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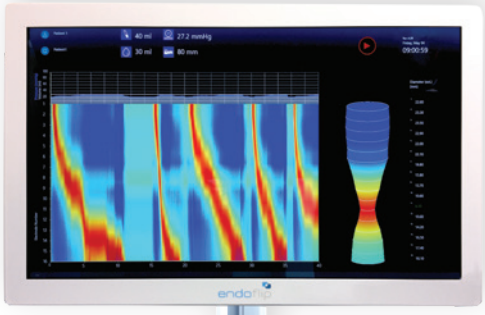
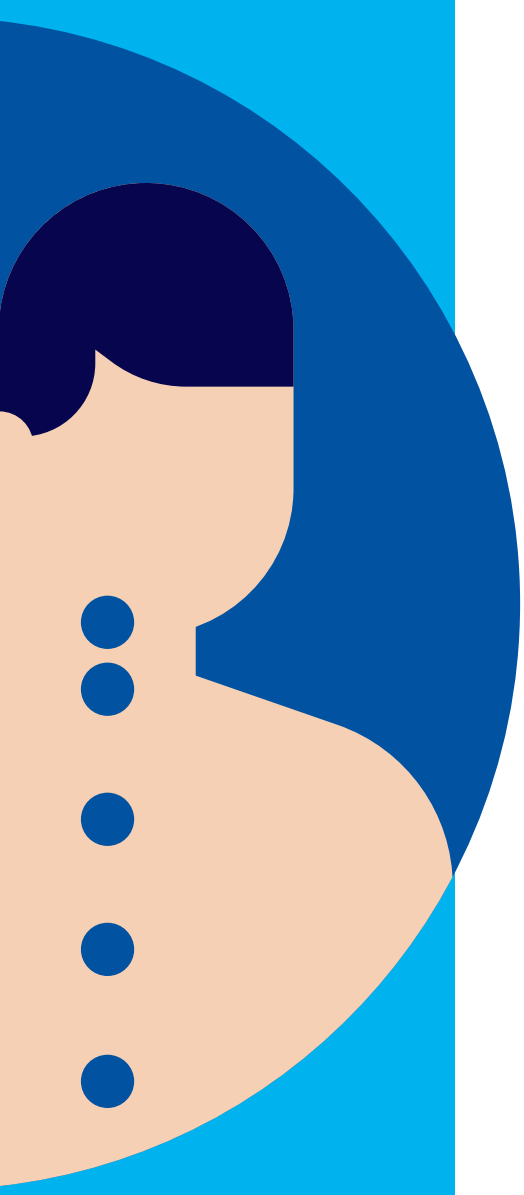
Objective means of diagnosing GERD & motility disorders[1]

Motility disorders often mimic symptoms of GERD, making diagnosis of esophageal symptomatic patients a challenge[2]

Bravo™ calibration-free reflux testing system

Endoflip™ impedance planimetry system





Shared symptoms

- Dysphagia
- Regurgitation
- Chest pain
- Heartburn
- Food impaction

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.

1 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

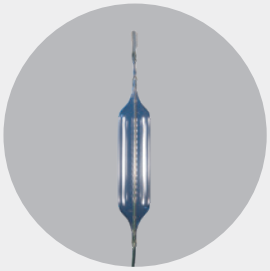
2 GERD

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]

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™

Positive
Endoflip™
may indicate
motility disorder

Negative
Endoflip™
helps to rule out
motility disorders

ManoScan™
Confirm
and classify
the motility
disorder

Bravo™
Confirm
or rule out
GERD

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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-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.

References

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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. Vakil 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 pomp inhibitor therapy. *Formulary.* 2004:39(8):406-412.
11. Medtronic. Bravo™ reflux testing system instructions for use (IFU). DOC-4009-01. 2017.

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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.

Indications:
The Bravo™ reflux testing 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™ reflux 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:
Contraindications for the Bravo™ reflux testing system include:

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

Risk Information:
The risks of Bravo™ reflux testing system include:

- Aspiration, tears or perforation in the mucosa, pain or discomfort (including chest pain) associated with the capsule, premature detachment, or failure to detach , which may necessitate endoscopic removal.
- The safety and efficacy has not been established for pediatric use on patients below the age of 4.
- Patients are restricted from undergoing an MRI study within 30 days of the start of a reflux study. Use of the Bravo™ reflux testing system in an MRI magnetic field will result in damage to the system and possible patient injury.
- Undergoing an MRI while the Bravo™ reflux capsule is inside the patient's body may result in serious damage to the patient's intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of any Bravo™ reflux capsule, the patient should contact the physician for evaluation and possible abdominal x-ray before undergoing an MRI examination.
- The Bravo™ reflux capsule contains a trocar needle that is made of stainless steel. Use caution in patients with known sensitivities to the metals that are contained including chromium, nickel, copper, cobalt, and iron. Tests last from 48 to 96 hours.
- Gastrointestinal endoscopy: Potential complications include, but are not limited to: perforation, hemorrhage, aspiration, fever or infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest.
- Nasal intubation: Potential complications include, but are not limited to: sore throat, discomfort, and nasopharyngeal damage resulting in bleeding and soft tissue damage.

Please refer to the product user manual or www.medtronic.com/gi for detailed information.