



# SmartPill GI Monitoring System

## Introduction & Safety Overview

# Intended Use/Indications for Use

The SmartPill GI Monitoring System measures whole gut and regional gut (stomach, small bowel and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Gastric transit time (gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.

Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.

The system measures pH, pressure and temperature throughout the entire GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

Not for use in pediatric populations

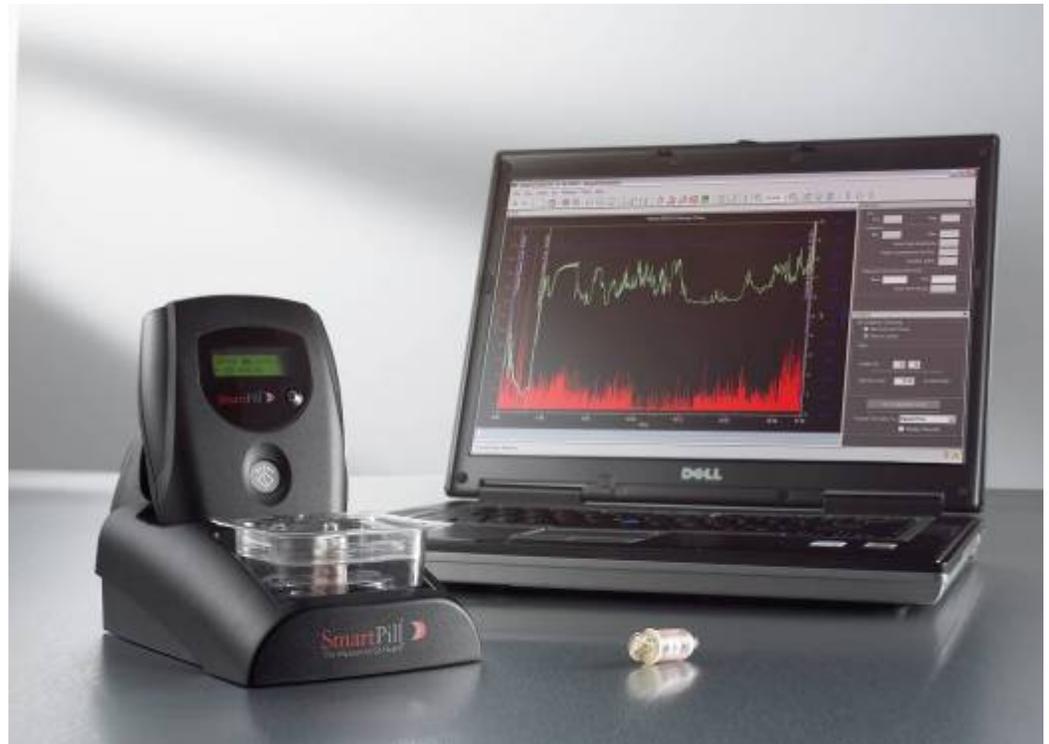
# Contraindications for Use

**The SmartPill capsule should not be administered to a patient with the following conditions:**

- history of gastric bezoar
- swallowing disorders
- suspected or known strictures, fistulas, or physiological/mechanical GI obstruction
- GI surgery within the past 3 months
- severe dysphagia to food or pills
- Crohns disease or diverticulitis
- implanted or portable electro-mechanical medical device

# System Components

- System Computer loaded with MotiGI software
- Data Receiver
- Docking Station
- Activation Fixture
- SmartPill Capsules
- Accessories



# Data Receiver



## Functions and Features

- Records the data transmitted by the SmartPill cap.
  - 5+ days of recording on a fully charged battery
- Holds the patient diary
- Event button turns the data receiver on & marks events
- Backlight control button – lights data display
- LCD displays real-time pH, pressure, capsule function & signal strength
- Attaches by belt clip or lanyard

**Caution:** Receiver must be fully charged in the “OFF” position before starting a test. Failure to charge in the “OFF” position can result in test data loss.

