



SmartPill® GI Monitoring System

User Manual MotiliGI® v3.0

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Limited Warranties

The SmartPill GI Monitoring System

Given Imaging warrants the system* for a period of one (1) year from date of purchase, and that the components of the system* have been designed, manufactured, packaged and tested and, if properly used, are free from any defect of workmanship or materials that would materially and adversely affect their intended use.

If any component of the system* fails during the period of this Limited Warranty for reasons covered by this Limited Warranty, Given Imaging, at its option, shall replace the specific failed component.

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Warning

Changes or modifications to this equipment not expressly approved by the party responsible for compliance (Given Imaging Ltd.) could void the user's authority to operate the equipment.

Appendix: Electrical Safety

This Limited Warranty is in lieu of and excludes all other warranties, whether expressed or implied, including without limitation warranties of merchantability or fitness.

Extended Warranty Options are available.

* Only the data receiver, docking station and activation fixture of the SmartPill GI Monitoring System are covered by this Limited Warranty:

The SmartPill Capsule

Given Imaging warrants each Capsule is free from defects in workmanship and materials until the Capsule's labeled expiration date.

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Customers are liable for all matters beyond Given Imaging's control such as handling, storage, cleaning, misuse, treatment, and diagnosis.

This warranty is in lieu of and excludes all other warranties whether expressed or implied warranties of merchantability or fitness.

The System Computer

The system computer is covered under the manufacturer's warranty.

Rx Only



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This device complies with Part 15 of the FCC. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

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Introduction and Components



Using this Manual

Complete user training and read this manual before running the SmartPill System. This manual contains important safety information and contraindications.

This manual makes use of 2 special notations: Warning and Caution, the meanings of which are:

Warning

Potentially hazardous situations which could result in serious adverse reactions (death or serious injury) or serious safety hazards to users and patients. All warnings are boxed.

Caution

Potentially hazardous situations which could result in minor or moderate injury or damage to the equipment or other property.

System Components

SmartPill Capsule Pack

Each capsule pack contains a single-use capsule, calibration buffer, instructions for use and a patient diary.

The capsule measures pressure, pH, and temperature to determine transit times of the stomach, small bowel, and colon. Transit times derived by capsule motility procedures provide alternatives to other tests such as gastric emptying scintigraphy, whole gut scintigraphy, and radio-opaque markers.

Caution

Do not use a SmartPill capsule if it has been dropped as this may affect function.



Capsule Operational Specifications

Attribute	Specification
Pressure Accuracy	0-99 mmHg ± 5 mmHg 100-350 mmHg $\pm 10\%$ of applied pressure
Pressure Range	0-350 mmHg
pH Accuracy	± 0.5 pH units
pH Range	1-9 pH units
Temperature Accuracy	$\pm 1^{\circ}\text{C}$ (between 20 – 42°C)
Transmission Frequency	434.2 MHz (radiating between 426 – 445 MHz)
Battery Life	Capsule and Data Receiver, >5 days
Weight	4.5 grams
Size	26 x 13mm

SmartBar

The SmartBar is a standardized meal that is ingested immediately before capsule ingestion. To accurately measure gastric emptying patients must consume a standard meal immediately before ingesting the capsule.

Data Receiver

The data receiver records biomedical data sent by the capsule. It is worn by the patient on a belt clip or a lanyard (around the neck). The data receiver features an Event button that when pushed places a marker in the electronic data. A patient diary for recording the time and reason for the event button use is stored on the backside of the receiver. The data receiver weighs approximately 225g (0.5 lb).

Caution

Use only the SmartPill Docking Station (REF 50100400) to charge and download data from the receiver.

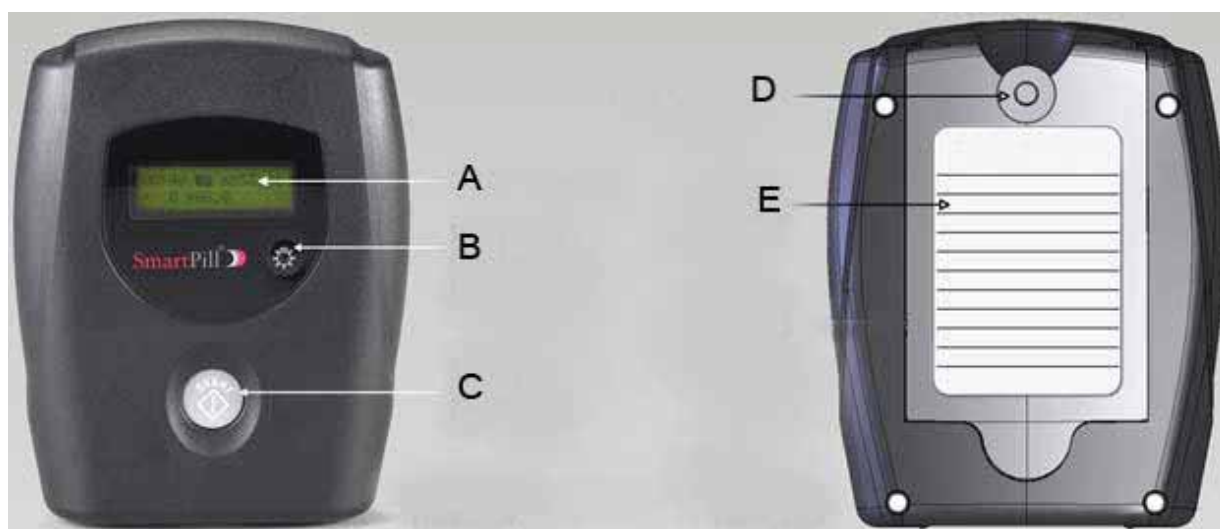


Figure 1

Feature	Description
A - Data Display	See Data Receiver Display Modes, Page 19 for more details.
B – Backlight Control Button	The backlight button turns on a light, enabling the display to be read in low light conditions. The backlight button is also used to turn the data receiver off. The backlight button and event button (described below) must be simultaneously depressed for 5 seconds to turn the data receiver off.
C – Event Button	The Event button turns the data receiver on. Patients press the event button when engaging in an event (light exercise, eating, going to the bathroom, sleeping, abdominal discomfort, pain, etc.) or experiencing any symptom which the clinician believes may affect GI physiology and may be of interest. Pressing the event button inserts a marker in the test data record.
D – Belt Clip and Lanyard	The data receiver is equipped with a belt clip and supplied with a lanyard. The patient has the choice of clipping the data receiver on a waist belt or wearing the data receiver suspended from a lanyard.
E – Patient Diary	The patient diary is to be used by the patient to record events, activities and symptoms listed in the patient instruction sheet, and the date and time the events occurred. The entries in the patient diary should correspond to the event button markers inserted into the test data record when the event button is pressed.

Docking Station

The docking station establishes electronic communication between the data receiver and the system computer for data download and serves as a charging stand for the data receiver. The docking station weighs approximately 200 grams (0.45 lbs).

Caution
Use only the Power Supply (REF 30100900) supplied with the SmartPill Docking Station.

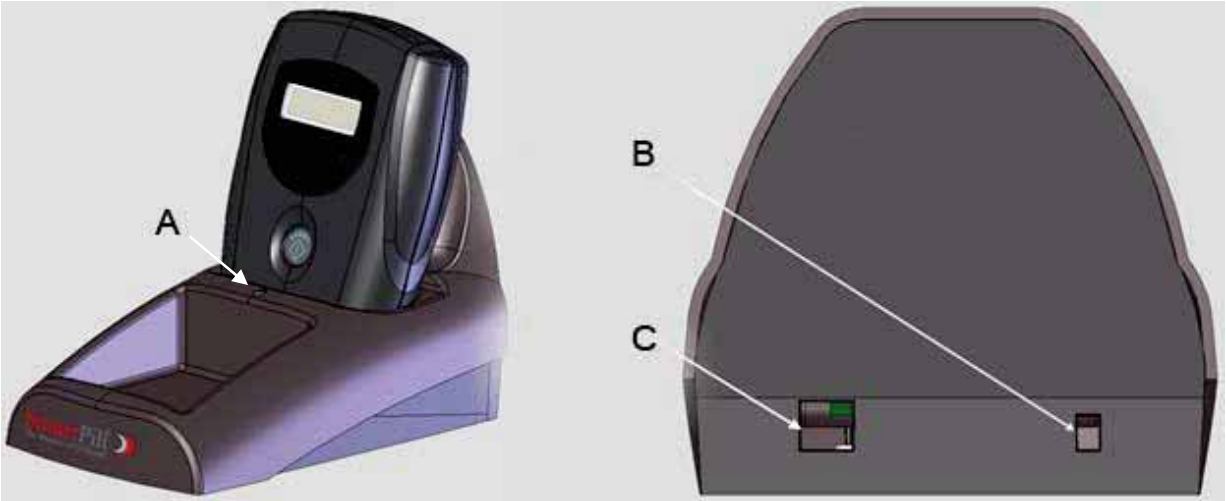


Figure 2

Feature	Description
A – LED Light	Indicates the state of data receiver. See table below.
B – DC Power Connector	Provides a connection point for the power supply.
C – USB Connector	Provides a connection point for the USB cable, connecting the docking station to the system computer.

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LED Color	State	Action Recommended
Red	Charging	Continue charging until the LED turns green.
Yellow	A charging circuit fault has occurred	Undock and then re-dock the data receiver in the docking station. If the yellow light persists contact technical support.
Green	Fully charged	The data receiver is ready for use.
Off	<ul style="list-style-type: none">• Docking station is not connected to an AC power source• Receiver is not fully connected to the docking station• Docking station or data receiver are in thermal shutdown	<ul style="list-style-type: none">• Connect the docking station to a source of AC power.• Undock and then re-dock the data receiver in the docking station.• Contact technical support for assistance.

Activation Fixture



The activation fixture turns the capsule on and off using strong magnets that interact with the capsule's internal power switch.

Warning

Individuals with pacemakers should not come within one (1) foot of the SmartPill activation fixture. The fixture contains strong magnets that could interfere with pacemaker operation.

Warning

Do not store the SmartPill Activation Fixture in the same room with or a room adjacent to MRI equipment. The fixture contains strong magnets and could become a dangerous projectile.

Caution

Keep the SmartPill Activation Fixture more than two (2) feet from magnetic media and computer monitors.

Caution

Do not store unused capsules within one (1) foot of the SmartPill Activation Fixture. Stray magnetic fields from the activation fixture may activate the capsule.

System Computer and MotiliGI Software

MotiliGI software comes installed on the system computer. MotiliGI receives and processes downloaded data from the data receiver, stores test data, provides data analysis tools, and graphically displays test results. MotiliGI features algorithms that calculate GET, SBTT, CTT, WGT, and motility indices of the antrum and

Appendix: Electrical Safety

duodenum. An optical mouse is supplied with the system computer. An electronic copy of this user manual is included in the software.

Caution

Use MotiliGI only on the system computer supplied with the SmartPill GI Monitoring System. Installing and operating MotiliGI on another computer is not recommended or supported by SmartPill Corporation.

Caution

Do not use the vertical pipe (|) character in text fields or the software will remove it.

Minimum System Computer Requirements

Manufacturer	Dell (preferred), IBM, HP, Toshiba
Operating System	Any of the following 32-bit Microsoft Windows versions: <ul style="list-style-type: none">• XP Professional Service Pack 3 (recommended)• Windows Vista Business• Windows Vista Ultimate• Windows 7 Professional (recommended)• Windows 7 Ultimate System does not work with 64-bit operating systems
Hard Drive	100 megabytes of available space for the MotiliGI application and 10 gigabytes of available space for test files (recommended)
Communication Port	1 open USB port
Peripherals	CD/RW Drive; printer is optional
Processor	Pentium IV 1 Gigahertz (GHz) or higher
Memory	1 gigabyte (GB) of RAM or
Display	1280 x 800 resolution widescreen aspect ratio (recommended) 96 dpi 32-bit color
Other	Microsoft .NET Framework 1.1 SP 1 Adobe Acrobat 7.0.8 or later

Accessories

Your starter kit includes the accessories below:

Accessory	Description
Starter Kit Backpack	A protective backpack that holds the system components.
Belt Clips and Lanyards	Attach to the back of the data receiver.
User Manual	Complete the user training and read this manual before running the SmartPill System. The user manual contains important safety information.
USB Cable	Connects the docking station to the system computer.
Power Cord	Powers the docking station
Patient Instruction Sheets	Instruction sheets to send home with the patient
Power Adaptor (non US systems)	Modifies the power supply.

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Warning

Do not connect items to the SmartPill GI Monitoring System that are not part of the system.

Use and Care of the System

Acronyms, Use, and Symbols

Acronyms

GET	Gastric emptying time
SBTT	Small bowel transit time
CTT	Colonic transit time
SLBTT	Combined small and large bowel transit time
WGTT	Whole gut transit time

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 (GI) tract transit times are used for evaluating motility disorders.

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

Suspected disease or condition to evaluate	Indicated Measurement	Use
Gastroparesis	GET	Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.
Chronic constipation	CTT	Aids in differentiating slow and normal transit constipation.
	SLBTT	A surrogate measure of colonic transit in patients with chronic constipation when CTT alone cannot be determined.

Caution

Do not use in patients younger than 18 years old.

Contraindications for Use

Do not use in patients with these diseases or conditions:

Appendix: Electrical Safety

- 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
- Crohn's disease or diverticulitis
- implanted or portable electro-mechanical medical device such as a cardiac pacemaker, defibrillator or infusion pump
- younger than 18 years old.

Data transmission from the capsule to the data receiver is influenced by patient BMI. Significant data dropout can occur in severely obese patients (>40 BMI).

Restricted Use

Caution

The SmartPill GI Monitoring System equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Not for use with oxygen or oxygen-enriched atmospheres.

Storage

Store SmartPill GI Monitoring System components and capsules at ambient room temperature (-15–40°C) and humidity (rH 30–90%).

Caution

Do not expose the capsules to UV light. UV light can permanently damage the pH sensor.

Caution

Do not store capsules within 30cm (1 foot) of the activation fixture. The fixture's magnetic field could inadvertently activate the capsules.

Power Requirements















System Computer	110/220 VAC, 50–60 Hz	May require the use of a power plug adapter
Docking Station	110/220 VAC, 50–60 Hz	May require the use of a power plug adapter
Capsule	3.1 VDC self-contained batteries	none
Data Receiver	8.4 VDC, self-contained,	none

rechargeable batteries








Recycling and Disposal Instructions

- Recycle the data receiver and docking station following the local, regional, and national regulations for electronic devices.
- The capsule contains silver oxide batteries. Recycle unused capsules following the local, regional and national regulations for electronic devices.
- Dispose of used capsules following local, regional and national regulations for disposing of human excrement.
- The calibration buffer contains sodium citrate, a common food preservative. Dispose of used buffer following local, regional, and national disposal regulations.

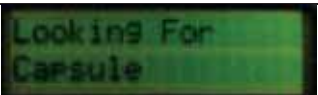

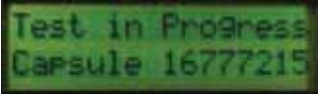
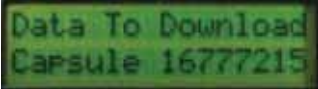
Device Markings





	Caution, consult accompanying documents
	Consult directions for use
	US FCC compliance
	Prescription use only
	Recycle. Dispose of properly
	Single use only. Do not reuse
	Part or catalog number
	Manufacturer
	Date of manufacture
	Use by YYYY-MM
	Lot number
	Minimum and maximum storage temperature
	Caution: Strong magnet
	Warning: Keep away from pacemakers

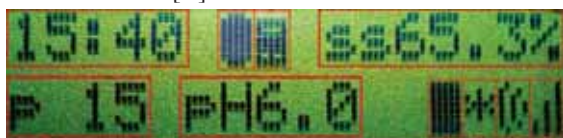
Appendix: Electrical Safety

 BF	Type BF equipment
 0123	CE marking and notified body number
	Authorized representative
	Sufficient for one test
IP57	Ingress protection rating
	Serial number
	Fragile
	Keep dry

Data Receiver Display Messages

	Looking for capsule—appears during test initiation before the receiver receives the first data packet from the capsule.
	Locked onto capsule—appears after the data receiver receives first data packet from the capsule.
	Test in progress—appears when a test is in progress and the data receiver is turned off and back on.
	Data to download—appears when the data receiver stops collecting data and has data to be downloaded.

Time	 Capsule and data receiver status icons / [X] indicates a failure	Signal Strength
Pressure	pH	 Indicates the data receiver is writing data from the capsule.
		 Indicates the event button is pushed.
		 The capsule's data was received. / [X] indicates the data was not received.





The receiver's battery life.

1 bar = 1 day of battery life.

3 bars = 3+ days.

Risks and Safety

Warning

This device does not differentiate between slow motility and functional outlet obstruction.

Non-Passage

Risks associated with capsule ingestion and transit are minimal. The primary hazard is capsule retention. Retention incidence, as determined by a review of published studies of capsule endoscopy in adults, is estimated as 0.75% in patients without known stenosis and 21% in patients with known stenosis. Stenosis and strictures can be complications in inflammatory bowel disease.

If you suspect a delay in passage and the Capsule is located in the stomach, a pro-motility drug could be administered to assist in emptying the capsule from the stomach. Alternatively, endoscopy could be performed in order to retrieve the capsule. If located in the colon, laxative therapy could be administered to facilitate capsule movement, or a colonoscopy could be performed in order to retrieve the capsule.

Adverse events reported in clinical studies involving the SmartPill are listed below.

Reported Adverse Events in Clinical Study Subjects (n=484)

Number of Events Reported	59
Number not related to the device	33
Number probably not related to the device	17
Number possibly related to the device	5
Number definitely related to the device	4

Reported Adverse Events in Clinical Practice

In clinical practice since 2007, the company identified 25 events whose circumstances suggested a potentially reportable event to regulatory authorities. After investigation and follow up, seven of these events were deemed reportable including three instances of esophageal retention, one gastric retention and three small bowel retentions.

Surgery was required for resolution in one instance of capsule small bowel retention that led to identification of a stricture. A bowel prep resolved the second instance of small bowel retention, and the third resolved with fluids and bed rest. Capsule retention in the stomach was resolved endoscopically. Two of the retentions in the esophagus were resolved endoscopically and in the third instance the patient vomited and then performed a self-applied Heimlick maneuver to expel the capsule. There

was one additional esophageal retention, eight gastric retentions, four small bowel retentions and five colonic retentions. These resolved either without intervention or with endoscopy/colonoscopy.

Patient-Contacting Materials

Patient-contacting materials include polyurethane, a polyurethane-polycarbonate blend, Teflon™ coated with polyhema, an ISFET pH sensor, epoxy and UV-cured adhesive. All patient contacting materials have been tested for biocompatibility and have been found non-toxic, non-sensitizing, and non-irritating.

The device does not contain natural rubber latex.

Care, Cleaning and Maintenance

Caution

Do not reuse capsules. The capsule is a single-use, disposable item.

Caution

Do not immerse the data receiver in water or other liquids. Immersion damages internal electrical components resulting in data receiver inoperability.

Caution

Do not immerse the docking station in water or other liquids. Immersion damages internal electrical components and could result in electrical shock.

Caution

The data receiver, docking station, power supply, and capsule are **not** user serviceable.

Data Receiver

Clean and disinfect the outside surfaces of the data receiver after each patient use.

1. Turn off data receiver by simultaneously depressing the backlight button and event button for 5 seconds.
2. Wipe outside surfaces with a cloth dampened (not saturated) with a mild detergent and water. Suitable detergents include dishwashing detergent (e.g., Joy, Dawn®, Palmolive®) solutions, or laboratory glassware cleaners such as Alconox®.
3. Wipe dry.
4. Disinfect by wiping outside surfaces with a cloth dampened (not saturated) with disinfectant. A solution of 10% household bleach can be used as a disinfectant.
5. Wipe dry.
6. Wait at least 5 minutes after cleaning and disinfection before turning the data receiver on or placing it in the docking station.
7. Conduct a preventive maintenance inspection. Check for cracks or damage. Shake the data receiver and listen for detached batteries. Do not use the data receiver if the case is cracked or damaged, or a rattling can be heard.

Caution

Do not attempt to replace batteries in the data receiver.

Docking Station

1. Unplug docking station from the power supply.
 2. Dust the surfaces of the docking station with a soft, dry cloth. Do not use water or liquids.
 3. Clean the gold connector pins with a swab and Isopropyl alcohol.
 4. Conduct a preventive maintenance inspection. Check for cracks or damage. Do not use the docking station if the case is cracked or damaged.
-

Caution

Do not use the components of the system with any other equipment.

Troubleshooting and Support

Contact technical support if you have a problem setting up or operating the system:

For swift and direct support, please be prepared to answer the following questions:

- What version of MotiliGI are you using? To determine what version you are using:
 - Select Help > About.
 - Refer to the version printed on the MotiliGI CD.
- What operation or steps did you take before the problem occurred?
- What operations or steps did you take after the problem occurred?
- What is the exact error message that appeared?
- If you have trouble with a capsule or other hardware component, have the component's lot and serial numbers ready. These numbers are on labels affixed to the hardware component or packaging.

Setting-Up the System

Getting Started

1. Remove the data receiver, docking station, activation fixture, USB cable, power adapter, and power cord from the starter kit case.
2. Unpack the system computer and power supply from its shipping container.
 - ▶ Connect the computer to a source of AC power.

Setting up the Computer

1. To login to the System Computer, enter the information below.

User Name	Password
-----------	----------


sgims1	12345
--------	-------

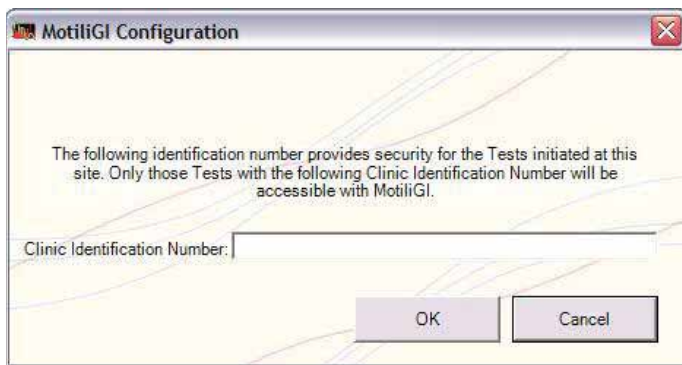
2. Ensure the system computer has the correct date, time, language and regional settings.

Changing the System Computer Date, Time, Language and Regional Options

1. Select Start > Control Panel > Clock, Region and Language
2. Change the desired settings.
 - ▶ Changing certain settings may require you to reboot the system computer.




Launching MotiliGI (for the first time)

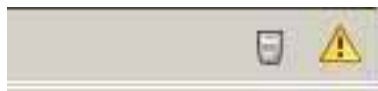
1. Open the MotiliGI software:
 - Click  on the desktop.
 - Select Start > All Programs > SmartPill folder > MotiliGI.
2. When launching MotiliGI for the first time, the MotiliGI License Agreement will appear. Review and click I Agree. You must accept the terms and conditions in order to run MotiliGI.
3. The MotiliGI Configuration appears. Enter an identification number or word (e.g. 001 or Main Office) to identify SmartPill tests run at your particular office.
 - If your institution or practice has more than one office, you may wish to use this feature to identify at which office a specific test was conducted.



4. Click OK. You will be asked to confirm the clinic identification number you entered; click Yes to proceed to the First Login Sequence screen.
5. Click OK. The administrator user login screen appears.
6. Create a username and password for the administrator account for MotiliGI. The username and password must contain a minimum of 5 alphanumeric characters.
7. Verify the password by re-entering it, and click Login. You will be required to enter this username and password each time you start the program. The MotiliGI Start-Up screen appears.

Connecting the Docking Station to the System Computer

1. Connect the docking station to an AC power source using the power cord.
2. Connect the docking station to the system computer using the USB cable.
3. Turn the data receiver on by depressing the event button.
4. Dock the data receiver by placing it in the docking station cradle. Push down on the top of the data receiver to ensure the data receiver is fully docked.
5. Confirm the system computer and docking station are communicating by noting the presence of the data receiver connected icon  in the MotiliGI status bar (the horizontal bar at the bottom of the MotiliGI user interface).
- If you observe the receiver communication disabled  and test state unknown  icons, either the docking station is not properly connected to the system computer, or the data receiver is not fully docked.



- ▶ Reseat the data receiver in the docking station and ensure the docking station is connected to both the computer and a power supply. The test state unknown icon will disappear once the connection is established. If it does not disappear, contact Technical Support for assistance.
6. Before starting a test, fully charge the Data Receiver. See Chapter 4: Charging the Data Receiver for instructions.

Preparing for a Test

Before the Test Day

Fully charge the data receiver the day or night before starting a test. Charging can take up to 5 hours.

Charging the Data Receiver

1. Ensure that the data receiver is off. If any characters appear on the display, turn off the data receiver by simultaneously pressing the 2 buttons on the front of the unit for approximately 5 seconds.

Caution

The data receiver must be turned off during charging. Charging the data receiver while turned on results in a partial charge. You may lose test data.

2. When the back light dims, release both buttons.
3. Plug the docking station into an electrical outlet.
 - ▶ If necessary, use a power adapter.
4. Firmly push the data receiver into the docking station to initiate charging. The docking station's LED turns red.



Figure 3

- Allow up to 5 hours for the data receiver to fully charge.
- The docking station's LED turns green when the data receiver is fully charged.

Caution

Charging or recharging the data receiver with a power source other than the SmartPill power supply may permanently damage the data receiver, docking station, or system computer and will void the product warranty.

Preparing the Patient**Before the Office Visit**

1. Review these requirements and restrictions with the patient. The test requires fasting for accurate results.

Schedule	Restriction
24 hours before the test	Do not consume alcohol.
8 hours before the start of the test	Do not eat or drink. Do not use tobacco.
6 hours after the start of the test	Do not use tobacco. Do not eat. Do not sleep. Do not consume alcohol.

