

WHY TEST FOR GERD?

Chronic heartburn occurs more than once per week, and has symptoms that can interfere with your daily routines. These symptoms include:

- Frequent indigestion or burning sensations in the center of the chest
- Sour or bitter-tasting fluids in the throat or mouth
- A back-up of acid in the throat, making lying flat and bending over uncomfortable

Frequent or chronic heartburn may be associated with a more serious problem known as GERD (gastroesophageal reflux disease). Damage caused by GERD can lead to more serious medical problems such as difficulty swallowing (dysphagia), narrowing of the esophagus (strictures), and Barrett's esophagus.

The Bravo™ pH monitoring system is a minimally invasive test for evaluation of heartburn or related symptoms. Your doctor will analyze results from this test to determine if acid reflux is causing your symptoms and decide the appropriate treatment for you.

Your procedure is scheduled for:

Do not have an MRI for 30 days, or if you have not positively verified the excretion of the Bravo™ pH capsule. Undergoing an MRI while the capsule is inside your body may result in serious damage to your intestinal tract or abdominal cavity.

I cannot have an MRI until: _____
Date

Instructions from physician or nurse:

For additional information call:

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

Risk Information:

The Bravo™ pH test is not for everyone. If you have bleeding diathesis, strictures, severe esophagitis, varices, obstructions, a pacemaker, or an implantable cardiac defibrillator, you should not undergo a Bravo™ pH test. Additionally, because the capsule contains a small magnet, you should not have an MRI study within 30 days of undergoing the Bravo™ pH test. Potential complications include, but are not limited to, the following events:

- perforation
- premature detachment of the pH capsule
- failure of the pH capsule to detach from the esophagus within several days after placement or discomfort associated with the pH capsule, requiring endoscopic removal
- tears in the mucosal and submucosal layers of the esophagus, causing bleeding and requiring possible medical intervention

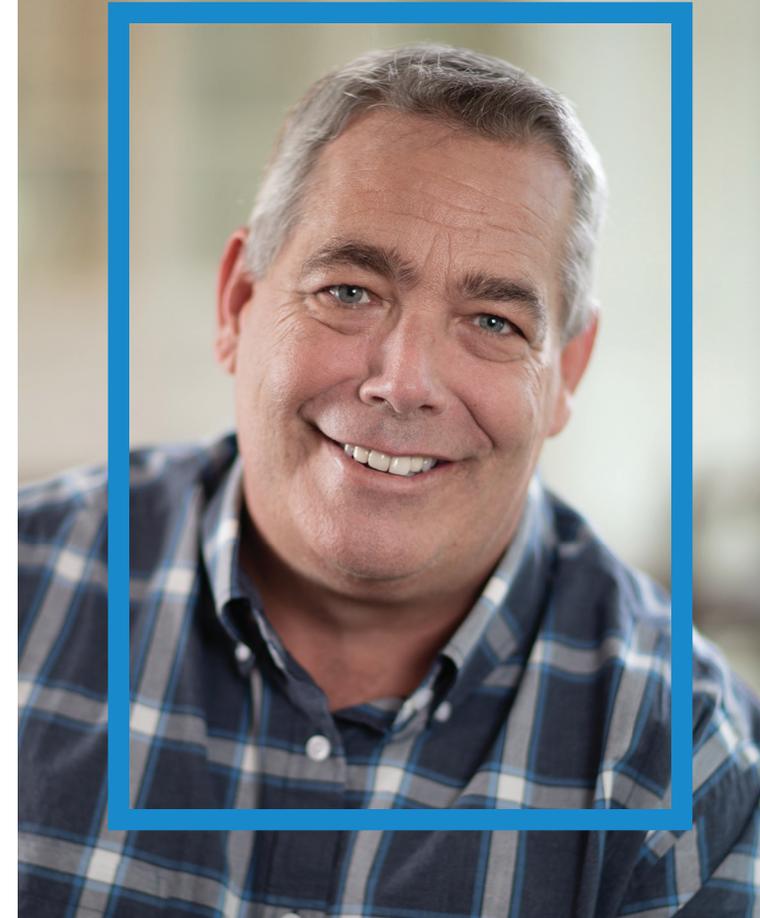
Potential complications associated with gastrointestinal endoscopy include:

- perforation or hemorrhage
- aspiration
- fever or infection
- hypertension
- respiratory arrest
- cardiac arrhythmia or arrest

Please consult your physician for a complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

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PREPARING FOR REFLUX TESTING

Bravo™ pH monitoring system

A simple way to evaluate your
gastroesophageal reflux symptoms

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HOW IT WORKS

The test involves a **miniature pH capsule**, which is approximately the size of a gel cap. The capsule is temporarily attached to the wall of your esophagus.

Your physician will first administer local anesthesia. Then, he will place a **Bravo™ pH capsule** into your esophagus using a delivery device.

The Bravo™ pH capsule will continually measure the pH in your esophagus. It will transmit this information to the Bravo™ pH recorder, which is worn on your belt. After the Bravo™ pH capsule has been placed, you will be instructed how to use the Bravo™ pH recorder. Then, you will leave your physician's office and will be able to **resume your normal activities**.

Once the test has been completed, you will need to return the Bravo™ pH recorder according to your physician's instructions. Then, **your test data can be downloaded** for analysis. Your physician will analyze the information in order to diagnose your condition.

Patient-friendly reflux testing

- Symptoms are monitored during your regular activities
- Testing is discreet and private



WHAT TO EXPECT

The Bravo™ pH capsule takes only moments to place in the esophagus. The test period lasts 48–96 hours, depending on your physician's requests. **After placement, the capsule communicates wirelessly with the Bravo™ pH recorder (meaning no tube or wire remains in your nose or mouth).**

Some patients experience a vague sensation that "something" is in their esophagus. Some patients say they feel the capsule when they eat, as food passes it. Chewing food carefully and drinking liquids may minimize this sensation.

You will be given a diary to write down the times you eat, lie down, and when you have reflux symptoms (coughing, heartburn, regurgitation). This information is important for your physician to make a diagnosis — make sure to keep your diary up to date. Your physician may also ask that you stop taking certain medications during the testing period. It is critical to follow these instructions carefully for an effective test. Your physician's office will instruct you on how to use the Bravo™ pH recorder and how to return the equipment.

ANSWERS TO YOUR QUESTIONS

What are the benefits of the Bravo™ pH monitoring system?

The Bravo™ pH monitoring system is wireless, making it convenient and discrete. You are **free to move about** as long as you stay within three feet (approximately one meter) of the recorder. You can bathe and get a restful night's sleep because you can place the recorder outside the shower or on your nightstand. The test will not be interrupted.

Will the test restrict my diet and activities?

No. One of the added benefits of the Bravo™ pH capsule is that it is so small that **you may eat normally and go about your daily routine**.

What happens after the test?

The data captured on the Bravo™ pH recorder will be downloaded to a computer and your doctor will view the test results. When the test is complete, the disposable Bravo™ pH capsule falls off the wall of your esophagus.

It passes naturally with your bowel movement through your digestive tract.

Important Reminder

This brochure is intended to supplement the direction and explanations from your doctor regarding the placement of the Bravo™ pH capsule. It does not replace your doctor's care, advice, and specific instructions regarding the preparation for your procedure.

