

Endoflip™ impedance planimetry system:

Caution:

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information:

Similar to most procedures, the products featured here have inherent procedure risks associated. Please refer to the individual product user manuals for detailed information.

Indication:

The Endoflip™ system is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders. The EF-325 series of catheters can make pressure and dimensional measurements in the esophagus, pylorus, and anal sphincters; whereas the BF-325 series and EF-825 catheters can make dimensional measurements in the esophagus, pylorus, and anal sphincters. The EF-620 catheter can make dimensional measurements in the esophagus. Other indications for use include:

To estimate the size of a stoma produced by a gastric band (all EndoFLIP® catheters) For use as an adjunct to a bougie for measuring the size of a gastric sleeve created during bariatric surgery, where it is suitable for diameter measurements for 22 to 60Fr sleeves (EF-620 catheter)

Contraindications:

The Endoflip™ system is contraindicated where endoscopy is contraindicated. The Endoflip™ system is contraindicated for use in patients with actively bleeding varices in the esophagus.

Bravo™ calibration-free reflux testing system:

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 Bravo™ calibration-free 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™ pH test

Indications:

- The Bravo™ monitoring system is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.
- The Bravo™ capsule can be attached following either endoscopy or manometry.
- The Reflux/Accuview software application is intended to record, store, view, and analyze gastroesophageal pH data.

Contraindications:

- Patients with bleeding diathesis, strictures, severe esophagitis, varices, or obstructions
- Patients with pacemakers or implantable cardiac defibrillators

References

1. Hirano I, Zhang Q, Pandolfino JE, Kahrilas PJ. Four day Bravo pH capsule monitoring with and without proton pump inhibitor therapy. *Clin Gastroenterol & Hepatol*. 2005;3(11):1083-8.
2. Chaudhury A, Mashimo H. Oropharyngeal & esophageal motility disorders. *Current diagnosis & treatment: gastroenterology, hepatology and endoscopy*. 3rd edition. 2016. chapter 13, page 164
3. Cassell, B., Sayuk, G. My approach to endoscopy - negative dysphagia. *Gastroenterology*. 2015 March 31, p.1.
4. ASGE Standards of Practice Committee, Muthusamy VR, Lightdale JR, Acosta RD et al. The role of endoscopy in the management of GERD. *Gastrointest Endosc*. 2015;81(6):1305-10.
5. Herregods, T. V. K., et al. Patients with refractory reflux symptoms often do not have GERD: *Neurogastroenterology & Motility*. 2015;27(9): 1267-1273.
6. Vakili N Prescribing proton pump inhibitors: is it time to pause and rethink? *Drugs* March 2012, Volume 72, (4), pp 437-445 72: 438.
7. Medtronic. Endoflip™ impedance planimetry system instructions for use (IFU). DD-41 Rev E. 2016.
8. Medtronic. Flip™ topography module instructions for use (IFU). DD-948 Rev A. 2017.
9. Sharma VK. The future is wireless: advances in wireless diagnostic and therapeutic technologies in gastroenterology. *Gastroenterol*. 2009;137(2):434-439.
10. Chitwood K. Perspectives on empiric and chronic proton pump inhibitor therapy. *Formulary*. 2004;39(8):406-412.
11. Medtronic. Bravo™ reflux testing system instructions for use (IFU). DOC-4009-01. 2017.

OBJECTIVE MEANS OF DIAGNOSING GERD & MOTILITY DISORDERS¹

Motility disorders often mimic symptoms of GERD, making diagnosis of esophageal symptomatic patients a challenge²



Endoflip™ impedance planimetry system



Bravo™ calibration-free reflux testing system



Tests aren't conclusive.

Up to 50%

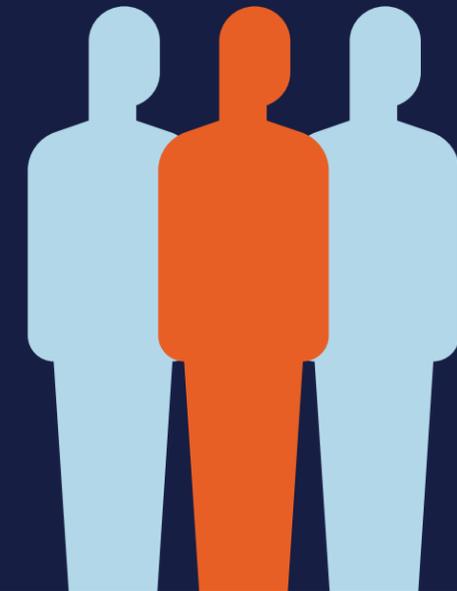
of endoscopies for predominant esophageal symptoms are negative.^{3,4}



And treatment isn't always effective.

One in three

patients referred with ongoing symptoms while using PPIs doesn't have GERD.⁵ And PPI use has been associated with osteoporosis and other risks.⁶



You need an objective means of diagnosing GERD and motility disorders.

That's why we offer two simple tests that can provide the therapeutic direction you're looking for.

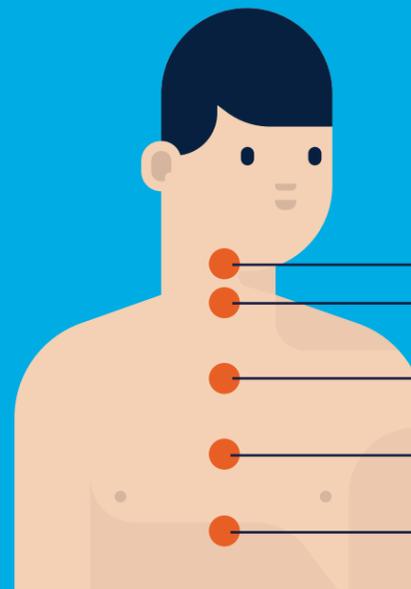
Dysphagia

Endoflip™ impedance planimetry system

The system provides an internal view of the esophagus and the gastroesophageal junction during endoscopic and surgical procedures. It's a simple, well-tolerated test that will help you:^{7,8}

- Measure pressure and dimensions of the esophagus and gastroesophageal junction
- Gain valuable insight — without fluoroscopy
- Identify or rule out major motility disorders

Shared symptoms



GERD

Bravo™ calibration-free reflux testing system

Reflux (pH) testing is the gold standard for diagnosing GERD.⁹ This capsule-based patient-friendly reflux test measures acid levels in the esophagus.^{9,10}

It has higher sensitivity than EGD and greater specificity than PPI trials, to help you obtain an objective diagnosis of GERD.^{1,11}

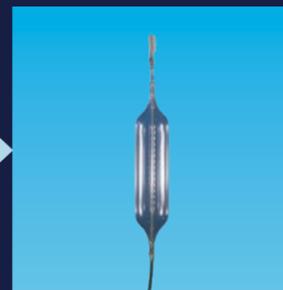
Test for GERD at the time of a negative endoscopy without disrupting your workflow. With on-demand placement of the Bravo™ calibration-free reflux testing system, you can simply pair, place, and go.



Esophageal symptomatic patient



Negative endoscopy



Endoflip™

Negative Endoflip™ helps to rule out motility disorders



Positive Endoflip™ may indicate motility disorder



Bravo™
Confirm or rule out GERD



ManoScan™
Confirm and classify the motility disorder