atmo BIOSCIENCES		-	-
		Doc No:	515_2032
		Version:	01
Document Title	Atmo Gas Capsule System User Manual AU English		

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Revision History

Version	*Date*	*Description*
1.0	21-Dec-2023 {{Dte_es_:signer5:date}}	NZ Release / Summative Release

IES Date field error correction

Atmo® Gas Capsule System

USER MANUAL

Version 2.0

General Information

Copyright

Limited Warranties

Atmo Biosciences warrants that the Atmo Gas Capsule System shall be free from defects in material and workmanship for the period specified below from the date of purchase by the initial consumer. Atmo Biosciences warrants the Atmo Gas Capsule System for a period of one (1) year from the date of purchase of the system.

If the product fails under conditions of normal use, Atmo Biosciences will repair or replace, at its option, the defective product or any of its components. This Limited Warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by Atmo Biosciences to perform such repairs Any product repaired or replaced under warranty will be returned, to the place of purchase, freight prepaid. The cost of transporting the product to an authorized service organization will be borne by the consumer.

This manufacturer's warranty is in lieu of all other express or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so in some instances the above limitation may not apply.

Atmo Biosciences shall not be responsible for any incidental or consequential damages claimed to have occurred as a result of the sale, installation or use of any Atmo Biosciences product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply. This warranty provides specific legal rights, and other rights may be available that vary from region to region.

The Atmo Gas Capsule: Atmo Biosciences warrants that each capsule is free from defects in workmanship and materials until the Capsule's expiration date.

The Atmo Mobile Device: The Mobile Device is covered under the manufacturer's warranty.

Contact Information

Manufacturer

Atmo Biosciences Ltd.
436 Elgar Rd
Box Hill, VIC 3128
Australia

Technical Support

Email: support@atmobiosciences.com

Website: https://atmobiosciences.com/

Contents

Introduction

Using this Manual

The following symbols are used in this User Manual:

	**WARNING:** Warnings are used to indicate a possible hazard that could result in death or serious injury.
	CAUTION: Cautions are used to indicate a possible hazard that could result in an invalid test result and/or damage to the device.
	**NOTE:** Notes are used to emphasize or add important additional information.

Indications for Use

The Atmo® Gas Capsule System measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Gastric 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, to aid in differentiating slow and normal transit constipation. In the case where ileocecal junction transit cannot be determined, the system will report combined Small and Large Bowel Transit Time **(SLBTT)**.

Transit times are derived from measures of temperature, hydrogen concentration, and carbon dioxide concentration, and indicators of oxygen level, Capsule tumble, and antenna reflectance.

Not for use in paediatric patients.

Contraindications

WARNING:

Do not use the Atmo Gas Capsule System in patients with the following diseases or conditions:

- Under 21 years of age (US) and under 18 years of age (EU and New Zealand)
- Suspected or known strictures
- Fistulas or physiological/mechanical gastrointestinal obstruction
- Gastrointestinal surgery within the past three months
- Diverticulitis
- Gastric bezoar
- Radiation enteritis
- Pregnancy
- Swallowing disorders/dysphagia to food or pills
- Patients with implantable or portable electromechanical medical devices, for example pacemakers
- Patients with a BMI ≥ 40

Medication Restrictions

The following medications may alter gut motility. It is recommended that the gastroenterologist consult with the patient about reducing or discontinuing these medications prior to commencing the study and for the duration of the study. See the table below for recommended discontinuation times.

Medication Restriction Periods

Restriction Period (including day of Ingestion)	**Medication Type**	**Examples**
Seven days before the study, including day of ingestion	Proton pump inhibitors	Omeprazole, Lansoprazole, Nexium™
Three days before the study, including day of ingestion	Histamine blockers	Zantac™
	Motility-altering medications	Cisapride, Domperidone, Metoclopramide
	Narcotic analgesics	Oxycodone, Codeine
	Anticholinergics	Phenergan™, Prochlorperazine
Two days before study, including day of ingestion	Antiemetics & 5-HT3 antagonists	Zofran™
	Macrolides	Erythromycin, Zithromax™
	5HT4 partial agonists	Cisapride
One day before study, including day of ingestion	Antacids	Gaviscon™, Mylanta™

WARNING:

- It is the responsibility of the clinician or gastroenterologist to judge the relative benefits and risks when changing patient medications.
- Patients with diabetes may require additional support to safely manage the pre-study fasting period, the consumption of the Motility Bar and the six-hour fasting after ingesting the Capsule. It is recommended that the gastroenterologist and the diabetic support team plan this in consultation with the patient.
- Patients with food allergies should review the ingredients to the Motility Bar (see Atmo Motility Bar section) to determine whether an alternative meal is needed.

Safety Instructions

It is the sole responsibility of the clinician or gastroenterologist to ensure that they have read and understood this User Manual before using the Atmo Gas Capsule System.

General Safety

CAUTION:

- For prescription use only.
- To ensure the correct operation of the Atmo Gas Capsule System, the guidelines and instructions in this User Manual must be followed.
- Ensure the Capsule is stored at: -10 to 45°C (14 to 113°F) and 30 to 90% relative humidity.
- Use only components supplied with the system. Do not use system components with other devices, or other devices with the system components.
- Do not attempt to modify any part of the system.
- Do not use the Receiver or Capsule if there are any visible signs of damage.