# Docking Station



## Functions and Features

- Cradles data receiver and transfers data to the system computer
- Charges the data receiver
  - LED glows **red** while charging
  - LED glows **green** when fully charged
  - LED glows **yellow** if there is a problem with the docking station
    - Un-dock & re-dock; if yellow light persists, contact Customer Service
    - Always charge data receiver in the “OFF” position
    - May take up to 5 hours to fully charge
- Well holds the SmartPill Capsule container



## Activation Fixture

- Turns the SmartPill Capsule ON & OFF

# Accessories

- User manual
- USB cable
- Power cord
- Patient instruction sheets
  - Also available  
in Spanish translation
- Belt clips / lanyards



# Proper Activation Method

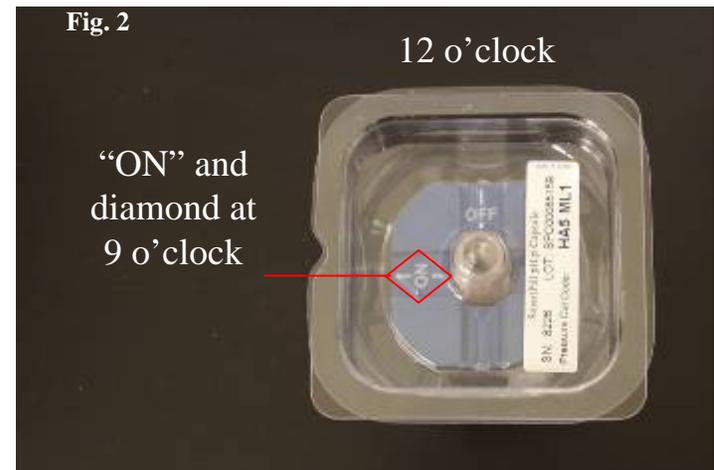
Capsules are very sensitive to the activation fixture and proper technique is important when activating. If you are unable to activate a capsule after three attempts, please call SmartPill Technical Support.

1. Orient the activation fixture so “ON” is at 9 o’clock (Figure 1).
2. Align the capsule container diamond with the activation fixture “ON” and place the capsule container on top of the activation fixture (Figure 2).

Fig. 1



Fig. 2



# Pre-Test Patient Preparation

## **Patient instruction sheets describe test procedure, test preparation & test restrictions**

- Patient must fast for 8 hours before the test
- No tobacco use during the fasting period
- Stop motility altering medications 48 hours before the test



# Pre-Test Patient Preparation

- Discontinue gastric pH altering medications such as proton pump inhibitors 7 days before the test (i.e. Nexium)
- Discontinue histamine blockers 2 days before the test (i.e. Pepcid, Zantac)
- Discontinue antacids one day before the test (i.e. Mylanta, Roloids)
- Insulin Dependent Patients: Instruct them to take  $\frac{1}{2}$  of their normal morning dose and monitor glucose levels according to normal routines

***These medication restrictions were imposed during SmartPill clinical studies and provide an environment for optimal test results. Medication restrictions are ultimately at the doctors discretion.***



# SmartBar – Standardized Meal

To accurately measure gastric emptying time, patients must consume a standardized meal immediately before ingesting the SmartPill Capsule. **SmartBar** is an FDA approved replacement for the standard egg beater meal (Tougas)<sup>1</sup>

- Included with every capsule purchase
- Standardizes procedure
- No preparation required

Ingredients: Whey crisp, rolled oats, rice syrup, corn syrup, invert sugar, concentrated whey protein, puffed wheat, apple juice concentrate, glycerine, molasses, contains 2% or less of: honey, defatted wheat germ, dried apples, dried cranberries, partially hydrogenated vegetable shortening (soy and/or cottonseed oils), natural and artificial flavors, potassium sorbate (as preservative), salt, vanilla.