2. Review the use of medications with the patient. Stop medications that alter motility or gastric pH. Examples of medications are provided below.
 - Unless the patient is well stabilized (condition and dose has been stable for 3 months or more), discontinue these medications prior to the start of the test.

Schedule	Type	Examples
7 days before the tests	Proton pump inhibitors	Omeprazole, Lansoprazole, Nexium
48 Hours	Histamine ₂ blockers	Zantac
48 Hours	Motility-altering medications	Cisapride, Domperidone, Metoclopramide (Reglan)
48 Hours	Antiemetics & 5HT ₃ antagonists	Zofran, Kytril
48 Hours	Macrolides	Erythromycin, Zithromycin
48 Hours	Anticholinergics	Phenergan, Compazine
48 Hours	5HT ₄ partial agonists	Zelnorm
24 Hours	Antacids	Maalox, Mylanta,

Appendix: Electrical Safety

Rolaids

- Insulin-dependent diabetic patients must take half of their normal morning dose of insulin and monitor glucose levels according to normal routines.
3. Review SmartBar ingredients and rule out any food allergies.
 - The SmartBar contains a small amount of gluten.
 - The SmartBar does not contain lactose.
 - The SmartBar does not contain nuts but is manufactured in a plant that processes nuts.

SmartBar Ingredients	Granola (Rolled Oats, Evaporated Cane Juice, Expeller Pressed Canola Oil, Defatted Wheat Germ, Oat Flour, Brown Rice Syrup, Molasses, Salt, Natural Flavor, Soy Lecithin), Whey Crisp, Rice Syrup, Corn Syrup, Whey Protein Isolate, Invert Sugar, Puffed Wheat, Apples, Maltodextrin, Sorbitol, Apple Juice Concentrate, Partially Hydrogenated Vegetable Oil (Cottonseed, Soybean), Honey, Natural and Artificial Flavor, Salt, Vanilla.	
Nutritional Composition	66% carbohydrate	3% fiber
(in % of weight)	17% protein	243 kcal
	2% fat	

If necessary, an egg based meal can be substituted for SmartBar. You must have a microwave to prepare this meal.

Ingredients	½ cup (120 g) Egg Beaters®, equivalent to the volume of 2 large egg whites; 60 kcal 2 slices of bread; 120 kcal	1.5 Tbsp. (30 g) strawberry jam; 75 kcal ½ cup (120 ml) water
-------------	--	--

Caution

To accurately measure regional gut transit times the patient must consume either SmartBar or the egg based meal **immediately before** ingesting the capsule.

During the Office Visit

1. Ensure the patient has adhered to restrictions required before the test.
2. Provide printed instructions (included in starter kit) to the patient. Additional copies can be purchased.
3. Review the schedule, restrictions, and use of medications with the patient. Inform the patient that failure to follow these instructions may invalidate the test.

Schedule	Restriction
6 hours after ingesting the capsule	<ul style="list-style-type: none">• Do not eat.• Do not take medication.

Appendix: Electrical Safety

	<ul style="list-style-type: none">• Do not use tobacco.
During the entire test	<ul style="list-style-type: none">• Do not consume alcohol.• If you are diabetic, monitor glucose levels and follow your personal treatment plan. If you are unsure, contact the doctor who manages your diabetes.• Avoid vigorous exercise such as sit-ups, abdominal crunches, and prolonged aerobic activity (greater than 15 minutes).• Do not wear the data receiver while bathing or showering.• Do not use laxatives, bowel cathartics, anti-diarrhea medications, alcohol and other drugs or medications that affect motility until after the capsule passes.

4. Instruct the patient to keep the receiver as close to the abdomen as possible except while bathing or showering:

- Positioned on a belt
- Suspended by a lanyard

Caution

Instruct patients not to use the lanyard when sleeping

Caution

Eating anything (except limited quantities of water) before the capsule has emptied will delay gastric emptying of the test meal and invalidate results.

5. Instruct the patient on the use of the patient diary and the data receiver's event button. Every time the patient presses event, the patient must record the time displayed on the data receiver and a brief description of the event or activity in the diary.



- ▶ Patients must press event for all bowel movements.

Pressing event:

- Marks bowel movements which are useful for verifying capsule exit.
- Marks other events and symptoms which may be useful when reviewing test data.
- Adds an event marker to the electronic data record.

Other events and symptoms you may ask the patient to mark and enter in the patient diary include:

eating a meal	nausea
getting up in the morning; going to bed at night	passing gas
cramping or pain	vigorous exercise or activity

Resumption of Normal Routine

6. Review these instructions and warnings with the patient.

Appendix: Electrical Safety

- Patients may resume a normal diet 6 hours after swallowing the capsule.
- Except for restrictions noted on the Patient Instructions Sheets, patients may resume normal activities when released from your office.

Warning

Magnetic Resonance Imaging (MRI) must not be performed on a patient who has ingested the capsule until capsule passage is confirmed by the physician's review of the MotiliGI graph or abdominal x-ray. An MRI test performed with an ingested capsule may result in damage to the GI tract.

Warning

Instruct the patient to contact your office if he or she experiences acute pain, sudden nausea, or vomiting beyond his or her typical pattern within 5 days of ingesting the capsule as these symptoms could indicate bowel obstruction.


Scheduling a Follow-up Office Visit

7. Schedule a visit to return the data receiver 4-5 days (96-120 hours) from the start of the test.

Starting a Test

Preparing the System

Perform these steps immediately before or after a patient's arrival at the office.

1. Turn on the system computer.
2. Open MotiliGI:
 - Click  on the desktop.
 - Select Start > All Programs > SmartPill > MotiliGI.
3. If prompted, enter a username and password. Click OK. The main startup screen appears.

Performing the Test – Test Initiation Wizard

Step 1: Connect the Data Receiver


Caution

Do not close MotiliGI while operating the Test Initiation Wizard because data can be lost. Complete or cancel the Wizard first.


Caution

You may cancel the wizard any time. However, a capsule exposed to the pH calibration buffer must be ingested within 2 hours or discarded.

1. Follow the prompts. Check the results:

Component	Success	Troubleshooting
Docking station's LED	Green	<ul style="list-style-type: none"> • Red The data receiver may not be fully charged. See Chapter 4: Charging the Data Receiver. • Yellow Undock and re-dock the data receiver in the docking station. If the yellow light persists, contact SmartPill Technical Support.
Data receiver display	The "Looking For Capsule" message appears.	<ul style="list-style-type: none"> • LCD is blank Turn on the data receiver by pressing the event button.
System Computer	<ul style="list-style-type: none"> • 2 beeps • These icons appear in the lower-right corner of the screen: <ul style="list-style-type: none"> •  	<ul style="list-style-type: none"> • No beeps <ul style="list-style-type: none"> • Check the computer's sound level. • Undock and re-dock the data receiver in the docking station. If there are still no beeps, contact Technical Support. • The "Receiver is Not Fully Charged" message appears. The charge is insufficient for a 5-day test.

Appendix: Electrical Safety

	<ul style="list-style-type: none">• 	<ul style="list-style-type: none">• Replace the data receiver with a fully charged receiver.• Allow additional charging time for the current receiver.
--	---	---

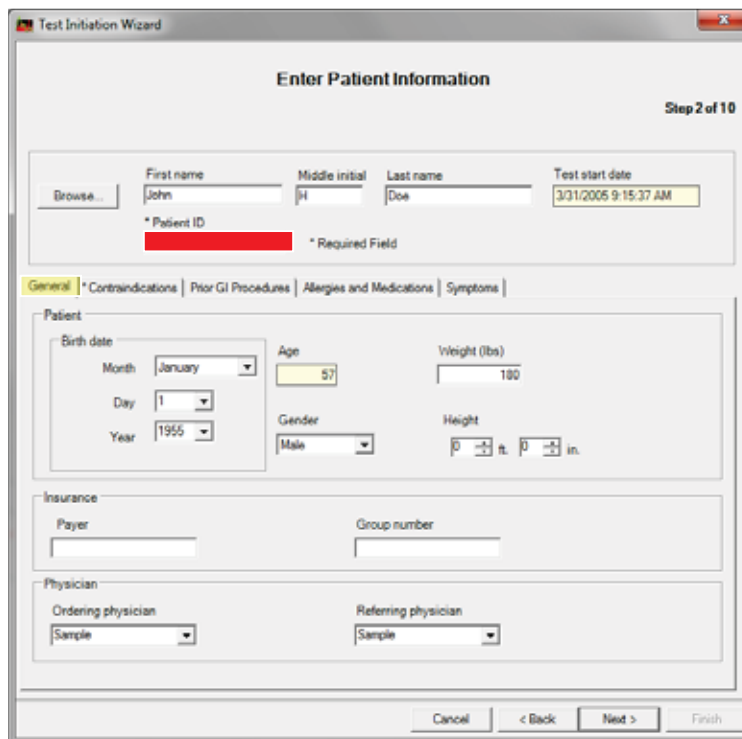
The data receiver must be turned off during charging. Charging the data receiver while turned on results in a partial charge. You may lose test data.

2. Click Next >.

Step 2: Enter Patient Information

Patient information becomes a permanent part of the patient's MotiliGI record.

General Tab



*indicates a required field

1. Enter the required information.

Contraindications Tab

You must view this screen.

2. Complete the applicable fields.

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The screenshot shows a software window titled "Test Initiation Wizard" with a close button in the top right corner. The main heading is "Enter Patient Information" and it is labeled "Step 2 of 10".

At the top, there are input fields for "First name" (containing "John"), "Middle initial" (containing "H"), "Last name" (containing "Doe"), and "Test start date" (containing "3/31/2005 9:15:37 AM"). Below these is a "Browse..." button and a "Patient ID" field containing "002005". A note indicates "* Required Field".

Below the input fields are five tabs: "General", "* Contraindications", "Prior GI Procedures", "Allergies and Medications", and "Symptoms". The "General" tab is currently selected.

Under the "General" tab, there are two sections of checkboxes:

- Does the patient have any of the following?**
 - ☐ Implanted or portable electro-mechanical devices
 - ☒ Physiological/mechanical GI obstructions, strictures or fistulas
 - ☐ Bezoar or history of bezoars
 - ☐ GI surgery within the past 3 months
 - ☐ Swallowing disorders including severe dysphagia to food or pills
 - ☐ Crohn's disease or diverticulitis
 - ☐ Patient is under 18 years of age.
- Do any of the following apply?**
 - ☐ The patient scheduled for an MRI within the next 2 weeks.
 - ☒ Within the last 48 hours, the patient used medications that alter motility.
 - ☒ Within the last 7 days, the patient took any proton pump inhibitors.
 - ☐ Within the last 48 hours, the patient took any Histamine2 blockers.
 - ☒ Within the last 24 hours, the patient took any antacids.

At the bottom of the window are four buttons: "Cancel", "< Back", "Next >", and "Finish".

Depending on your selections, other screens may appear. For example, an override screen for a contraindication or caution may appear.

- (Optional) Enter notes and click Physician Ok.
- (Optional) Click End Test.

3. Proceed to the optional tabs below or click Next >.

Optional Tabs: Prior GI Procedures, Allergies and Medications, Symptoms


Entering information in these tabs is optional. The symptoms tab includes a selection of ICD9 and ICD10 codes.

Creating Templates:

To save time you can create text descriptions that are saved in MotiliGI. These text templates can be reused from patient to patient. Text descriptions saved this way are called templates. We recommend creating general templates with blank lines to indicate where patient specific information can be inserted.

1. Click Create Template.
 - a. Enter a title for the prior abdominal surgery or implanted device. Examples:
 - Appendectomy
 - Gastric stimulator
 - b. (Optional) Click in the text field under the title. Enter descriptive details. Examples:
 - Date: _____
 - Name of the surgeon: _____
2. Click Save Template.

Using Templates

1. Click  for saved templates.
2. Select a template. Insert any patient specific information.
3. Click → to move information to the patient record.
- ▶ (Optional) To remove information from the patient's record, select it and click Remove Entry.

Appendix: Electrical Safety

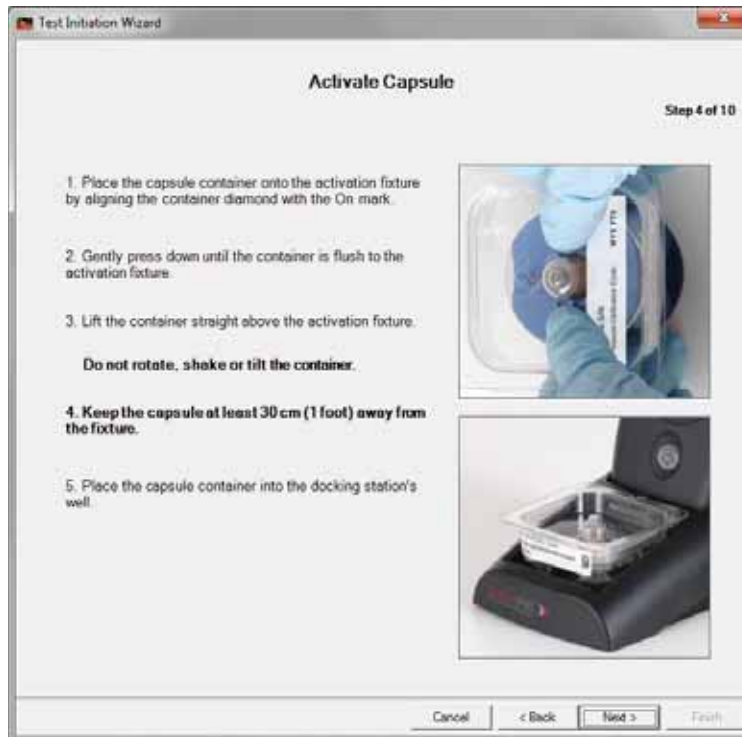
The templates remains in the Template list. To delete the selection, click Delete Template.

Step 3: Assemble Materials



1. Follow the prompts.
 - The capsule's instructions for use are in the inside pocket of the capsule pack.
2. Click Next >.

Step 4: Activate Capsule



1. Follow the prompts.



- 2.

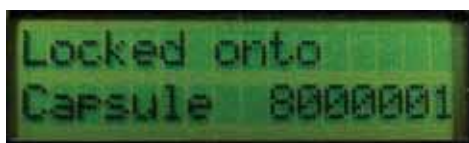
Figure 4 - Capsule Activation Window

Caution

Once the capsule is activated, keep the capsule at least one (1) foot away from the activation fixture. If the capsule is kept near the activation fixture, stray magnetic fields from the activation fixture may deactivate the capsule.

3. Confirm the capsule has activated:

- Observe the data receiver's display for at least 1 minute. The message "Locked onto Capsule" and the capsule's serial number will appear on the data receiver for approximately 4 seconds.



- The data receiver's display then indicates the capsule's data:

Capsule Serial number	SS = signal strength
P = pressure	The capsule's data was received. / [X] = The data was not received.

- The icon appears in the lower-right corner of MotiliGI: .

► If the capsule did not activate, repeat the procedure.

4. Click Next >.

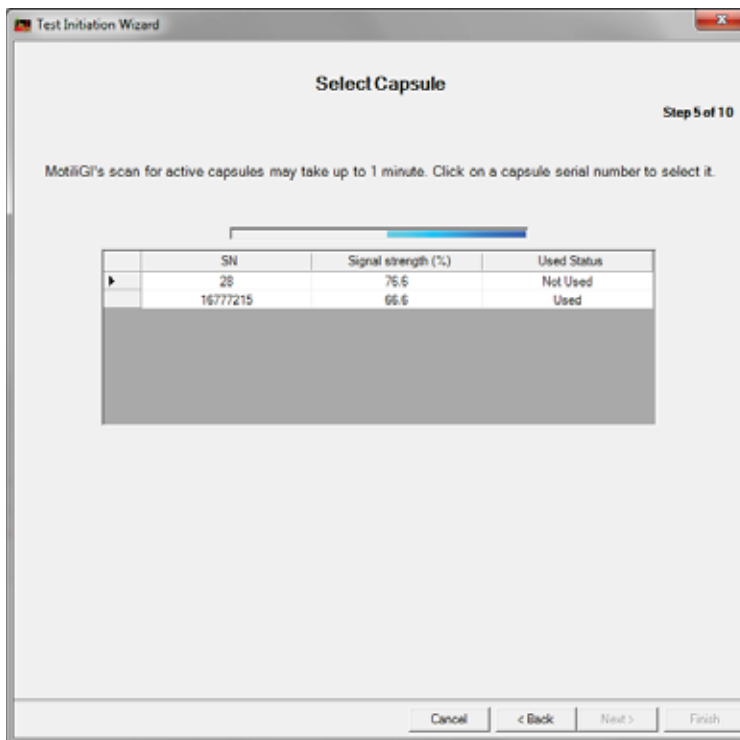
5. If you wish to deactivate the test, see *Aborting a Test – Deactivating the Capsule*, Page 44.

Step 5: Select Capsule

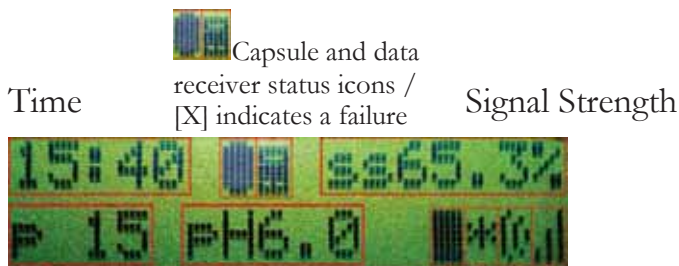
All activated capsules (ingested or not yet ingested) within range of the data receiver appear¹. This process may take up to 1 minute.

¹ The data receiver can detect the capsule in open air (not ingested) at distances of up to 40 feet.

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- To select the capsule you activated, click the row that matches the capsule container's serial number. An arrow indicates your selection.
 - If the software does not detect the capsule within a minute, observe the data receiver's display to confirm the capsule is active.
 - If the capsule is activated the data receiver displays this data during a test.

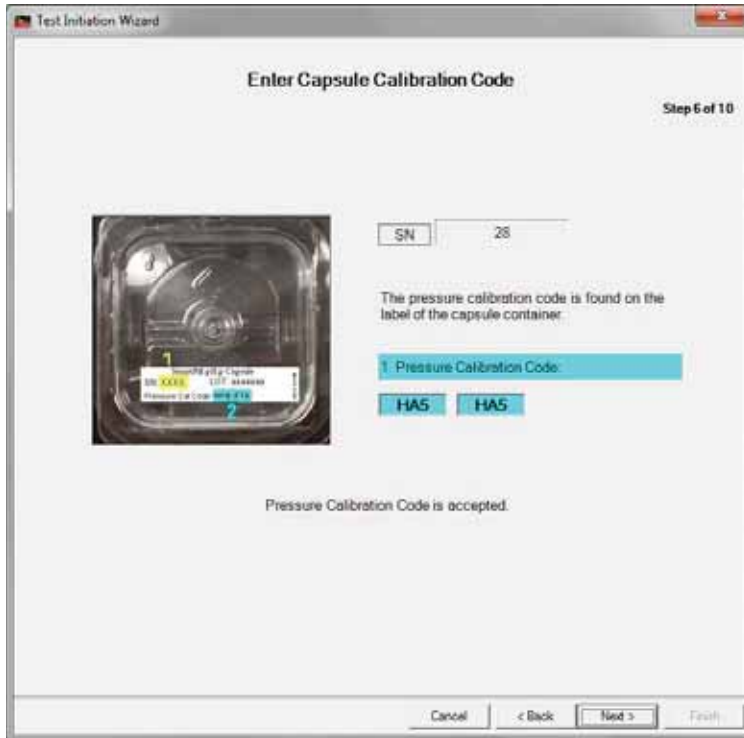


- Pressure pH
- Indicates the data receiver is writing data from the capsule.
 - Indicates the event button is pushed.
 - The capsule's data was received. / [X] = The data was not received.
 - The receiver's battery life.
1 bar = 1 day of battery life.
3 bars = 3+ days.

- Click Next >.

Step 6: Enter Pressure Calibration Code

1. Locate the calibration code found on the lid of the capsule container. Enter the code.



2. Click Next >.

Step 7: Add pH Calibration Buffer

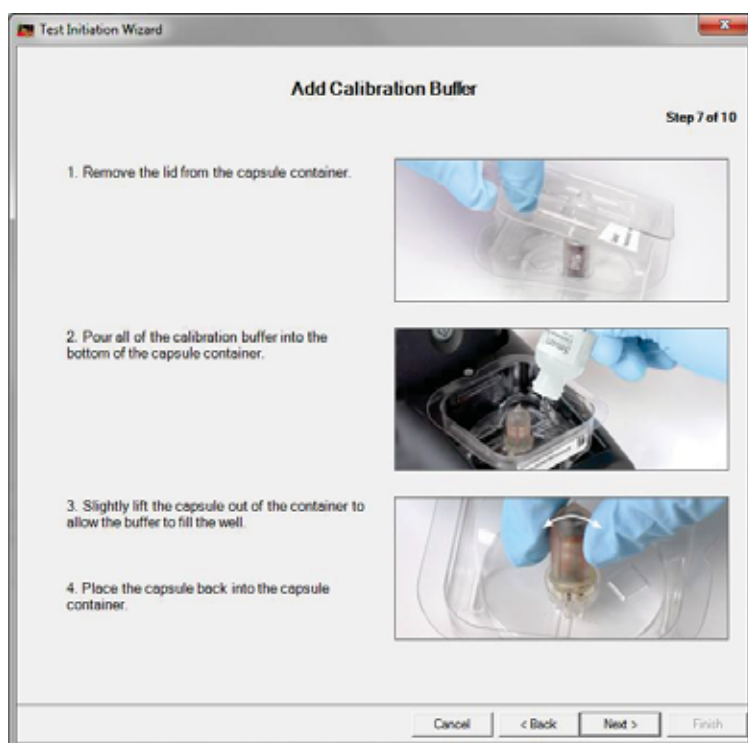
Caution

Once exposed to buffer, the capsule must be ingested within 2 hours or discarded. Confirm that the patient is available and prepared to proceed with the test **before** you begin Step 7.

1. Put gloves on and follow the prompts.

Caution

Wear gloves when handling the capsule. Do not touch the calibration buffer or capsule with your finger as this could cause an electrostatic charge.



Caution

The orientation of the capsule in the capsule container is important. When reinserting the capsule, ensure the pH sensor is in the same orientation relative to the diamond-shaped window of the capsule container.

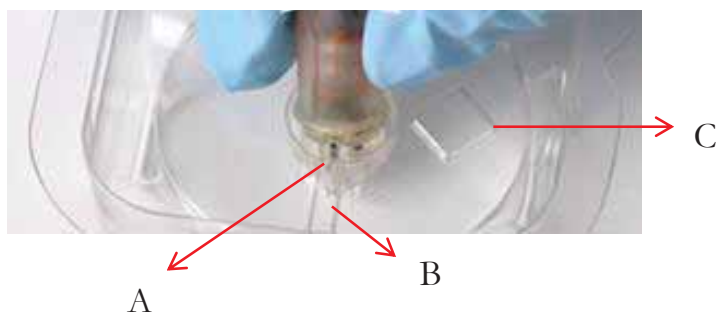


Figure 5 - Capsule Orientation

A – Capsule pH sensor

B – Buffer filling channel

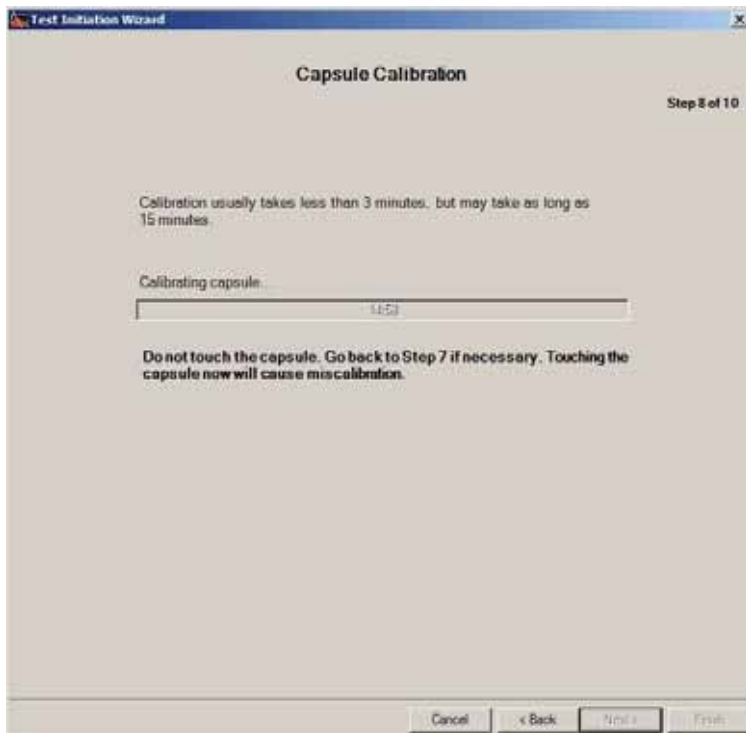
C – Diamond shaped window


Do not discard the capsule container's cover. The cover contains information that is needed if the test cannot take place as planned or assistance from Technical Support is required.

2. Click Next >.

Step 8: Capsule pH Calibration

No action is necessary. The software checks the status of the capsule and data receiver during this step.



- Calibration normally takes less than 3 minutes, but may take up to 15 minutes.
- During calibration, it is normal for fluctuations in the pH value to occur. Calibration is complete when all these signals appear:
 - The pH value stabilizes at 6.0.
 - The “pH Calibration Complete” message appears.
 - The MotiliGI status bar icon  indicates the capsule is ready for use and the data receiver is recording information from the capsule.

If the capsule does not calibrate within 15 minutes, this message appears: “pH Calibration Timeout.”

1. Ensure the capsule is immersed in buffer.
2. Click Back.
3. Click Next. The calibration process reinitiates.
 - If the calibration fails after 2 attempts contact Technical Support.

