NaviCam MotiliCap GI Monitoring System User Manual

AnX Robotica Corporation

Revision v1

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Rx
Only
CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

Chapter 1 Introduction

1.1 Important Information

A thorough understanding of the technical principles, clinical applications and risks associated with the NaviCam MotiliCap GI Monitoring System is necessary before using this product. Read this entire manual before using the system for the first time.

The product may only be used by healthcare professionals and patients who have received specialized training.

⚠ **CAUTION**

Failure to follow this instruction may result in damage to the equipment or pollution to environment

⚠ **WARNING**

Failure to follow instructions could result in injury or even death to operator, patient, or other personnel.

To avoid the risk of electric shock, this equipment must only be connected to a power supply that is properly grounded.

This device should be kept away from strong magnetic fields.

NOTE

If an event or information security issue is identified, immediately report it to AnX Robotica Customer Service.

1.2 About NaviCam MotiliCap GI Monitoring System

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

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

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

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

The NaviCam MotiliCap GI Monitoring System is comprised from the following components:

- MotiliCap Capsule (Catalog Number:TBD, Model: AJMC-1)
- Data Recorder (Catalog Number: TBD, Model: AJDR)
- PC Software(Motiliscan)
- Cell phone APP(MotiliCap)
- MotiliCap Bar

A description of each component is provided below.

1.2.1 MotiliCap Capsule (AJMC-1)

The capsule consists of a pressure sensor, a pH sensor, and a temperature sensor (Figure 1-1), which separately measure the pressure, pH, and temperature in the GI tract to determine transit times of the stomach, small bowel, and colon. The transit times calculated by capsule motility procedures can substitute for other test methods such as gastric emptying scintigraphy, whole-gut scintigraphy, and radiopaque markers.The capsule is for single use and is valid for 24 months.

Figure 1-1 Capsule

1.2.2 Data Recorder (AJDR)

The data recorder records biomedical data transmitted by the capsule. The patient can wear it either cross-body or around the neck using a lanyard. The data recorder weighs approximately 225 grams (0.5 lbs), as shown in Figure 1-2. The data recorder has a service life of 5 years.
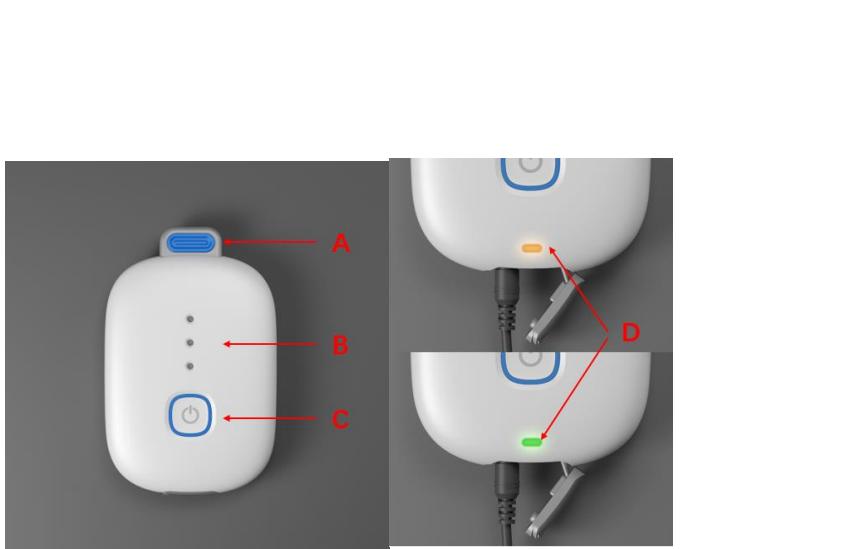
Figure 1-2 Data Recorder

1.2.2.1 Components of the Data Recorder

The data recorder primarily consists of four components: the lanyard hole, status indicator light, power button, and charging indicator light (Figure 1-2).

Table 1-1 Data Record Components

Component	Description
A - Lanyard hole	Secures the lanyard
B – Status indicator light	Indicates battery level and capsule pairing status
C - Power button	Press and hold to power on the data recorder
D - Charging indicator light	A dual-color LED indicating the charging status

1.2.2.2 Indicator Lights of the Data Recorder

The data recorder features two types of indicator lights: the status indicator light and the charging indicator light (see Table 1-2).

Table 1-2 State and Interpretation for the Data Recorder Indicator Lights

	State	Interpretation
LED-B status indicator light	Fully on or partially on	Indicates the battery level of the data recorder
	Fully off	The data recorder is either powered off or in power-saving mode

	Flashing in cycles	The data recorder has been powered on and is searching for the capsule
LED-D charging indicator light	Orange	The data recorder is in charging
	Green	The data recorder is fully charged

⚠ **CAUTION**

Only a MotiliCap compatible charger can be used for charging the data recorder, and a compatible USB data cable for data transfer.

When charging the data recorder, do not place it in a location that is difficult to access for disconnecting the device.

1.2.3 Motiliscan Software

The Motiliscan software is installed on a general-purpose computer. Before the examination, a case can be created by the software to start a test. After the test is complete, the software can receive and process downloaded test data from the data recorder, and graphically display the data for easy analysis and review. The Motiliscan software is capable of analyzing data and calculating motility indices such as GET, SBTT, CTT, and WGTT.

Minimum System Requirements for the Computer:

Table 1-3 Minimum System Requirements for the Computer

Operating system of the manufacturer	Microsoft Windows 10 and compatible versions
Processor	Intel® Core™ i5 Processors
Memory	8 GB
Hard Drive	256 GB
Port	USB2.0 and compatible ports
Display	24-bit color, 1920x1080 resolution
Browser	Chrome or Edge

1.2.4 MotiliCap App

The MotiliCap App is installed on a smartphone. This APP can connect to the data recorder via Bluetooth, display the connection status, and show information about the capsule connected to the data recorder. Users can also record daily events through this APP.

System Requirements for the Smartphone App:

Operating System: Android 9.0 and compatible versions or iOS 13.0 and compatible versions

Bluetooth: BLE 4.0 and compatible versions

1.2.5 MotiliCap Bar

The MotiliCap Bar 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.

⚠️ **WARNING**

Do not connect any items that are not part of the NaviCam MotiliCap GI Monitoring System to this system.

1.3 Chapters

Chapter 2 Indications, Contraindications and Warnings

2.1.Indications

The NaviCam MotiliCap GI Monitoring System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of GI tract transit times are used for evaluating motility disorders. The system measures pH, pressure and temperature throughout the entire GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

Table 2-1 Indications List

Suspected disease or condition to evaluate	Indicated Measurement	Measurement
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.

2.2.Contraindications

The Capsule should not be administered to a patient with the following conditions:

● history of gastric bezoar

● swallowing disorders

● suspected or known strictures, fistulas, or physiological/mechanical GI obstruction

● GI surgery within the past 3 months

● severe dysphagia to food or pills

● Crohn's disease or diverticulitis

●implanted or portable electro-mechanical medical device such as a cardiac pacemaker, defibrillator or infusion pump

⚠ **CAUTION**
Data transmission from the capsule to the data recorder is affected by patient BMI. In severely obese patients (BMI>40), significant data dropout may occur.

⚠ **CAUTION**

No for use with flammable anesthetic mixture in air or oxygen-enriched or di-nitrogen oxygen atmospheres

2.3. Adverse Events

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.

2.4.Warnings

Warning is used to suggest risks that may cause damage to patient or operator.

⚠The MotiliCap Capsule has not been tested and is not approved for use in children under the age of 18 years.

⚠Physiological/mechanical GI obstruction must be ruled out as a cause of patient symptoms before administering the MotiliCap test.

⚠An extension cord shall not be used to power or connect to the System.

⚠The operator should not touch the power supply of the System Computer and the patient simultaneously during set-up and maintenance.

⚠All power and data cords/cables connected to the MotiliCap GI Monitoring System should be positioned to prevent tripping and avoid cord crushing hazards.

⚠Do not connect items to the MotiliCap GI Monitoring System that are not part of the MotiliCap GI Monitoring System.

⚠Magnetic Resonance Imaging (MRI) must not be performed on a patient who has ingested the MotiliCap Capsule until Capsule passage is confirmed by physician review of the MotiliGI graph or KUB. An MRI test performed with an ingested Capsule may result in damage to the GI tract.

⚠️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.

⚠️If you suspect bowel obstruction, treat consistent with your management of a foreign object causing obstruction. Consider a KUB exam to determine if the Capsule is retained and its location within the GI tract.

⚠️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.

2.5.Recycling and Disposal

•The recycling of the data recorder must comply with local, regional, and national regulations for electronic devices.

•The capsule contains silver oxide batteries. Please recycle unused capsules according to local, regional, and national regulations for electronic devices.

•Dispose of used capsules according to local, regional, and national regulations for disposal of human excrement.

Chapter 3 System Settings

3.1 MotiliScan Launching MotiliScan (for the first time)

3.1.1 MotiliScan Launching MotiliScan

The MotiliScan software can be accessed using compatible browsers (Chrome, Edge, Safari). Before using the software, obtain the access URL, login ID, and initial password from your MotiliScan software administrator.

