

# Medtronic



Bravo™ calibration-free reflux testing system

## Simply pair, place, and go.

pH, or reflux, testing is the gold standard for diagnosing GERD.<sup>1</sup> This capsule-based reflux test measures pH in the esophagus.<sup>1,2</sup> It has higher sensitivity than EGD and greater specificity than PPI trials, to help you assess for GERD.<sup>3</sup>



Extended  
data collection.  
Calibration-free.



## Easy-to-use recorder

### The Bravo™ calibration-free reflux recorder features:

- Multiple event buttons that allow patients to mark symptom events and record symptom duration during meal and supine times<sup>4</sup>
- USB cable interface that enables quick and direct data upload as well as flexible recorder battery recharging<sup>4</sup>
- Internal, rechargeable battery that eliminates the need for battery replacement prior to each study<sup>4</sup>

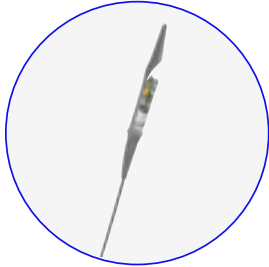
## Ready-to-use capsule

### The Bravo™ calibration-free reflux capsule

Simply activate, pair with the recorder, place in patient, and start measuring pH level.<sup>4</sup>

The wireless pH system is well tolerated by adult and pediatric† patients – enabling prolonged monitoring up to 96 hours.<sup>5</sup> This increases the likelihood of detecting reflux events and the ability to determine whether they are associated with symptoms.<sup>5</sup>

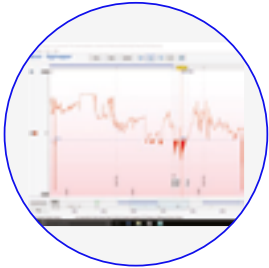
- Calibration-free capsule that takes away the need to manage and store buffer solutions and testing tubes in the endoscopy suite
- †4 years of age or older.



## Simple workflow

### Reflux software v6.1 system features:

- Saved settings that reduce the need to update prior to each procedure
- Simple study and data upload procedures



### 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.

### Risks:

- Aspiration, tears or perforation in the mucosa, pain or discomfort associated with the capsule, premature detachment, or failure to attach the capsule to the esophagus, 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.

### References:

1. Sharma VK. The future is wireless: advances in wireless diagnostic and therapeutic technologies in gastroenterology. *Gastroenterol.* 2009;137(2):434-439.
2. Chitwood K. Perspectives on empiric and chronic proton pump inhibitor therapy. *Formulary.* 2004;39(8):406-412.
3. Hirano I, Zhang Q, Pandolfino JE, et al. Four day Bravo pH capsule monitoring with and without proton pump inhibitor therapy. *Clin Gastroenterol & Hepatol* 2005;3:1083-1088.
4. Bravo™ Reflux Testing System User Guide DOC-4009-04
5. Richter JE, Pandolfino JE, Vela MF, et al. Utilization of wireless pH monitoring technologies: a summary of the proceedings from the Esophageal Diagnostic Working Group. *Diseases of the Esophagus.* 2013 Nov;26(8):755-765.

**This material is only intended for distribution in Europe. Indications, claims, and intended use may be different in other regions.**

Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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