Step 9: Ingestion

1. Follow the prompts. Record the time of completion in the patient diary.

Caution

The meal must be eaten immediately before capsule ingestion.

Appendix: Electrical Safety



Caution

To avoid loss of data during Step 9.2, avoid separating the capsule and data receiver by more than 5 feet.

The data receiver records biomedical data from within the patient's GI tract. Every few seconds, the pH and pressure readings update on the data receiver's display.

- ▶ Dispose of the pH calibration buffer following all applicable regulations. The buffer is a solution of sodium citrate pH 6.0.

2. Click Next >.

Step 10: Complete Discharge Checklist

Test Initiation Wizard

Complete Patient Discharge Step 10 of 10

Review with the patient:

- Patient instruction sheet.
- Use of patient diary.
- Date of return for the data receiver.
- Physician's emergency contact information.

☒ I have completed the patient's discharge.

Cancel < Back Next > Finish

1. Review the discharge checklist with the patient. Instruct the patient to wait 3 minutes in the bathroom before flushing the toilet after each bowel movement. Explain that to confirm body exit, the patient must let the capsule communicate with the data receiver after bowel movements.

2. Review these warnings:

Warning

Magnetic resonance imaging (MRI) must not be performed on a patient who has ingested the capsule until capsule passage is confirmed by physician review of the MotiliGI graph or abdominal x-ray. An MRI test performed with an ingested capsule may result in damage to the GI tract.

Warning

Instruct the patient to contact your office if he or she experiences acute pain, sudden nausea, or vomiting beyond his or her typical pattern within 5 days of ingesting the capsule as these symptoms could indicate bowel obstruction.

Warning

If you suspect bowel obstruction, treat consistent with your management of a foreign object causing obstruction. Consider an abdominal x-ray to determine if the capsule is retained and its location within the GI tract.

3. Schedule an appointment for the patient to return the data receiver.

The capsule typically passes naturally within 2–5 days after ingestion depending upon the patient's condition.

Guidelines:

Indication for Use

Measuring GET

Measuring WGTT

Return Data Receiver After

24-48 hours


2–5 days

4. Check the box I have completed the patient's discharge.
5. Click Finish. The Patient Information screen appears.
6. Do any of the following:
 - Enter notes regarding the patient's capsule ingestion.
 - Close MotiliGI.
 - Use Live Monitoring mode to view live data while the patient is still in the office.

Live Monitoring Mode (optional)

You may view live data from the capsule while the patient is still in the office.

Prerequisites:

- The test has begun.
 - The docking station is connected to the system computer.
 - The data receiver is in the docking station.
1. Click  or select Action > Live Monitoring. The Live Monitoring control panels appears on the right.

It may take several minutes for sufficient data to be captured before the MotiliGI graph begins to show a noticeable progression of pressure, pH, and temperature data values.

Caution

The patient must remain in close proximity of the docked data receiver during live monitoring. If the patient moves away from the data receiver, test data may be permanently lost.

- You may remove the data receiver from the docking station at any time during live monitoring without data loss if the data receiver is kept near the patient during the transition from being docked to being worn by the patient. When you remove the data receiver from the docking station, live monitoring stops.
 - The MotiliGI software cannot save test data displayed during live monitoring, but the data are stored on the data receiver and are downloaded as part of the completed test.
2. To exit live monitoring, click Stop on the live monitoring control panel.


Aborting a Test – Deactivating the Capsule

Caution


If a test is aborted before the capsule has been exposed to buffer solution, the capsule may be deactivated but must be used within two (2) hours or discarded.

Caution

If a test is aborted before ingestion and the capsule has not been exposed to buffer solution, the capsule may be deactivated but must be used within one month or before its expiration date is reached, whichever is sooner. Otherwise discard the capsule (refer to Recycling and Disposal Instructions, page 18).

1. Place the capsule's container onto the activation fixture.
2. Align the diamond-shaped window on the capsule's container with the Off mark on the activation fixture.
3. Leave the capsule container in place for 5 seconds and then lift straight up and off the activation fixture.
4. Confirm the capsule is deactivated:
 - Place the capsule container in the docking station's well and observe the data receiver's display. The capsule is off if this icon  (lower right) is replaced with an X. The X may take 1-2 minutes to appear.

Ending a Test

To determine capsule exit, you can observe the data display on the data receiver for at least 2 minutes. If the data receiver is receiving data from the capsule, this icon  appears every 20–40 seconds, which confirms that the capsule is still in the patient. No evidence of the icon within the 2-minute observation is presumptive evidence of capsule exit. Actual passage can only be confirmed clinically by examination of the graph or physical examination.

Returning the Data Receiver


Following the test, the patient returns the data receiver and patient diary to your office. A nurse or medical technician can perform these steps.

1. Collect the data receiver.
2. Ask the patient about his or her experience with the SmartPill test. Use MotiliGI's Post-Test Notes screen for recording information:
 - Did the patient experience any unusual cramping, pain or discomfort?
 - At any time during the test was the patient separated from the data receiver?
 - Did the patient observe the capsule in their stool confirming body exit?
3. Collect the patient diary.
 - ▶ Review the diary's contents to ensure the patient's notes are legible and comprehensible.
4. Release the patient.

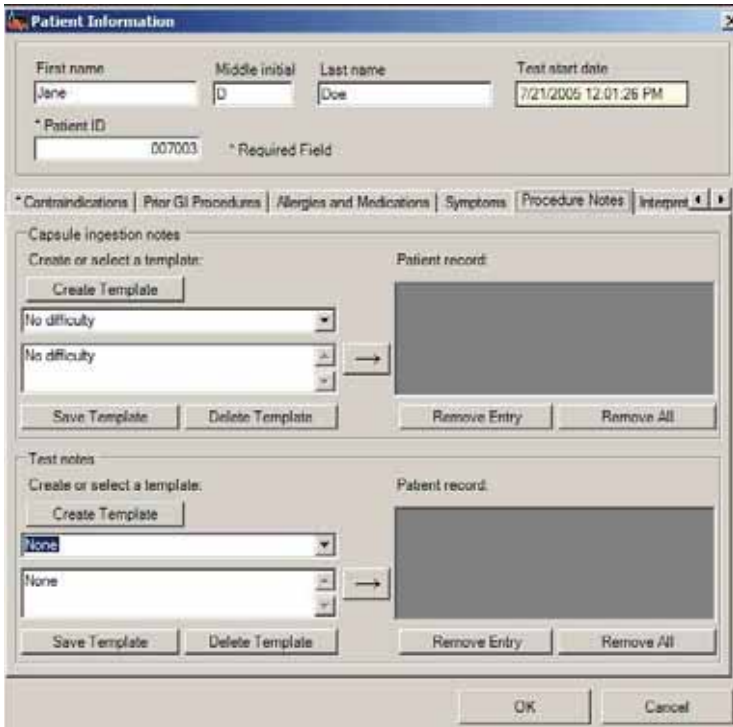
Downloading a Test

1. Turn on the data receiver.
2. Connect the docking station to a source of AC power and to the system computer's USB port.
 - ▶ Check the data receiver's battery power. If battery power bars are not visible in the lower-right corner of the data receiver, turn the data receiver off and charge it for 10 minutes before downloading.
3. Dock the data receiver in the docking station.
4. Launch the MotiliGI software and log in.
 - The software detects when the data receiver contains test data. A message asks whether you want to open the patient's information.
5. Click Yes. The patient's file opens. The file name appears in MotiliGI's title bar.
6. Download the data:

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- Select Action > Download Data.
- Click the  toolbar icon.

The Patient Information screen opens.



Post Test Notes

7. In the Procedure Notes tab, click in the post-test notes field to enter notes elicited from the patient which were captured when the patient returned the data receiver.
 - See Adding and Creating a Template.
8. Click OK. (If you click Cancel, the data receiver continues to record capsule data and events.)

The Test Download screen appears.

Duration of test	Duration of download (typical)
2 days	<3 minutes
4 days	<5 minutes

MotiliGI protects current test data stored on the data receiver until current test data is completely downloaded.

When the download is complete the MotiliGI software displays the entire test graph and the Test Summary screen.

9. Turn the data receiver off and place in the docking station to be recharged.

Confirming Capsule Exit

Caution

Physicians should confirm capsule exit. Monitor patients until capsule passage is confirmed.

1. Use one of these methods:

- Ask the patient whether the capsule was observed in his or her stool.
- Download the test. Analyze the MotiliGI graph for evidence of exit: an abrupt drop in temperature or loss of signal that coincides with a diary entry for a bowel movement.
- If you cannot confirm capsule exit cannot using these methods, or suspect a bowel obstruction, consider an abdominal x-ray and treat consistent with your management of a foreign object causing obstruction. An abdominal x-ray determines whether the capsule is retained and its location within the GI tract.

If you suspect a delay in passage and the capsule is in the stomach, consider:

- A pro-motility drug to help empty the capsule from the stomach.
- Endoscopy to retrieve the capsule.

If the capsule is in the colon, consider:

- Laxative therapy to facilitate capsule movement.
- Colonoscopy to retrieve the capsule.

Analyzing the Test

The MotiliGI software identifies capsule ingestion, gastric emptying, ICJ, body exit, and computes GET, SBT^T, CTT, SLBT^T, WGTT^T, and motility indices.

You can:

- Match events with patient diary entries.
- Analyze test to mark capsule ingestion, gastric emptying, ICJ and body exit.
- Compare the markers you defined with markers identified by the MotiliGI software.

Introduction to the Test Analysis Wizard


After downloading a test, a message appears asking if you want to analyze the test.

1. Click Yes. The Test Analysis Wizard appears.

You may close the wizard at any time. If you close the wizard before completing the analysis:

- The Test Summary screen does not appear.
- The test report will contain the note “Test data not reviewed by physician.”
- The test wizard automatically saves.

To re-open the wizard:

- Click the  toolbar icon.
- Select Action > Analyze Test.

The test analysis wizard resumes from your last completed step.

Appendix: Electrical Safety

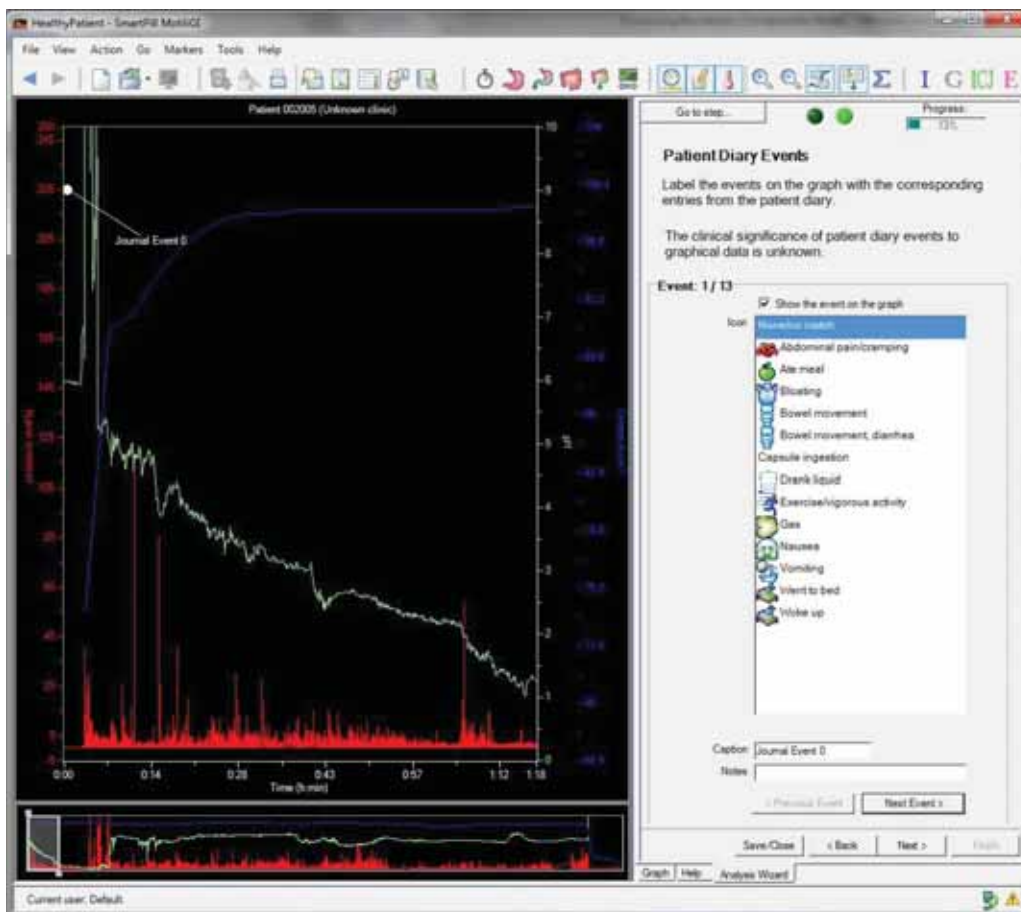
The screenshot shows a software window titled "Test Analysis Wizard". At the top, there is a progress bar with four steps: 1 (Go to step), 2 (yellow circle), 3 (green circle), and 4 (green circle). The main area is titled "Select Capsule Ingestion" and contains the text "Select an option:". Below this, there are three bullet points: "3. [Mark ingestion on the graph.](#)", "• [Help me locate ingestion.](#)", and "• If you are unable to locate ingestion, click Next." At the bottom of the main area, there is a section titled "4. Observations" with a large empty text box. The bottom of the window features a toolbar with buttons: "Save Data", "< Back", "Next >", and "Finish". A status bar at the very bottom contains the text "Graph Help Analysis Wizard".

Figure 6 - Test Analysis Wizard

- | | |
|---|---|
| 1 | Navigates to any step of the wizard that you have completed |
| 2 | Yellow light: You must take action to complete this step.
Green light: You have completed this step. |
| 3 | To take an action, click a link. |
| 4 | You can enter notes. |

Analyzing the Test

Patient Diary Events



The graph displays each event in succession.

1. Match each journal event with a recorded event, based on time, from the diary.
 - a. Select an event icon, displayed in this step.
 - b. (Optional) Enter a caption and notes.
 - c. Click Next Event to navigate through all events in the graph.
 - To go back to an event click Previous Event.
 - If you cannot find a matching event in the diary:
 - Select None/No Match from the list.

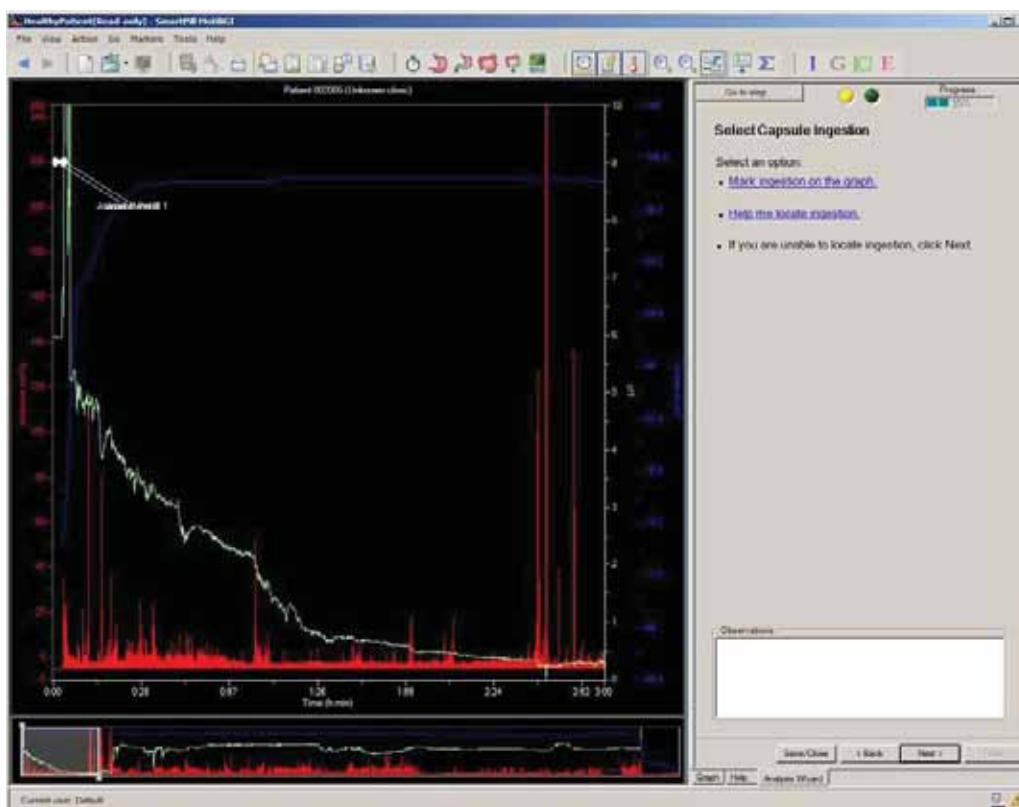
Appendix: Electrical Safety

- Hide the event by uncheck the box Show the Event on the Graph.

You can edit this information at any time by using the Point Annotation Viewer or the Annotation Viewer:

2. Click Next >.

Select Capsule Ingestion



Term	Definition
Ingestion	The point where you observe the temperature beginning to rise to body temperature.

Often, a pH spike to an off-scale value then a decrease to physiologic pH occurs just before ingestion due to exposure of the capsule to air.²

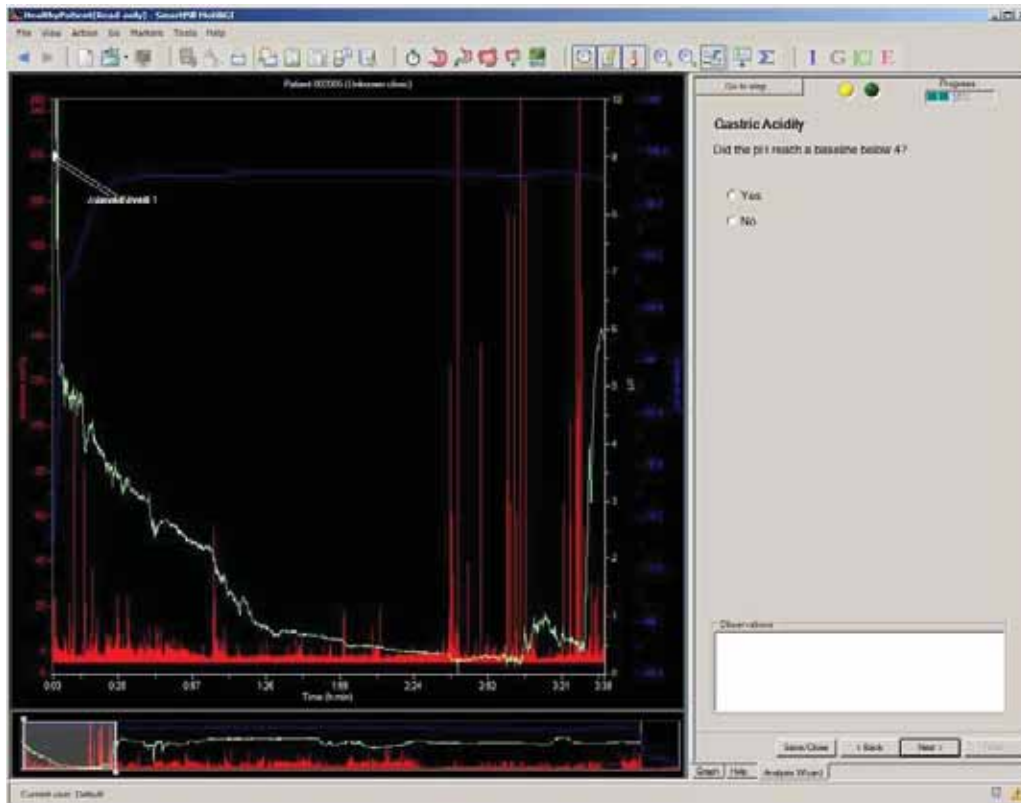
1. Click Mark ingestion on the graph

² Fackler, WK, et. al. Ambulatory gastric pH monitoring: proper probe placement and normal values. Aliment Pharmacol Ther 2001; 15:1155-1162

Appendix: Electrical Safety

2. Move the cursor over the graph and click on the location where you believe ingestion occurred.
3. Click Next >.

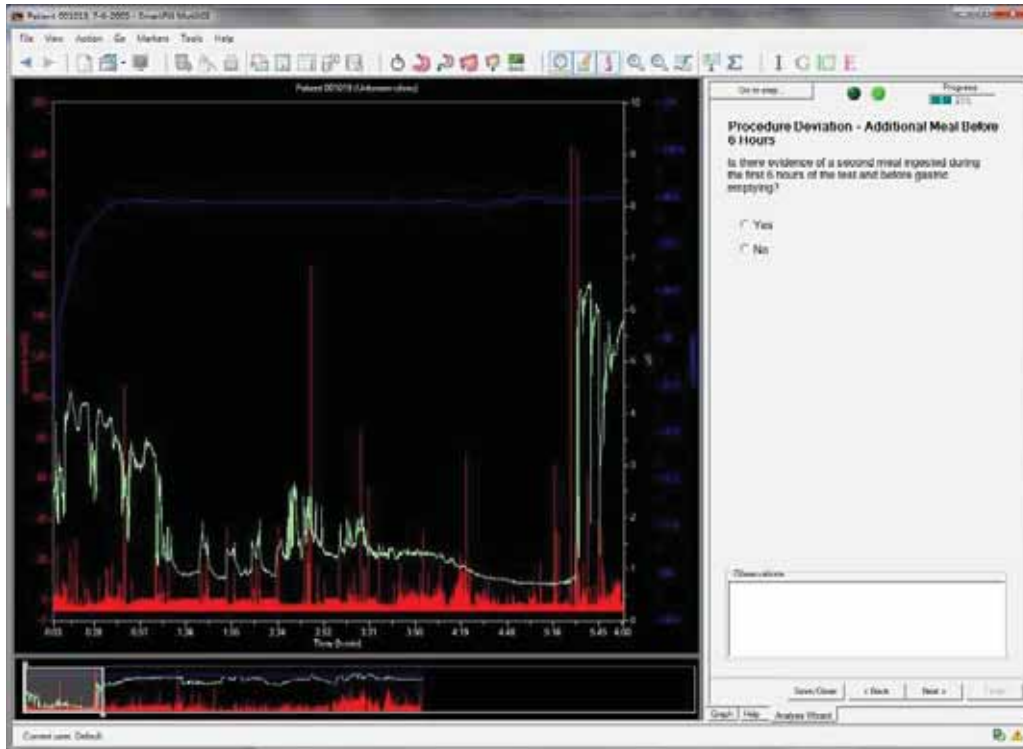
Gastric Acidity



A stomach baseline pH below 4 indicates normal acidic conditions. Baselines above 4 may indicate ineffective gastric acid production, buffering due to meals, or medications that suppress gastric acid.

- Click Next >.

Procedure Deviation – Additional Meal Before 6 Hours



Snacks or meals may be recorded in the diary. A rise in pH and drop in temperature may indicate a meal response in the stomach. In figure above there is no evidence of an additional meal prior to capsule gastric emptying. See the figure below describing an ingested liquid meal

Caution

Eating anything (except limited quantities of water) before the capsule has emptied the stomach will delay gastric emptying and invalidate GET results.

► Click Next >.

Food and liquid intake cause a rise in pH which can be mistaken as gastric emptying.

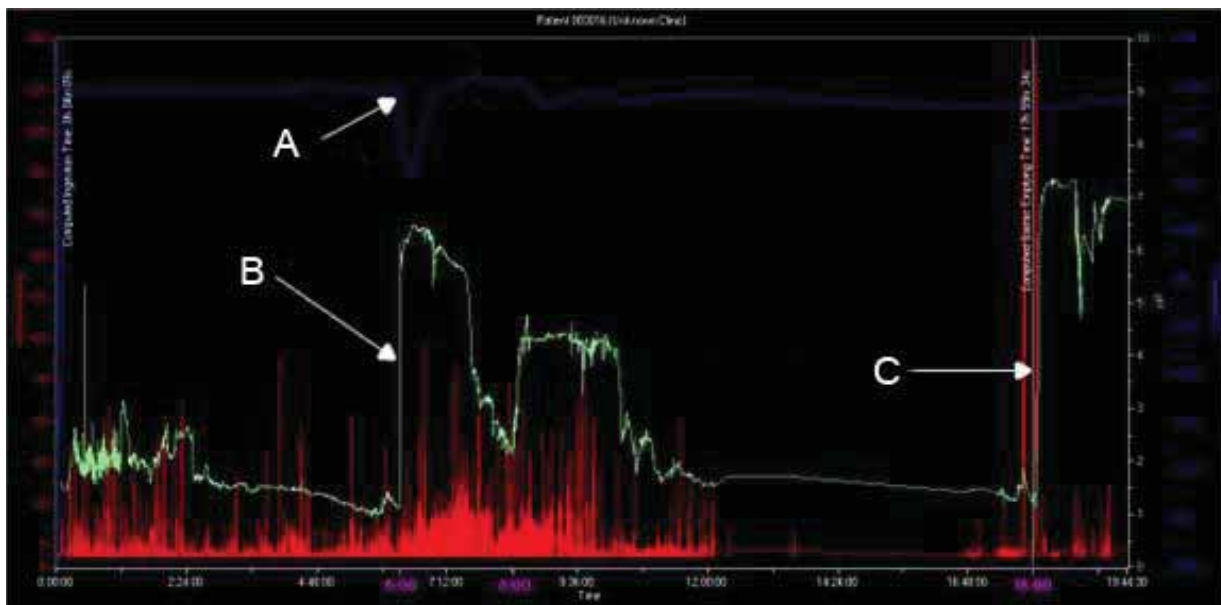
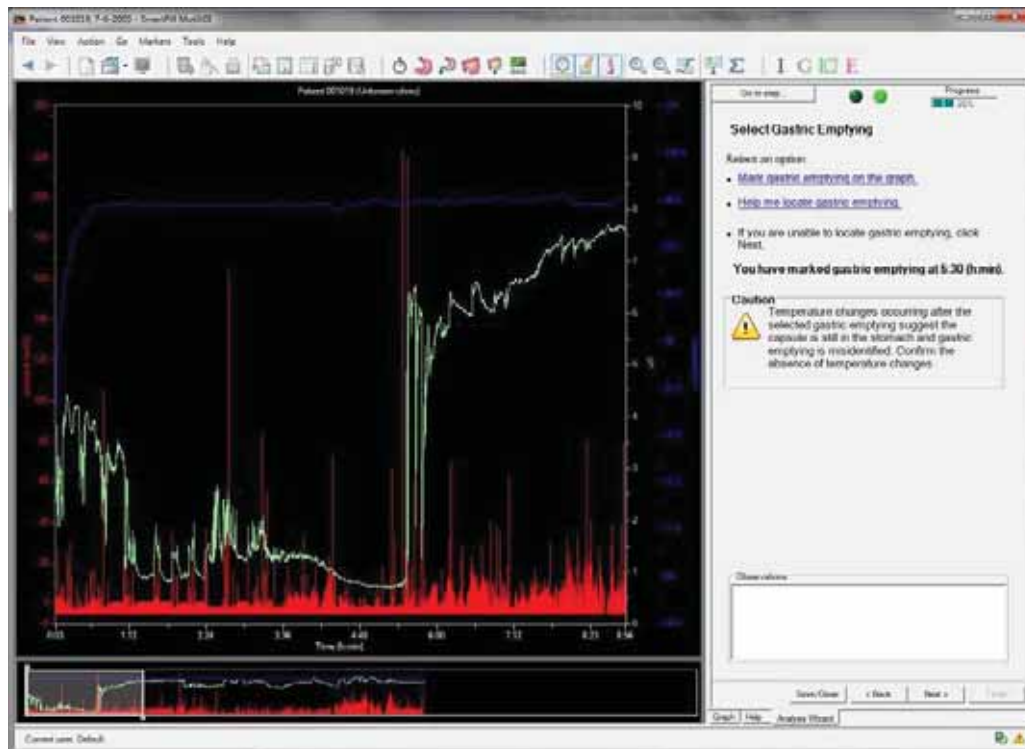


Figure 7 - Eating a meal

In the figure above, the patient ingested a liquid meal (Ensure) at 6 hours after capsule ingestion and ate dinner approximately 8 hours after capsule ingestion. The ingestion of food (Ensure and dinner) caused an abrupt rise in pH (B) and a decrease in temperature (A).

