

A key component for virtual colonoscopy.

PROTOCOL[®]
TOUCH

Automated Carbon Dioxide
Insufflation System for
Virtual Colonoscopy



BRACCO DIAGNOSTICS:
THE CT COLONOGRAPHY COMPANYSM

LIFE FROM INSIDE

Consistent, Productive, Comfortable

An essential component for successful Virtual Colonoscopy

Consistent

Regulated pressure gradually distends the colon, and maintains that distention for the duration of the study

- Automated insufflation with CO₂ results in more consistent distention and less variability from user to user¹
- As compared with manual room air insufflation, automated insufflation with CO₂ provides improved colonic distention, as demonstrated in two clinical trials^{2,3}
- Volume display allows the monitoring and recording of the volume of CO₂ used, unlike manual room air insufflation in which the amount of air introduced is not monitored
- Regulated pressure avoids pressure spikes and minimizes the level of patient discomfort often experienced with hand insufflation³



Courtesy of Dr. Perry J. Pickhardt, University of Wisconsin, Madison, USA.

Comfortable & Safe

Automatic distension with CO₂ is the method of choice, to optimize colonic distension and to maximize patient comfort⁴

- Rapid absorption of CO₂ results in improved comfort after the procedure, as compared with room air insufflation^{2,3,5}

- Automated low-pressure insufflation may reduce colonic spasm as compared with manual methods, particularly in segments with advanced diverticular disease³
- Automated insufflation combined with pressure relief valves and automatic flow stop features help protect against overinsufflation
- Over-pressure alarms and safety shutdown features further help protect against over insufflation

Productive

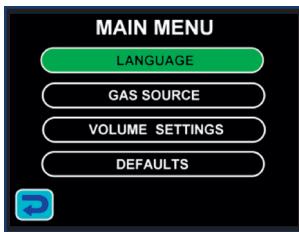
- Automated insufflation may decrease the demands on staff time, particularly during the insufflation process⁵
- Automatically replaces gas lost during the procedure
- Visual displays allow for quick reference of pressure and volume, and alerts the operator when the CO₂ cylinder is low
- Adjustable pressure up to 35 mmHg allows for user control when necessary



PROTOCO₂L TOUCH® offers the same reliability you've come to expect, but now with additional features to further simplify and streamline the procedure

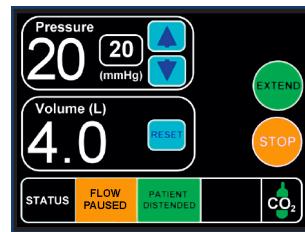
- No special utilities required: PROTOCO₂L TOUCH uses standard medical grade (USP) D or E size carbon dioxide cylinders, or a central supply source, and connects to a standard hospital electrical receptacle
- PROTOCO₂L TOUCH displays instantaneous gas pressure reading, records the total volume delivered during the procedure, and alerts the operator when the CO₂ cylinder is low
- An accessory cart provides storage facilities for CO₂ cylinders, and a dedicated holder for administration sets

Insufflation System



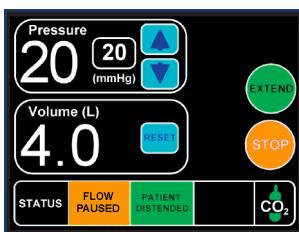
User Interface

- PROTOCO₂L TOUCH® has a main menu linking the user to fully customizable settings, which include volume pause, a possibility to change the gas source, language selector, a ready-to-scan feature, and first and final pressure input
- PROTOCO₂L TOUCH has an easy-to-use, intuitive interface
- Backlit color LCD touch screen provides health care professionals with a userfriendly interface



CO₂ Supply Features

- An improved gas gauge featuring a 2-color icon lets the user know when the gas cylinders are running low and need replacing: Green (full), Orange (running low), flashing Orange (empty)
- The gauge both visually and audibly alerts the user when the gas supply is low
- The PROTOCO₂L TOUCH now offers the possibility to attach a CO₂ central supply source or a conventional CO₂ cylinder



Ready-to-Scan

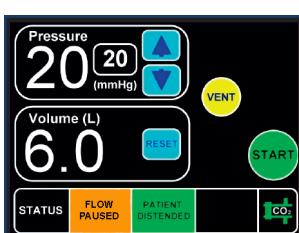
- The software interface enables users to determine when colon insufflation is complete
- Proprietary software takes pressure and volume into account to trigger the ready-to-scan feature

- The ready-to-scan feature reduces the likelihood of a poor quality scan, by alerting the user to the optimal time to start the scan
- The ready-to-scan feature increases the likelihood of getting an optimal scan at the first attempt
- PROTOCO₂L TOUCH identifies the steady-state pressure and the point at which optimal colonic distention should most likely be achieved



Language Options

- Customizable language options allow the user to choose among the following languages: English, Spanish, French, German, Italian, Portuguese, Swedish, Finnish, Norwegian, Danish, Greek, Turkish, Dutch, Czech, Polish, Korean, Japanese



Pressure Vent

- The user-activated pressure vent allows users to eliminate pressure within the administration set and the colon