Open your browser and enter the access URL to start using the MotiliScan software.

3.1.2 MotiliScan Logging In to MotiliScan

You will enter the login page (Figure 3-1) after opening the MotiliScan. Enter you user name and password, and then click [Login] to log in to MotiliScan.
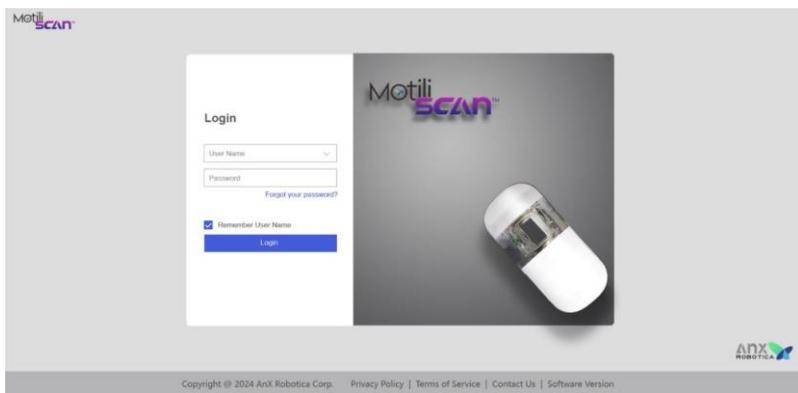
Figure 3-1 MotiliScan Login Page

On your first login, you will need to change the default password for your account. As shown in Figure 3-2, enter your current password, your new password, and confirm your new password, then click [Confirm] to complete the password change.

⚠️ **CAUTION**

The password is required to be at least 8 characters long and needs to contain numbers and upper and lower case letters.
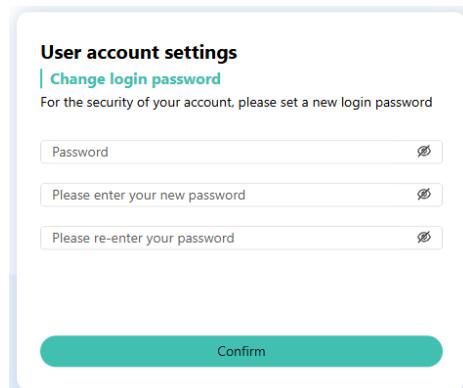
Figure 3-2 Changing Login Password for MotiliScan

3.2.Connecting the Data Recorder to the Computer

Figure 3-3 Connecting the Data Recorder to a Computer

1) Connect the data recorder to a computer using a USB cable (Figure 3-3).

2) Press and hold the power button on the data recorder for more than 2 seconds to turn it on. You will know the data recorder has been powered up when the indicator light turns on and you hear a beep.

3) Open the MotiliScan, and log in to enter the home page (Figure 3-4).
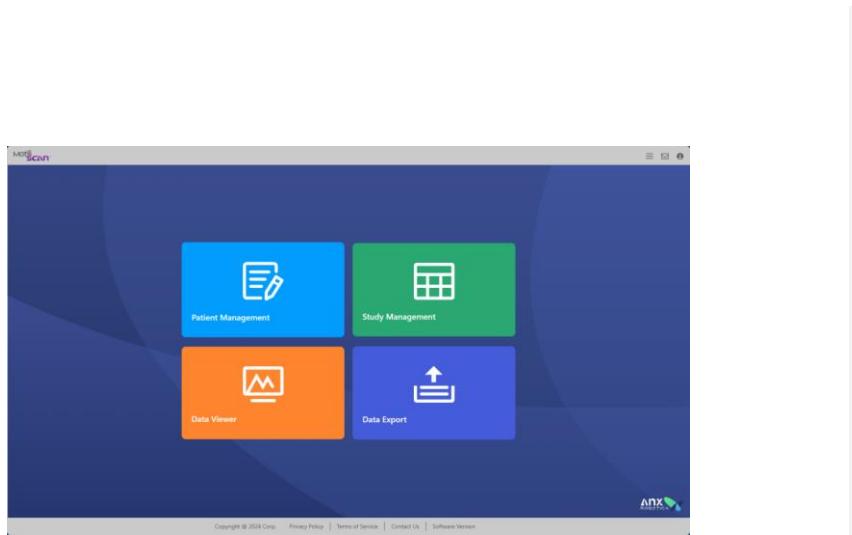
Figure 3-4 MotiliScan Home Page

4) Click [Patient Management] on the home page to open the tab (Figure 3-5) and check if the data recorder appears in the list on the left side. If the data recorder shows up in the list, it indicates that the data recorder is correctly connected to the computer.
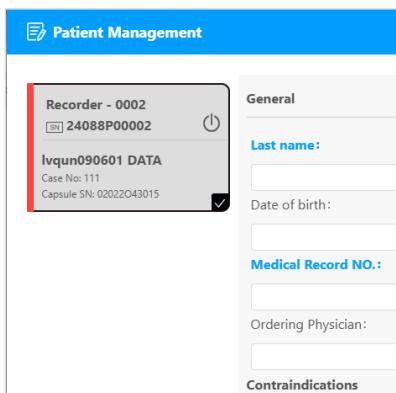
Figure 3-5 Data Recorder Has Been Correctly Connected to the Computer

⚠ **CAUTION**

If the data recorder does not appear in the list, check if the data cable is properly connected to the computer and the data recorder, and if the data recorder has been powered on. If the data recorder still does not show up after checking, contact our technical support for assistance in verifying if the recorder service is activated, or for further checking.

5) Before starting the test, ensure the data recorder is fully charged. For instructions, refer to Section 4.1: Charging the Data Recorder.

Chapter 4 System Operation

4.1 Charging the Data Recorder

Before the Test Day

Fully charge the data recorder the day or night before starting a test (Figure 4-1).

Figure 4-1 Charging the Data Recorder

- Ensure the data recorder is off. If the LED indicating the working status of the data recorder is flashing, connect it to the PC software and turn off the data recorder.
- Connect the dedicated charger to the data recorder to start charging. The current charging status is indicated by the data recorder's charging indicator light (Figure 4-2).

Figure 4-2 Flashing Status of Charging Indicator Light on the Data Recorder

- It takes up to 3 hours to fully charge the data recorder.
- When the data recorder is fully charged, the charging indicator light on the recorder will switch from orange to green.

⚠️ **CAUTION**

The data recorder must be turned off during charging. Charging the data recorder while turned on may result in insufficient charging, leading to incomplete testing.

⚠️ **CAUTION**

Charging or recharging the data recorder with a power source other than the MotiliCap power supply may permanently damage the data recorder, or computer and will void the product warranty.

4.2. Preparing the Patient

4.2.1 Before the Office Visit

1. Review these test requirements and restrictions with the patient (see Table 4-1). Fasting is required for accurate test results.

Table 4-1 Test Requirements and Restrictions

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 and stop any medications that may alter gastric motility or gastric acid pH. Examples of such medications are listed in Table 4-2. These medications should be discontinued before the test unless the patient is well stabilized (condition and dose has been stable for 3 months or more).

Table 4-2 List of Examples of Medications to be Discontinued

Schedule	Type	Example
7 days before the test	Proton pump inhibitors	Omeprazole, Lansoprazole, Nexium
48 hours	Histamine$_2$ blockers	Zantac
48 hours	Motility-altering medications	Cisapride, Domperidone, Metoclopramide (Reglan)

48 hours	Antiemetics and 5HT3 antagonists	Zofran, Kytril
48 hours	Macrolides	Erythromycin, Zithromycin
48 hours	Anticholinergics	Phenergan, Compazine
48 hours	5HT4 partial agonists	Zelnorm
24 hours	Antacids	Maalox, Mylanta, Rolaids

⚠ **CAUTION**

Patients with insulin-dependent diabetes must take half of their normal morning dose of insulin and monitor blood glucose levels according to their normal routines.

3. Review MotiliCap Bar ingredients and rule out any food allergies.

- The MotiliCap Bar contains a small amount of gluten.
- The MotiliCap Bar does not contain lactose.
- The MotiliCap Bar does not contain nuts but ismanufactured in a plant that processes nuts.

MotiliCap Bar 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 MotiliCap Bar. You must have a microwave to prepare this meal.

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

	2 slices of bread;120kcal	

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⚠ **CAUTION**
To accurately measure regional gut transit time, the patient must consume a MotiliCap Bar or egg-based meal immediately before ingesting the capsule.

4.2.2. During the Office Visit

1. Ensure the patient adhere to the restrictions required before the test.
2. Provide the patient with a printed product manual and show the packaging list.
3. Provide a brief usage training for the patient.

Schedule	Restriction
6 hours after ingesting the capsule	Do not eat. Do not take medication. Do not use tobacco. Do not consume alcohol during the entire test. If you are diabetic, monitor your blood glucose levels and follow your individual treatment plan. If unsure, contact the doctor managing your diabetes. Avoid vigorous activities such as sit-ups, abdominal crunches, and prolonged aerobic exercises (over 15 minutes). Do not wear the data recorder while bathing or showering. Do not use laxatives, bowel cathartics, antidiarrheals, alcohol, or other medications affecting peristalsis until the capsule has passed.

