

BRAVO™ CALIBRATION-FREE REFLUX TESTING SYSTEM

Quick reference guide



Figure 1

Step 1: Prepare the capsule delivery device

- 1) Check the expiration date on the capsule.
- 2) Without bending or kinking the delivery device, carefully remove it from the external shipping box, and then from the inner pouch (Fig. 1).
- 3) Remove the capsule's plastic cover, and magnetic clip. The capsule will automatically turn on when the magnetic clip is removed.
- 4) Set the magnetic clip aside (Fig. 2).
- 5) After opening the capsule package, make sure the capsule trocar needle is not advanced (Fig.3).

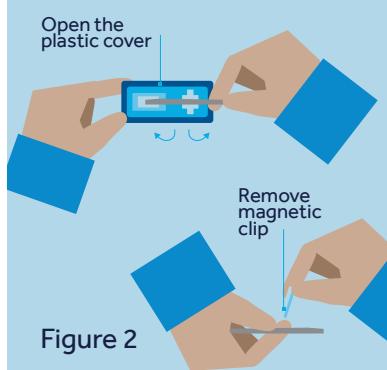


Figure 2

Step 2: Prepare the vacuum pump

- 1) Make sure the vacuum flow knob is turned to maximum.
- 2) With your gloved finger covering the suction chamber, verify that the vacuum gauge reading is at least 550 mmHg. Make a note of the gauge reading (Fig. 4).
- 3) Remove your finger from the suction chamber. Verify that the vacuum gauge reading drops by at least 50 mmHg to 500 mmHg or lower.
- 4) Turn off the vacuum and detach the tubing from the delivery device.

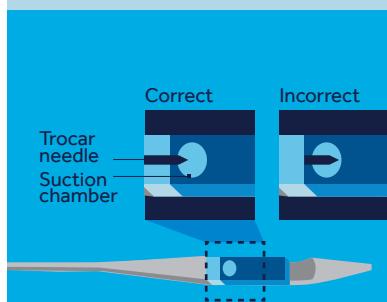


Figure 3

Step 3: Start the recording

- 1) If the recorder is turned off or in sleep mode, turn it on. Make sure it is fully charged.
- 2) From the main menu, select **Start Study** and press **Enter**.
- 3) If you see a "Last study not uploaded!" message, it means the recorder has detected existing data from a previous study that has not been uploaded.
- 4) To stop and upload the existing data, press **Cancel** and connect to the PC. Follow the instructions on the recorder. When the data is uploaded, start the new study again by selecting **Start Study** from the main menu.
- 5) To continue (overwrite the existing data without uploading it), press **Next** and then **Yes** to confirm.
- 6) The recorder will start searching for the capsule's signal, and the "Clearing data..." message will appear, followed by "Waiting for pH capsule 1."
- 7) When you see the message, "Does this pH capsule ID number match the delivery device number?" Press **Yes** or **No**. You'll find the capsule ID on the package label. Bravo™ calibration-free reflux capsules have a 5-digit ID; Bravo™ reflux capsules have a 4-digit ID. If the ID doesn't match, the search will begin again.
- 8) If the recorder still does not recognize the capsule or displays a capsule mismatch error, repeat the procedure.
- 9) If this is a two-capsule study, repeat the process.
- 10) When capsule recorder pairing is complete, the recorder will automatically start recording and the screen will display the symptom buttons.
- 11) Verify that the recorder is displaying pH values and that the capsule status LED on the recorder is blinking blue.

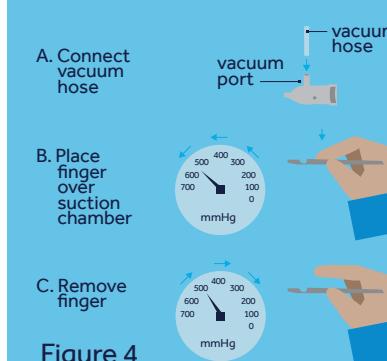
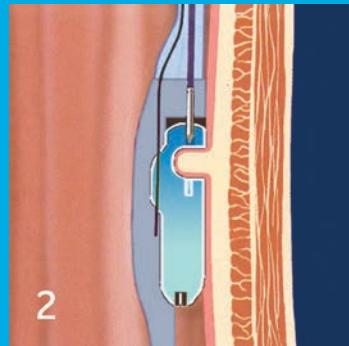
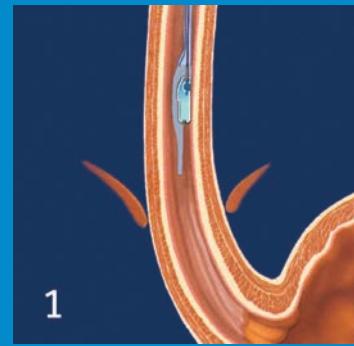


