.<br><br>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 Bracco Diagnostics Inc. Professional Services. |

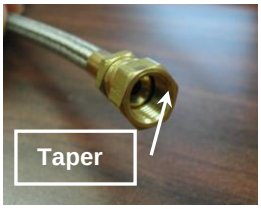
| Condition | Possible Causes | Field Checkout |
|---|---|---|
| ***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR does not deliver CO$_2$.***<br><br>What could be the problem? | Empty $CO_2$ supply tank or valve closed | After successfully Powering-up your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, examine the GAS SUPPLY Indicator in the Status Bar.<br><br>Make sure that the tank Valve for the $CO_2$ supply tank is open. Your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should sense the pressure from the $CO_2$ supply tank and the GAS SUPPLY Indicator should illuminate as follows: Green (full), yellow (low), flashing yellow (empty).<br><br>  <br><br><br>If during Power-up or operation of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, the $CO_2$ in the supply tank is depleted, the illuminated GAS SUPPLY Indicator will transition from green to yellow, to flashing yellow . Once the GAS SUPPLY Indicator is flashing yellow, the unit will periodically beep and no longer deliver $CO_2$.<br><br>  <br><br><br>If this occurs, reconnect the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR to a full $CO_2$ supply tank to continue operation.<br><br>Should the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR's $CO_2$ Gas Supply Indicator fail to indicate full after verifying the $CO_2$ supply tank is full and the tank valve is open, you will need to contact Bracco Diagnostics Inc. Professional Services. |

| Condition | Possible Causes | Field Checkout |
|---|---|---|
| "CONTINUED"<br><br>***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR does not deliver CO$_2$.***<br><br>What could be the problem? | PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR flow rate incorrect | To check the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR's ability to deliver CO$_2$ to the patient, follow these verification steps:<br><br>After Powering-up and making sure that your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is connected to a CO$_2$ supply tank or central gas supply, depress the VOLUME RESET button, zero will appear in the VOLUME LITERS display.<br><br>  <br><br>Set the Pressure to 25 mm Hg. Press the green START button to begin insufflation.<br><br>  <br><br>Using a wrist watch with a second hand or a stop watch, allow the unit to deliver 4.0 liters of CO$_2$. The unit should reach this volume and automatically return to stop between 90 and 120 seconds. During this time interval, place your finger at the trip of the Administration Set. You should feel gentle pulses of CO$_2$ exiting. |

| Condition | Possible Causes | Field Checkout |
|---|---|---|
| "CONTINUED"<br>***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR does not deliver CO$_2$.***<br><br>What could be the problem? | PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR flow rate is incorrect |  <br>At start-up, your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should normally deliver the flow of $CO_2$ to the patient incrementally as follows: 1 LPM for 0 to 0.5 Liters of delivered volume, 2 LPM for greater than 0.5 to 1 Liter of delivered volume and a maximum of 3 LPM for delivered volumes greater than 1 Liter. This procedure verifies this performance parameter. If you are unable to successfully replicate these steps, contact Bracco Diagnostics Inc. Professional Services or check the routing of the patient Administration Set to make sure that it is ***not*** kinked, occluded or leaking. |

| Condition | Possible Causes | Field Checkout |
|---|---|---|
| ***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is not distending the colon enough.***<br><br>What could be the problem? | PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR delivery pressure incorrect. | To Check the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR's ability to deliver $CO_2$ at a set pressure please follow these verification steps:<br><br>Attach an Administration Set to the Gas OUTPUT of your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR. Engage the tubing clamp at the distal end of the Administration Set.<br><br>  <br><br>Adjust the set delivery pressure to 25 mm Hg on the Operating Screen.<br><br>Press the green START button to start the delivery of $CO_2$. As the flow of $CO_2$ starts, the Effluent Trap belonging to the Administration Set should start to inflate. Additionally, the PRESSURE Display on the Operating Screen should start to increase.<br><br>  <br><br>Once the Effluent Trap is full, the PRESSURE displayed by the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should reach approximately 35 to 45 mm Hg. |

| Condition | Possible Causes | Field Checkout |
|---|---|---|
| "CONTINUED"<br><br>***My PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is not distending the colon enough.***<br><br>What could be the problem? | PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR delivery pressure incorrect. | With the pressure holding steady between 35 to 45 mm Hg, place the inflated Effluent Trap in your hand. While in this position, use your thumb to gently squeeze it flat.<br><br>As the Effluent Trap is squeezed, the pressure on the display will rise. Maintain a uniform pressure on the Effluent Trap such that the pressure displayed remains between 55 and 65 mm Hg for 5 seconds. At the end of the 5 second time, an audible click should be heard from the unit and the $CO_2$ in the Effluent Trap should freely vent from the system. During venting, the PRESSURE display should blink and the unit should beep.<br><br>  <br><br>Remove finger pressure from the Effluent Trap. Verify reinflation to 35 to 45 mm Hg.<br><br>Your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR should also vent in accordance with the checkout steps prescribed above. If you are unable to replicate unit operation as prescribed here contact Bracco Diagnostics, Inc. Professional Services.<br><br>Depending upon the particular patient and clinical set-up, it may be necessary to use pillows or foam positioning blocks underneath a patient's sternum and/or pelvis to improve colonic distention while in the prone position. By elevating these portions of a patient's anatomy, the abdominal cavity should distend more freely and redistribute the patient's weight on the CT table. |