Electrical Safety

WARNING:

To reduce the risk of electrical shock:

- Use only the supplied Power Supply and USB Cables.
- Do not attempt to disassemble or service any part of the system. The system contains no user serviceable parts.
- Do not attempt to remove or replace the Receiver battery (see Troubleshooting and Support for further information)
- Clean only the external surfaces of the Receiver, Mobile Device, and Belt using the recommended cleaning agents (see Receiver and Belt Reprocessing Instructions and Other Device Cleaning Instructions).
- Do not attempt to clean the inside any of the system components.
- Do not use the Receiver if there are any visible signs of swelling or deformation. If any signs of swelling or deformation are detected, put the Receiver aside and contact your Atmo Biosciences representative.
- Do not immerse the Receiver in liquid (including showers/baths). Partial or full immersion in liquid may damage the Receiver.

Biohazards

WARNING:

- The Receiver and Belt require cleaning, as per Section 8.1, after each patient's use. Follow your clinic's procedures for handling biohazardous material between receiving and cleaning these items.
- The use of suitable safety gloves is recommended while cleaning the returned Receiver and Belt.

Electromagnetic Immunity (EMI) - Electromagnetic Compatibility (EMC) Compliance

The Atmo Gas Capsule complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause interference; and
- This device must accept any interference, including interference that may cause undesired operation of the device.
- The Receiver and Power Supply have been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. They comply with the emission and immunity requirements described in IEC 60601-1-2:2014+AMD1:2020.
- The clinician must take action to remove sources of electromagnetic interference (such as televisions, monitors, radios, and power supplies) if it hinders the operation of the system.
- Do not use the Capsule (FCC ID: 2BA23-AGC1) and Receiver in proximity to sources of strong electromagnetic radiation, as these may interfere with their correct operation.
- For EMC compliance related to the use of the Mobile Device, please refer to the relevant user documentation specific for that device.

Radio Interference

The following is a list of known sources of radio interference that may interfere with the system. However, the momentary nature of these interference sources is unlikely to affect the study.

- Any device running in the ISM 433MHz band.
- Garage door remote control openers
- Automobile Remote Keyless Systems (in EU and Asia).
- Wireless home automation systems.

	**WARNING:** Any changes or modifications to the Atmo Gas Capsule System not expressly approved by the grantee could void the user's authority to operate this equipment.

About the Atmo® Gas Capsule System

The Atmo Gas Capsule System is an integrated system consisting of the following components (Figure 1).

