

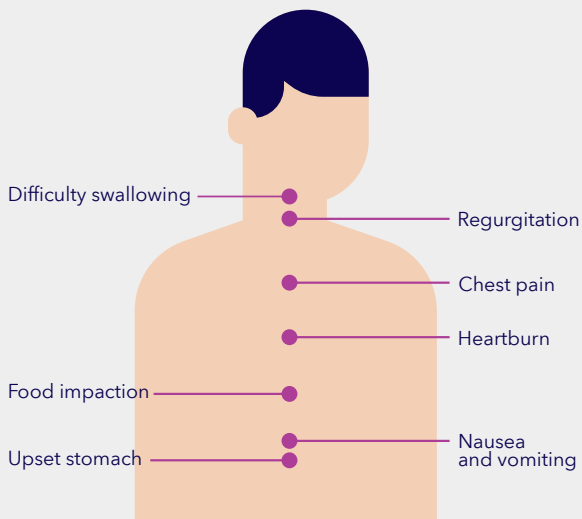
# Medtronic

## Preparing for reflux testing

Digitrapper™ reflux testing system

An innovative solution to evaluate your gastroesophageal reflux symptoms on or off anti-reflux therapy.





## Why test for GERD?

Chronic heartburn occurs more than once per week, and has symptoms that can interfere with your daily routines. These symptoms may 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 disease 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 Digitrapper™ reflux testing system is a **catheter-based test** for evaluation of heartburn or related symptoms. Your physician will analyze results from this test to understand the root cause of your symptoms and **determine the appropriate treatment** for you.

## How it works

After administering local anesthesia, your physician will place a Digitrapper™ reflux catheter through your nose and into your esophagus. The catheter probe is connected to a small recording device called a pH recorder.

Throughout the test period, the Digitrapper™ reflux catheter will **measure the pH in your esophagus**. It will transmit this information to the Digitrapper™ reflux recorder, which is worn on your belt.

After the Digitrapper™ reflux catheter has been placed, you will be instructed how to use the Digitrapper™ reflux recorder. Then, you will leave your physician's office and will be able to resume your normal activities.

Once the test has been completed, please follow your physician's office instructions on where to get the reflux catheter removed and return the recorder. Then, your test data can be downloaded for analysis. Your physician will analyze the information in order to diagnose your condition.



## Simple and efficient reflux testing

- Monitors symptoms during your regular activities
- Captures and records reflux events even if you are on anti-reflux therapy

## What to expect

The catheter probe takes only moments to place in the esophagus. **The test period lasts 24 hours.**

Some patients may feel a slight irritation in the back of their throat. Chewing food carefully and drinking liquids may minimize this sensation.

Your physician will instruct you how to use the Digitrapper™ reflux recorder. Symptom keys on the pH recorder allow you to record your mealtime, sleep periods, and reflux symptoms. Follow the instructions on when to press keys to record episodes. Your physician will correlate these events and episodes with the acid levels in your stomach.

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 to make a diagnosis - make sure to keep your diary up to date.

Please do not remove the battery or get the recorder wet during the study.



# Answers to your questions

## What are the benefits of the Digitrapper™ reflux testing system?

The Digitrapper™ reflux testing system is a **catheter-based study** that records the amount and acidity of stomach contents backing into the esophagus.

This test allows for evaluation of reflux symptoms, both on or off reflux medication.

## Will the test restrict my diet and activities?

No. One of the added benefits of the Digitrapper™ reflux catheter is **you may eat normally** and go about your daily routine.

## What happens after the test?

After the test is complete, please follow your physician's instructions on where to get the reflux catheter removed and return the recorder. The data captured on the Digitrapper™ reflux recorder during the procedure will be downloaded to a computer. Your physician will review the reflux episodes and how they relate to physical activity, meals, symptoms, etc.

## Important Reminder

This brochure is intended to supplement the direction and explanations from your physician regarding the Digitrapper™ reflux testing system. It does not replace your physician's care, advice, and specific instructions regarding the preparation for your procedure. Should you encounter any difficulties or discomfort during the study, call your physician immediately.

# Medtronic

Your procedure is scheduled for:

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Instructions from physician or nurse:

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For additional information call:

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**Indications for Use:** The Digitrapper™ recorder obtains measurement of pH levels and impedance levels within the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), and stomach. It is used to acquire pH and impedance levels and to store the corresponding data. The data can be uploaded to the AccuView™ analysis software, where the information can be viewed for diagnostic and analytic purposes.

**Contraindications:** Patients with an inability to tolerate nasal intubation. Patients with significant bleeding disorders for whom nasal intubation is contraindicated. Patients with a known esophageal obstruction preventing passage of the instrument.

**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 catheter insertion into the nasal passage associated with the Digitrapper™ pH and impedance testing system include: discomfort, nasal pain, minor bleeding, runny nose, throat discomfort, irregular heartbeat with dizziness, and perforation. In rare instances, the catheter may be misdirected into the trachea causing coughing or choking, or the catheter may shift up or down causing false results. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. The system is not compatible for use in an MRI magnetic field.

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