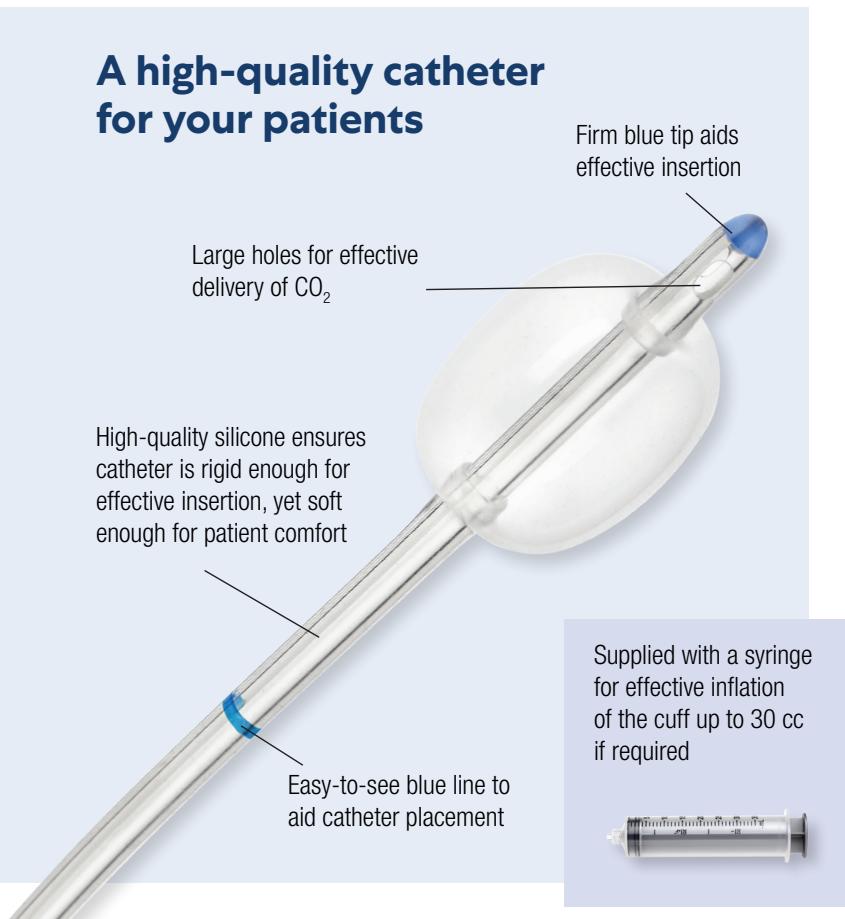


Administration Set

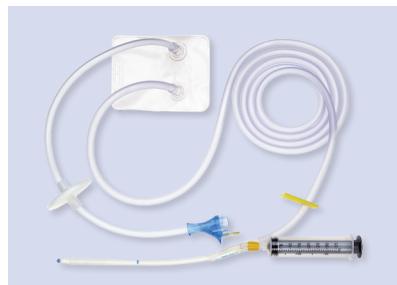
- An in-line fluid trap captures colon effluent and removes it from the “path” of the CO₂ for proper insufflation
- A hydrophobic filter helps to protect the PROTOCO₂L TOUCH Insufflator from cross contamination
- Simple connection and detachment from PROTOCO₂L TOUCH Insufflator

- The venting system now offers a one-touch solution to immediately relieve intracolonic pressure thereby reducing patient discomfort

A high-quality catheter for your patients



PROTOCO₂L TOUCH[®] Administration
Set is latex free, with vinyl tubing, syringe and plastic tubing clamp. The system includes a silicone rectal catheter with retention cuff, >.02 µm hydrophobic filter, 100mL effluent collection container and connector to PROTOCO₂L TOUCH Colon Insufflator.



For USP Medical Grade CO₂ tanks (cylinders) supplied outside of the USA please note that the tank should be within 430mm to 780mm in height to securely fit in the Protocol Accessory Cart, model 6405. Tank designations vary by country.

Please check with your local distributor for compatibility.

INDICATIONS AND USAGE:

The PROTOCO₂L TOUCH[®] COLON INSUFFLATOR administers and regulates carbon dioxide as a distention media to the colon during CT Colonography (CTC or Virtual Colonoscopy) and conventional Colonoscopy.

IMPORTANT SAFETY INFORMATION / CONTRAINDICATIONS FOR USE:

The PROTOCO₂L 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.

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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. The PROTOCO₂L TOUCH Operator's Manual may be obtained by contacting Bracco Diagnostics Inc. Professional Services Department at 800-257-5181, Option 2.

PROTOCO₂L TOUCH is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540.

PROTOCO₂L TOUCH is a registered trademark of E-Z-EM, Inc.

References:

1. Shinnars TJ, Pickhardt PJ, Taylor AJ, Jones DA, Olsen CH. Patient-controlled room air insufflation versus automated carbon dioxide delivery for CT colonography. *AJR*. 2006;186:1491-1496.
2. Burling D, Taylor SA, Halligan S, et al. Automated insufflation of carbon dioxide for MDCT colonography: distension and patient experience compared with manual insufflation. *AJR*. 2006;186:96-103.
3. Pickhardt PJ. Screening CT colonography: how I do it. *AJR*. 2007;189:290-298.
4. Neri E, et al. The second ESGAR consensus statement on CT colonography. *Eur Radiol*. 2013; 23:720-729.
5. Dachman AH. Advice for optimizing colonic distention and minimizing risk of perforation during CT colonography. *Radiology*. 2006;239:317-321.

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