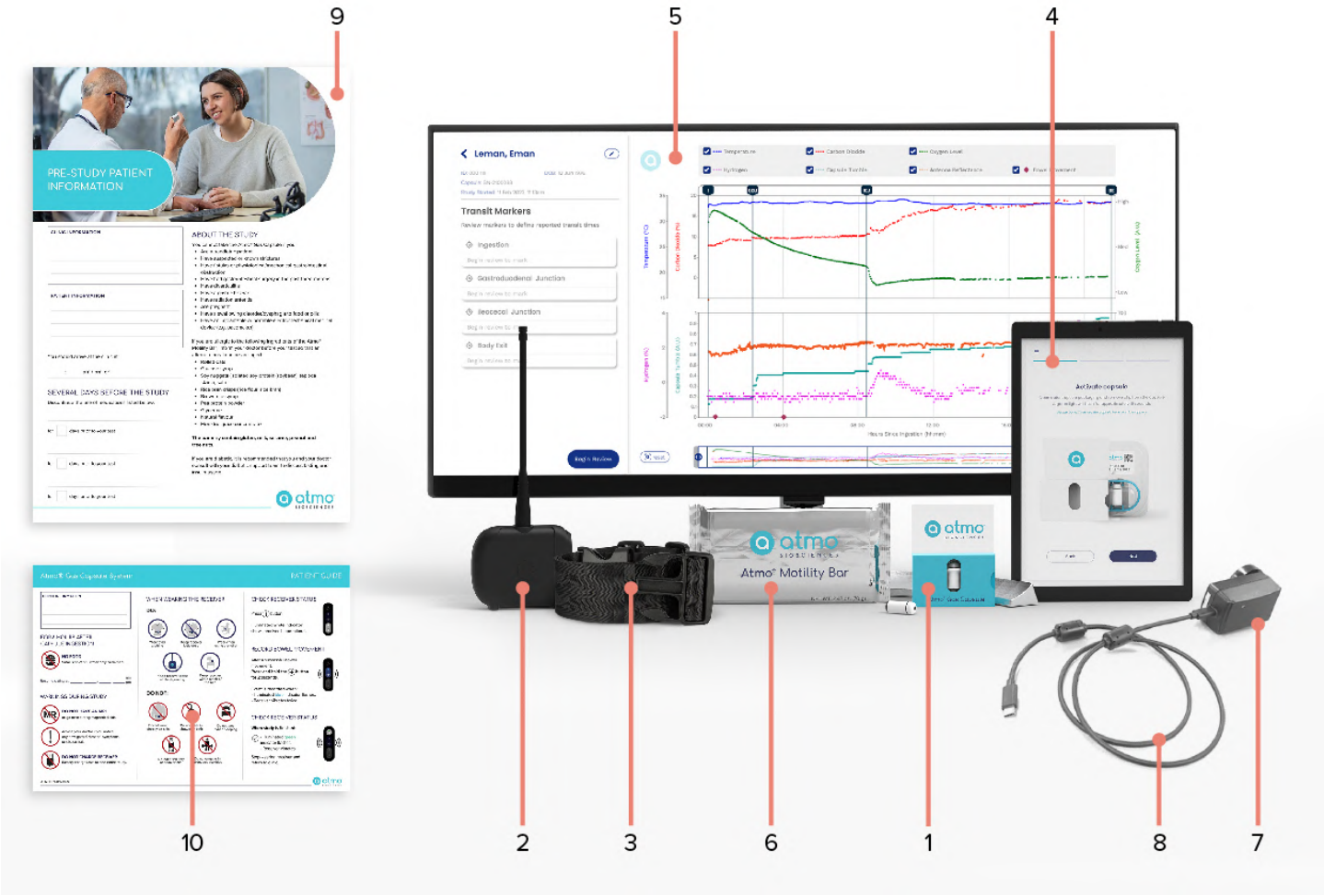


Figure 1. Atmo Gas Capsule system components

1. Atmo Gas Capsule (Capsule): The ingestible component with onboard sensors that measures whole and regional gut transit times
2. Data Receiver (Receiver): Stores information transmitted by the Capsule
3. Patient Belt (Belt): Holds the Receiver on the patient
4. Mobile Device: Used to initiate study and upload results via the Clinic App
5. Clinician Portal: Used to review data and create Motility Study Report(s)
6. Motility Bar: Standardised meal ingested with the Capsule
7. Power Supply: Charges Receiver and Mobile Device
8. USB Cable: Connects Mobile Device to Receiver and to the Power Supply
9. Pre-Study Information Template: Preparation instructions that are given to the patient prior to the study
10. Patient Guide: Study guidance information given to the patient after Capsule Ingestion

Atmo System Components

Atmo® Gas Capsule

The Atmo Gas Capsule is a non-sterile, single-use, Capsule (see Figure 2), which is ingested by the patient.

Following ingestion, the Capsule senses several modalities that are used to detect gastrointestinal landmarks, allowing the subsequent calculation of transit metrics.

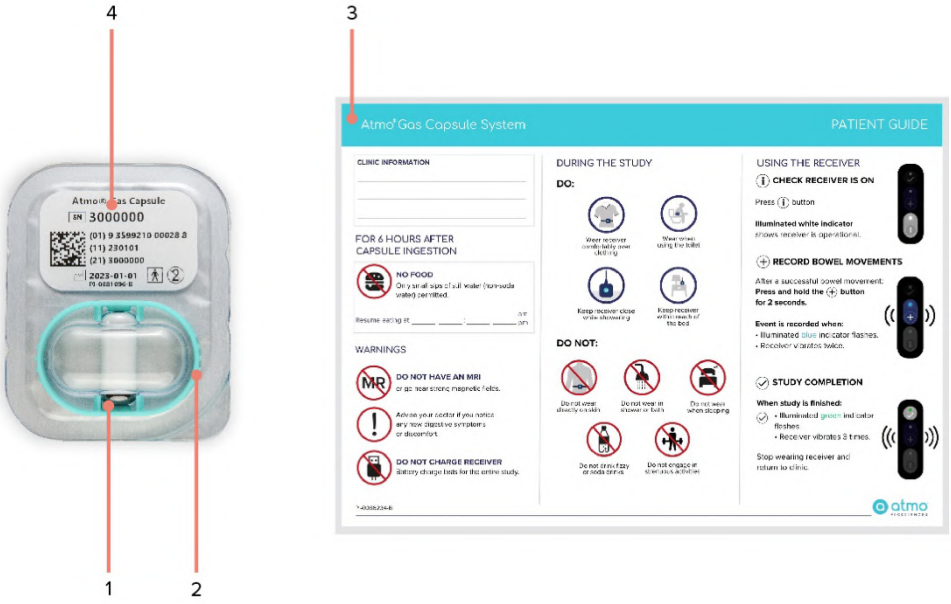


Figure 2. Atmo Gas Capsule and Atmo Patient Guide

The individually packaged Capsule includes the following components (see Figure 2):

1. Atmo Gas Capsule
2. Storage Clip
3. Atmo Patient Guide
4. Label including serial number (SN), barcode and expiry date

Storage

Capsules must be stored in their original packaging away from direct sunlight or strong magnetic fields, between -10 to 45°C (14 to 113°F) and 30 to 90% relative humidity.

⚠	**WARNING:** • Do not use the Capsule near Magnetic Resonance Imaging (MRI) equipment.
⚠	**CAUTION:** • Do not remove the magnetic storage clip from the Capsule until immediately before Ingestion. Removing the storage clip will activate the Capsule and start to consume battery life. • Do not use the Capsule if it has been dropped. Take care to avoid dropping the Capsule as this may damage the Capsule and impact correct operation. • Do not use the Capsule if there are any visible signs of damage. • The Capsule must be kept in the original packaging until ready for use by the patient. • The Capsule must be inspected for damage or visible contaminants prior to ingestion. • The Capsule is a non-sterile, single-use, disposable item, and does not need to be retrieved.

Atmo® Data Receiver

The Receiver is used to wirelessly collect data transmitted by the Capsule during a study (see Figure 3). It is held within the Receiver Belt and is worn by the patient during their daily activities.

	NOTE: The Receiver automatically manages power during use and cannot be turned on or off.