Figure 4

BRAVO™ CALIBRATION-FREE REFLUX TESTING SYSTEM

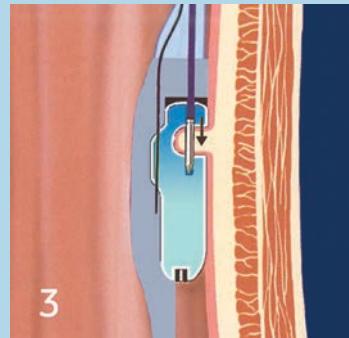
Quick reference guide



Capsule delivery

Step 1: Place the capsule

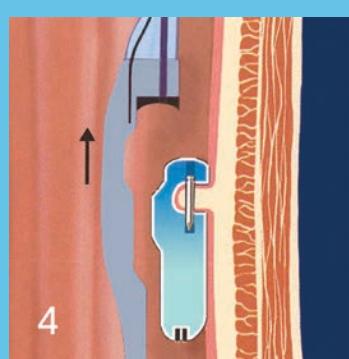
- 1) Determine the desired location for the capsule in the esophagus:
 - Using an endoscope, the capsule is typically placed 6 cm above the squamo-columnar junction. Measure and record the distance traveled by the endoscope to the desired location.
 - Using a trans nasal manometry catheter, the capsule is typically placed 5 cm above the proximal aspect of the landmarks (LES). Use a correction factor of approximately 4 cm to account for the longer pathway that the manometry catheter has to travel through the nasopharynx..
- 2) Remove the endoscope from the patient.
- 3) With the vacuum off, complete the following steps:
 - Mark the placement location of the pH capsule on the delivery device. The depth markings on the delivery device are indexed from the capsule's pH sensor.
 - Carefully advance the delivery device through the mouth (with the capsule facing the patients' tongue) to the desired location in the esophagus.
 - Holding the delivery device as straight as possible in a relaxed horizontal position, stabilize it by the patient's mouth to make sure it does not move.
- 4) Endoscopically check the esophageal inlet to verify the desired placement of the delivery device in the esophagus. Carefully remove the delivery device immediately if it has entered the trachea.



Step 2: Apply suction

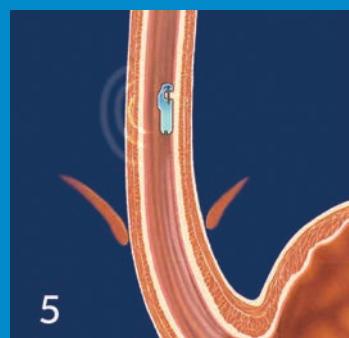
Apply suction to draw a small amount of tissue into the capsule's suction chamber:

- 1) Attach the vacuum hose to the handle.
- 2) Turn on the vacuum source and verify that the gauge reading is the same you noted during vacuum setup.
- 3) After the vacuum level of at least 550 mmHg has been reached and the vacuum stabilized, allow 30 seconds for the tissue to fill the suction chamber.



Step 3: Attach capsule

- 1) Remove the safety tab.
- 2) Swiftly press the plunger on top of the handle all the way down until it stops at its locking position. This will advance the trocar needle into the suction chamber.
- 3) Using your thumb, rotate the plunger from the side 1/8th of a turn clockwise to release the capsule from the delivery device. The plunger will spring up so the white line is visible on the sixth rib of the plunger.



Step 4: Turn off vacuum source and remove delivery device

Discard according to local waste management guidelines.

Step 5: Confirm

- At the clinician's discretion, endoscopically confirm the capsule's attachment.
- Confirm that the recorder is recording pH values and the capsule status LED on the recorder is blinking blue.

Note: This quick reference guide does not replace the product user manual and it is provided for your convenience only.
Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information: The risks of the Bravo™ reflux testing system include premature detachment, discomfort, failure to detach, failure to attach, capsule aspiration, capsule retention, tears in the mucosa, bleeding, and perforation. Endoscopic placement may present additional risks. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. Because the capsule contains a small magnet, patients should not have an MRI study within 30 days of undergoing the Bravo™ reflux test. Please refer to the product user manual or medtronic.com/gi for detailed information.

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