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## Nutritional Composition

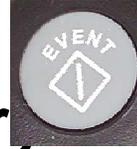
(in % of weight)

- 75% carbohydrate
- 21% protein
- 3% fat
- 3% fiber
- 255 kcal

**Note:** The standard egg beater meal (Tougas)<sup>1</sup> may be used as a substitute for those patients with dietary restrictions. Performance characteristics of the SmartPill Capsule were determined through use of the SmartBar and the standard egg meal. The effect on test results using an alternative substitute meal (for example to address a known food allergy) is not known.

[1] Tougas G., McCallum R.W. Assessment of gastric emptying using a low fat meal: establishment of international control values. *Am J Gastroenterol* 2000; **95** (6): 1456-62

# Patient Instructions – Post Ingestion



- **Event button and patient diary**
  - Record bowel movements, meals, and other information of interest.
- **Keep data receiver on body at all times**
  - Data receiver can be removed for bathing and sleeping, but must be kept as close as possible to minimize data loss
  - Instruct the patient to wait 3 minutes in the lavatory before flushing the toilet after each bowel movement
- **Refrain from using laxatives, anti-diarrhea and other motility affecting medications until the capsule has passed**
- **Avoid vigorous exercise such as abdominal crunches and prolonged aerobic activity (greater than 15 minutes) during the monitoring period**

# Patient Instructions – Post Ingestion

- No food for 6 hours after ingesting the capsule; A normal diet can be resumed at 6 hours
- Diabetic patients should monitor glucose levels and follow their personal treatment plan
- Schedule return of data receiver

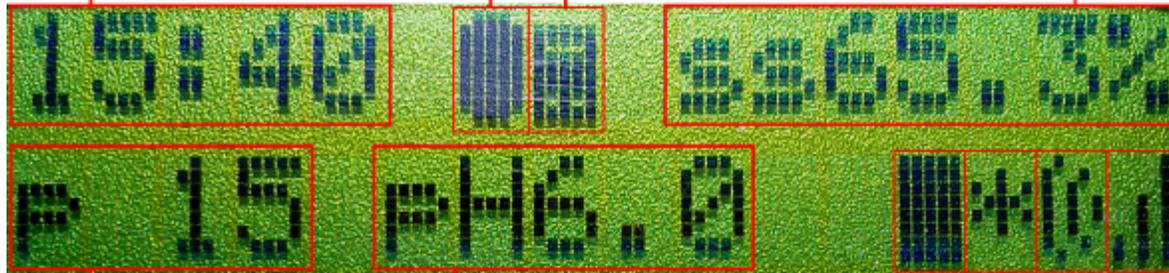
# Capsule/Receiver Communication

Time of Day  
(Hours:Minutes)

Indicates Capsule Status  
(solid (shown) means Okay  
"X" means Capsule Failure)

Receiver Signal  
Strength

Indicates Data Receiver Status  
(solid (shown) means Okay  
"X" means Receiver Failure)