Figure 3. Atmo Data Receiver

The Data Receiver has the following (see Figure 3):

1. Antenna
2. End-of-Study Indicator
3. Bowel Movement Button and Indicator
4. Info Button (i) and Status Indicator
5. USB-C Port
6. Reset Switch

Data Receiver Buttons and Indicators

Info Button and Status Indicator Light Emitting Diode (LED)

When the info button is pressed the status indicator LED will light up.

To check status, press the info button.

Orange LED

When the Orange LED is illuminated the Receiver is not charged. The Receiver needs charging before a study can be started.

Green LED

When the Green LED is illuminated the Receiver is charged. The Receiver is ready to be used for a study.

White LED

When the White LED is illuminated (during study initiation) the Receiver has been paired with a Capsule for a study.

Bowel Movement Button and Indicator LED

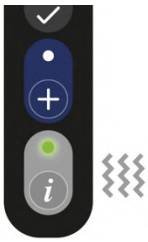
To register a bowel movement, hold the bowel movement button for 2 seconds.

A blue LED will light up and there will be a double vibration to confirm event was recorded.

To check status, press the info button.

The bowel movement indicator will light up blue and there will be a double vibration if a bowel movement has been recorded in the last 5 minutes.

End-of-Study Indicator LED



When the Receiver has determined that a study is complete, the end-of-study indicator will temporarily light up green and the Receiver will vibrate three times.

Return the Receiver and Belt to the clinic. Bowel movement recording is disabled.

USB-C Port & Reset Switch

The USB Cable port is used to upload data from the Receiver to the Mobile Device, and to charge the Receiver using the supplied USB Cable (see Figure 4).

Figure 4. Receiver USB-C Port

Reset Switch

The reset switch is used to reset the Receiver and is activated using a pencil tip or similar (see Figure 5).

Figure 5. Receiver Reset Switch

	NOTE: The Reset Switch is not for use by the patient and is only to be used when instructed (see Troubleshooting and Support).

Storage

When not in use, the Receiver can be stored in a cool, dry location away from direct sunlight.

	**NOTE:** Ensure the Receiver is fully charged before being used in a study. The Receiver can take up to five hours to fully charge.
	**WARNING:** • Do not use the Receiver if there are any visible signs of swelling or deformation. If any signs of swelling or deformation are detected, put the Receiver aside and contact your Atmo Biosciences representative. • If the Receiver battery indicator light is still blinking orange after it has been connected to the Power Supply for 24 hours, disconnect the Receiver from the Power Supply and contact your Atmo Biosciences representative. • Do not immerse the Receiver in liquid (including showers/baths). Partial or full immersion in liquid is not recommended and may damage the Receiver. • Do not attempt to remove or replace the Receiver's rechargeable battery (For further information on the battery see Troubleshooting and Support).
	**CAUTION:** • Do not remove the Receiver antenna. • Do not charge the Receiver in a high temperature environment greater than 45 degrees Celsius (or 113 degrees Fahrenheit) or near heat sources. Charging in these conditions will trigger a protection feature that will slow or stop charging.

Atmo Patient Belt

The Atmo Patient Belt is used to hold the Receiver during a study and ensure that the Receiver is kept at the optimal distance from the Capsule (see Figure 6). The Receiver and Belt are worn outside of clothing for patient comfort, and with the interface facing up to provide easy access to the Receiver user interface.

Figure 6. Atmo Patient Belt with the Receiver

1. Belt
2. Studs to secure Receiver within Belt
3. Antenna (inside Belt)
4. Receiver
5. Belt Clip
6. Elastic Loop
7. Length Adjustment Buckle

Adjusting the Belt Length

The Belt length can be adjusted to suit the patient's waist by using the Length Adjustment Buckle for coarse adjustments and the Clip end for fine tuning the fit. To change between the shortest and longest Belt lengths, the Elastic Loop needs to be pulled past the Length Adjustment Buckle (see Figure 7).

Figure 7. Adjusting the Belt Length

Storage

When not in use, store the Belt in a cool, dry location away from direct sunlight.

⚠	**WARNING:** To reduce the possibility of injury or strangulation, the Belt must only be worn around the abdomen.
⚠	**CAUTION:** • Take care to avoid pinch injury while clipping the Belt. • Do not over-tighten the Belt.

Atmo Mobile Device

The Mobile Device is used to perform tasks including study initiation, downloading patient study data from the Receiver, and uploading data to the Clinician Portal. The Mobile Device comes with the Atmo Clinic App preinstalled (see Figure 8).