At approximately 12 hours after capsule ingestion, the pH returned to baseline (below pH 2) and remained at baseline until the capsule emptied the stomach 18 hours after ingestion (C).

Select Gastric Emptying



Use GET to evaluate the patient's gastric emptying function. Generally, an abrupt increase of 3 or more pH units occurs as the capsule exits the stomach and enters the duodenum.

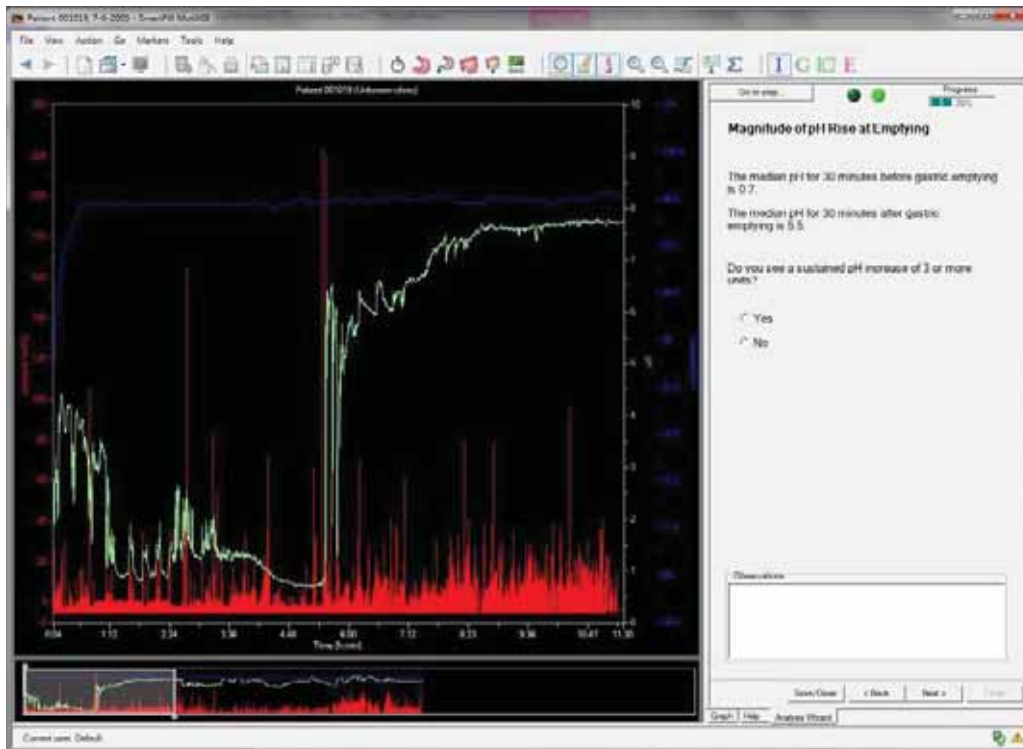
Term	Definition
Gastric emptying	The beginning of the first increase in pH that results in a sustained pH rise.
Sustained pH increase	No transient pH drops occur for greater than 10 minutes.

Caution

Medications, therapies, and diseases may alter gastric or small bowel pH. Alterations in gastric and/or small bowel pH may mask the physiological pH landmark for gastric emptying time.

1. Click Mark gastric emptying on the graph.
2. Move cursor over to the Motilab graph and click on the graph where you believe gastric emptying occurred.
3. Click Next >.

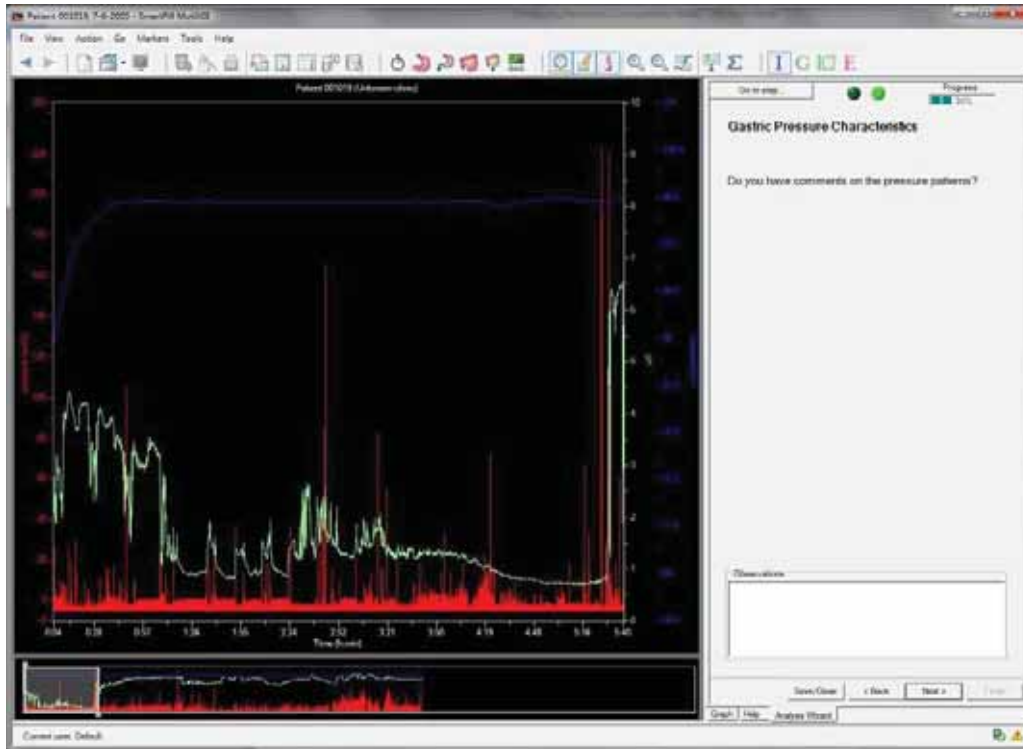
Magnitude of pH Rise at Emptying



Term	Definition
Duodenal pH baseline	Determined by observing the pH within the first 30 minutes after gastric emptying.
Sustained pH increase	No transient pH drops occur for greater than 10 minutes.

► Click Next >.

Gastric Pressure Characteristics



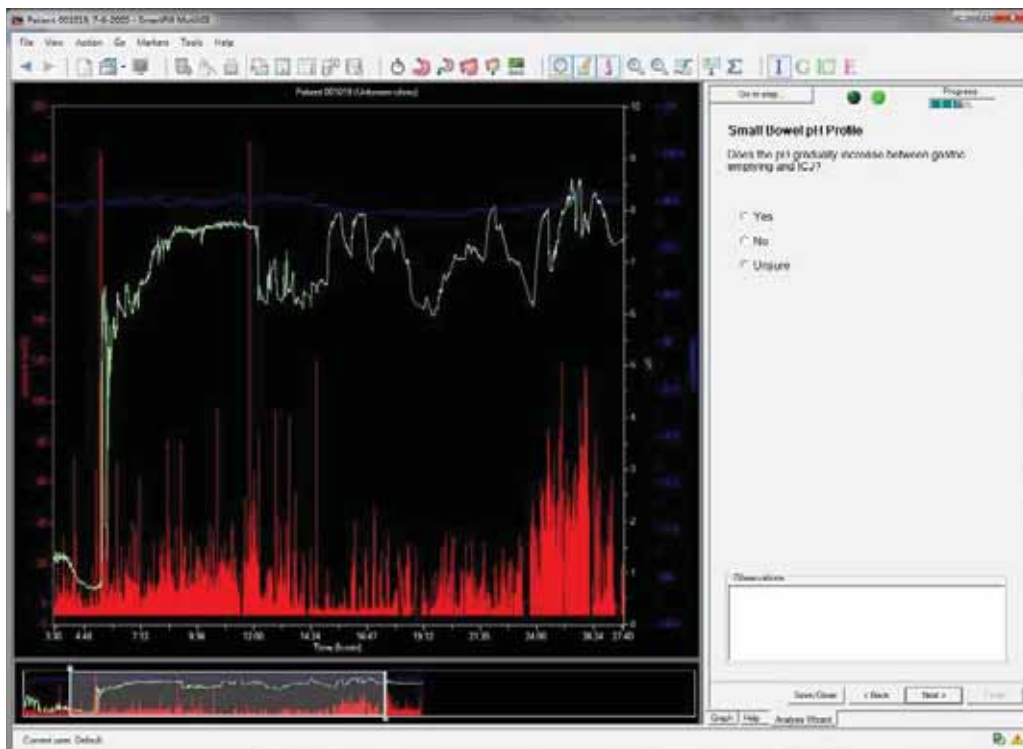
The relevance of SmartPill pressure patterns in the stomach to pressure patterns obtained using manometry is unknown.

► Click Next >.

Small Bowel pH profile

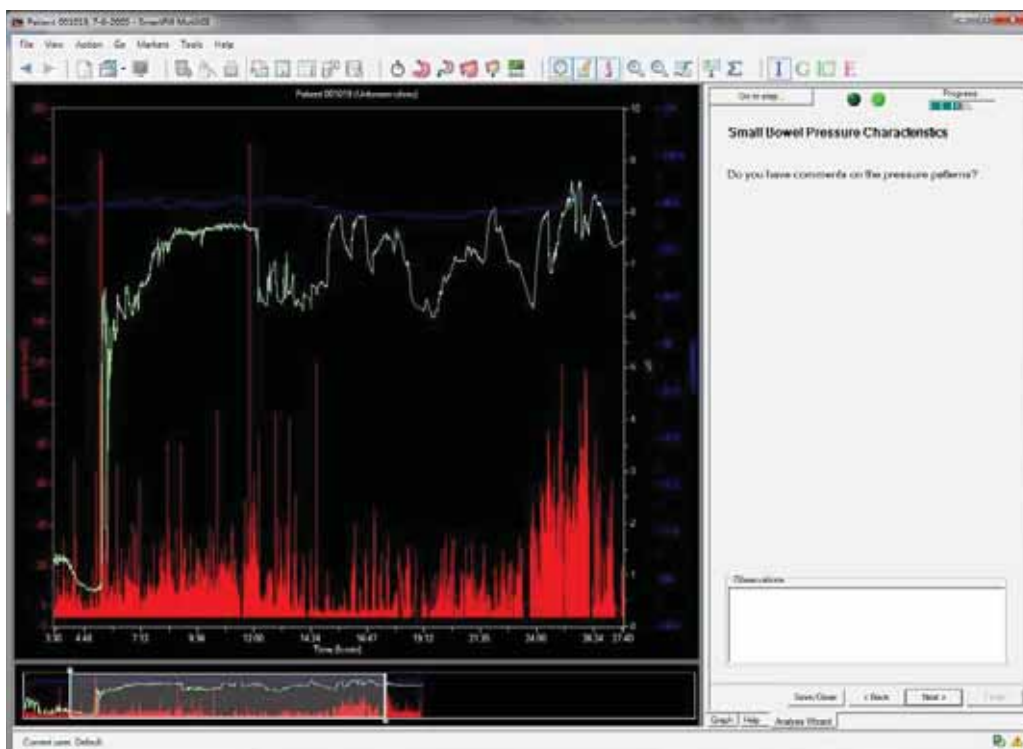
1. Determine whether you observe a gradually rising pH profile characteristic of the small bowel.

Appendix: Electrical Safety



2. Click Next >.

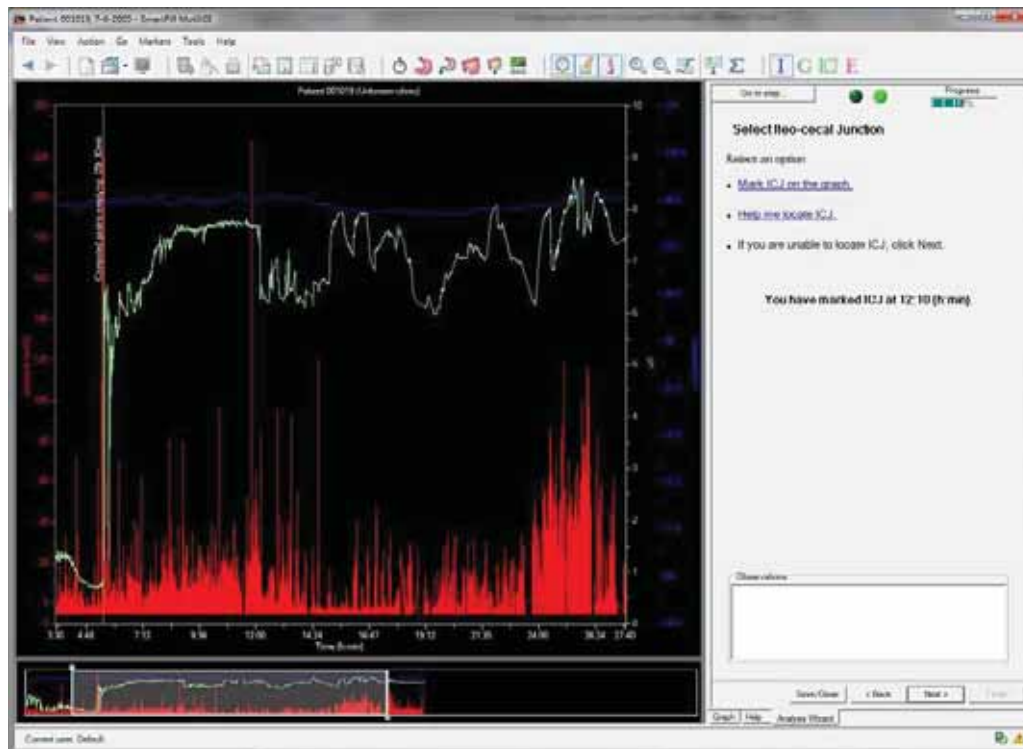
Small Bowel Pressure Characteristics



The clinical significance of SmartPill pressure patterns in the small bowel is unknown.

► Click Next >.

Select Ileo-Cecal Junction



The standard small bowel pH profile shows a gradual pH rise usually followed by a plateau of the pH pattern. Transient pH drops may interrupt this profile but returns to their previous level within 10 minutes.

The pH drop associated with the capsule passing through the ICJ occurs after the gradual sustained increase in pH through the small bowel. This drop of approximately 0.5–1.0 pH units usually occurs between 2–6 hours after gastric emptying.³

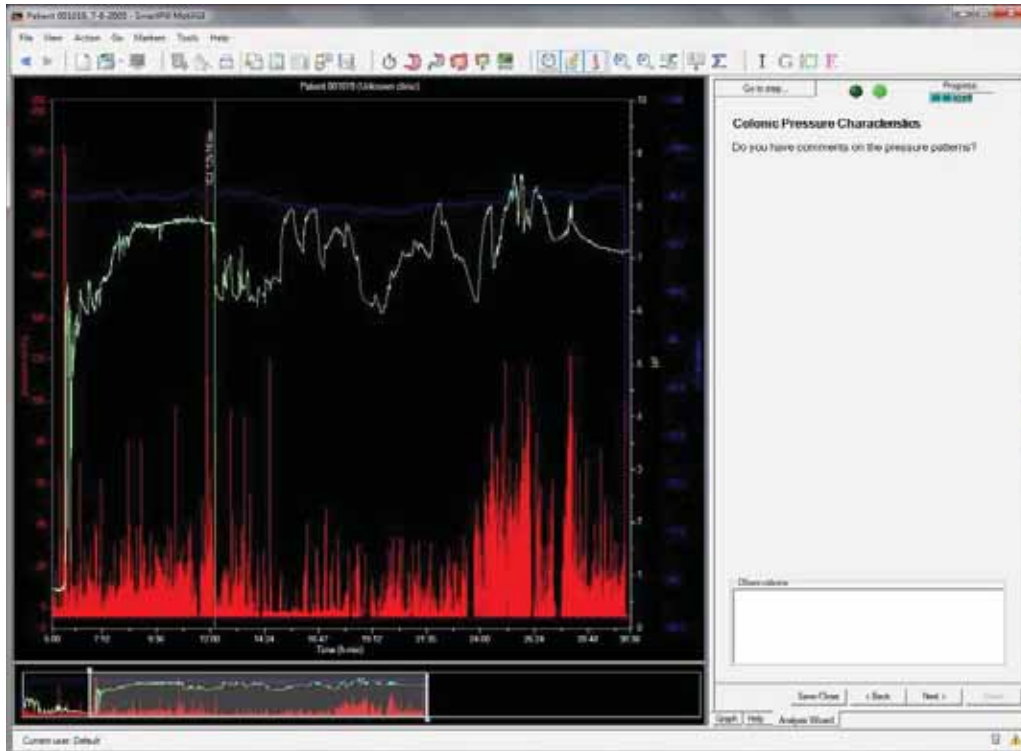
Before ICJ, the pH rises smoothly and continuously in comparison to a more erratic profile after ICJ.

Term	Definition
ICJ	Ileo-Cecal Junction, the start of pH decrease of approximately 0.5–1.0 units.

► Click Next >.

³ Zarate N., Scott SM. Accurate localisation of a fall in pH within the ileo-caecal region: validation using a dual scintigraphic technique. *Am J Physiol Gastrointest Liver Physiol* 2010; 299 (6): G1276-86.

Colonic Pressure Characteristics



The relevance of SmartPill pressure patterns in the colon to colonic pressure patterns obtained using manometry is unknown.

- Click Next >.

Warning: Data Collected During Capsule Low Voltage

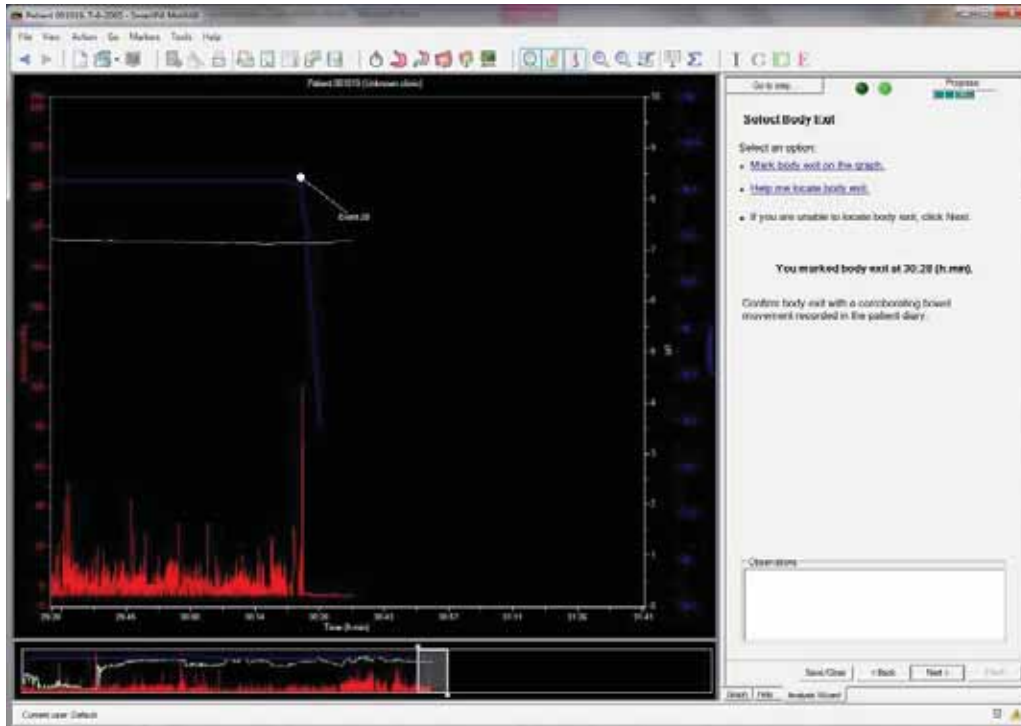
If the MotiliGI software detects a low voltage condition in the capsule, a warning appears.

Caution

When a low voltage warning is present, body exit confirmation cannot be determined solely by temperature drop. Low voltage may cause loss of signal before capsule exits the body. Whole gut and small/large bowel transit times are not definitive without the body exit endpoint. Regional transit times are not valid without start and endpoints.

1. Read and understand the warning.
2. To acknowledge this warning, check the box I Understand.
3. Click Next >.

Select Body Exit



Term	Definition
Body exit	<ul style="list-style-type: none"> The time of the last temperature reading at body temperature, coinciding with an abrupt loss of capsule data. The time of the last abrupt rise in pressure.

An abrupt loss of signal from the capsule does not reliably indicate body exit. You must corroborate (to within 30 minutes) body exit with a recorded bowel movement in the patient diary.

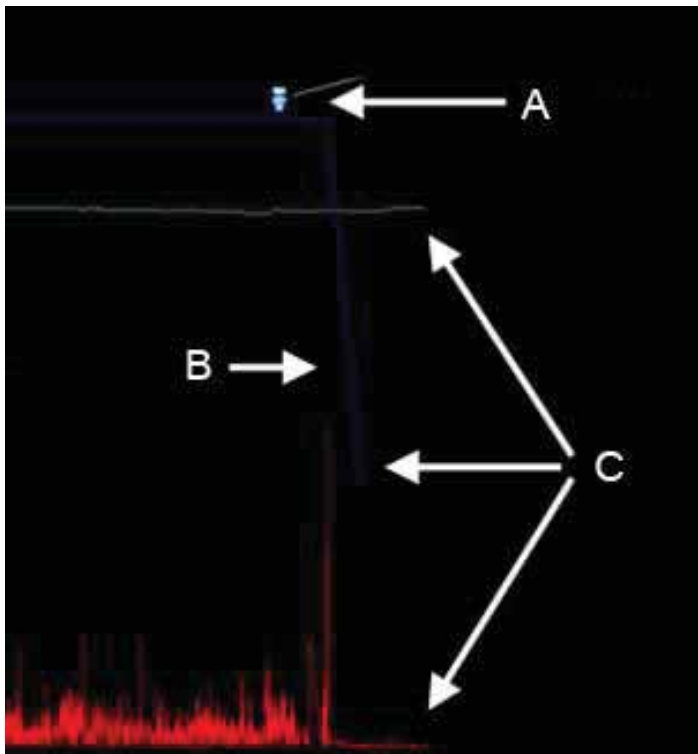


Figure 8 - Body Exit

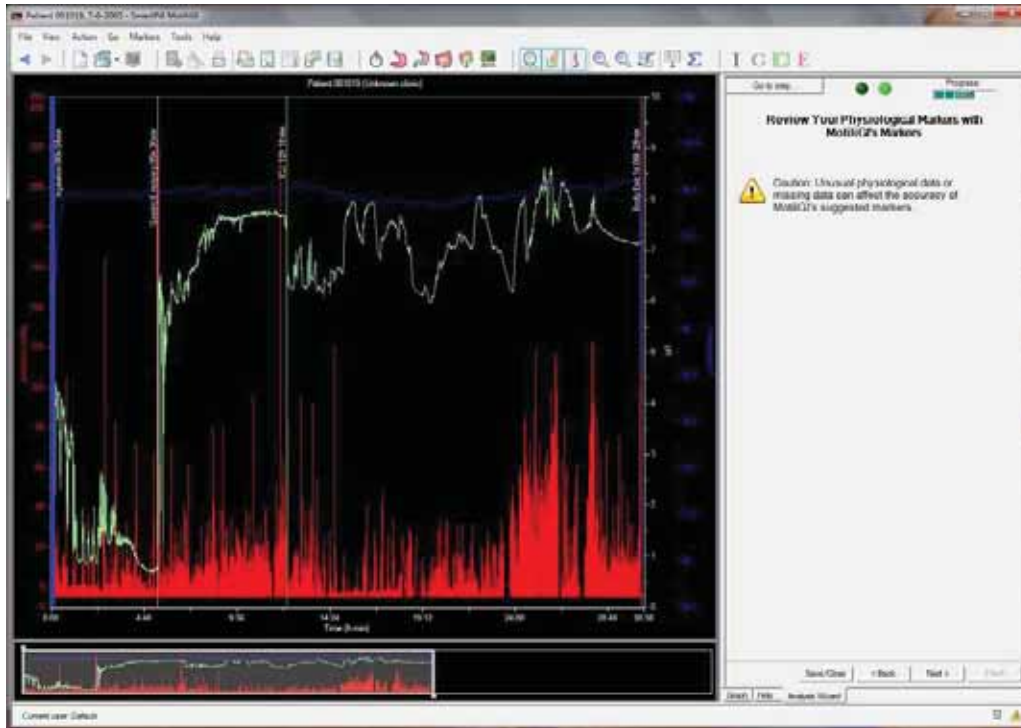
The figure above provides an optimal representation of body exit including a bowel movement event marker on the graph and in the patient diary temperature drop (A), a decrease in temperature (B) and an abrupt loss of data (C).