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

•Suspended by a lanyard

⚠ **CAUTION**
Instruct the patient not to use the lanyard while sleeping

⚠ **CAUTION**
Eating anything (except small amounts of water) before gastric emptying can delay the gastric emptying of the test meal, and invalidate the results.

5. Instruct the patient on using the MotiliCap APP. The patient should record events in the APP whenever daily events occur.

The patient must record the event in the MotiliCap APP for bowel movements.

Recording events:

- Marks bowel movements which are useful for verifying capsule exit.
- Marks other events and symptoms which may be useful when reviewing test data.

Other events and symptoms that you may ask the patient to mark and record 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

4.2.3.Resuming the Normal Routine

Review these instructions and warnings with the patient.

⚠ **WARNING**

Magnetic Resonance Imaging (MRI) must not be performed on a patient who has ingested the MotiliCap Capsule until Capsule passage is confirmed by physician review of the MotiliGI graph or KUB. 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.

Patients can resume normal eating 6 hours after swallowing the capsule.

Except for the restrictions noted on the patient instructions sheet, patients can resume normal activities when released from your office.

4.2.4. Scheduling a Follow-up Office Visit

Schedule a follow-up visit to return the data recorder within 4-5 days (96-120 hours) after the start of the test.

4.3.Starting a Test

4.3.1.Preparing the System

1) Open the MotiliScan, complete login and enter the home page before or after the patient arrives at the office.

2) Turn on the data recorder, and connect the data recorder to the computer using a USB cable.

> ⚠️ **CAUTION**
> For operating instructions, refer to Chapter 3: System Settings.

4.3.2. Performing the Test

4.3.2.1. Entering Patient Information

On the MotiliScan home page, click [Patient Management] to open the tab (Figure 4-3). In the recorder list on the left side of the tab, select the recorder to which information needs to be entered, and then sequentially enter the patient information on the right side of the tab.

Figure 4-3 MotiliScan Patient Management Tab

After completing the information entry, click [Check in], which will create the entered patient case in the recorder and case list.

> ⚠️ **CAUTION**
> The items shown in blue in the Patient Management Tab are required fields, while the others are optional.

> ⚠️ **CAUTION**
> Once the entered information is submitted, it will overwrite the existing case data saved in the recorder. If there are case data not completely exported from the recorder at the time of submission, the software will provide a reminder, saying "Complete the data export before submitting new patient information; otherwise, it may result in the loss of the original case data."

4.3.2.2. Activating the Capsule

The capsule will be automatically activated once it is taken out of the packaging.

⚠ **CAUTION**

Once the capsule is activated, keep it at least one foot away from the capsule packaging. The stray magnetic fields generated by the packaging may deactivate the capsule nearby.

⚠ **CAUTION**

The capsule must be ingested or discarded within 2 hours after being taken out of its packaging.

4.3.2.3.Confirming the Capsule Has Been Activated

Check if the capsule LED is flashing. If the capsule is not activated, place it back into the packaging and remove it again.

If you need to abort the test, refer to section 4.3.2.11 on Aborting a Test - Deactivating the Capsule. the test and deactivating the capsule.

4.3.2.4. Connecting the Capsule to the Data Recorder

After completing the information entry, the MotiliScan software will open the Data Viewer page (Figure 4-4), and the data recorder will automatically connect to the powered-on capsule.

To confirm the capsule has been connected to the data recorder:

● Check if the capsule status LED on the data recorder is flashing; a steady-on light indicates that the capsule has been connected to the data recorder.

● Open the Data Viewer page of the MotiliScan software to check if the capsule information is displayed. (Refer to Section 4.3.2.5: Check If the Capsule and Data Recorder are Working Properly.)

If the capsule is not connected to the data recorder, troubleshoot using the following methods:

● The capsule SN must match the one entered during information entry for the data recorder to automatically connect to the capsule. Otherwise, the MotiliScan software will prompt a mismatch in the capsule SN. In this case, you can choose to update the entered serial number to the current capsule SN or return the current capsule to its packaging to power it off, then turn on the capsule that matches the entered serial number.

● Check if the capsule is activated (refer to Section 4.3.2.3 - Confirming the Capsule Has Been Activated) and ensure the capsule is close to the data recorder. If the capsule is distant from the data recorder, connection may fail.

● If it still cannot be connected, try replacing a capsule and attempting again.

4.3.2.5.Check if the Capsule and Data Recorder are Working Properly

After completing the information entry, the MotiliScan software will open the Data Viewer page (Figure 4-4). Alternatively, you can also open the Data Viewer page by clicking [Data Viewer] on the home page or the Study Management page.

Figure 4-4 MotiliScan Data Viewer Page

① Displays capsule information.

② Display all connected recorders.

③ Displays measurement data returned by the capsule.

④ Contains various operational functions for the chart.

⑤ Display the measurement data returned by the capsule in the form of a chart.

⑥ Displays the summary of cases saved in the current recorder, and abnormal state information.

⚠ **CAUTION**

The measurement data displayed on this page is not real-time and is subject to a one-minute delay due to the capsule data transmission mechanism.

！ Check if the Capsule and Data Recorder are Working Properly:

1) Check if the capsule information is displayed. If the capsule information is not displayed, it indicates that the capsule is not connected. Refer to Section 4.3.2.4 to establish a connection between the capsule and the recorder.

2) Check if the capsule has successfully transmitted measurement data. (Due to the capsule data transmission mechanism, there is a one-minute delay in the displayed data, so you need to wait one minute for the data to refresh.)

3) Check if the Data Viewer page displays any abnormal information regarding the data recorder and capsule.

Once the above checks are normal, you can proceed to the next step.

4.3.2.6.Ingesting the Capsule

1) Instruct the patient to wear the data recorder.

2) Ask the patient to consume a standard meal and swallow the capsule immediately after finishing the meal.

3) The data recorder will record biomedical data from the patient's digestive tract. At regular intervals, the recorder will store the data measured by the capsule.

4.3.2.7.Completing Discharge Instructions

● Instruct the patient to wait 3 minutes in the bathroom before flushing the toilet after each bowel movement. Explain that this is to confirm whether the capsule has been excreted.

● Instruct the patient to use the MotiliCap AP to log their daily activities each time. For operating instructions, refer to the next section.

⚠ **小心CAUTION**

Inform the patient that the data recorder should not be away from the body for extended periods during the examination; otherwise, the data may be permanently lost.

4.3.2.8. Using the MotiliCap APP to Log Diary Events

The MotiliCap APP is used during the examination to record activity diaries that may affect the examination data.

1) Open the MotiliCap APP

Tap the MotiliCap icon on the your cellphone's home screen to open the app.

2) Connect the Data Recorder

Before recording the patient diary, the recorder needs to be connected.

After opening the MotiliCap, if the data recorder has not been connected previously, you will enter the connection page. Follow the prompts to scan the QR code on the data recorder to connect, as shown in Figure 4-5.
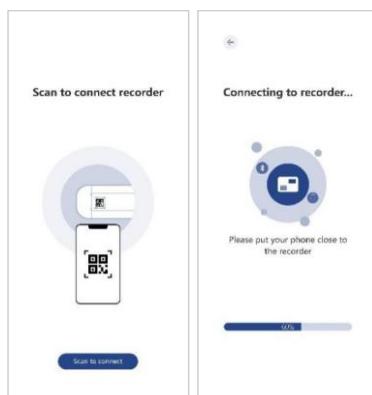
Figure 4-5 Connecting the Data Recorder

⚠ **CAUTION**

Ensure that the phone's Bluetooth is turned on, and the recorder is powered on before scanning the QR code. Keep the phone and recorder close during the connecting.

If the data recorder has been connected before, you will enter the home page (Figure 4-6). Click the [Menu] button ☰ in the upper right corner to expand the menu, select [Change recorder], and then scan the QR code to connect.

⚠ **CAUTION**

Changing the data recorder will erase any saved diaries, so ensure that the diary has been fully synced before changing the recorder.

3) Home Page Display

After a successful connection, you will enter the home page (Figure 4-6).
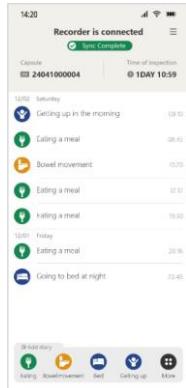
Figure 4-6 MotiliCap APP Home Page

On this page, you can view the capsule SN, test time, diary sync status, and the list of added diaries.

4) Add Diary

Use the add diary functional component at the bottom of the home page (Figure 4-7) to add diary.