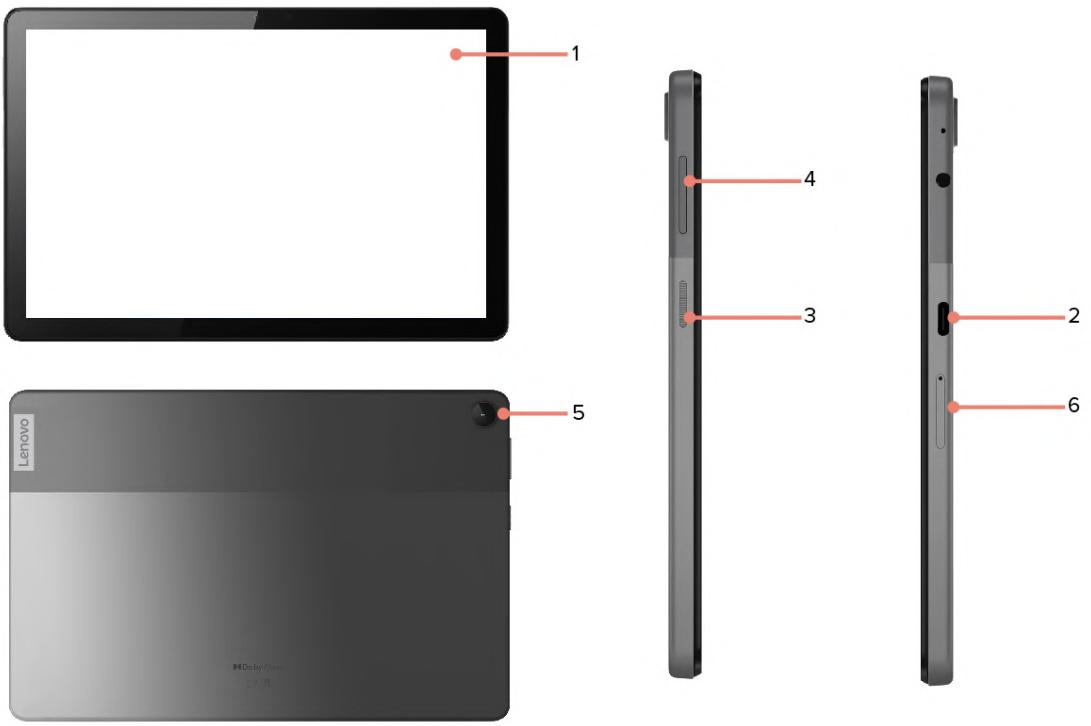


Figure 8. Atmo Mobile Device

1. Touchscreen displaying Clinic App
2. USB-C Port
3. Power Button
4. Volume Up/Down Button
5. Camera
6. SIM card tray hole

Storage

When not in use, keep the Mobile Device connected to the supplied Power Supply and store in a cool, dry location away from direct sunlight.

	NOTE: • The Mobile Device and App are managed by Atmo. Any Mobile Device configuration, including updates will be remotely managed by Atmo. • For information and instructions about the use of the Mobile Device, see the documentation supplied with the Mobile Device.

Atmo Power Supply & USB Cable

Figure 9. Atmo Power Supply & USB Cable

1. Power Supply
2. USB Cable

The Power Supply and supplied USB Cable (see Figure 9) are used to charge the Receiver and Mobile Device before Capsule ingestion. The USB Cable is also used during study initiation and study data upload (see Initiating a Study and Uploading Study Data).

	NOTE: • The USB Cable is required to connect the Receiver to the Mobile Device. • Only use the Power Supply and Cable provided. • The Power Supply is for in-clinic use only, and should not be given to the patient.

Figure 10. Atmo Motility Pre-Study Information Template

The Pre-Study Information Template (see Figure 10) is used by the clinic to create a personalised study overview that should be given to the patient before the study commences. The template is prepared and printed out for the patient before the beginning of the study and contains information on test preparation, what to expect during the study, and any restrictions or requirements.

The information template can be accessed electronically via the Atmo Resources and Support website (by using login credentials provided with onboarding documents): resources.atmobiosciences.com.

	NOTE: The patient must be supplied with the pre-study information before the day of the study to ensure that all preparation steps, including fasting, have been completed.

Atmo Clinician Portal

Patient study data is uploaded to the Clinician Portal using the Mobile Device. The Clinician Portal stores and processes the data, and allows the gastroenterologist to analyse, review and export the results.

Example view of an ingestion review screen (see Figure 11):