Caution

If the diary does not contain a bowel movement entry concomitant with a temperature drop and/or loss of pressure and pH signal, the patient should be monitored for symptoms of bowel obstruction. If the patient exhibits symptoms consistent with bowel obstruction, a KUB exam is indicated.

► Click Next >.

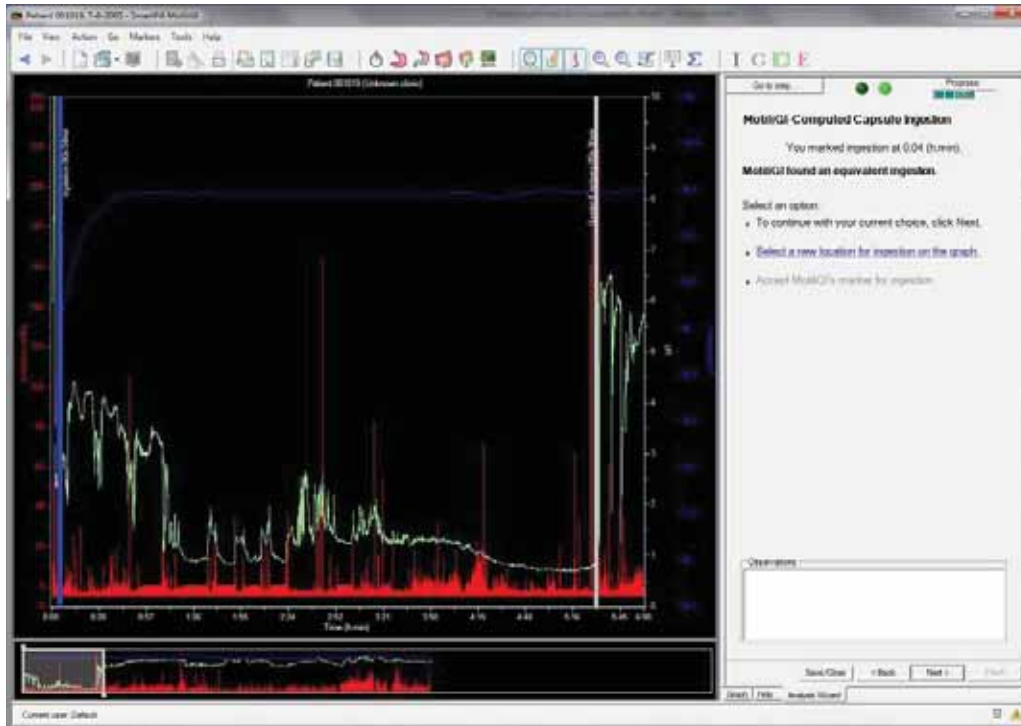
Review Your Physiological Markers with MotiGI's Markers



Term	Description
Computed markers	Dashed vertical line on the graph, labeled “computed.”
Your markers	Solid vertical lines.
Equivalent	Your marker and the computed marker are within 5 minutes of each other, labeled “equivalent.” The computed time is grayed out.

- Click Next >.

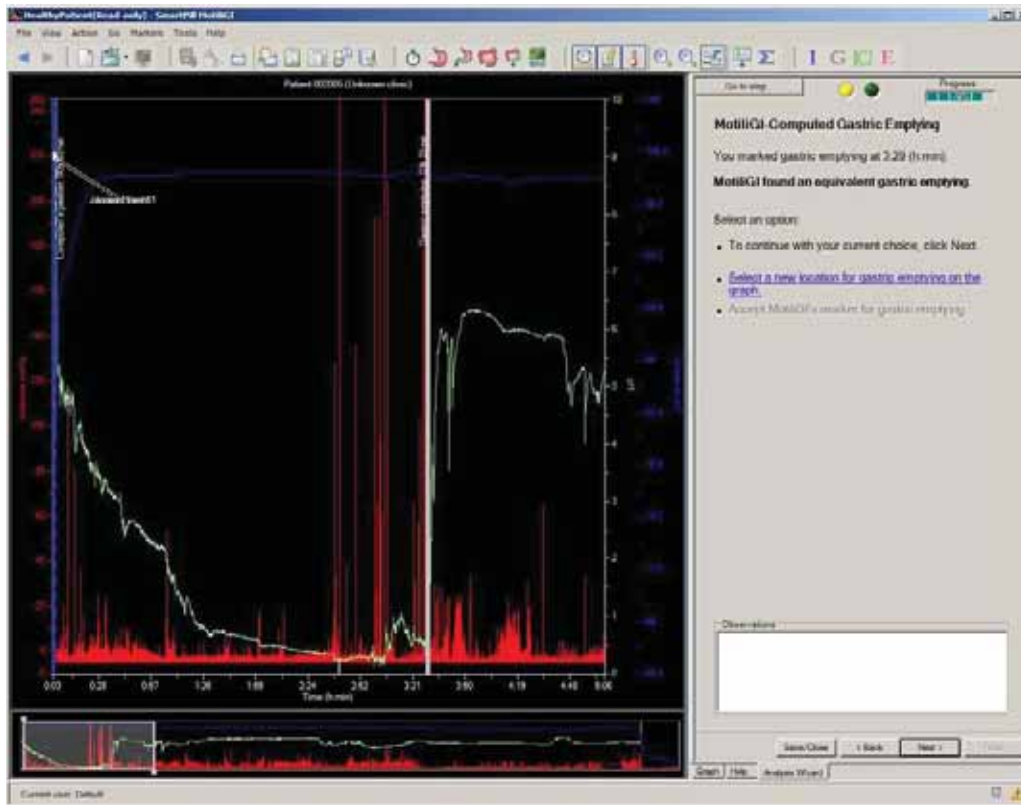
MotiliGI-Computed Capsule Ingestion



MotiliGI determines ingestion by finding the point at which temperature stabilized at body temperature.

1. Follow the prompts.
2. Click Next >.

MotiliGI-Computed Gastric Emptying

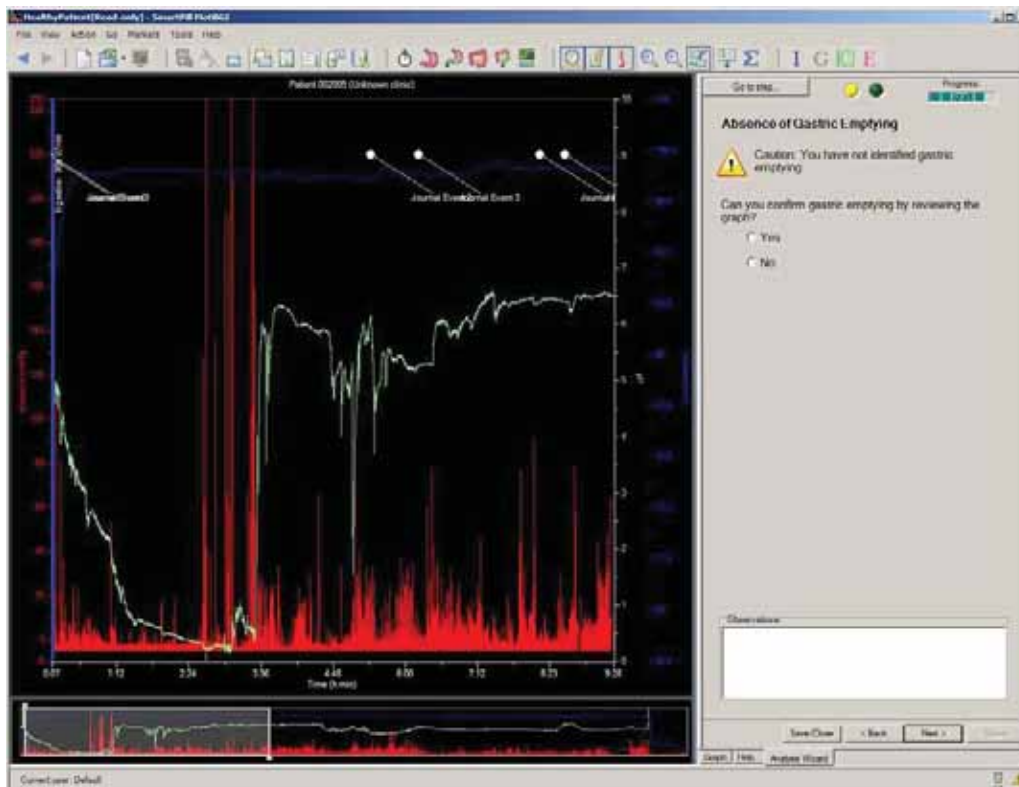


MotiliGI selects gastric emptying by finding the beginning of the abrupt, sustained pH rise. Medications, therapies, and diseases that alter gastric or small bowel pH may influence the accuracy of computed gastric emptying.

1. Follow the prompts.
2. Click Next >.

Absence of Gastric Emptying

If you did not identify gastric emptying, the wizard reminds you of the omission and asks you to select gastric emptying.



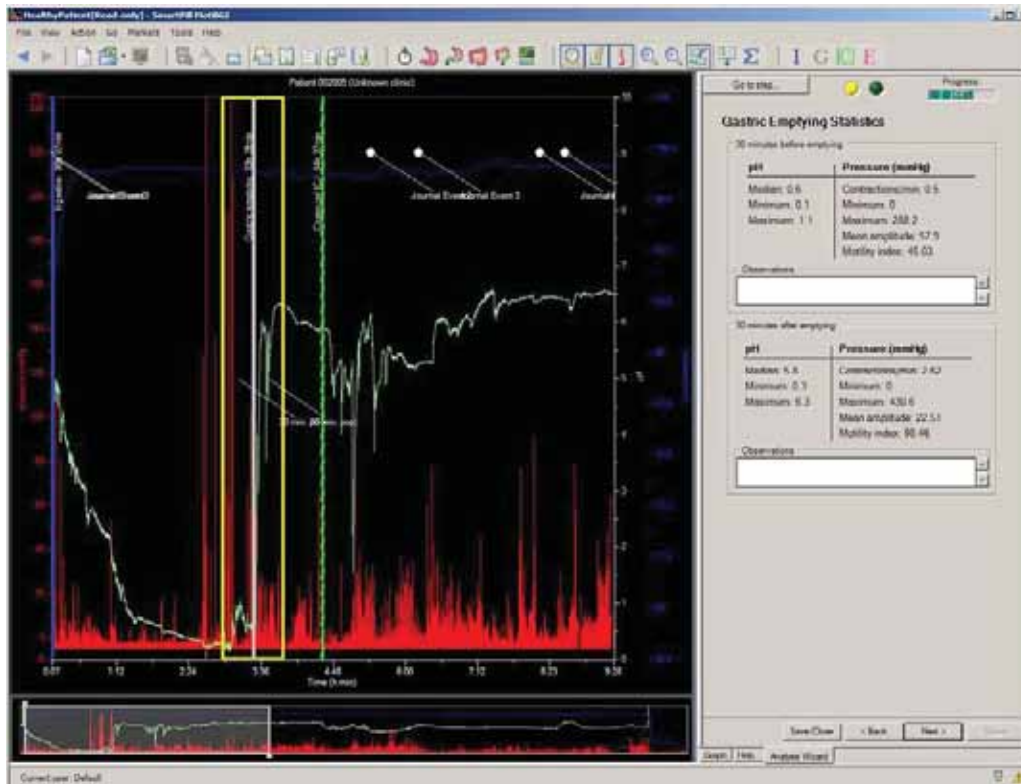
- To review the MotilGI computed gastric emptying, click <Back.

Caution

If gastric emptying is not observed, body exit should be confirmed by analysis of data. If body exit cannot be confirmed, the patient should be monitored for symptoms of bowel obstruction. If the patient exhibits symptoms consistent with bowel obstruction, a KUB exam is indicated to determine capsule exit or retention.

1. Follow the prompts and select Yes or No.
2. Click Next >.

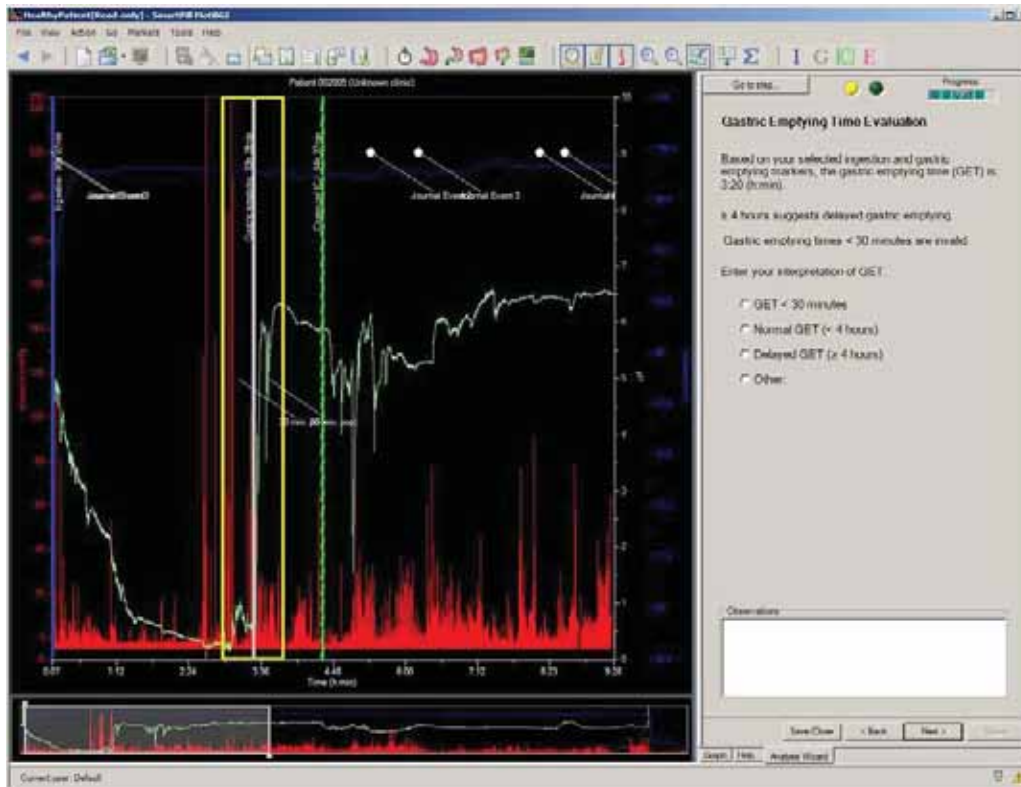
Gastric Emptying Statistics



This step allows you to enter observations about the gastric emptying statistics.

- Click Next >.

Gastric Emptying Time Evaluation

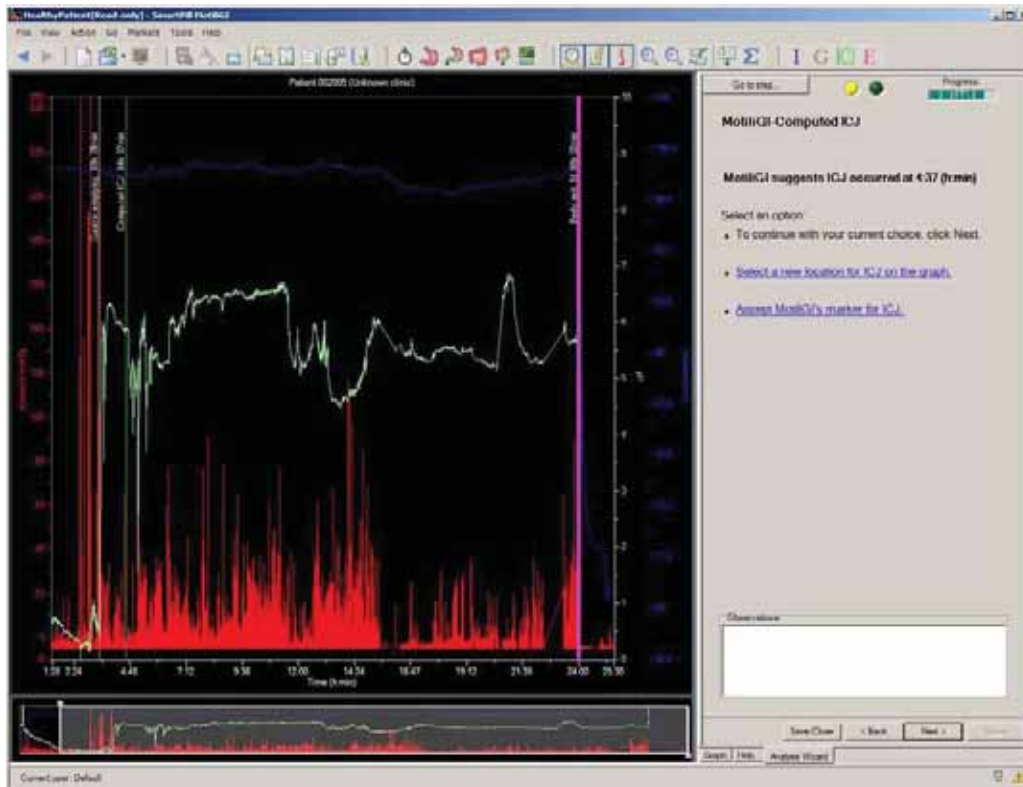


Use GET to evaluate the patient's gastric emptying function.

Term	Definition
Premature gastric emptying	Within 30 minutes of ingestion.
Normal gastric emptying	After 2 hours but before 4 hours of ingestion.
Delayed gastric emptying	After 4 hours of ingestion.

- Click Next >.

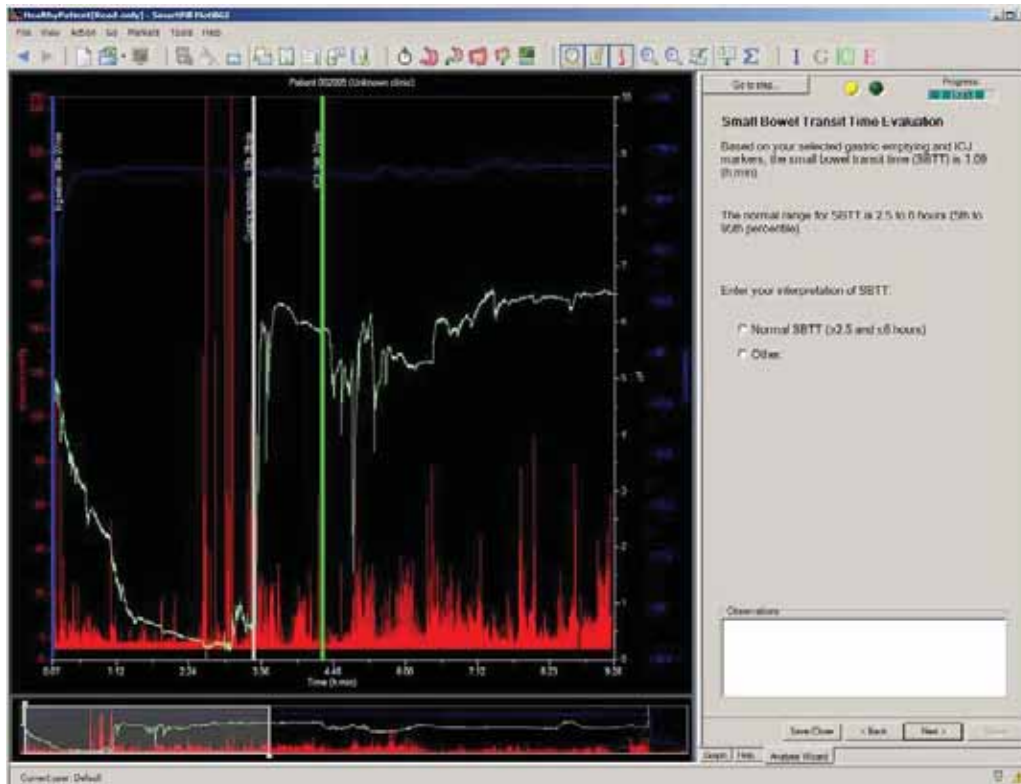
MotiliGI-Computed ICJ



MotiliGI selects ICJ by looking for the first and largest pH drop between 30 minutes and 6 hours after gastric emptying.

1. Follow the prompts.
2. Click Next >.

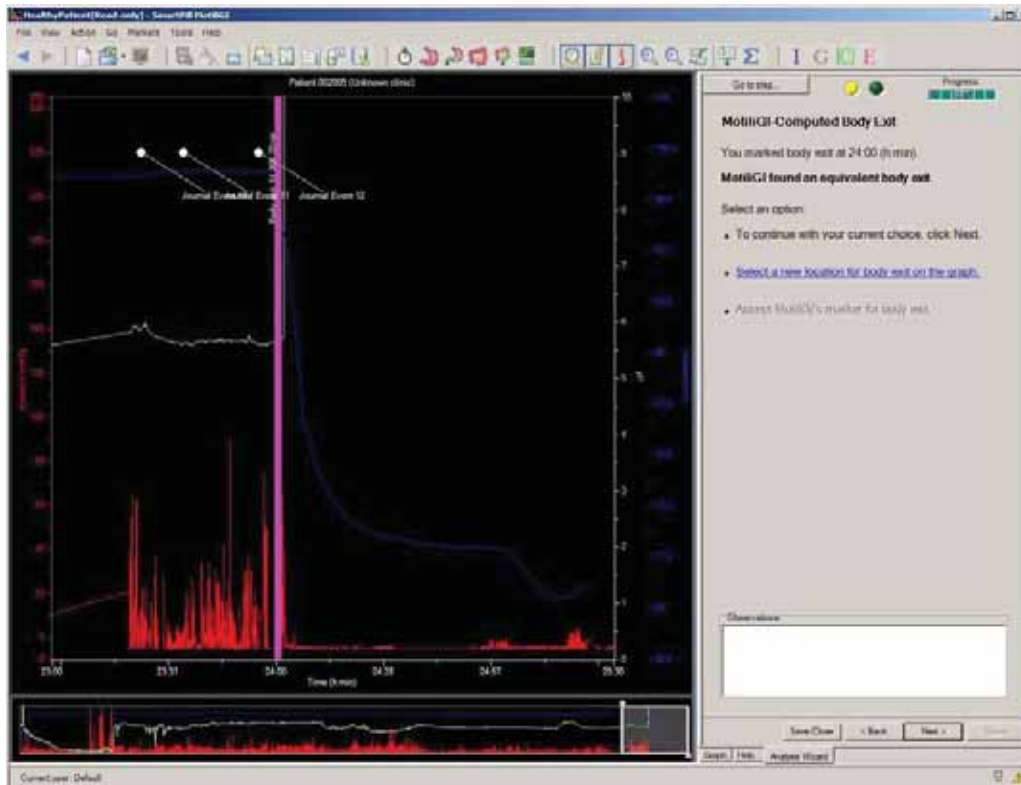
Small Bowel Transit Time Evaluation



The clinical significance of SmartPill's transit time in the small bowel is unknown.

- Click Next >.

MotiliGI-Computed Body Exit



MotiliGI selects body exit based on temperature and pressure. An abrupt loss of signal from the capsule does not reliably indicate body exit. You must corroborate (to within 30 minutes) body exit with a recorded bowel movement in the patient diary.

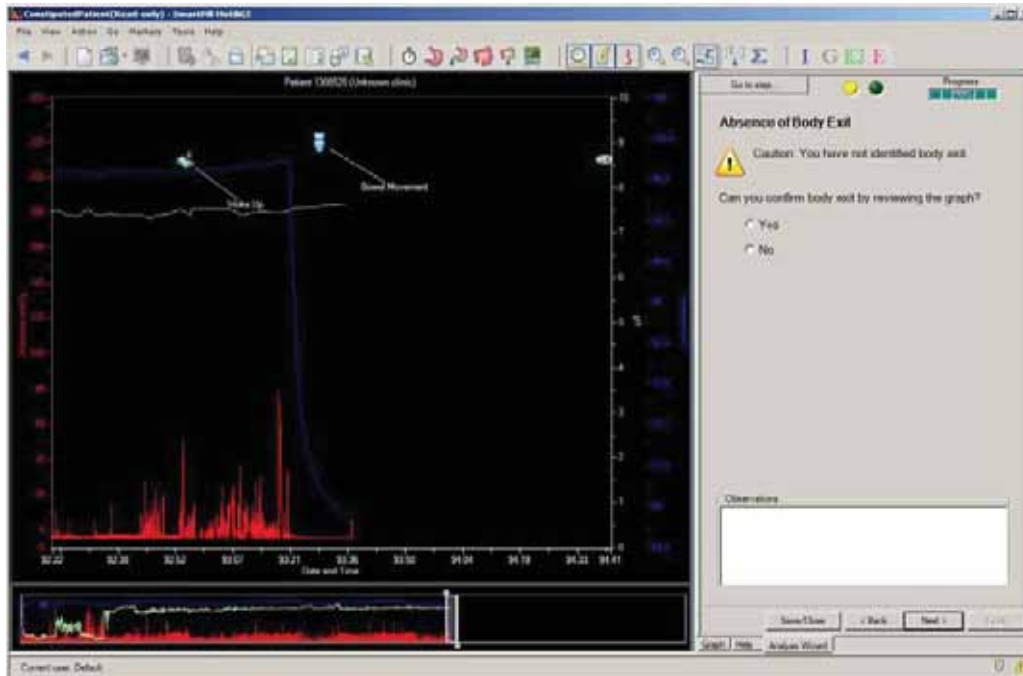
Caution

If the diary does not contain a bowel movement entry concomitant with a temperature drop and/or loss of pressure\pH signal, the patient should be monitored for symptoms of bowel obstruction. If the patient exhibits symptoms consistent with bowel obstruction, a KUB exam is indicated.