Figure 4-7 Add Diary Functional Component

The component lists common diary types. You can also click "More" to open a full list of diary types for selection. The types of diary you can add include:

- Bowel movement
- Eating a meal
- Getting up in the morning
- Going to bed at night
- Cramping or pain
- Nausea
- Passing gas
- Vigorous exercise or activity

25 / 64

● Other (custom type, requires manual input)

Select the corresponding diary type based on the actual situation. A confirmation window will pop up (Figure 4-8) to confirm the selected diary type and time. Click "Add" to successfully add the diary.
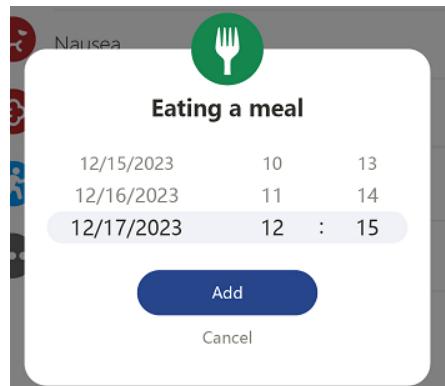
Figure 4-8 Add Diary Confirmation Tab

⚠ **CAUTION**

Adding a diary does not require a connection to the data recorder; the diary will automatically sync to the recorder when it is connected.

4.3.2.9. Informing to Return the Data Recorder

● Schedule an appointment for the patient to return the data recorder.

The capsule is typically excreted naturally within 2-5 days after ingestion depending upon the patient's condition.

Guidelines

Measuring GET   24-48 hours

Measuring WGTT   2-14 days

● Inform the patient to return the data recorder after the capsule is excreted.

● Inform the patient to check for the exit of the capsule after each bowel movement. If the capsule exit is observed, the recorder should be returned immediately.

● If the capsule exit is not observed, but the three indicator lights on the recorder start to flash in a cycle, it indicates that the capsule has been disconnected. In this case, try wearing the recorder and keep

it close to the abdomen. If the flashing state continues for more than 20 minutes, return to the office for further investigation.

4.3.2.10.Live Monitoring Mode (Optional)

While the patient is still in the office, live data measured by the capsule can be viewed. Refer to Section 4.3.2.5: Check if the Capsule and Recorder are Working Properly to open the Data Viewer page to view the data.

⚠️ **CAUTION**

The measurement data displayed on this page is not real-time and is subject to a one-minute delay due to the capsule data transmission mechanism.

⚠️ **CAUTION**

During live monitoring, the patient must remain in close proximity to the paired recorder. If the patient is away from the recorder for an extended period, the examination data may be permanently lost.

During real-time monitoring, you can disconnect the data recorder from the computer at any time, and data will not be lost after disconnection. Once the recorder is disconnected from the computer, live monitoring stops.

The MotiliScan software cannot save the examination data displayed during live monitoring, but the data will be stored on the recorder and exported as part of the case data upon completion of the examination.

To stop live monitoring, click [Stop] 🔘 on the Data Viewer page, or exit the page directly.

4.3.2.11.Aborting a Test - Deactivating the Capsule

Place the capsule back into its packaging, and it will automatically shut down.

⚠️ **CAUTION**

If the test is aborted before ingestion, there is a risk of battery depletion for the capsule. It is recommended to complete swallowing within one hour; otherwise, the capsule should be discarded (refer to the recycling and disposal instructions).

4.3.2.12. Ending a Test

To determine if the capsule has been expelled, the patient should check for the presence of the capsule in their stool. Additionally, they can observe the indicator lights on the recorder; if the lights are flashing, it indicates that the capsule has been disconnected. If the indicator lights have been continuously flashing for more than 20 minutes and the patient had a bowel movement before the flashing occurred, it can be considered that the capsule has been expelled. Accurate capsule exit can only be clinically confirmed through data analysis or physical examination.

4.3.2.13. Returning the Devices

After the test ends, the patient should return the recorder and mobile phone. The nurse or medical technician can perform the following steps:

1) Collect the recorder and mobile phone.

2) Ask the patient about their experience with the MotiliCap test:

- Did the patient experience any unusual cramping, pain, or discomfort?

- Was the data recorder ever separated from the patient at any time during the test?

- Did the patient observe the capsule in their stool?

3) Confirm the capsule exit (refer to Section 4.3.2.14), after which the patient may leave.

4.3.2.14. Confirming Capsule Exit

⚠️ **CAUTION**

The physician should confirm whether the capsule has been expelled. Monitor the patient until the capsule exit is confirmed.

Using one of the following methods:

- Ask the patient if they found the capsule in their stool.

- Export the examination data (refer to Section 4.4: Data Export and Management) and analyze the data charts (refer to Section 4.5: Data Analysis) to look for evidence of capsule exit: a sudden drop in temperature or signal loss that coincides with a diary entry for a bowel movement.

If you cannot confirm capsule exit using the above methods, or suspect a bowel obstruction, consider a KUB and treat consistent with your management of a foreign object causing obstruction. A KUB determines if the capsule is retained and its location within the gastrointestinal tract.

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

- Administer pro-motility drug to assist in emptying the capsule from the stomach.

- Retrieve the capsule via endoscopy.

If the capsule is in the colon, consider the following measures:

- Administer laxatives to facilitate the movement of the capsule through the gut.

- Retrieve the capsule via colonoscopy.

4.4.Data Export and Management

4.4.1.Exporting the Test Data

After collecting the data recorder and mobile phone from the patient completing the test, the data stored in the recorder should be exported to MotiliScan for data analysis.

4.4.4.1 Syncing Diary Data

Before exporting data from the recorder, ensure that the diary stored on the mobile phone is fully synced to the recorder.

Open the MotiliCap APP and go to the home page to check if the diary sync status is "Sync Complete", as shown in Figure 4-9.
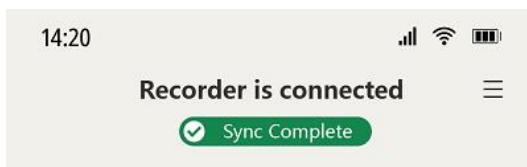
Figure 4-9 Diary Sync Status

If the sync status is "To be Synced", it indicates that the diary has not fully synced to the recorder, and syncing operations need to be executed until the status changes to "Sync Complete".

1) Turn on the data recorder and press the recorder button to ensure the indicator light is on.

2) Bring the mobile phone close to the recorder; the MotiliCap APP should be able to automatically connect to the recorder and begin syncing the diary, changing the status to "Syncing".

3) Wait for the syncing to complete, and the status will change to "Sync Complete".

⚠ **CAUTION**

Ensure that the mobile phone's Bluetooth is turned on and the recorder's indicator light is on; otherwise, the MotiliCap APP will not connect to the recorder.

4.4.1.2Exporting Data

After you confirm the diary sync is complete, exporting the stored data from the recorder to MotiliScan can begin.

1) Turn on the data recorder and press the recorder button to ensure the indicator light is on.

2) Connect the recorder to the computer via USB.

3) Open MotiliScan and click [Data Export] on the home page to open the tab (as shown in Figure 4-10).
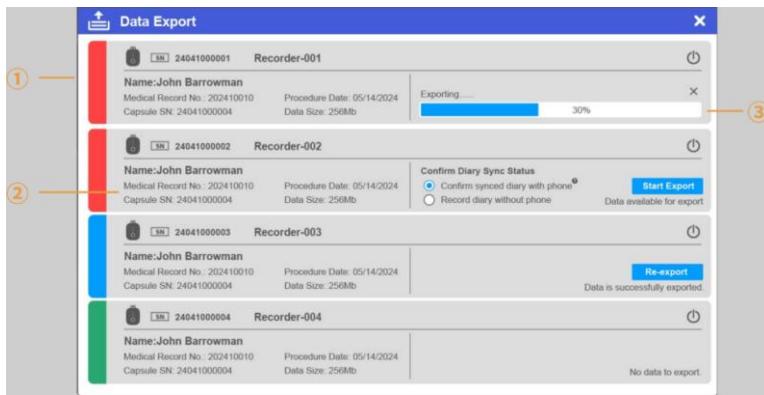
Figure 4-10 MotiliScan Data Export Tab

① All connected recorders will be displayed in this window.

   Red mark: Indicates that the test data exists in the recorder and has not been exported.

   Blue mark: Indicates that the test data has been fully exported from the recorder.

   Green mark: Indicates that there is no test data in the recorder.

② Displays the case information stored in the current recorder.

③ Shows the export progress once the data export begins.

4) The Data Export window lists the connected recorders. Select the recorder needing data export (red mark) and confirm whether the diary on the mobile phone has synced with the recorder (for confirmation method, refer to Section 4.4.1.1: Syncing Diary Data), then check the options as necessary (as shown in Figure 4-11).
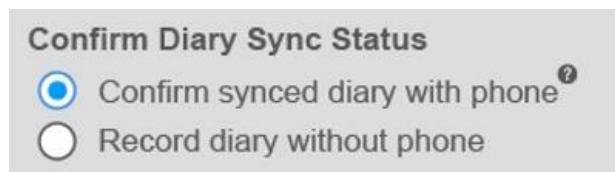
Figure 4-11 Confirm Diary Sync Status

5) After confirming diary sync, click [Start Export] to begin exporting data. The progress will be displayed during the export, and upon completion, a message will appear stating, "Data is successfully exported".

⚠ **CAUTION**

Do not disconnect the recorder from the computer during the export process, as this may interrupt the export.

⚠ If the export process is unexpectedly interrupted, check if the recorder and computer are properly connected, ensure the recorder is powered on and the indicator light is lit, then click [Start Export] to attempt to continue the export. If the export still cannot be initiated, contact our technical support for assistance.