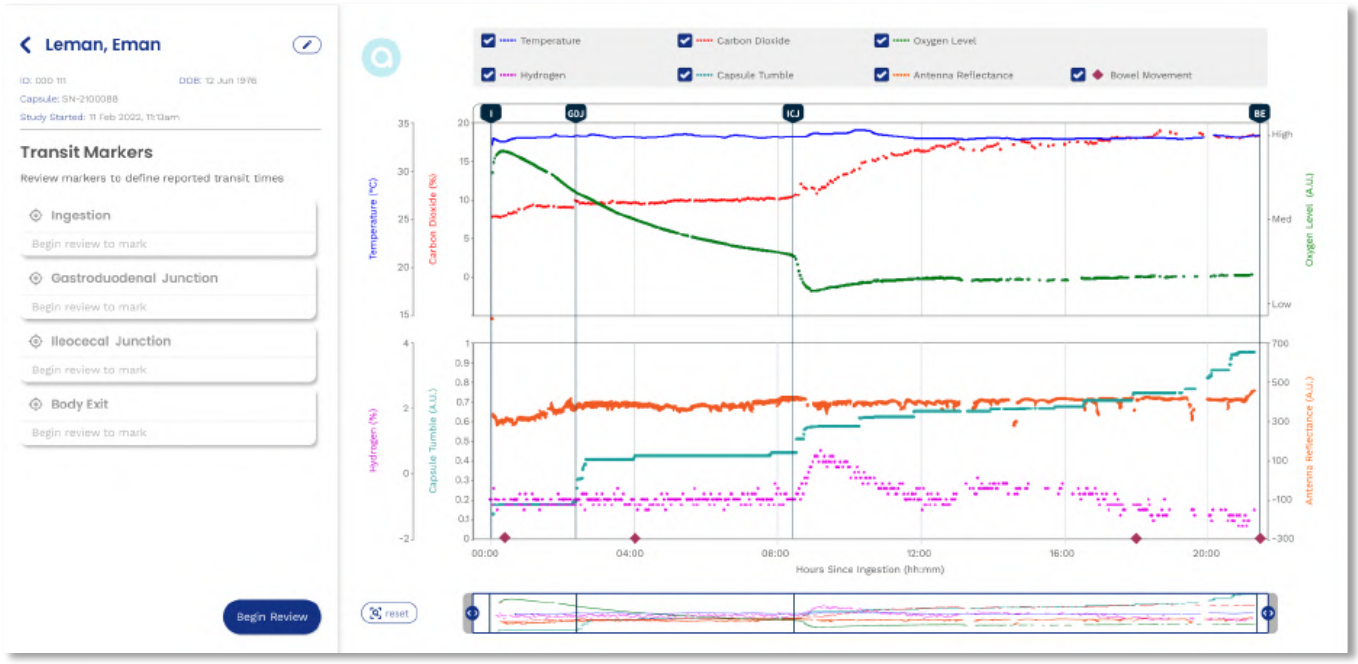


Figure 11. Ingestion Review Screen

	NOTE: The version of the Clinician Portal interface shown in this manual may not match the live service. The latest version of the manual can be found in the Clinician Portal online.

Atmo Motility Bar

The Atmo Motility Bar (see Figure 12) is a pre-packaged nutrient bar, designed as a standardised meal to be consumed by the patient prior to ingesting the Capsule. It is an alternative to the 'Egg Beater' meal.

Figure 12. Atmo Motility Bar

	NOTE: The bar can be substituted for an Egg Beater meal during studies.
	ALLERGY WARNING: The Atmo Motility Bar contains soy and may contain traces of other allergens. The bar is not manufactured in an allergen-free facility.

Atmo Motility Bar Ingredients

The bar contains the following ingredients:

- Rolled oats
- Glucose syrup
- **Soy** nuggets (isolated soy protein (soybean), Tapioca starch, salt)
- Rice bran crisps (rice flour, rice bran)
- Brown rice syrup
- Pea protein powder
- Glycerine
- Natural flavour
- Monkfruit juice concentrate

The bar may contain gluten, milk, sesame, peanut and tree nuts.

Storage

The bar must be kept in its original packaging and be stored in a cool, dry location away from direct sunlight.

Unpacking, Setup and Storage

Unpack and Storing Box

Remove all product packages from the shipper box. Check that all items have arrived and match the list of items on the packing list. Please inspect all packaging and content for any visible signs of damage. If any damage is detected, contact Atmo Biosciences.

	CAUTION: Do not remove the magnetic storage clip from the Capsule until immediately before Ingestion. Removing the storage clip will activate the Capsule and start to consume battery life.

Storage

Store all components in a safe location away from direct sunlight.

Setting up the Atmo Data Receiver

Remove the Receiver from the packaging and connect it to the Power Supply via the USB Cable. The Receiver may take up to five hours to charge for the first time. The indicator above the info button (***i***) will light up green when fully charged.

Setting Up the Atmo Mobile Device

1. Remove the Mobile Device from the packaging.
2. Connect the Mobile Device to the Power Supply using the supplied USB Cable and plug the Power Supply into a power outlet.
3. Once the Mobile Device is at 100% charge (this can be checked by pressing the Power Button), press and hold the power button to turn the Mobile Device ON.
4. The Clinic App should start automatically.

Connecting to the Internet

Internet connection is required for use of this device. The Atmo Mobile Device can connect to the internet in two ways; via Wi-Fi or through a mobile network using a SIM card.

Connecting to Internet via Wi-Fi

1. Tap the three bars in the top-left corner of the Clinic App (see Figure 13).
2. Select “WiFi Settings” in the sidebar menu that opens.
3. Select the desired WiFi network from the list and connect using that network’s credentials (you may need to contact your Clinic IT Administrator).