1. Follow the prompts.
2. Click Next >.

Absence of Body Exit

If you did not identify body exit, this step appears.



- To review the computed body exit, click <Back.

Caution

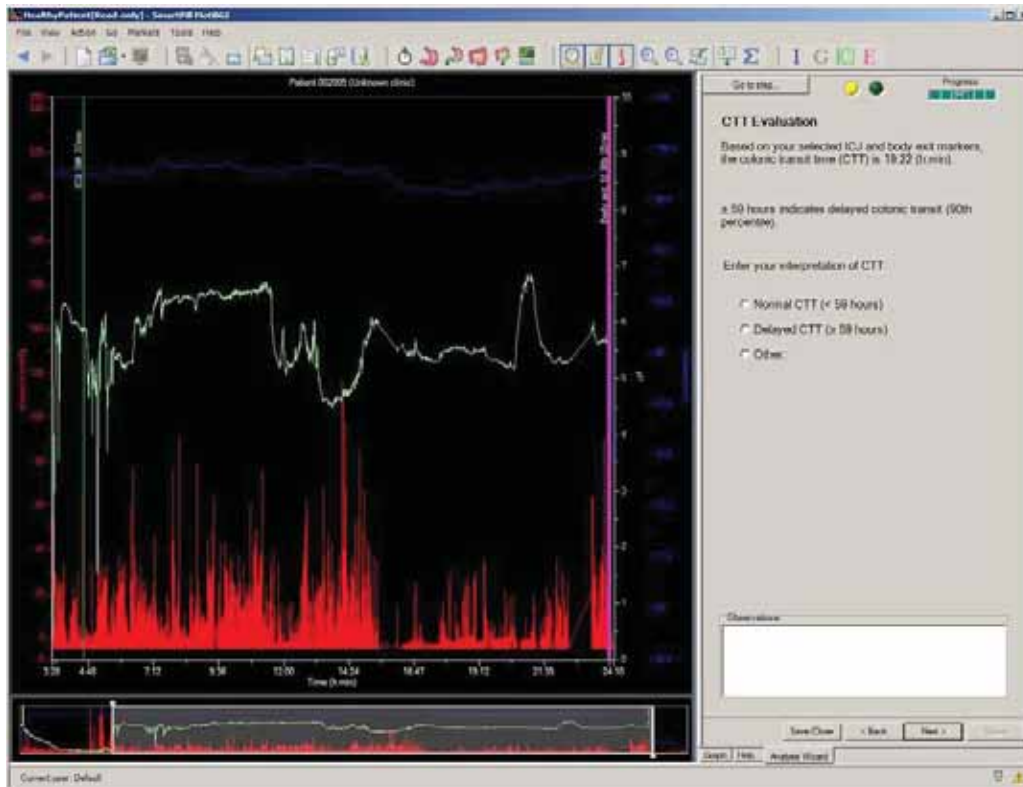
If the diary does not contain a bowel movement entry concomitant with a temperature drop and/or loss of pressure and pH signal, the patient should be monitored for symptoms of bowel obstruction. If the patient exhibits symptoms consistent with bowel obstruction, a KUB exam is indicated.

Caution

If MotiliGI displays a low voltage indication on the graph, the validity of data collected during the low voltage state cannot be determined, including any temperature drops that mimic body exit.

1. Select Yes or No.
2. Click Next >.

Colonic Transit Time Evaluation

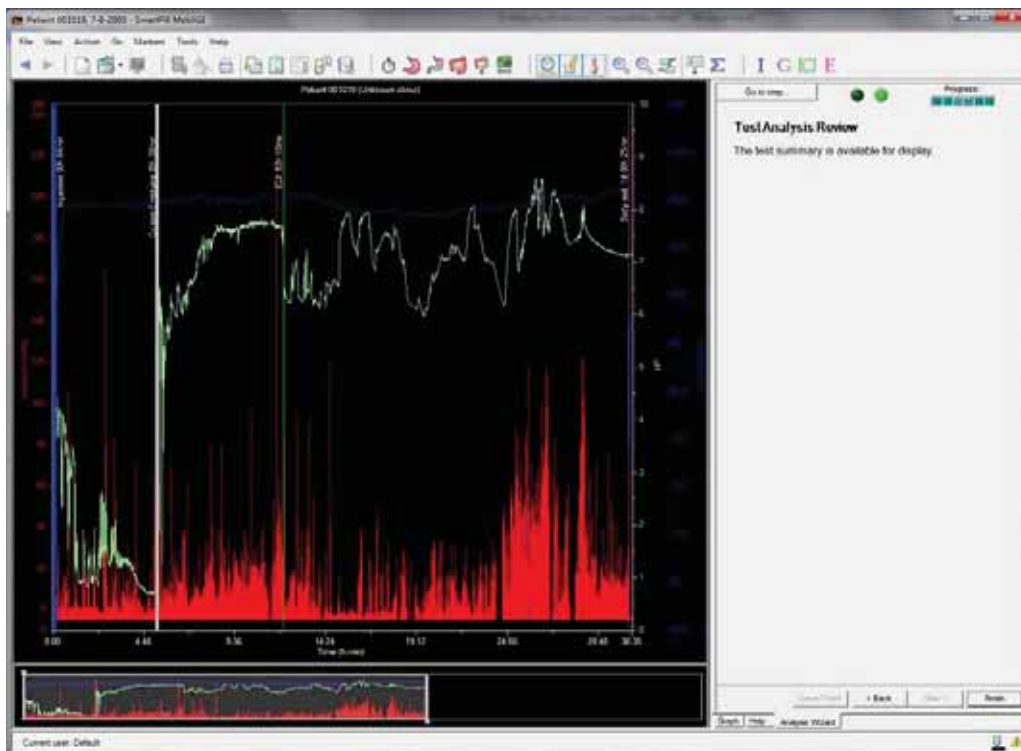


MotiliGI uses your interpretation of ICJ (colonic entry) and body exit events to compute the CTT.

- ▶ Click Next >.

Test Analysis Review

The analysis is complete.




- ▶ Click Finish.

Reading Test Summary Reports

When the test analysis wizard is complete, a summary report of results and descriptive data appears.

These reports summarize test data, statistics, and observations, and help evaluate delayed gastric emptying, constipation and gastrointestinal motility.

You can display the test summary reports any time:

- Click the  toolbar icon.
- Select View > Test Summary.

Transit Data Tab



This tab lets you compare your transit time data to the computed data.

The screenshot shows a 'Test Summary' window with tabs for 'Transit Data', 'Descriptive Data', 'Interpretations', and 'Properties'. The 'Transit Data' tab is active. It contains a 'Patient Information' section with fields for Patient Name, ID (001019), and Test Start Date (7/6/2005). Below this is a 'Transit Times' section with a table comparing 'Physician-Confirmed (hr:min)' and 'Computed (hr:min)' values for five different transit time metrics. At the bottom are 'Generate Report' and 'OK' buttons.

	Physician-Confirmed (hr:min)	Computed (hr:min)
Gastric Emptying Time ≥ 4 hours suggests delayed gastric emptying	5:25	5:25
Small Bowel Transit Time Normal range 2.5 to 6 hours	6:35	6:35
Colonic Transit Time ≥ 5.9 hours indicates delayed colonic transit	18:22	18:22
Small/Large Bowel Transit Time ≥ 4.5 hours indicates delayed SLBTT	24:58	24:58
Whole Gut Transit Time Normal < 73 hours	30:24	30:24

- If one or more endpoint markers are not defined, n/a (not applicable) appears for the transit time value.
- Combined small and large bowel transit time (SLBTT) can be used as a surrogate measure for CTT when CTT cannot be determined.

You can edit the data at any time, and the corresponding reports update accordingly:

Action	Tools to use	For more information
Edit ingestion time, gastric emptying time and body exit time	Graph marker tools 	Chapter 8: MotiliGI Features
Edit or enter motility statistics	Statistics Mode tools 	Chapter 8: MotiliGI Features

Descriptive Data Tab

This tab summarizes calculated pressure and pH data points. The clinical significance of these pressure and pH descriptive statistics is unknown.

Test Summary

Transit Data | **Descriptive Data** | Interpretations | Properties

Patient information

Patient name: Doe, John H. ID: 002005 Test start date: 3/31/2005

	Motility index	Contractions per minute	Pressure (mm Hg)		pH		
			Mean	High	Low	Median	High
Stomach		0.5	2.1	347.1	-0.1	0.7	5.2
Antrum	45.0	0.5	3.2	288.2	0.1	0.6	1.1
Duodenum	98.5	2.6	3.6	430.6	0.3	5.8	6.3
Small bowel		2.4	2.9	430.6	0.3	6.0	6.3
Colon		2.2	3.0	121.5	1.5	5.5	6.8

Test notes

Gastric values are derived from the physician-defined ingestion and the physician-defined gastric emptying.
 Antrum values are derived from the physician-defined gastric emptying.
 Duodenum values are derived from the physician-defined gastric emptying.
 Small bowel values are derived from the physician-defined gastric emptying and the physician-defined ICJ.
 Colonic values are derived from the physician-defined ICJ and the physician-defined body exit.


OK

Interpretations Tab

This tab displays notes made during analysis and provides a text section for capturing post-test observations, conclusions and recommendations. The information entered in this tab becomes part of the patient's record.

Alternatively, you can enter interpretations through the Interpretations tab of the Patient Information screen. Interpretations can be entered before or after the test is downloaded.

Click  to use preconfigured templates to describe test interpretations.

Goal	Action
Create a template	Enter a title in the Template field and a description in the text field below it. Click Save Template.
Delete a template	Select the title in the Template list. Click Delete Template.
Add the description to the patient's record	Select the template title. Click  .
Remove the description from the patient's record	Select the description in the Patient record box. Click Remove Entry.
Print a description in the final report	Select checkboxes in the Patient record box.

Properties Tab

This tab displays information about the equipment used for the test.

The screenshot shows a software window titled "Test Summary" with a tabbed interface. The "Properties" tab is selected. It contains three sections: "Receiver information", "Capsule information", and "MotiliGI information". Each section has input fields for various parameters, some of which are currently set to "Unknown".

Section	Parameter	Value
Receiver information	Serial number	Unknown
	Software version	Unknown
	Protocol version	Unknown
Capsule information	Serial number	28
	Calibration factor	55
MotiliGI information	Software version	Unknown

An "OK" button is located at the bottom right of the window.

Examples of Physiological Markers

Ingestion

The ingestion landmark starts the test and is the beginning of GET. MotiliGI determines the ingestion landmark by finding the point just before temperature stabilizes to body temperature, as illustrated below. The pH also starts to become more acidic.

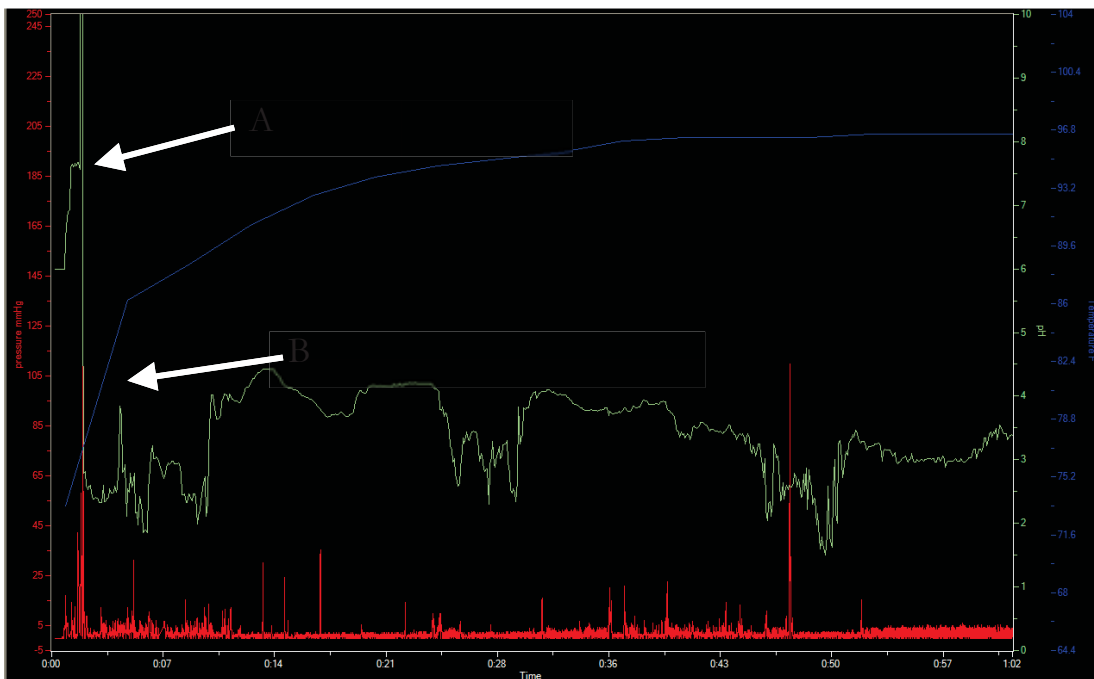


Figure 9 - Ingestion

Gastric Emptying

Gastric emptying marks the end of GET and the start of SBT^T as shown below.

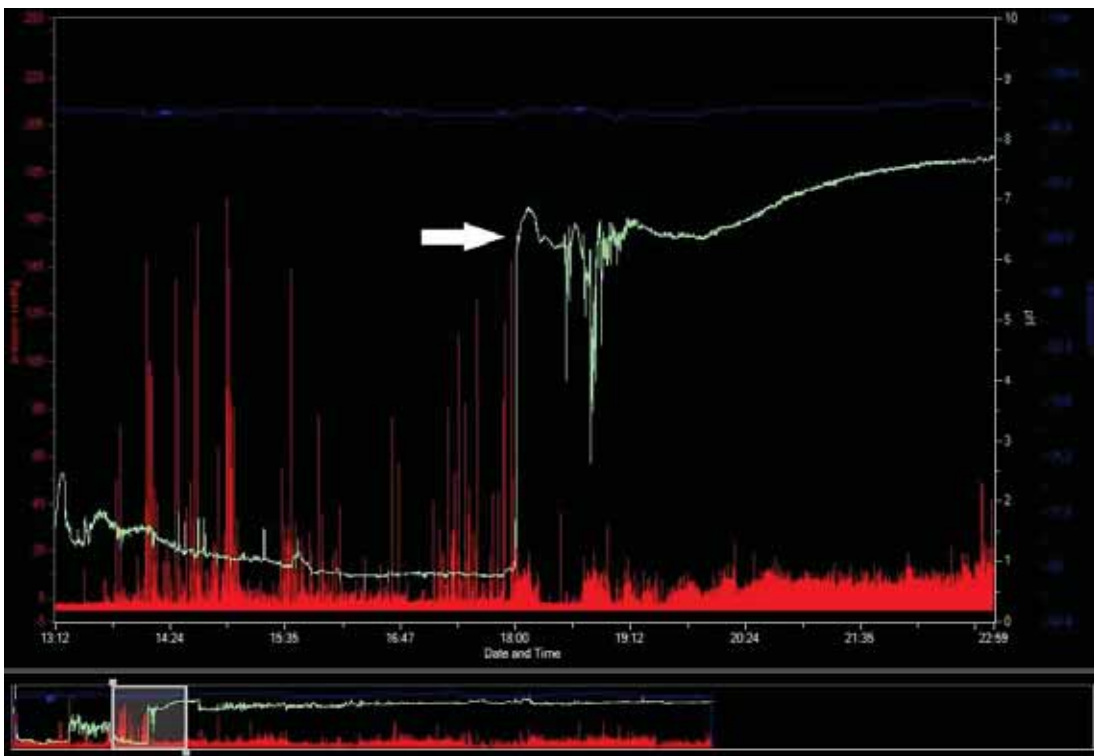


Figure 10 - Gastric Emptying

MotiliGI looks for an abrupt increase of 3 or more pH unit as the capsule exits the stomach and enters the duodenum.

Factors that may influence gastric emptying include:

- Medications, therapies, and diseases that alter gastric or small bowel pH.

ICJ

ICJ is usually found between 2 to 6 hours after gastric emptying, as seen below. ICJ marks the transition of the capsule from the small bowel into the colon. ICJ marks the end of SBT^T and the start of CTT^T.

How to find ICJ:

1. Locate gastric emptying
 2. Look for a steady rise in pH followed by a plateau.
 3. Look for a 1 to 2 unit pH drop between 2 to 6 hours after gastric emptying
- A high amplitude spike in pressure is often seen near ICJ
 - After ICJ an erratic pH profile in the colon is characteristic

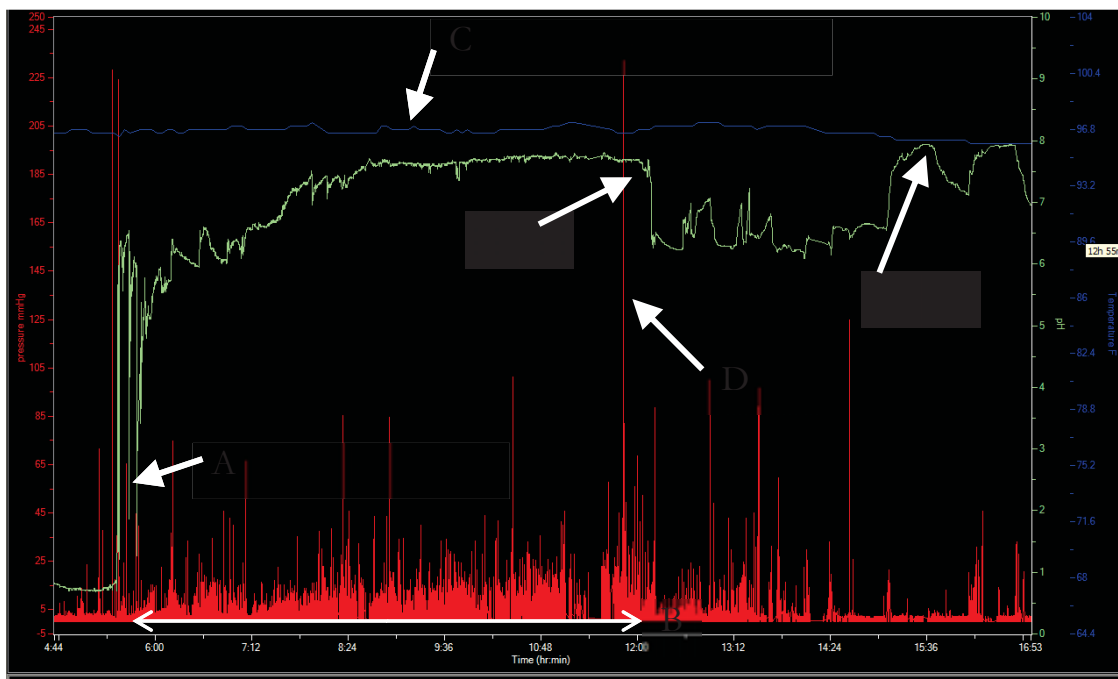


Figure 11 - ICJ

Body Exit Time

Body exit marks the end of the test as shown below. Body exit marks the exit of the capsule from the body and the end of WGTT^T and CTT^T.

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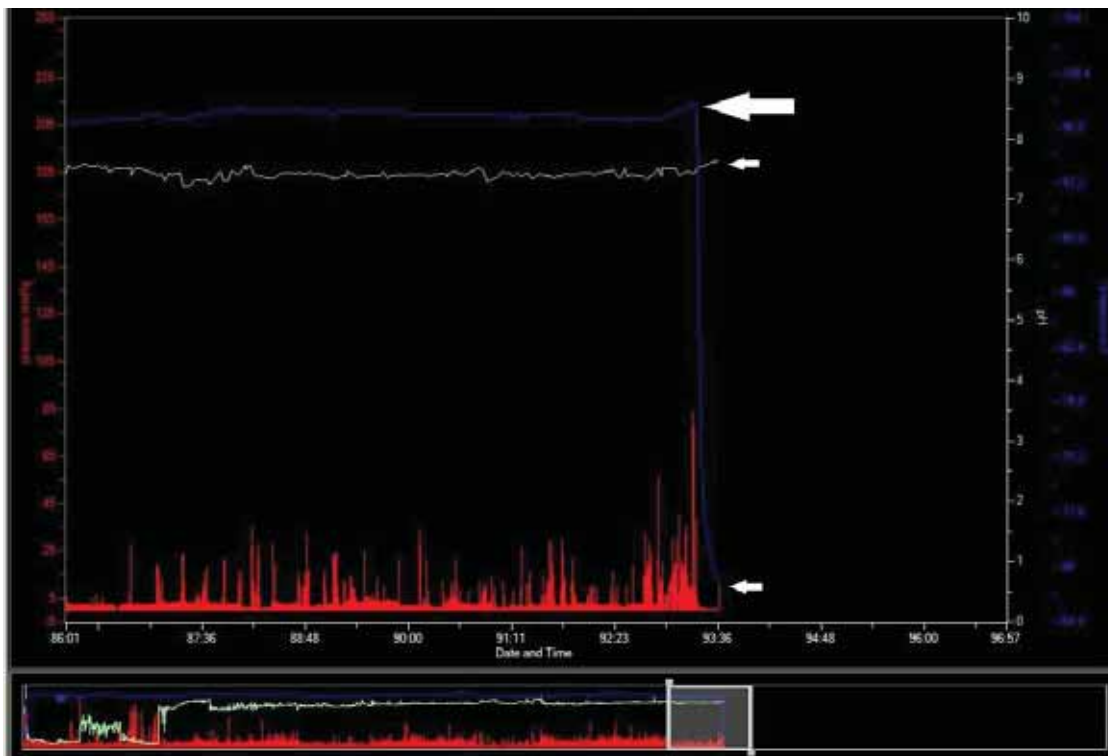


Figure 12 - Body Exit

MotiliGI Features

MotiliGI User Interface

The MotiliGI user interface consists of main dropdown menus, toolbar, graph area, control panels, time slider control and status bar.

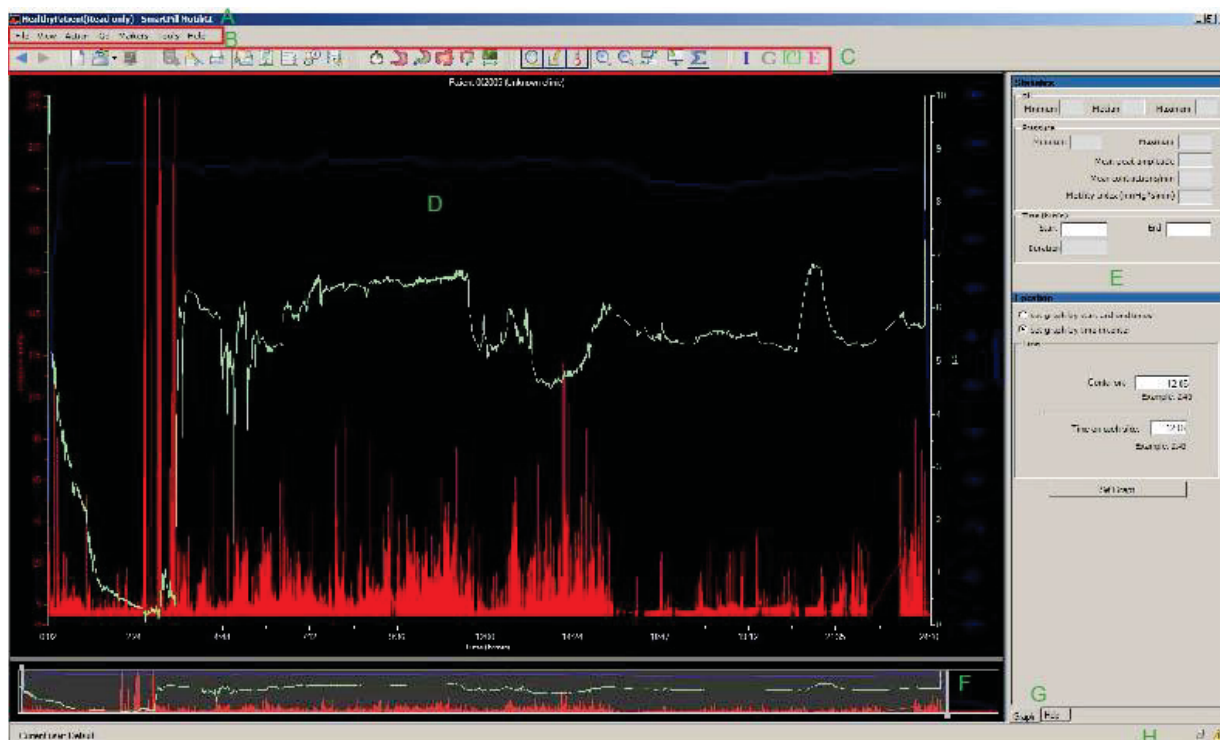


Figure 13 - MotiliGI User Interface

Titlebar

Labeled A on Figure 13.




The titlebar displays the filename constructed from the Patient ID and the time and date of the beginning of the test, for example Patient ID #207516, 9:29:44 AM, 28 March, 2007.

Main Menus

Labeled B on Figure 13.

Toolbar Icons

Labeled C on Figure 13.