6) After the test data is exported from the recorder, you can turn off the recorder to save power. The recorder does not have a physical button to turn it off. The MotiliScan is used to turn it off. In the recorder list in the Data Export tab, click the [Turn Off Recorder] button ⏻ ; after second confirmation, the recorder will be turned off.

4.4.2.Study Management

All created cases will be displayed on the Study Management page. Open MotiliScan and select the Study Management module from the home page to enter the Study Management page (Figure 4-12).

Figure 4-12 MotiliScan Study Management Page

① Quick access to functional pages, including Patient Management, Data Viewer and Data Export.

② Search and filter functions of the case list:

- The search function allows searching cases by Name, Capsule SN, MRN, Provider, or Indication.

- Cases can be filtered by Procedure Date, Study Status, and Assign Status.

- To clear all search and filter criteria, click [Reset] to reset.

③ Function area, including various operation options for selected cases:

- Select: Click [Select] to enter multi-select mode, allowing multiple cases to be deleted or assigned. Click [Cancel] to exit multi-select mode.

- Open Data: Open the test data of the selected case and enter the Data Analysis page (refer to Section 4.5: Data Analysis).

- Details: Open the details page for the selected case (Figure 4-13), where the entered case information is displayed, and can be edited.

Figure 4-13 Study Detail Page

- Report: If a report exists for the selected case, the report tab will display the generated report (Figure 4-14).

Figure 4-14 Report Details Tab

- Assign: Assign the selected case to a specified user. This opens the assign case tab (Figure 4-15), where you can select a user to complete the assignment. The name of the assigned user will appear in the Provider column of that case.
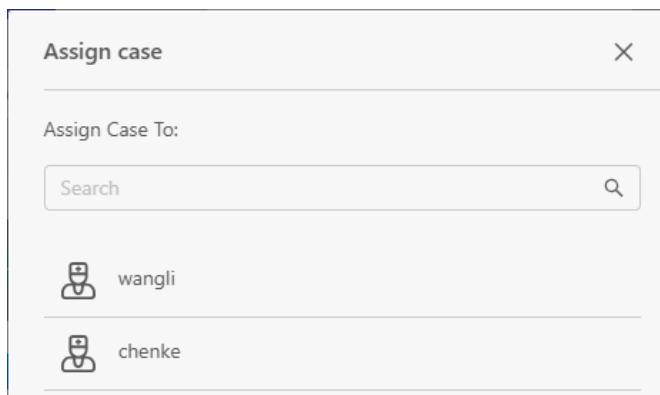
Figure 4-15 Assign Case Tab

- Delete: <u>Delete the selected case.</u> **This action requires a second confirmation; please proceed with caution, as deleted cases cannot be recovered.**

④ Case list, showing all created cases. The Status column indicates the case status for easy tracking:

Check in The test data for the case has not yet been exported.

Ready The test data for the case has been exported, but no test report has been issued.

Reported A test report has been issued for the case.

4.5.Data Analysis

The MotiliScan software provides data analysis features, allowing you to:

- View data graphs and run the data analysis wizard to analyze data.

- View test summaries and statistical data after completing the data analysis.

- Edit and generate test report.

The MotiliScan software can automatically identify the time points for capsule ingestion, gastric emptying, ICJ, and capsule exit, and calculate statistical data such as GET, SBTT, CTT, SLBTT, and WGTT.

4.5.1.Opening Data Analysis

After completing data export (refer to Section 4.4: Data Export and Management), you can open the data analysis page to analyze test data.

First, open theStudy Management page (refer to Section 4.4.2:Study Management), then select the case where data export has been completed, double-click the case or select it and click [Open Data] to open the Data Analysis page (Figure 4-16).

Figure 4-16 MotiliScan Data Analysis Page

① Function area, including the following functions:

- Study MGMT: Close the Data Analysis page and return to the Study Management page.

- Data Analysis: Open the data analysis wizard to perform data analysis (refer to Section 4.5.1.4: Data Analysis Wizard).

- Test Summary: Open the test summary window to view all statistical data (refer to Section 4.5.1.5: Test Summary).

- Generate Report: Open the report page to edit and generate test reports (refer to Section 4.5.1.6: Generate Report).

- Set Marks: Set important node marks that are automatically marked by MotiliScan, but can be modified here.

  As shown in Figure 4-17, select the mark to be edited from the expanded menu to open the editing tab. You can directly input the time to be modified in the time edit box, or click [Mark on the graph] 🧍 to mark the time on the graph. To restore the automatically marked time by MotiliScan, click [Auto Compute]. After editing is complete, click [Save] to save the change.
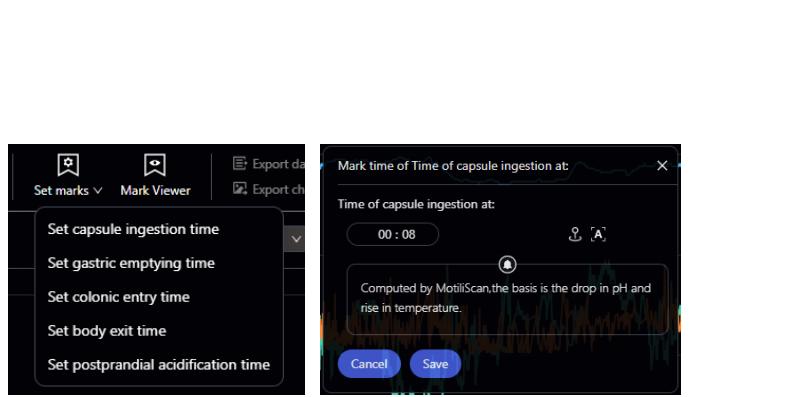
Figure 4-17 Set Marks

- Mark Viewer: Open the mark viewer window to view all markers and diaries, which allows manual addition of diaries and markers (refer to Section 4.5.1.3: Mark Viewer).

- Export Data: Function to be developed, currently unavailable.

- Export Chart Image: Function to be developed, currently unavailable.

- Patient Info: Open a tab displaying the details of the current case.

- Device Info: Open a tab displaying the information of the currently associated device (Figure 4-18).
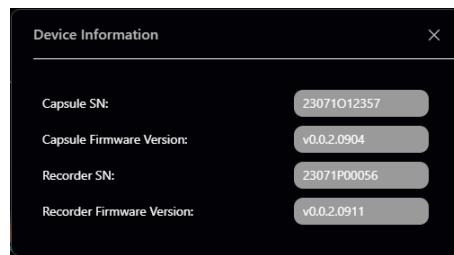
Figure 4-18 Device Information

- Settings: enables setting the display of graphs and statistical data; a function to be developed, currently unavailable.

Graph Tools, including various operational functions for the graph:

- ：Back or undo back of graph zoom state.

- ：Control the display of pressure, pH, and temperature data on the graph.

- Mark Display：Mark Display: Control the display of each type of mark on the graph.

- **⊡**: Display capsule ingestion time on the graph.

- **⊡**: Display gastric data on the graph.

- **⊡**: Display gastric emptying time on the graph.

- **⊡**: Display small bowel data on the graph.

- **⊡**: Display capsule exit time on the graph.

- **⊡**: Display all data on the graph.

- **⊡R**: Toggle between absolute and relative time; function to be developed, currently unavailable.

② Display all diaries, arranged according to the time on the horizontal axis, with unique icons for each diary type, as shown in Table 4-1. You can click the diary icon to show the diary details.

Table 4-1 Diary Icon

Diary Icon	Name
	Bowel Movement
	Eating a meal
	Getting up in the morning
	Going to bed at night
	Cramping or pain
	Nausea
	Passing gas
	Vigorous exercise or activity
	Other

③ Display pressure, pH, and temperature data in graph form. Each data type has its own color:

- ● ■ Green: pH
- ● ■ Red: Pressure 1 (mmHg)
- ● ■ Orange: Pressure 1 (mmHg)
- ● ■ Blue: Temperature (°F or °C)

④ Display global data view and GI tract sectional view.

⚠ **CAUTION**

The display of GI tract sections depends on the marking of capsule ingestion time, gastric emptying time, time of capsule entering the colon, and capsule exit time.

⑤ Display data, including statistical data calculated based on pressure and pH, as well as transit times in different parts of the GI tract.

4.5.2.Graph Operations

1) Data graph allows zooming; after zooming in, you can view more details. Two methods are available to zoom in on the graph:

- ● Using the mouse wheel: Scroll the mouse wheel up to zoom in around the pointer; scroll down to zoom out.

- ● Using the global view: Drag the left and right edges of the slider on the global view, as shown in Figure 4-19, to set the time points for the left and right endpoints of the graph. (The content covered by the slider equals what is displayed on the data graph.)
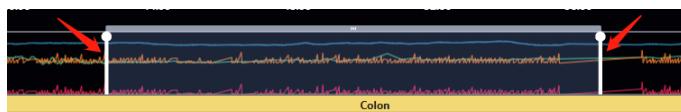
Figure 4-19 Zooming the Graph Using Global View

After zooming in on the graph, you can right-click on the graph to enter drag mode; moving the mouse left or right allows you to view adjacent hidden data while maintaining the current zoom ratio. Alternatively, dragging the global view slider achieves the same function.