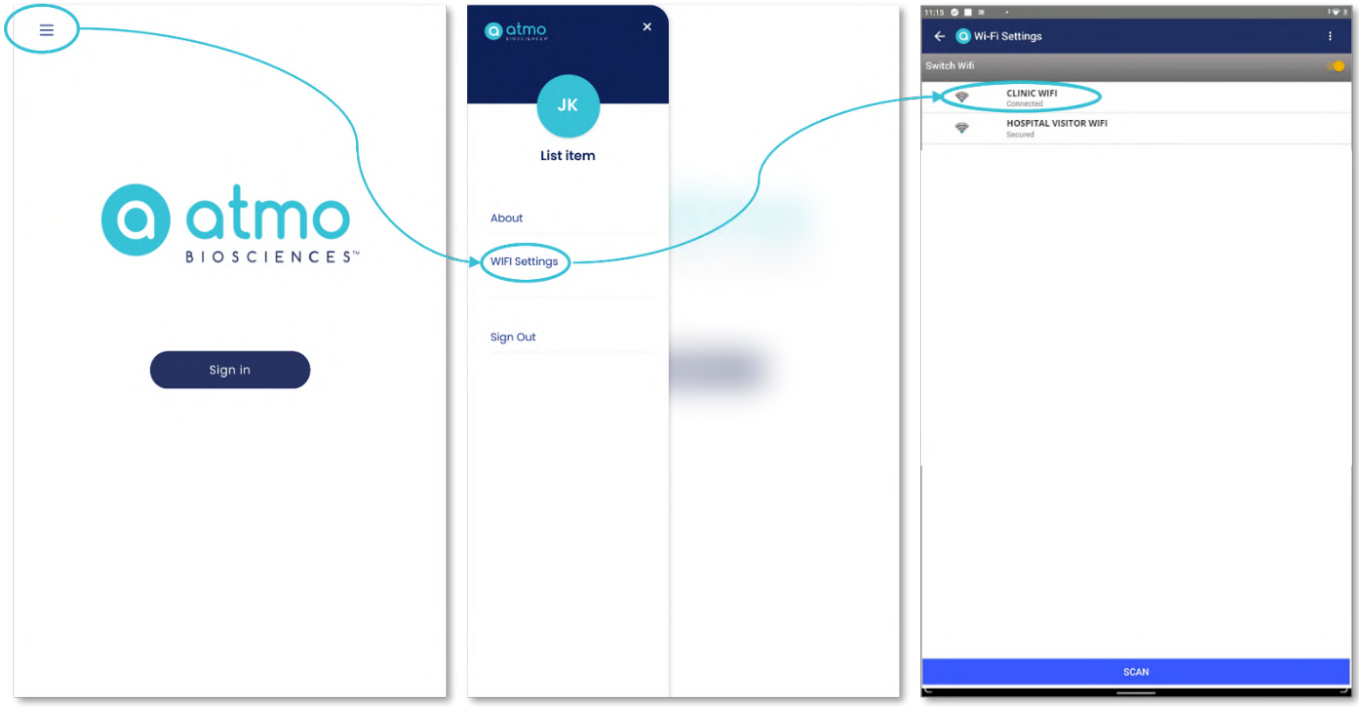


Figure 13. Connecting the Atmo Mobile Device to Internet via Wi-Fi

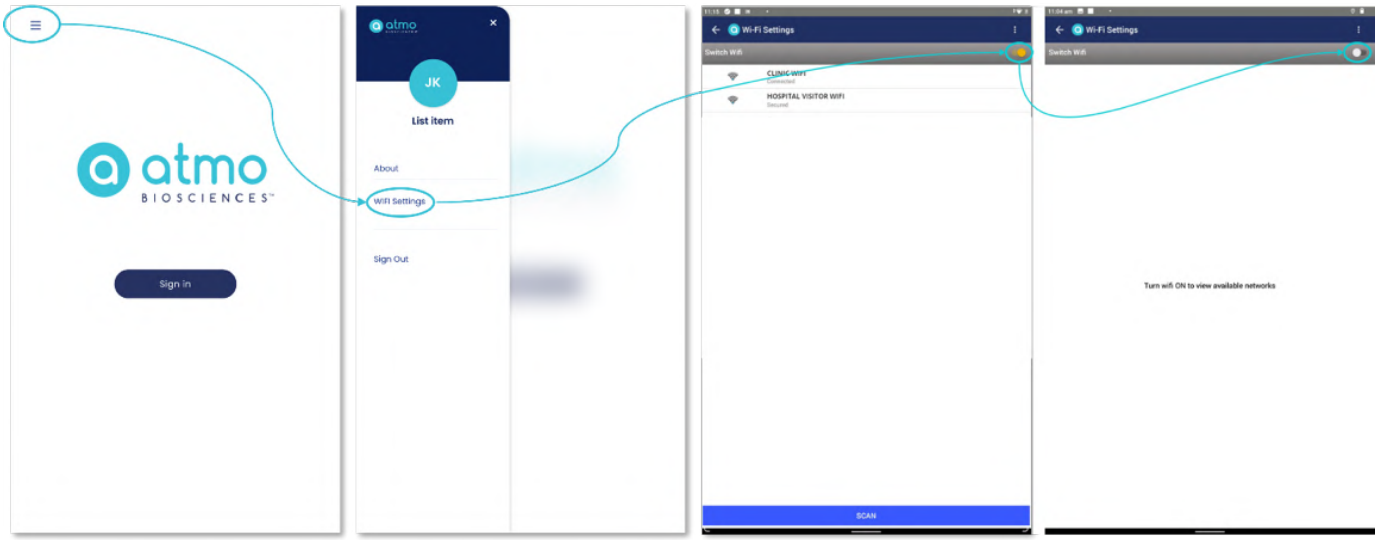
	NOTE: If no networks show up, press the Scan button on the bottom of the screen.

Connecting to Internet via Mobile Network

1. Remove the SIM card tray from the Mobile Device by inserting a SIM card pin (or paperclip) into the SIM card tray hole.

2. Place the SIM card face down onto the SIM tray and insert into the Mobile Device.

3. Tap the three bars in the top-left corner of the Clinic App.



4. Select “WiFi Settings” in the sidebar menu that opens.

	NOTE: The Atmo system will preferentially attempt to access internet through the Wi-fi even if a connection does not exist. Wi-fi must be turned off to use a Mobile Device sim card.

Organisation Settings and User Management

Using the Clinician Portal, users can access specific functions based on their assigned user roles. Each user can have multiple roles. Upon signing in, each user will be automatically directed to their designated page.

User Roles

The Clinician Portal is used by:

- **Gastroenterologists:** Licensed Gastroenterologists, Gastroenterology Registrars/fellowship trainees and;
- **Practice Managers:** Managers overseeing a Clinic or Organization and;
- **Capsule Administrators:** Registered Nurses, Nurse Practitioners, Clinical Nurse Specialists, Nurse Educators, Clinical Nurse Consultants, Physician Assistants.