Pressure value

Flashing Indicates  
Receiver is Writing Data  
from the Capsule

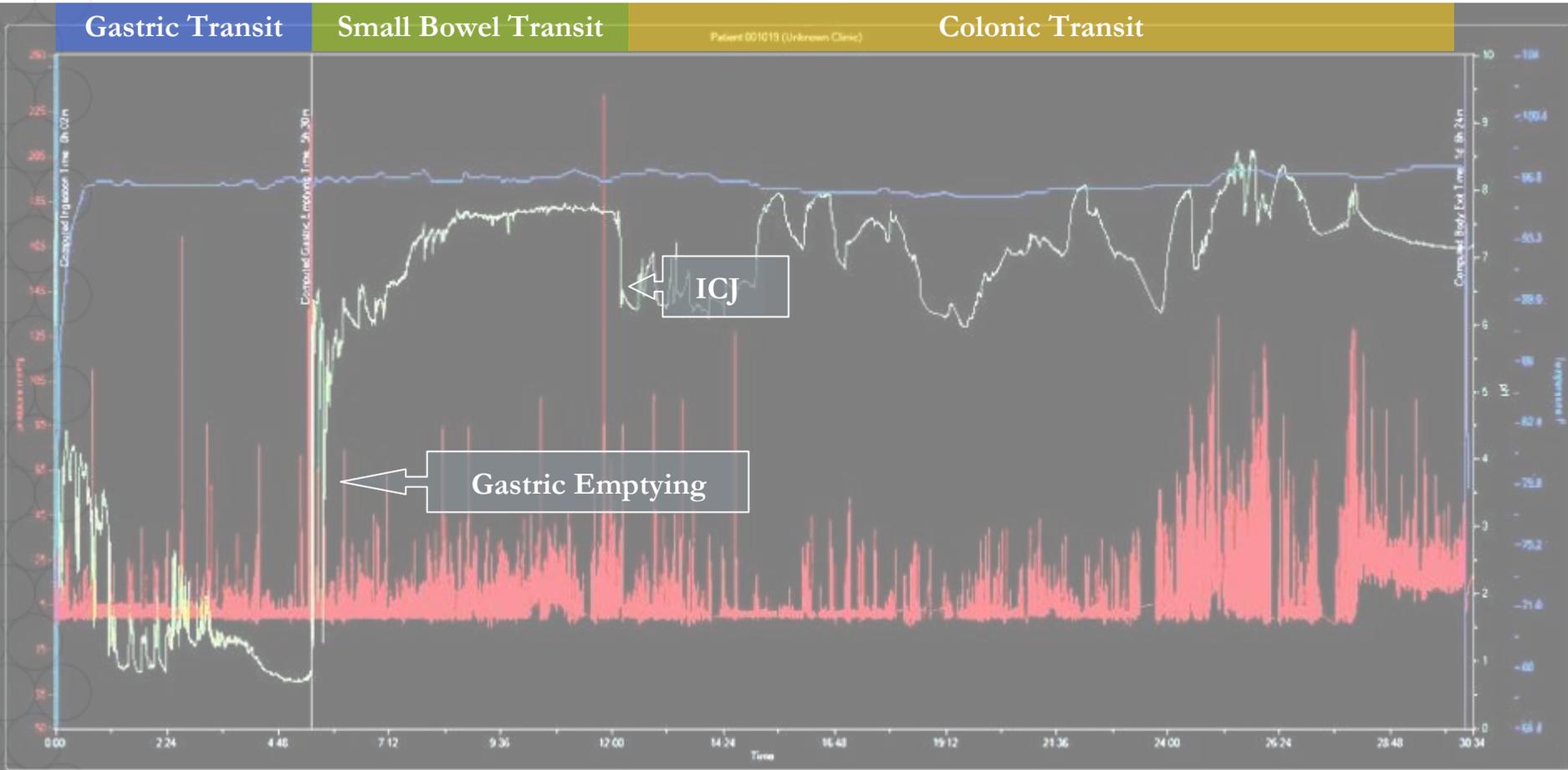
pH value

Flashes When Event  
Button is Pressed

Capsule Packet Received  
("Radar Symbol" - an "X" means packet missed)