2) Move the cursor over to the graph and double click on the graph to place a mark at the pointer's time point (as shown in Figure 4-20) while showing the value of that mark. After inputting comments, the mark can be saved.
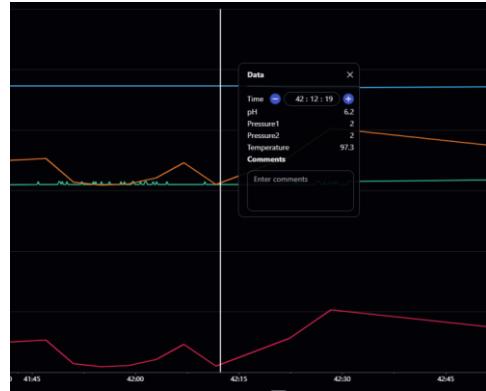
Figure 4-20 Placing a Time Point Mark

3) Move the cursor over to the graph, hold down the left mouse button and drag to select a segment of data. After releasing, you can choose [Data Statistic] and [Zoom in], as shown in Figure 4-21.

Figure 4-21 Box Selection on Graph

Selecting [Data Statistic] allows you to place a time segment mark (as shown in Figure 4-22) while displaying the value of that mark. After inputting comments, the mark can be saved.
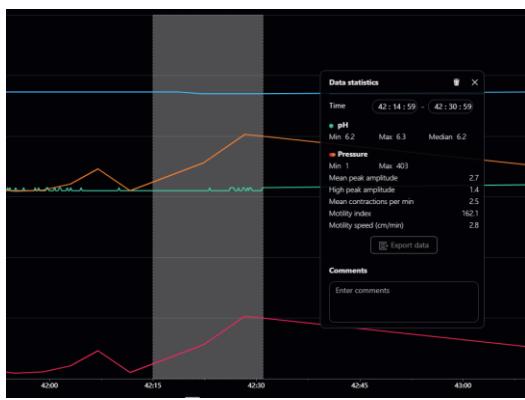
Figure 4-22 Placing a Time Segment Mark

Selecting [Zoom in] will enlarge the graph to the selected time segment.

4.5.3. Mark Viewer

Through the mark viewer, you can view all marks, including diaries.

Click [Mark Viewer] to open the mark viewer tab (Figure 4-23), where all marks and diaries are listed.
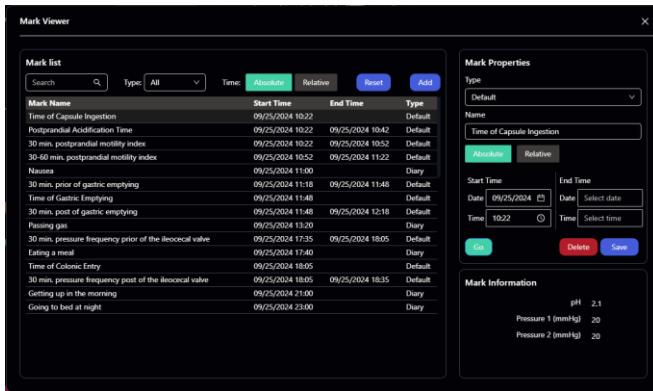
Figure 4-23 Mark Viewer

You can perform the following operations:

● Use the search tool on the top of the list to search for mark names, filter by mark type, switch mark time formats (absolute time, relative time), and clear all search and filter conditions.

● Select a mark to view its detailed parameters and values on the right side of the list.

● Click [Add] to enter addition mode, where you can add a diary or custom mark; after setting all parameters, click [Save] to complete the addition.

4.5.4.Data Analysis Wizard

Use the data analysis wizard to analyze data. Click [Data Analysis] to open the data analysis wizard. The data analysis will guide you step by step through the analysis process. The steps are as follows:

1) Display Alert Content (Figure 4-24). Read carefully. To continue, click [Confirm and Next] to accept the alert.

Figure 4-24 Data Analysis – Caution

2) Confirm Diary Events (Figure 4-25). Review the diary content, and if confirmed, click [Confirm and Next] to proceed. If you need to manually add a diary, click [Add Diary] to open the Mark Viewer tab to add (refer to the relevant section).

Figure 4-25 Data Analysis – Confirm Diary Events

3) Confirm Time of Capsule Ingestion (Figure 4-26). Check if the capsule ingestion time is correct. If incorrect, you can directly input the necessary time in the time edit box, or click [Mark on the graph] to mark the time on the graph. To restore the time automatically marked by MotiliScan, click [Auto Compute]. If the time cannot be marked, check [Unable to mark the capsule ingestion]. After confirmation, click [Confirm and Next] to proceed.
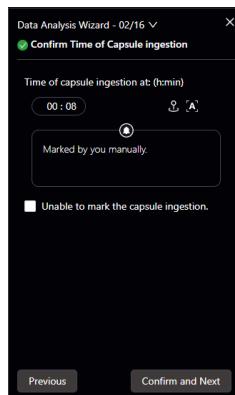
Figure 4-26 Data Analysis – Confirm Time of Capsule ingestion

4) Confirm Postprandial Acidification Time (Figure 4-27). Check if the postprandial acidification time is correct. If incorrect, you can directly input the necessary time in the time edit box, or click [Mark on the graph] to mark the time on the chart. To restore the time automatically marked by MotiliScan, click [Auto Compute]. If the time cannot be marked, check [Unable to mark the postprandial acidification time]. After confirmation, click [Confirm and Next] to proceed.
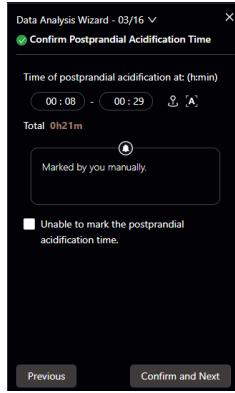
Figure 4-27 Data Analysis – Confirm Postprandial Acidification Time

5) Confirm Gastric Acidity (Figure 4-28). Check the data graph to confirm whether the gastric pH has any values below 4, and select based on actual conditions. After selection, click [Confirm and Next] to proceed.
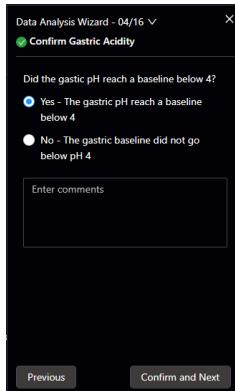
Figure 4-28 Data Analysis – Confirm Gastric Acidity

6) Confirm Additional Meal Before 6 Hours (Figure 4-29). Check the diary to confirm whether the patient had any additional meals besides the standard meal within 6 hours after the start of the test, and select based on actual conditions. After selection, click [Confirm and Next] to proceed.
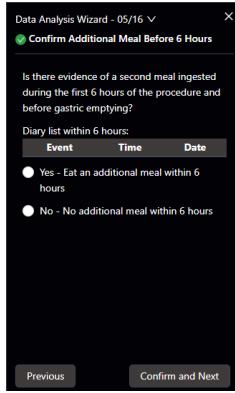
Figure 4-29 Data Analysis – Confirm Additional Meal Before 6 Hours

7) Confirm Time of Gastric Emptying (Figure 4-30). Check if the time of gastric emptying is correct. If incorrect, you can directly input the necessary time in the time edit box, or click [Mark on the graph] to mark the time on the chart. To restore the time automatically marked by MotiliScan, click [Auto Compute] . If the time cannot be marked, check [Unable to mark the gastric emptying]. After confirmation, click [Confirm and Next] to proceed.
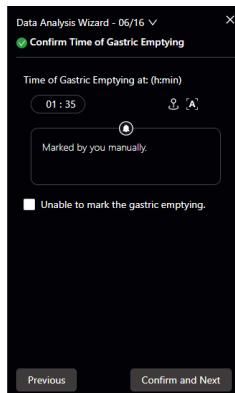
Figure 4-30 Data Analysis – Confirm Time of Gastric Emptying

8) Confirm Emptying Time Evaluation (Figure 4-31). Confirm the gastric transit time and select based on actual conditions. After selection, click [Confirm and Next] to proceed.
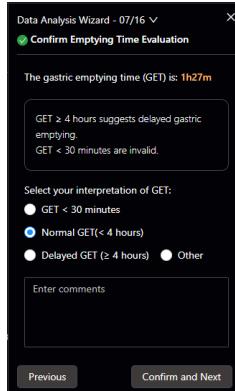
Figure 4-31 Data Analysis – Confirm Emptying Time Evaluation

9) Magnitude of pH Rise at Emptying (Figure 4-32). Please confirm the magnitude of pH change from 30 minutes before gastric emptying to 30 minutes after gastric emptying, and select based on actual conditions. After selection, click [Confirm and Next] to proceed.
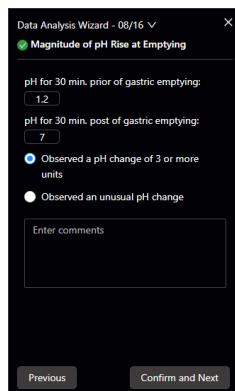
Figure 4-32 Data Analysis – Magnitude of pH Rise at Emptying

10) Gastric Pressure Characteristics (Figure 4-33). Enter comments based on actual conditions, then click [Confirm and Next] to proceed.
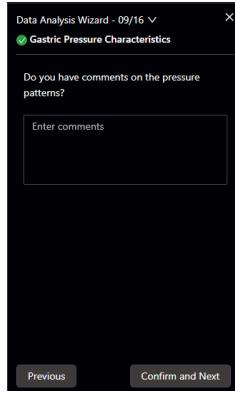
Figure 4-33 Data Analysis – Gastric Pressure Characteristics

11) Small Bowel pH Profile (Figure 4-34). Check the data graph to confirm the magnitude of pH changes in the small bowel, and select based on actual conditions. After selection, click [Confirm and Next] to proceed.