	Back to Previous View
	Forward to Next View
	New – Start a new test

Appendix: Electrical Safety

	Open – Open a test. You can choose to open by patient name or filename.
	Live Monitoring
	Download Data
	Analyze Test
	Print
	Print Preview
	Generate Report
	Test Summary
	Patient Info
	Annotation Viewer
	Display Ingestion
	Display Stomach
	Display Gastric Emptying
	Display Small/Large Bowel
	Display Body Exit
	Display Entire Test
	Show/Hide Pressure
	Show/Hide pH
	Show/Hide Temperature
	Zoom In
	Zoom Out
	Show/Hide Annotations
	Annotations
	Statistics
	Set Ingestion Marker

	Set Gastric Emptying Marker
---	-----------------------------

	Set ICJ Marker
---	----------------

	Set Body Exit Marker
---	----------------------

Graph Area

Labeled D on Figure 13.

The graph area presents plots of pressure, pH, and temperature data captured throughout the test, and point and range annotations.

The left Y-axis is the pressure scale, the right Y-axes are pH and temperature scales, and the X-axis is the elapsed time of the test.

Data Panels

Labeled E on Figure 13.

MotiliGI's two data panels, positioned to the right of the graph area, provide information and controls related to test "Statistics" and graph "Location."

To show or hide the data panel:

- ▶ Double-clicking the bar between the graph and the data panels.

Time Slider Control

Labeled F on Figure 13.

The time slider control shows what appears in the main graph in relation to the entire test.

Display Tabs

Labeled G on Figure 13.

Navigate between the Graph (statistics panel), Help (user manual) and Analysis Wizard (not pictured).

To show or hide the data panel:



- ▶ Double-clicking the bar between the graph and the data panels.

Status Bar






Labeled H on Figure 13.

The status bar displays the username, and data receiver and test status icons. MotiliGI uses 7 icons to indicate the status of the data receiver and test.

Data Receiver Status Icons

Icon	Description
	Disconnected – No USB connection exists between MotiliGI and the data receiver.
	Connected – MotiliGI is communicating with the data receiver.


Test Status Icons

Icon	Description
	Capsule Not Found – MotiliGI is not receiving data from a capsule and indicates a capsule has not been activated or the capsule is out of range of the data receiver.
	Test Status Unknown – MotiliGI cannot determine the status of the test.
	Test Ready to Begin – MotiliGI is properly communicating with the data receiver and the capsule. This icon appears during capsule calibration.
	Test in Progress – The test has begun. The data receiver is recording data from the capsule.
	Test Ended – Data collection has stopped. This icon appears during data download.

MotiliGI Keyboard Shortcuts

Keyboard Shortcut	Effect
Control X	Cut text from any form field, copied to the clipboard
Control C	Copy text from any form field to the clipboard
Control V	Paste text from the clipboard to any form field
Tab	Move from one text field to the next
Enter	Press the default button for the current form, panel, or dialog box


Opening a Test by the Patient's Name

- Open a test:
 - Click  on the toolbar.
 - Click File > Open
- Select By Patient Name. The Find Patient window appears.

Clinic #	First name	Last name	Patient #	Test Start Date	Downloaded?
			001015	6/3/2005 8:50:21 AM	Yes
			001019	7/6/2005 8:22:05 AM	Yes
1	craig	ginapp	105	11/8/2006 8:51:39 AM	Yes

- To show all tests in the Results box, click Show All Tests.
- To reduce the size of the list, enter all or part of the patient's name or patient ID. You can also enter a test date or range of dates in the "Find by test date" box.
3. Click Search. MotiliGI displays matching tests in the Results box.
4. Click a row to select the patient's test.
5. Click Open.

Opening a Test by the File Name

1. Open a test:
 - Click  on the toolbar.
 - Click File > Open
2. Select By Filename. The Open File screen appears.
3. Browse to the test file:
 - Windows XP: C:\Documents and Settings\All Users\Application Data\SmartPill\Tests
 - Windows 7: C:\ Program Data\SmartPill\Tests
4. Click Open.


Closing a Test

- Select File > Close.

MotiliGI saves changes to the test when you close.

Exiting MotiliGI

MotiliGI saves changes to the test when you exit. To exit MotiliGI, either:

- Select File > Exit
- Close using the  in the upper right hand corner.

Caution

Do not close MotiliGI while operating the Test Initiation Wizard because data can be lost. Complete or abort the Wizard first.

Caution

Do not close MotiliGI while downloading a test because data can be lost. Allow the test to fully download.

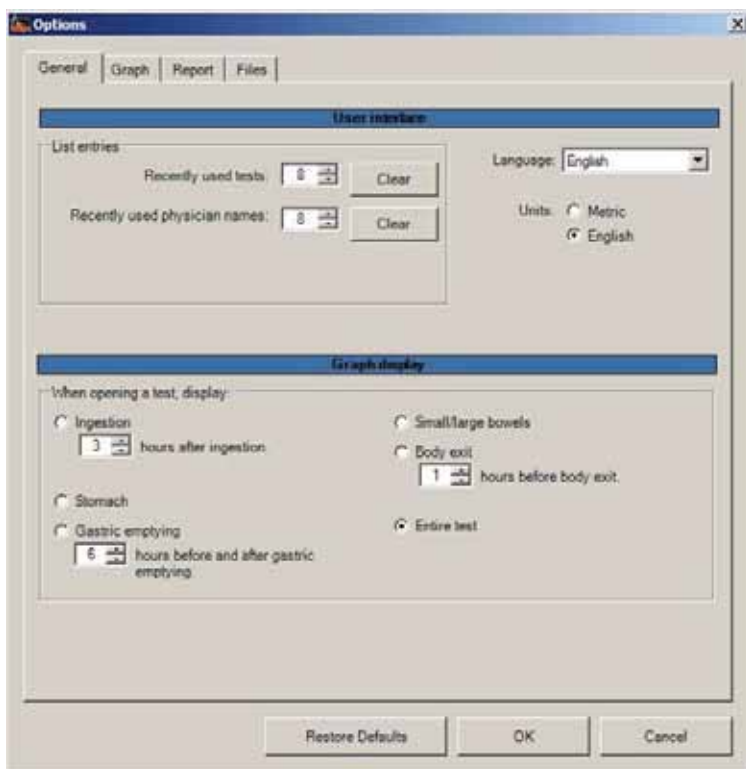
Setting General User Preferences

Each user can have saved preferences for the General, Graph and File tabs. Report preferences apply to all users.

To customize the look and feel of the user interface:

- Select Tools > Options.

General Tab



You can select preferences for the User Interface:

- The number of tests appearing in the File > Recent Tests menu.

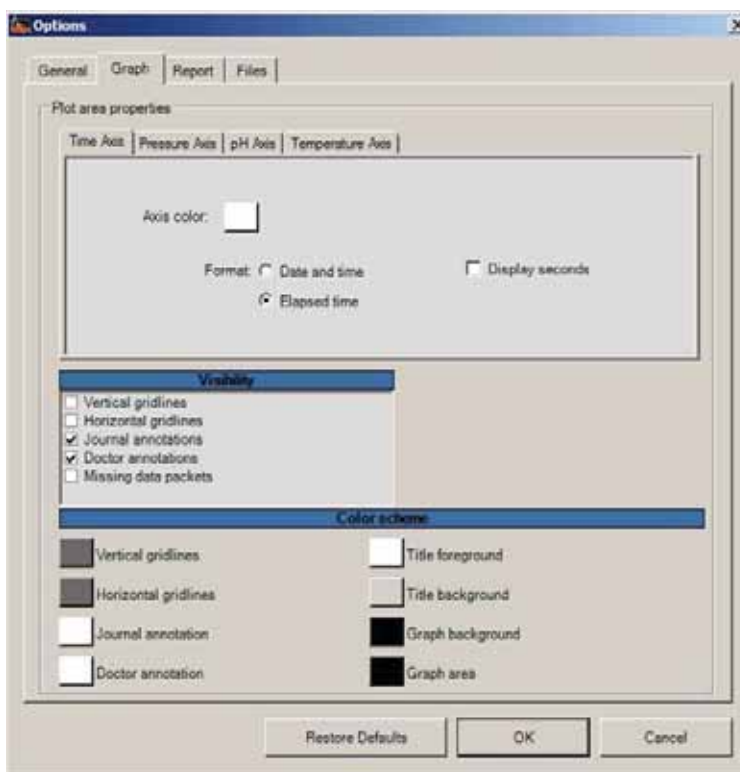
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- The number of physician's names appearing in the Ordering and Primary Care Physician drop down lists on the General tab of the Enter Patient Information screen.
- The display language. Changes will take effect when you restart MotiliGI.
- The unit of measure, English or metric.

You can select preferences for the view displayed when MotiliGI opens a test:

- Ingestion and the number of hours displayed after ingestion
- Stomach
- Gastric emptying and the number of hours displayed before and after gastric emptying
- Small/large bowel
- Body exit and the number of hours displayed before body exit
- Entire test

Graph Tab



You can select preferences for the Plot Area Properties for Time, Pressure, pH and Temperature:

- Color, line style, and point style of data plot

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- Show or hide the plot
- The ranges, tick values and colors of the X and Y axes

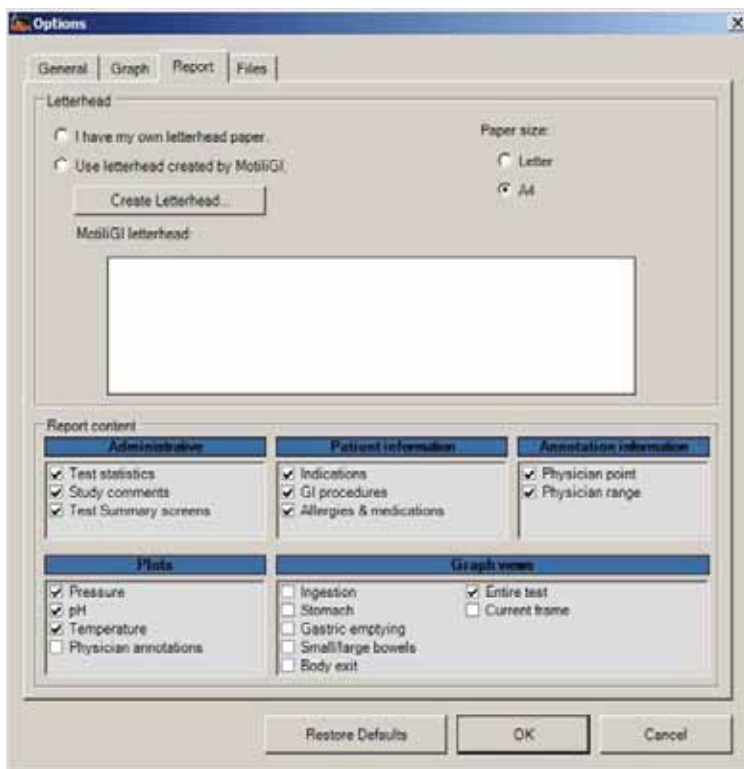
You can select preferences for Visibility:

- Show or hide gridlines, annotations, and missing data packets

You can select preferences for Color Scheme:

- The color of gridlines, annotations, title text, and background color

Report Tab



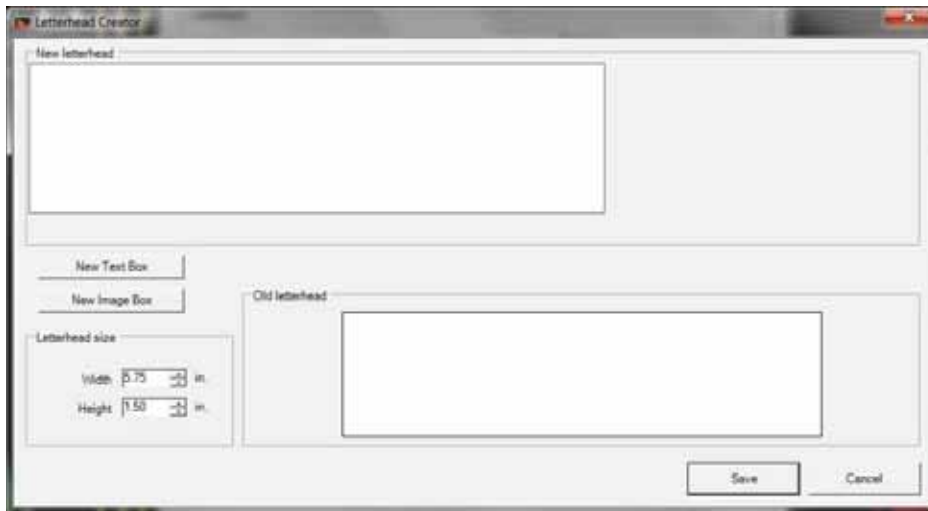
You can select an option for printing reports. MotiliGI lets you print reports on your own letterhead stationery or create a custom letterhead.

You can select report options. You can choose to include the following in the report:

- Letterhead and paper size
- Administrative information including test statistics, study comments, and screen prints of the Test Summary screens.
- The patient's information.
- The Annotation information including statistics and notes.
- The plots to be graphed: pressure, pH, temperature and annotations.
- The graph views of the test.

Creating Report Letterhead

1. Select Tools > Options > Report Tab.
2. Choose paper size.
3. Click Create Letterhead.
 - The Letterhead Creator appears:



Add text to the letterhead

1. Click New Text Box. A text box appears in the new letterhead.
2. Type the desired text.
3. Click and drag the text box to move to a location in the Letterhead Canvas.
 - You can modify the font, resize the text box or delete the text box.
 - a. Right-click in the text box.
 - b. Choose desired option.
 - c. To resize the text box drag your mouse to the desired size and click to apply.
 - d. Click OK.
4. Click Save.

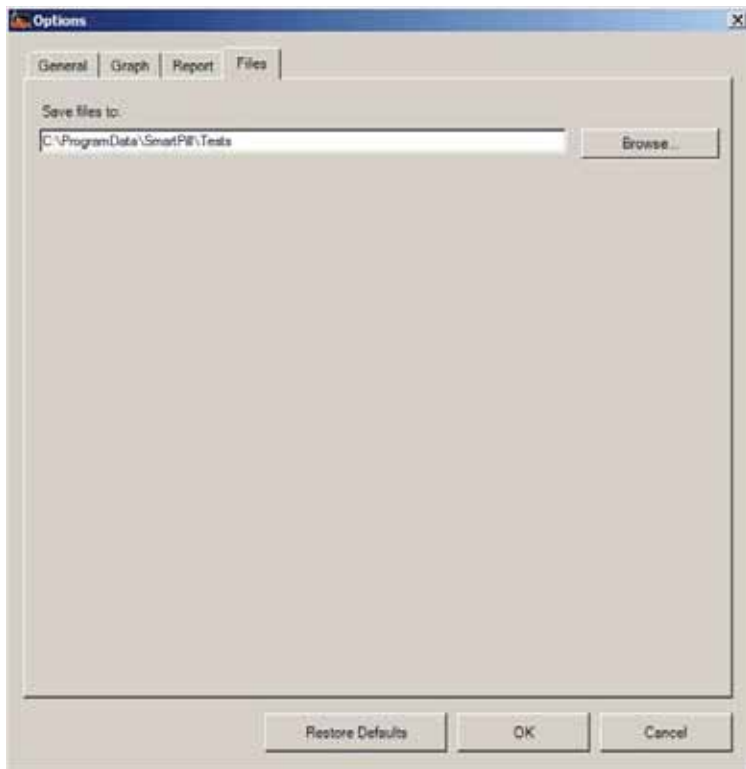
Add an image to the letterhead

1. Click New Image Box. An image box appears in the new letterhead.
2. Right-click in the image box to select an image.
3. Click Browse for Image... An Open Image screen appears.
4. Find and select a bitmap, JPEG or GIF file.
5. Click OK.
 - You can modify the image appearance, resize or delete the image box.
 - ▶ Right-click in the image box. Choose desired option.

- To resize the image box drag your mouse to the desired size and click to apply.

6. Click Save.

Files Tab



You can select the target folder to save files to.

- Click Browse to find target folder.
- Type in the folder location.

Setting Preferences Back to Default


- ▶ Click Restore Defaults to return **all** tabs and settings to default states. Your language preference remains the same.

Editing Patient Information

Edit patient information any time after the start of the test. Patient information is initially entered in the test initiation wizard. You can edit information on all tabs within the patient information screen.

If you edit the patient ID, MotiliGI updates the electronic test filename, log filename and the folder containing the files with the new patient ID number and it will ask you to confirm. If you previously generated a report (WordPad document), your report filename and patient ID number will not be updated. You will need to generate a new report.

1. To access the patient information either:

- Click  on the toolbar
- Click View > Patient Info.



The screenshot shows a 'Patient Information' window with the following fields and options:

- First name**, **Middle initial**, **Last name**: Text input fields.
- Test start date**: 7/6/2005 8:22:05 AM
- * Patient ID**: 001019 (marked as a required field)
- Genom** | *** Contraindications** | **Prior GI Procedures** | **Allergies and Medications** | **Symptoms** | **Procedure Notes**: Tabbed interface.
- Patient** section:
 - Birth date**: Month (March), Day (28), Year (2007)
 - Age**: 5
 - Weight (lbs)**: 0
 - Gender**: [Dropdown]
 - Height**: 0 ft, 0 in.
- Insurance** section:
 - Payer**: [Text field]
 - Group number**: [Text field]
- Physician** section:
 - Ordering physician**: [Dropdown]
 - Referring physician**: [Dropdown]
- OK** and **Cancel** buttons at the bottom.

2. Edit the patient's information.

3. Click OK.

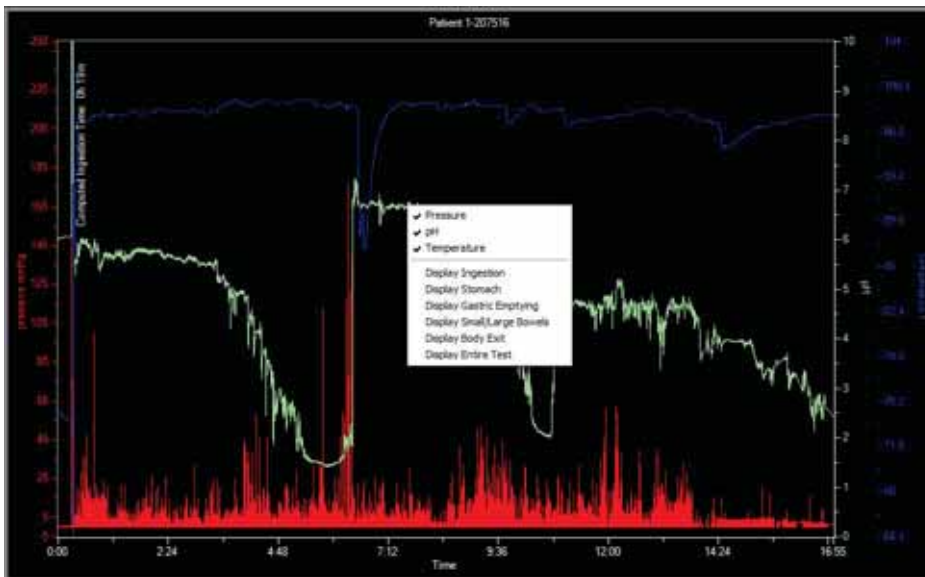
Changing the Graph Display

Selecting Data Plots

MotiliGI gives you 3 methods to select the data (pressure, pH and temperature) displayed on the graph:

Method 1 – Context Menu

- Right-click on the graph and select a data plot. A checkmark indicates the plot appears on the graph.



Method 2 – Toolbar Icons

- ▶ Click on a “Show/Hide” data plot icon.



Show/Hide Pressure



Show/Hide pH





Show/Hide Temperature

Method 3 – Main Menu

- ▶ Click View > Plots. Select a data plot icon to toggle the plot.

Changing the Test View

- To undo any view operation, click the  toolbar icon.
- To redo a view operation, click the  toolbar icon.

MotiliGI prefers the physician-determined marker rather than the computed marker to define the regions.

MotiliGI gives you several methods to select a test view.

Method 1 – Context Menu







- ▶ Right-click on the graph and select a desired view.

Method 2 – Main Menu

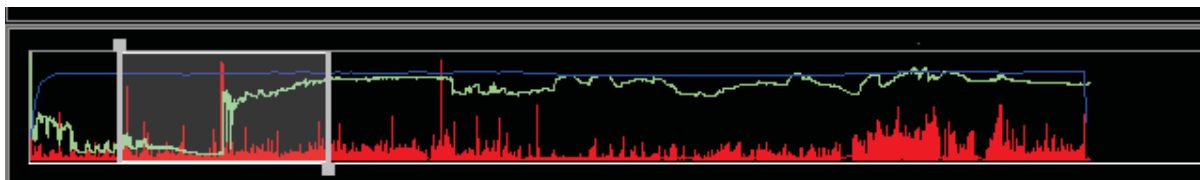
- ▶ Click Go and choose a desired view.

Method 3 – Toolbar Icons

- ▶ Click on a display icon

	Display Ingestion – Test data around the ingestion marker.
	Display Stomach – Test data between the ingestion marker and the gastric emptying marker.
	Display Gastric Emptying – Test data around the gastric emptying marker
	Display Small/Large Bowel – Test data from the gastric emptying marker to the body exit marker.
	Display Body Exit – Test data around the body exit marker.
	Display Entire Test – Test data from the ingestion marker to the body exit marker.

Method 4 – Time Slider Control



The portion of the test shown in the graph area is highlighted in white.

To move the slider:


1. Place your cursor on the slider. The cursor changes to a finger.
 2. Click and drag the cursor to the left or right.
 3. Release the cursor. The main graph updates.
- You can also move the slider with the scroll wheel on the mouse.

To zoom with the slider:



1. Place your cursor over the border of the highlighted area. The cursor changes to a double arrowhead.
2. Click and drag the border to the left or right.
3. Release the cursor. The main graph updates.

Method 5 – Zoom Controls



To zoom in:

1. From the toolbar, select . The cursor changes to a magnifying glass icon.
2. Select an area to view by:
 - Clicking on a graph location (This method only zooms in on the X axis)

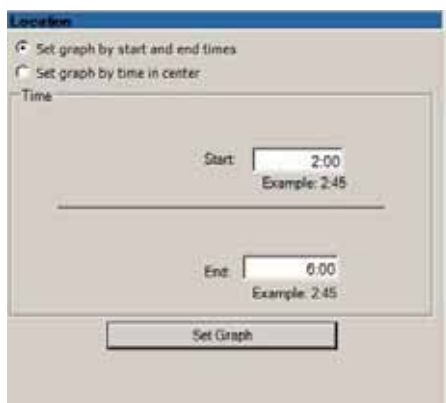
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- Clicking and dragging your mouse to select a graph region (This method zooms in on both the X and Y axis)
3. Click  to exit the zoom in mode. The cursor returns to normal.
 - To return to your last view use the  icon.

To zoom out:

1. From the toolbar, select . The cursor changes to a magnifying glass icon.
2. Select an area to view by clicking on a graph location.
3. Click  to exit zoom out mode. The cursor returns to normal.

Method 6 – Using the Data Panel: Location



1. Define a window of time by selecting Start and End Times or Time In Center
2. Enter the time you wish to display.
3. Click Set Graph.

Changing Axis Scales

Y Axes

To change the scale of the pressure, pH or temperature axis:

1. Double-click on the desired axis.
2. Enter the new axis scale minimum and maximum values.
3. Click OK.

To restore the scale to the saved user preferences:

1. Double-click on the desired axis.
2. Click Restore Axis Defaults or Restore Defaults for All Axes.

- Click OK.

X Axis


To change the time format between calendar date/time and elapsed time either:

- Double-click on the time axis to toggle between elapsed time or real date/time.
- Go to Tools > Options > Graph > Time Axis

Analyzing Data

Showing and Hiding Annotations


Annotations include patient diary events, range annotations, and point annotations. Annotations are visible by default.

- To toggle the visibility of all graph annotations, click  on the toolbar.

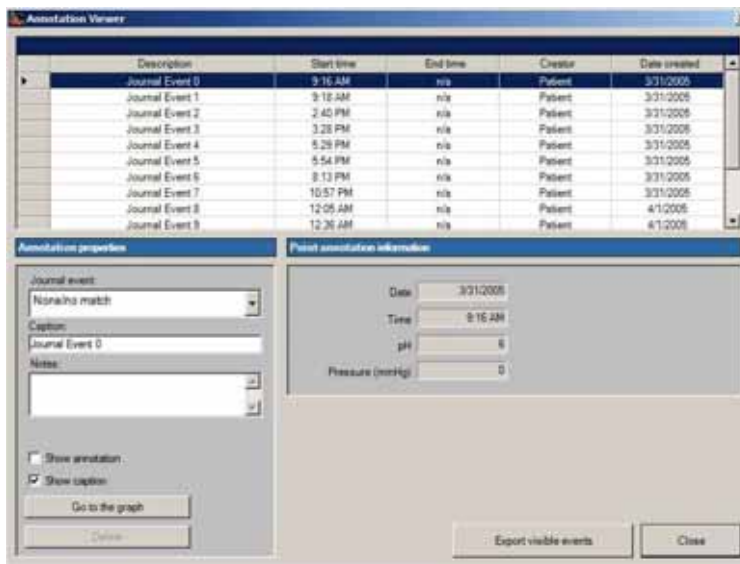
Editing Patient Diary Events

To view and edit patient diary events

- Open the Annotation Viewer:

- Click  on the toolbar.
- Select View > Annotation Viewer.

The Annotation Viewer screen appears.



- Click the event you wish to edit. The event details appear in the annotation properties box.
- Select an icon from the Journal Event drop-down list. The Update button appears.

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- (Optional) You can enter text in the Caption box and in the Notes box. Caption text shows on the graph, while Notes text shows in the Annotation Viewer and in the printed report.
- You can click the checkboxes to show or hide the annotation and the caption.