| Condition | Possible Causes | Field Checkout |
|---|---|---|
| ***My $CO_2$ supply Tank is prematurely emptying.***<br><br>What could be the problem? | Valve on $CO_2$ supply tank left open all of the time. | We recommend attaching your PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR accessory to either "D" or "E" size $CO_2$ supply tank. For USP Medical Grade $CO_2$ tanks (cylinders) supplied outside of the USA please note that the tank should be within 430mm to780mm in height to securely fit in the Protocol Accessory Cart, model 6405. The Protocol Accessory Cart is not required for use with the Protocol Touch Insufflator.<br><br>Tank designations vary by country. Please check with your local distributor for compatibility<br><br>Be sure to close the $CO_2$ supply tank valve whenever the unit is not in use.<br><br>The pneumatic design of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is not intended to provide a full time gas seal from the $CO_2$ supply tank while the device is not being used or in storage. Should the $CO_2$ supply tank valve inadvertently be left open, there is a high likelihood that the $CO_2$ supply tank contents will gradually empty over several days. |
| | High Pressure Hose from $CO_2$ supply tank is not installed properly | If after opening and closing the $CO_2$ supply tank valve with your procedure schedule, you still encounter problems with $CO_2$ supply tank prematurely emptying, there is the possibility that the High Pressure Hose from the $CO_2$ supply tank to the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR unit is leaking.<br><br>Please inspect the high pressure hose connection in accordance with the following procedure: Using an adjustable wrench, detach the High Pressure Hose from PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR's rear panel. Inspect the tapered surface of the free standing nipple on the PROTOCO$_2$L TOUCH™ COLON 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.<br><br>   <br><br>Repeat this inspection procedure at the identical tapered gas connection at the opposite end of the hose. |

| Condition | Possible Causes | Field Checkout |
|---|---|---|
| "CONTINUED"<br><br>***My $CO_2$ supply Tank is prematurely emptying.*** | High Pressure Hose from $CO_2$ supply tank is not installed properly<br><br>(Continued from previous page.) | Inspect the $CO_2$ supply tank Yoke and verify that the plastic disc that creates the gas seal at the $CO_2$ supply tank valve is in-place and free from defect.<br><br>  <br><br><br>After verifying all High Pressure Hose sealing surfaces are clean and free of defect; reconnect the High Pressure Hose to the $CO_2$ supply tank Yoke and PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR. Use an adjustable wrench to tighten securely. **DO NOT USE ANY TEFLON TAPE OR THREAD SEALING COMPOUNDS.**<br><br>Reconnect the Yoke to the $CO_2$ supply tank valve making sure that the plastic sealing disk is in place.<br><br>Open the $CO_2$ supply tank valve. If $CO_2$ continues to prematurely empty or should you hear $CO_2$ escaping from any of these connections or the High Pressure Hose itself, contact Bracco Diagnostics, Inc. Professional Services. |

# Section 15.0 EMC TABLES

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR will be tested by Underwriters Laboratory to the following electro-magnetic compatibility standards:

| **Table 1**<br>**Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The PROTOCO$_2$L TOUCH$^{TM}$ COLON INSUFFLATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the PROTOCO$_2$L TOUCH$^{TM}$ COLON INSUFFLATOR should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| CISPR 11<br>RF Emissions | Group 1 | The Colon Insufflator 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<br>RF Emissions | Class A | |
| IEC 61000-3-2<br>Harmonic Emissions | Class A | |
| IEC 61000-3-3<br>Voltage fluctuations / flicker emissions | Complies | |

**Table 2**
**Guidance and manufacturer's declaration – electromagnetic immunity**

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is intended for use in the electromagnetic environment specified below. The customer or the user of PROTOCO$_2$L TOUCH™ COLON 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<br>Electrostatic discharge (ESD) | +/-6 KV contact<br><br>+/-8 KV air | +/-6 KV contact<br><br>+/-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<br>Electrical fast transient burst | +/-2 KV for power supply lines<br><br>+/-1 KV for input/output lines | +/-2 KV for power supply lines<br><br>+/-1 KV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-5<br>Surge | +/-1 KV differential mode<br><br>+/-2 KV common mode | +/-1 KV differential mode<br><br>+/-2 KV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 61000-4-11<br>Voltage dips, short interruptions and voltage variations on power supply input lines | <5 % *Ut*<br>(>95 % dip in *Ut*)<br>for 0.5 cycle<br><br>40 % *Ut*<br>(60 % dip in *Ut*)<br>for 5 cycles<br><br>70 % *Ut*<br>(30% dip in *Ut*)<br>for 25 cycles<br><br><5 % *Ut*<br>(>95 % dip in *Ut*)<br>for 5 sec | <5 % *Ut*<br>(>95 % dip in *Ut*)<br>for 0.5 cycle<br><br>40 % *Ut*<br>(60 % dip in *Ut*)<br>for 5 cycles<br><br>70 % *Ut*<br>(30% dip in *Ut*)<br>for 25 cycles<br><br><5 % *Ut*<br>(>95 % dip in *Ut*)<br>for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR requires continued operation during power mains interruptions, it is recommended that the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR be powered from an uninterruptible power supply or battery. |
| IEC 61000-4-8<br>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: *Ut* is the A.C. mains voltage prior to application of the test level.

**Table 3**
**Guidance and manufacturer's declaration – electromagnetic immunity**

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is intended for use in the electromagnetic environment specified below. The customer or the user of the PROTOCO$_2$L TOUCH™ COLON 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 PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| IEC 61000-4-6<br>Conducted RF | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms | **Recommended separation distance**<br>$d = 1{,}2 \sqrt{P}$ |
| IEC 61000-4-3<br>Radiated RF | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d = 1{,}2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2{,}3 \sqrt{P}$ 800 MHz to 2.5 GHz<br>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).<br>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].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

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 PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is used exceeds the applicable RF compliance level above, the PROTOCO$_2$L TOUCH™ COLON 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 PROTOCO$_2$L TOUCH™ COLON 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 PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR**

The PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PROTOCO$_2$L TOUCH™ COLON INSUFFLATOR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PROTOCO$_2$L TOUCH™ COLON 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.

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