Figure 4-34 Data Analysis – Small Bowel pH Profile

12) Small Bowel Pressure Characteristics (Figure 4-35). Enter comments based on actual conditions, then click [Confirm and Next] to proceed.
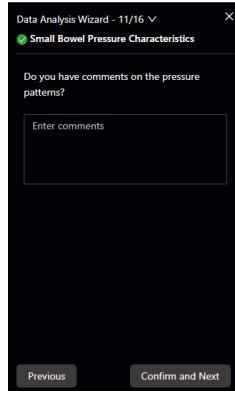
Figure 4-35 Data Analysis – Small Bowel Pressure Characteristics

13) Confirm Time of Colonic Entry (Figure 4-36). Check the time the capsule entered the colon is correct. If incorrect, you can directly input the necessary time in the time edit box, or click [Mark on the graph] to mark the time on the chart. To restore the time automatically marked by MotiliScan, click [Auto Compute] . If the time cannot be marked, check [Unable to mark the colonic entry]. After confirmation, click [Confirm and Next] to proceed.
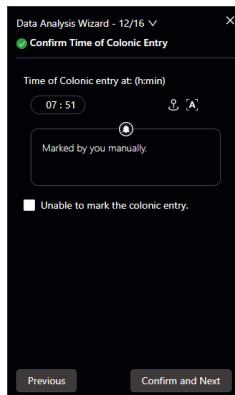
Figure 4-36 Data Analysis – Confirm Time of Colonic Entry

14) Small Bowel Transit Time Evaluation (Figure 4-37). Confirm the transit time of the small bowel and select based on actual conditions. After selection, click [Confirm and Next] to proceed.
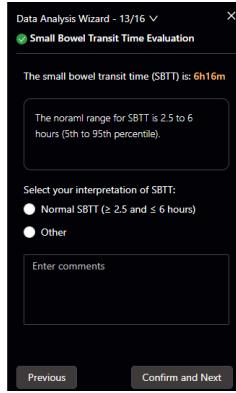
Figure 4-37 Data Analysis – Small Bowel Transit Time Evaluation

15) Colonic Pressure Characteristics (Figure 4-38). Enter comments based on actual conditions, then click [Confirm and Next] to proceed.
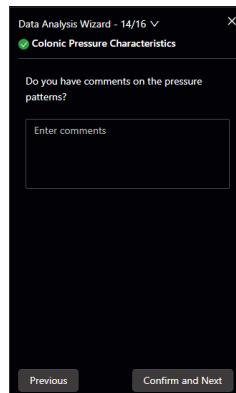
Figure 4-38 Data Analysis – Colonic Pressure Characteristics

16) Confirm Time of Body Exit (Figure 4-39). Check if the time the capsule exited the body is correct. If incorrect, you can directly input the necessary time in the time edit box, or click [Mark on the graph] to mark the time on the chart. To restore the time automatically marked by MotiliScan, click [Auto Compute]. If the time cannot be marked, check [Unable to mark the body exit]. After confirmation, click [Confirm and Next] to proceed.
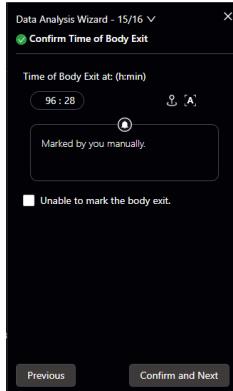
Data Analysis – Confirm Time of Body Exit

17) CTT Evaluation (Figure 4-40). Confirm the colonic transit time and select based on actual conditions. After selection, click [Confirm and Next] to proceed.
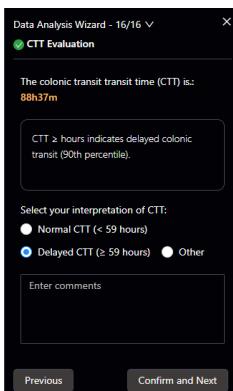
Figure 4-40 Data Analysis – CTT Evaluation

18) Data Analysis Complete (Figure 4-41). Click [Open Test Summary] to view all statistical data (refer to Section 4.5.1.5: Test Summary).
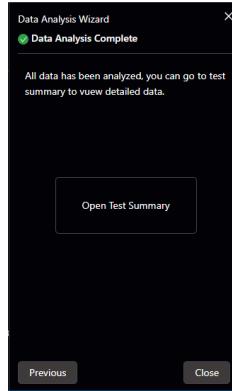
Figure 4-41 Data Analysis – Data Analysis Complete

4.5.5.Test Summary

After completing the data analysis wizard, you can open the test summary to view all statistical data.

Click [Test Summary] to open the test summary tab, as shown in Figures 4-42 and 4-43.
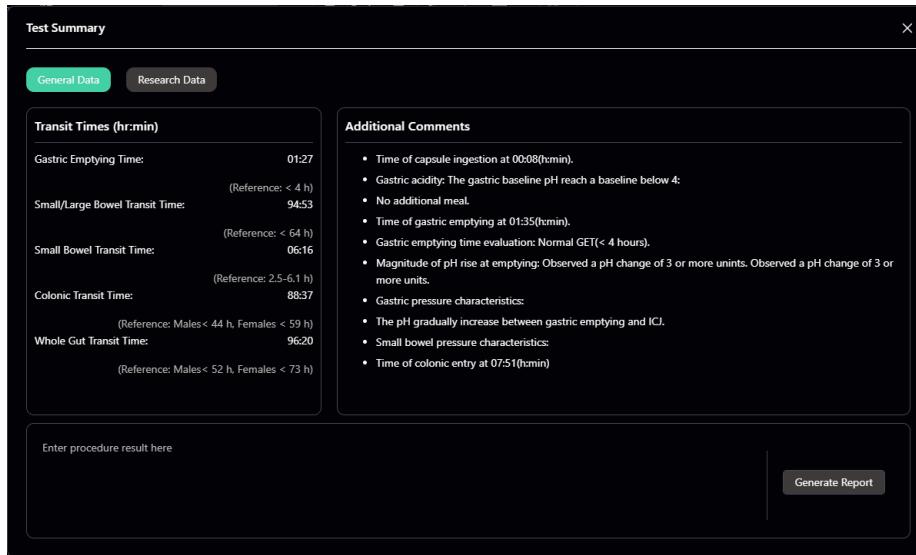
Figure 4-42 Test Summary – General Data

Region	Motility Index	Motility Speed(cm/min)	Mean peak ampliitude	Mean contractions per min.	Pressure(mmHg)		pH		
					Mean	High	Low	Median	High
Stomach	270.8	-	4.4	2.5	1	486	0.6	6.3	7.9
Small Bowel	550.8	-	2.6	1.2	1	486	0.6	1.9	5.9
Colon	557.3	10.1	3.1	2.8	1	378	5.3	6.5	7.2
Small/Large Bowel	246	4.4	4	1.8	1	459	4.9	6.3	7.9

- Postprandial Acidification Time: ---.
- Postprandial Motility Index: 30 minute is 3.1, 30-60 minute is 3.3.
- Pressure Frequency: 30 minute before the ileocecal valve is 11.9, 30 minute after the ileocecal valve is 11.9.

Figure 4-43 Test Summary – Research Data

The General Data tab displays the transit times of various parts of the GI tract, as well as the data confirmed at each step in the data analysis wizard.

The Research Data tab presents necessary data for research, including Motility Index, Motility Speed, Mean peak amplitude, etc.

After reviewing the data, you can directly enter the test results in this window and then click [Generate Report] to open the report page for editing and generating the report (refer to section 4.5.1.6: Generating a Report).

4.5.6. Generating a Report

After completing the data analysis, you can edit the test report and then generate it.

Click [Generate Report] to open the report page, as shown in Figure 4-44.

Figure 4-44 Report Page

To complete the report editing and generation:

1) Enter the Procedure Result and Recommendation. If the Procedure Result has already been entered in the Test Summary window (refer to section 4.5.1.5: Test Summary), this page will automatically fill in the previously entered content.

2) Select the data graph content to print.

3) The middle of the page shows a real-time preview of the report, allowing you to edit while viewing the report preview.

4) You can choose to check De-identify to remove patient privacy information from the report.

⚠ **CAUTION**

This operation is reversible; removal only affects printed or exported reports and does not directly delete original data.

5) You can choose to check Electronic Signature to sign the report electronically.

6) You can set the report generation date, which defaults to the current date.