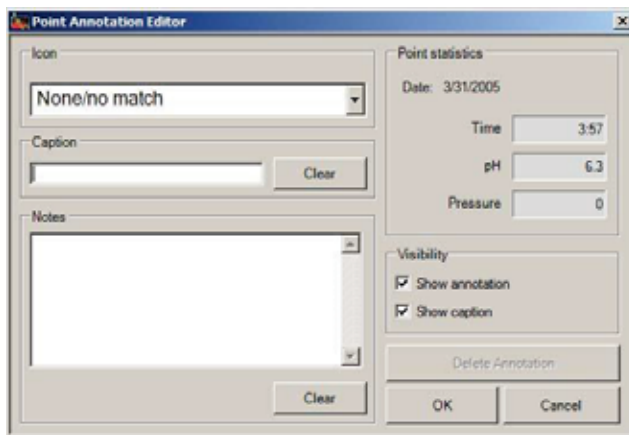
4. Click Update to save changes.


Disregard diary entries and events that do not have a reasonable time correlation.

Creating New Event Annotations

To enter an event that does not appear on the graph:

1. Click  on the toolbar. The cursor changes to a similar icon.
2. Click on the graph at the appropriate time to create the annotation. The Point Annotation Editor appears.

The image shows a software window titled "Point Annotation Editor". It contains several input fields and checkboxes. On the left, there is an "Icon" dropdown menu with "None/no match" selected, a "Caption" text box with a "Clear" button, and a "Notes" text area with a "Clear" button. On the right, under "Point statistics", there are fields for "Date" (3/31/2005), "Time" (3:57), "pH" (6.3), and "Pressure" (0). Below these are "Visibility" checkboxes for "Show annotation" and "Show caption", both of which are checked. At the bottom right, there is a "Delete Annotation" button and "OK" and "Cancel" buttons.

3. Select an icon from the Icon dropdown box.
 - ▶ (Optional) You can enter text in the Caption box and the Notes box. Caption text shows on the graph. Notes only show in the Annotation Viewer, Point Annotation Editor and in the printed report.
 - You can view the time, pH and pressure values at the selected graph point.
 - You can click the checkboxes to show or hide the annotation and the caption.
4. Click OK.
 - ▶ To exit the Annotation mode, click  on the toolbar. The cursor returns to normal.


Editing Event Annotations

Event icons cannot be moved, only deleted or hidden. An event created by the patient pushing the event button on the data receiver cannot be deleted; it can only be hidden. Physician-created annotations can be deleted.

To edit an event annotation's icon or text:

Double-click the event icon. The Point Annotation Editor appears.

To move an annotation's caption on the graph:





1. Click  on the toolbar.
2. Move cursor over the caption text. The cursor changes to a crosshair.
3. Click and drag the caption text to a new location.

To delete an annotation:

1. Double-click the event icon. The Point Annotation Editor appears.
2. Click Delete.

Adding or Changing the Location of Physiological Markers

Physiological markers are used to compute transit times. MotiliGI-computed markers appear on the graph as dotted vertical lines. Physician-defined markers appear on the graph as solid vertical lines.

Physiological Markers	Marker Color	Toolbar Icon
Ingestion - Time the capsule was ingested	Blue	
Gastric emptying - Time the capsule left the stomach	Silver	
Ileo-cecal junction - Time the capsule entered the colon	Green	
Body exit - Time the capsule left the body	Magenta	

To add or change the location of a marker:

1. Click the appropriate toolbar icon. The cursor changes to a crosshair.
2. Click the graph to set the marker at a location. The cursor returns to normal.

To clear (delete) a physician-defined marker:

- Select Markers > Clear Defined Markers...


You can choose to clear one or all physician-defined markers.

To hide a marker:

- Select Markers > Show/Hide Markers

You can choose to show/hide one or all physician-defined and MotiliGI-computed markers.



Viewing Transit Times

- Click  on the toolbar.
- Select View > Test Summary

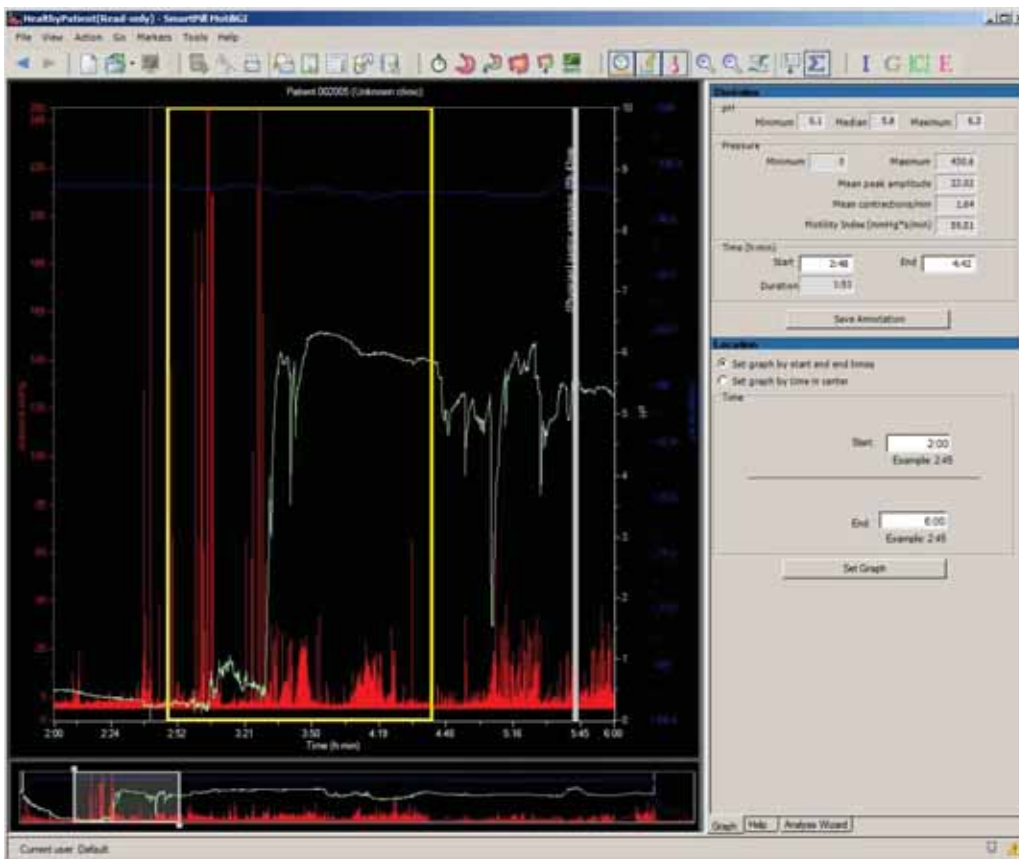
The Test Summary screen appears. Transit times computed using the physician-defined markers appear on the left and MotiliGI-computed markers appear on the right.

Calculating Statistics

To enter the Statistics mode:

1. Click  on the toolbar. The cursor changes to .
2. Click and drag to select any area of the graph.

A yellow box appears around the selected area and creates a range. The Statistics panel displays pressure, pH and temperature statistics for the range.



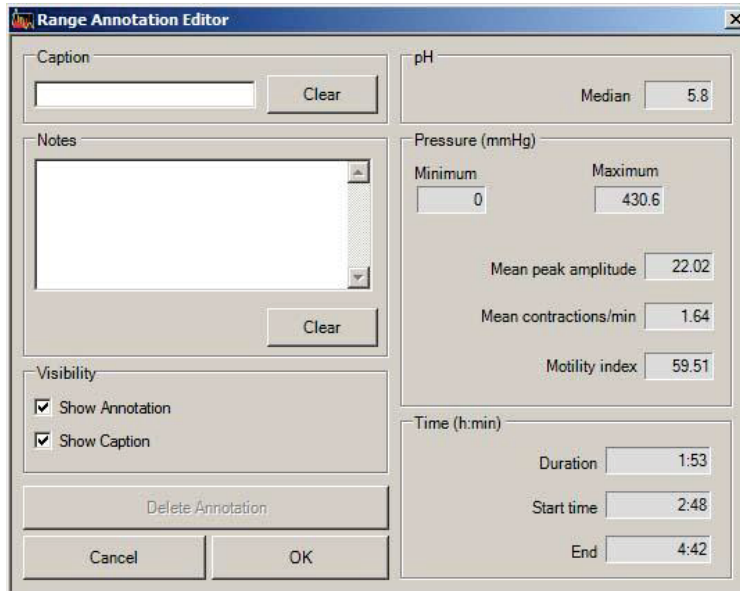
To save the range as an annotation on the graph:

1. On the statistics panel, click Save Annotation. The Range Annotation Editor screen appears.

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- (Optional) You can enter text in the Caption and Notes boxes.
- You can click the checkboxes to show or hide the annotation and the caption.

2. Click OK.





The Range Annotation Editor dialog box is shown. It has a title bar with a close button. The dialog is divided into several sections: a 'Caption' section with a text box and a 'Clear' button; a 'Notes' section with a text area and a 'Clear' button; a 'Visibility' section with two checked checkboxes, 'Show Annotation' and 'Show Caption', and a 'Delete Annotation' button; and a 'Statistics' section on the right. The 'Statistics' section includes a 'pH' section with a 'Median' value of 5.8, a 'Pressure (mmHg)' section with 'Minimum' (0) and 'Maximum' (430.6) values, 'Mean peak amplitude' (22.02), 'Mean contractions/min' (1.64), and 'Motility index' (59.51). Below this is a 'Time (h:min)' section with 'Duration' (1:53), 'Start time' (2:48), and 'End' (4:42) values. At the bottom are 'Cancel' and 'OK' buttons.

You can create and save multiple range annotations.

- To exit the Statistics mode, Click  on the toolbar. The cursor returns to normal.

To edit a range annotation:


1. Click  on the toolbar. The cursor changes to .
2. Double-click the border of a range. The Range Annotation Editor screen appears.
3. Edit the annotation.
4. Click OK.

To view the statistics of a range annotation:

Hold the cursor over the yellow border of the range. The statistics appear in the Data Panel - Statistics.

Creating Output

Generating a Report

1. You can either:
 - Click  on the toolbar, or

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- Select Action > Generate Report

The report opens in Microsoft WordPad. MotiliGI immediately saves the report to the patient's folder using a default name.

Caution

Edits made to the WordPad report will not be saved to the MotiliGI test.

To save the report:


1. Select File > Save As.
2. Type in a new name in File Name.
3. Click Save.

Saving the Report as a PDF File


1. In WordPad, select File > Print. The Windows Print screen appears.
2. In the Printer Name drop down menu, Select PDFill PDF Editor.
3. Click Print. The Save PDF File As screen appears.
4. Enter a filename
5. Click OK.

Printing the Graph

You can use Print Preview to check the graph before you print it. To preview, either

- Select File > Print Preview, or
- Click  on the toolbar.

To print the graph, either:

- Select File > Print...
- Click  on the toolbar. The Windows Print screen appears. Follow the on-screen instructions.

Exporting Data to Excel

You can export test data (pH, pressure and temperature) to a text file in comma-separated value format. You can export data from the current graph view or from the entire test.

To Export the Current Graph View

1. Select File > Export > Test Data Snapshot. A Save As screen appears.
 - MotiliGI creates a folder that contains separate CSV files for pH, pressure and temperature.

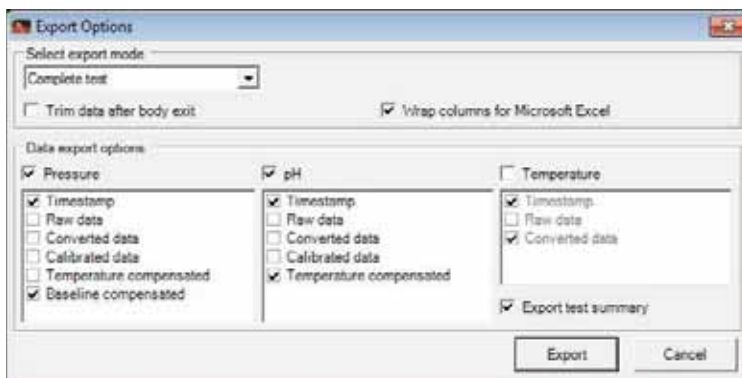
2. Name the folder.
3. Click Save.

To Export the Entire Test

1. Select File > Export > Complete Test Data. A Save As screen appears
 - MotiliGI creates a folder that contains separate CSV files for pH, pressure and temperature.
2. Name the folder.
3. Click Save.

To Export Individual Data Sets

1. Select File > Export > Customize Export. The Export Options screen appears.



2. Select the desired preferences.
 - You can select to export data sets from the complete test or current view.
 - Check Trim After BET if you do not want to export data after body exit.
 - Check Wrap Columns for Microsoft Excel. This feature wraps data sets larger than 32000 rows into adjacent columns.
 - Under Data Export Options, select one or more data sets to export.
 - Under each data set, select one or more parameters to export.
 - Check Export Test Summary to export the transit and descriptive data from the Test Summary Screen.
3. Click Export.

Data Parameter Definitions

- Timestamps are in milliseconds starting at capsule calibration.
- Raw Data is in millivolts.
- Converted Data is raw data multiplied by the sensor's scale factor.

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Data Set	Units
pH	pH units
Pressure	mmHg
Temperature	°C

- Calibrated Data is converted data adjusted by the calibration point (pH 6, atmospheric pressure, room temperature).
- Temperature Compensated is the calibrated data adjusted for sensor drift due to increased temperature.
- Baseline Compensated is temperature compensated data with the baseline adjusted to 0.

Exporting Images to JPEG or GIF

You can export graphs to an image file in JPEG or GIF format. You can export images from the current graph view or from the entire test.

To export the image of the current graph view:

1. Select File > Export> Graph Image Snapshot. A Save As screen appears.
2. Name the file.
3. Select file type from the dropdown box.
4. Click Save.

To export the image of the entire test:

1. Select File > Export> Complete Graph Image. A Save As screen appears.
2. Name the file.
3. Select file type from the dropdown box.
4. Click Save.

System Administrator Tools

Password Management

Logging into the System Computer

For security purposes, after 5 unsuccessful attempts to logon, the user will not be allowed to logon for 15 minutes

Enter the Windows user name and password noted below.

User Name	Password	Privileges
sgims1	12345	Can operate the computer and save documents. Can install programs, printers or change system settings by using MotiliGI Administrator. <ul style="list-style-type: none"> To change the user name or password, contact Technical Support for assistance.
Administrator	Password supplied by Technical Support	Used in emergency situations. Can install programs, printers or change system settings.

Windows Administrative Logon (IT Administrator use only)

Under normal circumstances, use of this account should not be necessary.

To log in as the Windows administrator:

1. Turn on the SmartPill System Computer
2. Log into the Windows sgims1 account (see system computer above).
3. Go to the Windows Start Menu > SmartPill> MotiliGI Administrator.
4. Enter the MotiliGI Administrator password and click Login.
5. Click Retrieve Key
6. Upon retrieving the key, contact Technical Support to obtain an administrative password that can only be used once.

After obtaining the password:

7. Go to Start>Log Off
8. Log into Windows. Enter “Administrator” into the username field and the password provided by SmartPill into the password field.

Logging into MotiliGI

When using MotiliGI for the first time, an administrator account is set up. The administrator has privileges to set up additional users and, edit user names and passwords.

Forgotten Password

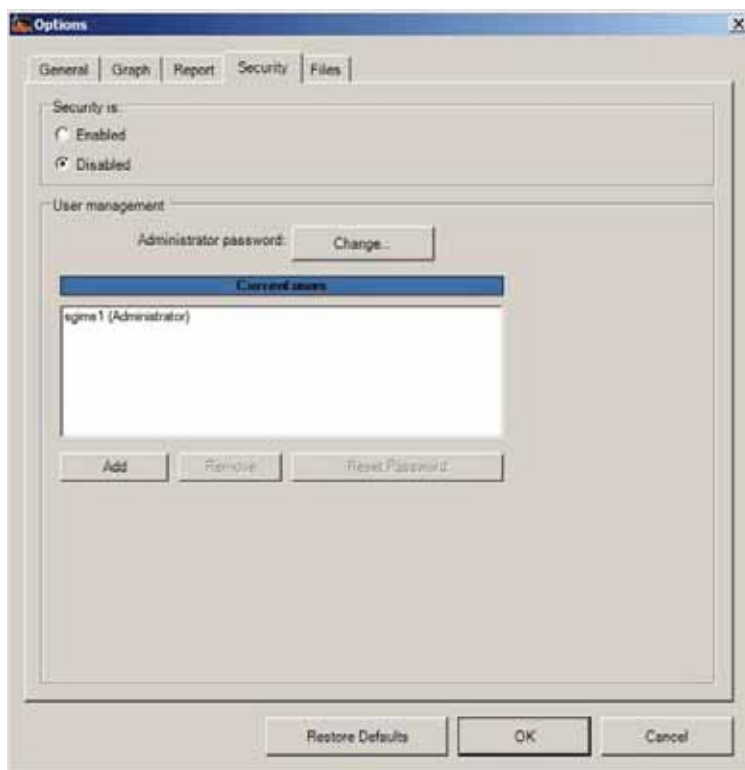
If a user has forgotten his or her password, the administrator must log into MotiliGI and reset the user's password. If the administrator has forgotten his or her username or password, they must call Technical Support.

- The Reset Password option resets the selected user's password to 12345.

MotiliGI Security

Security Tab

You must be logged into MotiliGI as the administrator to view the security tab.



To log in as the administrator:

1. Go to Tools > Login In As...
2. Type in the administrator username and password.
3. Click Log In.

To change the security settings:

- Go to Tools > Options > Security

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Security enabled is the default setting and requires users to log in with their username and password. Security disabled eliminates the login (user authentication) step. The user will be logged into the default user account.

Recommendation: Assign a unique username and password to each MotiliGI user. The username is used as the Technician Name in the printed report.

Adding a User


1. Go to Tools > Options > Security.
2. Under User Management click Add.
3. Under Add User, enter a user name and password (both require a minimum of 5 alpha-numeric characters).
4. Click OK.

The new user will appear in the Current Users box.

Removing a User

- ▶ Select the username from the list of current users and click “Remove.” To change a username, select the user from the list of current users, click “Remove” and then add a new user.

Backing Up Patient Files


1. Verify that MotiliGI is closed (not running).
2. Insert a blank CD into the CD Drive or insert a USB drive into a USB port.
3. Double-click on the Tests icon on the Desktop.
4. Right-click on the patient record folder, click Send To > Compressed (zipped) Folder.
5. Right-click on the Patient_XXXX.zip file you just created, where XXXX is the patient's ID. Click Send To > DVD/CD-RW Drive (D:) *or* Removable Disk (E:).
6. Click  on the toolbar.
7. Right-click on the Log folder, click Send To > Compressed (zipped) Folder.
8. Right-click on the Log.zip file you just created and click Send To > DVD/CD-RW Drive (D:) *or* Removable Disk (E:).

If you are writing to a CD:

- a. Click on the balloon You have files waiting to be written to the CD.
- b. Under the CD Writing Tasks heading, click Write these files to CD.
- c. Confirm that the files have been written to the CD by opening the DVD/CD-RW Drive (D:) in Windows Explorer.

If you are writing to a USB drive:

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- a. Confirm the files have been saved by opening the Removable Disk (E:) in Windows Explorer.
- b. Click  located on the right side of the Start bar. Select Safely remove the Removable Disk (E:).

Installing Software

To install third-party software, log into the system computer as the system computer administrator – or –utilize SmartPill's MotiliGI Administrator application.

Caution

Exercise caution installing third-party software (e.g. applications, drivers) on the system computer. Installing third-party software not listed below may increase the potential for software conflicts with MotiliGI.

SmartPill Approved Third-Party Software

Microsoft Excel	Adobe Acrobat Reader	Printer drivers
Microsoft Word	PDFill PDF Editor	Windows Accessories

MotiliGI Administrator

MotiliGI Administrator serves two purposes:

- It provides the means to install a limited set of software.
- It provides access to the administrative account.

Launching MotiliGI Administrator

1. Turn on the system computer
2. Log into the system computer using the sgims1 account.
3. Go to the Start Menu > SmartPill> MotiliGI Administrator
4. Create a password.
- ▶ The password is case sensitive, must be at least five characters long, and must be confirmed. The MotiliGI Administrator password is independent of MotiliGI and must be entered for each subsequent running of MotiliGI Administrator.
5. Retype the password and click Login.



Figure 14

After logging in, the MotiliGI Administrator screen will appear.



Figure 15

Installing Software from a CD

1. Place the CD in the CD-ROM drive and click Update from CD. The contents of the CD will be displayed in the center box of the main screen.
2. Double click on the file you wish to install.

Installing Software from a File on the System Computer Hard Drive

1. Locate the file you wish to install.
2. Move the file into C:\Program Files\SmartPill\ MotiGI Administrator\Update\ Directory
3. Click Update from Folder. The contents of the update directory will be displayed in the center box of the screen.



Figure 16

4. Double click on the file you wish to install.

Uninstalling MotiliGI

Caution

If you find it necessary to uninstall MotiliGI, ensure you have backed up and/or saved patient test files, exported data files and reports (except those that have been saved as PDFs) to another location on your hard drive or to external media (e.g., auxiliary or external hard drive, CD).

You must be logged into the system computer as the Windows administrator to uninstall MotiliGI.

1. Backup any data files you have created.
2. Close MotiliGI.
3. Log into the computer as the Windows administrator.
4. Go to the Windows Start Menu > Control Panel > Add/Remove Programs.
5. Locate and select MotiliGI in the programs list, click Add/Remove.
6. Select Yes to confirm removal of MotiliGI.
7. Delete the folder C:\Program Files\SmartPill\ MotiliGI
Administrator\Update\ Directory

Installing MotiliGI

Use MotiliGI Administrator to reinstall or upgrade MotiliGI from a CD.

1. Reboot the system computer and log into the sgims1 Windows account. You must reboot the computer immediately prior to upgrading MotiliGI to avoid any problems.
2. Go to Start > All Programs > SmartPill folder > MotiliGI Administrator.
3. Enter the password and click Login.
4. Insert the MotiliGI CD into the CD-ROM drive.
5. Click Update from CD.



Figure 17

6. Double-click on the MotiliGI folder.
7. Double-click on Setup.exe. Follow all instructions in the installation wizard.
8. When the wizard finishes, close the wizard and close MotiliGI Administrator.
9. Reboot the PC.

If you are installing MotiliGI on a computer other than your system computer (for reading test data only), you will need to install Adobe Acrobat Reader 7.0 or greater for MotiliGI to run properly. MotiliGI is only compatible with Windows XP and Windows 7 32-bit operating systems. MotiliGI is not warranted for use with any other operating system.

MotiliGI relies on the Microsoft .NET framework version 1.1. If you are installing MotiliGI on another computer to view test files, run the Windows Update feature of the Microsoft website (<http://update.microsoft.com/windowsupdate>) to check for and install any critical updates to the Microsoft .NET framework before completing the installation.

The first time the data receiver is connected to the system computer, Windows XP will acknowledge it has found a new USB device and will load the drivers necessary for it to communicate with the data receiver. You may see a dialog box pop up asking for the Windows Administrator username and password. Do not take action – MotiliGI administrator will automatically fill in the required information after a few seconds and the installation will continue.

Appendix: Electrical Safety

External equipment intended for connection to signal input, signal output or other connectors shall comply with relevant IEC standard (e.g. IEC 60950 for IT equipment and the IEC 60601 series for medical electrical equipment). In addition, all such combinations – systems – shall comply with the standard IEC 60601-1-1, Safety requirements for medical electrical systems. Equipment not complying with IEC 60601-1 shall be kept outside the patient environment, as defined in the standard.⁴ Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact a qualified biomedical engineer or Given Imaging.

The following tables outline the SmartPill GI Monitoring System's compliance with INTERNATIONAL STANDARD, International Electrotechnical Commission (IEC) IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.

Guidance and manufacturer's declaration – electromagnetic emissions

The SmartPill GI Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartPill GI Monitoring System assures that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SmartPill GI Monitoring System uses RF energy exclusively for its internal function. Thus the RF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR 11	Class B	The SmartPill GI Monitoring System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	IEC 61000-3-2	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

⁴ The normal distance is at least 1.5 m from the patient or the patient support.

Guidance and manufacturer's declaration – electromagnetic immunity

The SmartPill GI Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartPill GI Monitoring System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV on AC mains ± 1 kV on measurement I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV on Line to Neutral ± 2 kV on Line or Neutral to protected earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\%$ U_T ($> 95\%$ dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles $< 5\%$ U_T ($> 95\%$ dip in U_T) for 5 sec	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The SmartPill GI Monitoring System is intended for use in the electromagnetic environment specified below. The user of the SmartPill GI Monitoring System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the SmartPill GI Monitoring System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey. (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartPill GI Monitoring System is used exceeds the applicable RF compliance level above, the SmartPill GI Monitoring System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SmartPill GI Monitoring System.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SmartPill GI Monitoring System

The SmartPill GI Monitoring System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartPill GI Monitoring System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartPill GI Monitoring System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.17 \sqrt{P}$	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Device Classifications

	SmartPill pH.p Capsule	SmartPill Data Receiver	SmartPill Docking Station
Power:	Internally Powered Equipment	Internally Powered Equipment	Class I Equipment
Electric Shock Protection:	Type BF Applied Part	Type BF Applied Part	Ordinary Equipment
Harmful Ingress Water:	Watertight Equipment (IP57)	Ordinary Equipment	Ordinary Equipment
	Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE. Not for use with oxygen or oxygen enriched atmospheres.	Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE. Not for use with oxygen or oxygen enriched atmospheres.	Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE. Not for use with oxygen or oxygen enriched atmospheres.
Mode of Operation:	Intermittent operation	Continuous Operation	Continuous Operation

Connectivity Restrictions

External equipment intended for connection to signal input, signal output or other connectors shall comply with IEC 60601 series for medical electrical equipment. In addition, all such combinations – systems – shall comply with the standard IEC 60601-1-1, Safety requirements for medical electrical systems. Equipment not complying with IEC 60601-1 shall be kept outside the patient environment, as defined in the standard.⁵

Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact a qualified biomedical professional or the SmartPill Corporation.

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⁵ The normal distance is at least 1.5 m from the patient or the patient support.

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