Receiver Battery Life

# SmartPill Tracing

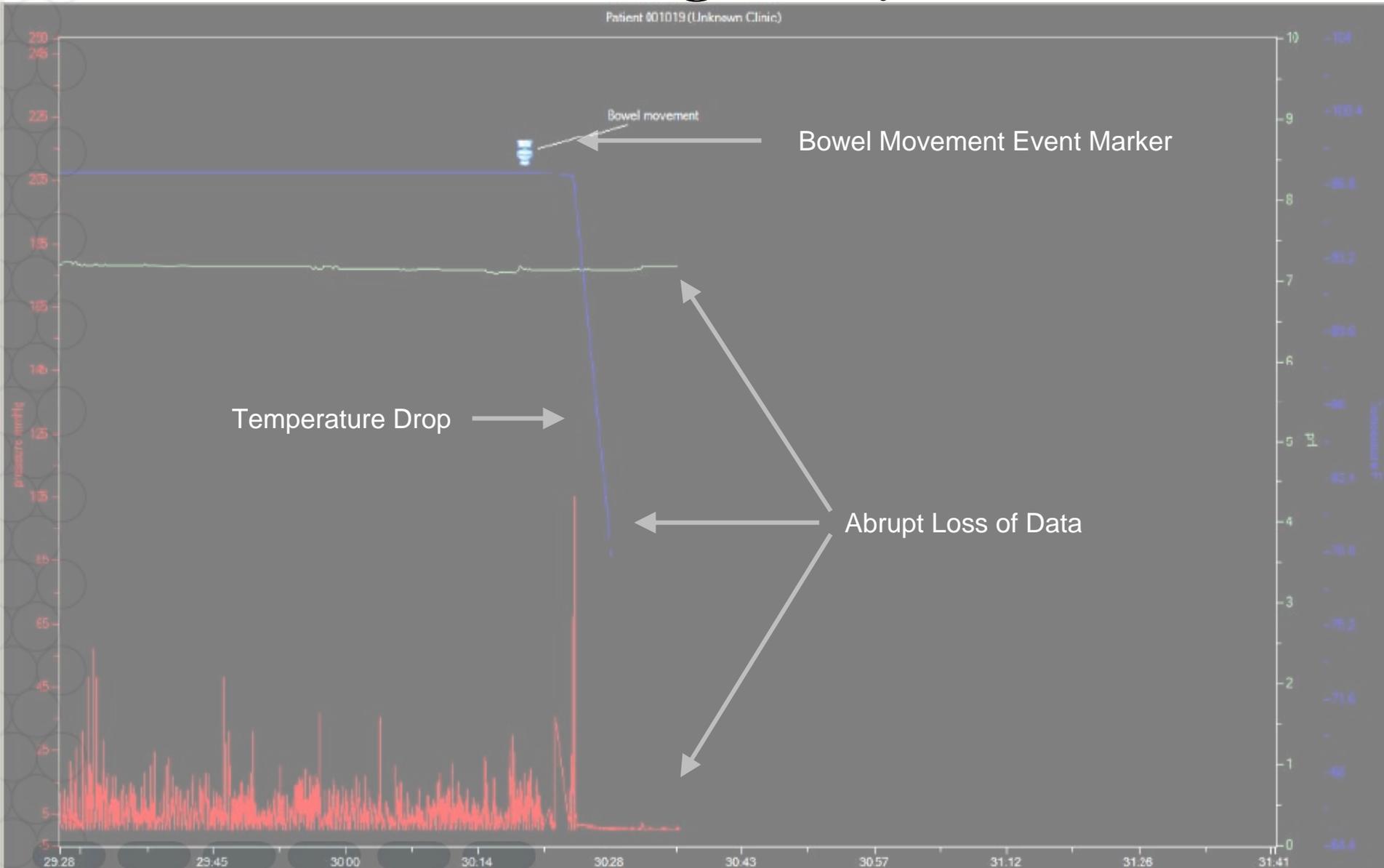


# Confirming Body Exit

## **Confirm by one of the following methods:**

- Patient observation of the capsule in their stool.
- An abrupt drop in temperature on the MotiliGI graph and/or loss of signal which coincides with a bowel movement recorded in the patient diary.
- A KUB exam (note: If the capsule is present in the colon a KUB exam is not necessary).

# Confirming Body Exit



# Capsule Low Voltage Indication

- Data collected during and after a low voltage state may not be valid.
  - A temperature drop under low voltage cannot be used as confirmation of capsule exit.  
Monitor the patient for symptoms of capsule retention OR confirm capsule exit by KUB.