7) After completing all edits and settings, click [Generate Report] to generate the report. The generated report will display a window as shown in Figure 4-44. You can choose to [Print] 🖶 or [Save As] ▣ to a local file directory.
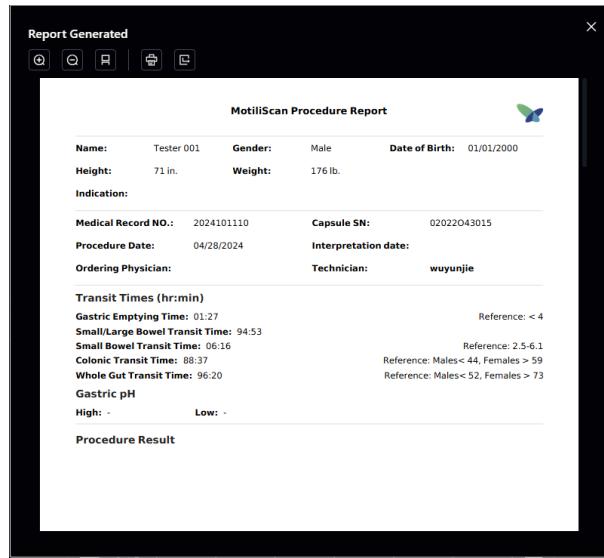

Figure 4-45 Report Generated Tab

Chapter 5 Data Recorder Indication Information

Data Recorder Indicator Light Status:
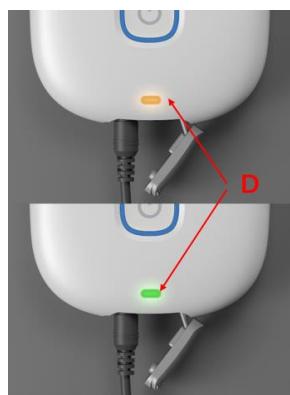
Figure 5-1 Data Recorder Indicator Light

Indicator light	Status	Interpretation
LED-B status indicator light	Fully on or partially on	Indicates the battery level of the data recorder
	Fully off	The data recorder is either powered off or in power-saving mode
	Flashing in cycles	The data recorder has been powered on and is searching for the capsule
LED-D charging indicator light	Orange	The data recorder is in charging
	Green	The data recorder is fully charged
	Orange and green alternating flashing	The data recorder charging is abnormal

⚠️ **WARNING**

Do not observe the LED light up close for extended periods during use.

Chapter 6 Clinical Manifestation (Risk Analysis)

⚠️ **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.

Materials in Contact with the Patient

White middle shell	Polycarbonate
Transparent middle shell	Polycarbonate
Pressure-sensitive membrane	Silicone
Adhesive for white middle shell and pressure-sensitive membrane	Silicone adhesive (KN-300X)
Adhesive for white middle shell and transparent middle shell	Acrylic polyurethane
pH film	Polyacrylonitrile-vinyl imidazole bromide

All materials in contact with the human body have undergone biocompatibility testing and are non-toxic, non-sensitizing, and non-irritating. The device does not contain natural latex.

Chapter 7 Installation and Training

This system requires no installation. For upgrades to the PC software and mobile app, contact after-sales support. Before use, carefully read this user manual and follow the physician's instructions. If you experience any discomfort during use, promptly consult a professional doctor.

Chapter 8 Serviceable and Maintenance

1.1. **Capsule**

⚠️ **CAUTION**

Do not reuse the capsule. The capsule is a single-use item.

1.2. **Data Recorder**

⚠️ **CAUTION**

The data recorder is not serviceable or components cannot be replaced.

Clean and disinfect the outer surface of the recorder after each patient use.

● Connect the recorder to PC software and click the "Turn Off Recorder" button to turn off the data recorder.

● Should be manually cleaned after every use by wiping the equipment surface gently with a cotton ball lightly dipped in 70% isopropyl alcohol and let it dry for 15 minutes.

● Conduct preventive maintenance checks. Check for cracks or damage. Shake the data recorder and listen for any detached batteries. If the casing is cracked or damaged, or if you hear rattling, do not use the recorder.

⚠️ **CAUTION**

Do not immerse the data recorder in water or other liquids. Immersion could damage the internal electrical components and render the data recorder inoperable.

The data recorder, power supply, and capsule are not user-serviceable.

Do not attempt to replace the batteries in the data recorder.

⚠️ **WARNING**

Unauthorized modifications to the data recorder, power supply, or capsule may cause harm.

Chapter 9 Precautions and Troubleshooting

Issue/phenomenon	Troubleshooting method/consequence	Solution
LED does not light up when holding the power button	Check if the battery is depleted	Charge the device
	Connected to PC software via a data cable, the data recorder is recognizable	LED is damaged. Contact after-sales support for repair
	Connected to PC software via a data cable, the data recorder is unrecognizable	
Charging indicator does not light up during charging	Check if the charging cable is properly connected	Reconnect the charging cable
	Charging indicator still does not light up after changing a charger	Contact after-sales support for repair
Data recorder cannot be powered off	Restart PC software and reconnect. It still cannot be powered off	Contact after-sales support for repair
Failed to connect to the data recorded after scanning with the APP	Check if Bluetooth and location permissions on the phone are enabled	Enable Bluetooth and location permissions on the phone
Data recorder cannot connect to PC software	Check if the data cable is properly connected	Reconnect or replace the data cable, or change a USB port
Capsule not powered on after being removed from packaging		Reinsert the capsule into the packaging and remove it again
Data recorder exposed to water	Data recorder is damaged by water ingress	Quickly dry the data recorder with a towel or tissue
Data recorder lanyard disconnected	Inconvenient for carrying	Use another lanyard for carrying
Data recorder got severely bumped and cracked	Data recorder is damaged	Contact the physician to assess if the data recorder needs to be replaced

⚠ 小心CAUTION

Keep the data recorder charging cable and lanyard out of reach of children or pets to prevent the risk of strangulation.

⚠️ **警告**

Report any changes in product performance immediately to the AnX Robotica Customer Service Department.

If the provided solution does not resolve the problem, report it immediately to the Customer Service Department of AnX Robotica.

Chapter 10 Technical Parameters

10.1. Capsule

Physical performance:

Length:	26 ± 1.0mm
Diameter:	13 ± 1.0mm
Weight:	4.5 ± 1.0g
Material:	Biocompatible materials

Operating performance:

Pressure Accuracy	0-99 mmHg ± 5 mmHg 100-350 mmHg ± 10% of applied pressure
Pressure Range	0-350 mmHg
pH Accuracy	± 0.5 pH units
pH Range	1-9 pH units
Temperature Accuracy	± 1℃ (20 – 42℃)
Transmission Frequency	433 MHz (single frequency point)
Battery Life	>5 days
Battery Type	Silver Oxide (Zn/Ag2O) cell ≥30mAh
Rated Voltage	3VDC
Safety Type	Internal power source, type BF, continuous operation device
Ingress Protection Rating	IPX8

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Operating Temperature Range	+5~40℃
Operating Humidity Range	15~100%
Operating Atmospheric Pressure	700~1060 hPa
Storage Temperature Range	-25~70 ℃
Storage Humidity Range	0~90 %
Storage Atmospheric Pressure	700~1060 hPa

10.2.Data Recorder

Operating performance:

Recording Time	≥5days
Storage Capacity	32MB
Battery Type	Polymer Lithium-Ion Battery (2S1P 7.6V)
Battery Capacity	2000mAh
Input Voltage	DC5V/3A
Safety Type	Internal power source, type BF, continuous operation device
Operating Temperature Range	+5~40℃
Operating Humidity Range	15~90%
Operating Atmospheric Pressure	700~1060 hPa
Storage Temperature Range	-25-70℃
Storage Humidity Range	0~90 %

Storage Atmospheric Pressure	700~1060 hPa
Ingress Protection Rating	IP22

FCC SDoC statement

FCC Supplier's Declaration of Conformity

Capsule (2ATXZMO7010)

Data Recorder (2ATXZMO8001)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

⚠️ **CAUTION**

The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

10.3.Guidance and Manufacturer's Declarations

The NaviCam Capsule Endoscope System with NaviCam Stomach Capsule complies with the requirements of IEC 60601-1-2:2014, EN 60601-1-2:2015.

Chapter 11 Labeling and Acronyms

11.1.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

11.2. Labeling

Label Symbols	Description
⚠	Caution, consult accompanying documents
	Consult Instruction for use
FCC	US FCC compliance
Rx Only	Prescription use only
	No Recycle. Dispose of properly
	Single use only. Do not reuse
REF	Part or catalog number
	Manufacturer
	Date of manufacture

⧖	Use by YYYY-MM
LOT	Lot number
🌡	Minimum and maximum storage temperature
⚠ Warning magnetic field	Caution: Strong magnet
🚫	Warning: Keep away from pacemakers
🛉	Type BF equipment
▽Σ	Sufficient for one test
IP22	Ingress protection rating
IPX8	Ingress protection rating
SN	Serial number
🍷	Fragile
☂	Keep dry

⚠ **CAUTION**

The data recorder is compact in size. For aesthetic purposes, the label content is only clearly visible at a distance of 60 cm under 100 lux lighting.