Gastroenterologists

Gastroenterologists can access and review studies in the Clinician Portal. Upon signing in, Gastroenterologists will be directed to the Studies page (see Section 10. Study Analysis and Reporting).

Practice Managers

Practice Managers can manage organisations and user settings in the Clinician Portal and access the following features:

- Manage organisation settings.
- Manage users in the organisation.
- Maintain the users' personal information and modify their role-based access.
- View patient study list. Upon signing in, Practice Managers will be directed to the Organisation Users page (see Practice Manager Settings).

Capsule Administrators

Capsule Administrators can edit their account password in the Clinician Portal, but have no access to all other features. Upon signing in, Capsule Administrators will be directed to the Welcome Page (see Figure 14).

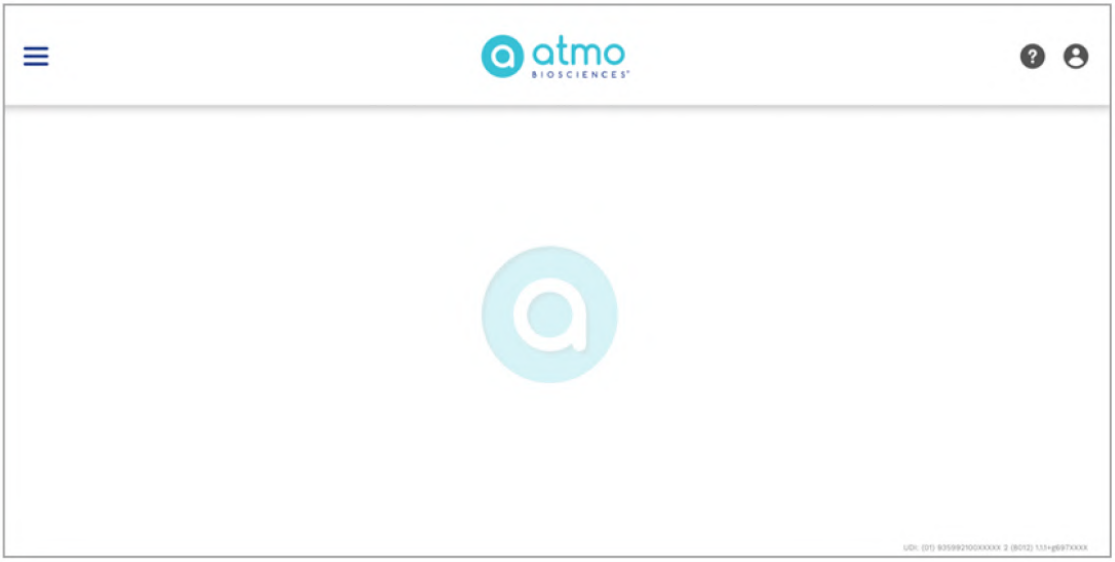


Figure 14. Welcome page after Capsule Administrators sign in

Accessing the Clinician Portal

Sign-In

1. Go to https://atmobiosciences.com/.
2. Enter your registered email address and password on the login screen and select **Sign In**. To reset your password, click on 'Forgot Password' and you will receive an email confirmation at your registered email address.

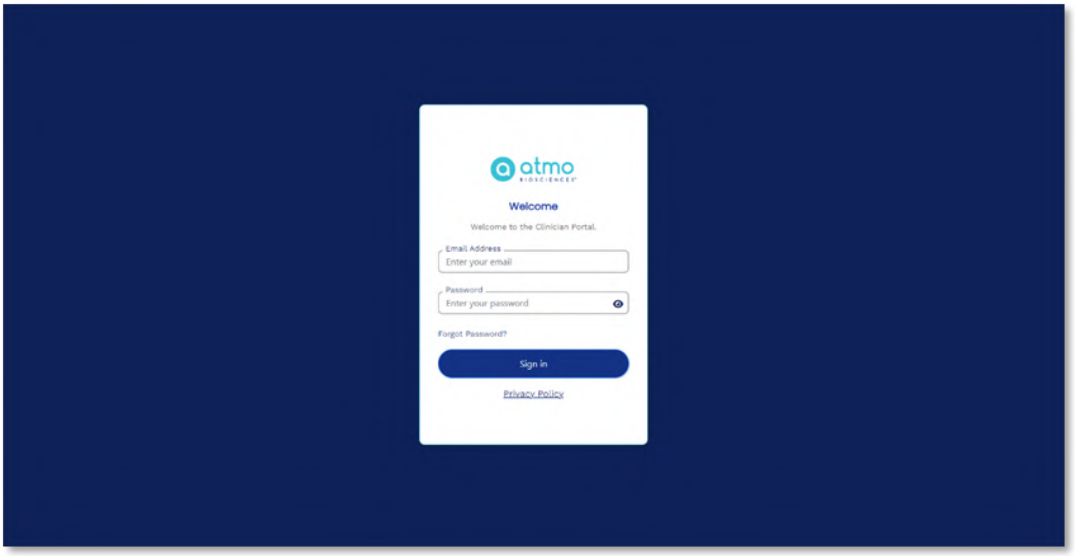


Figure 15. Clinician Portal Sign in page

General Controls

After signing in, you will be directed to the page depending on your user role (see User Roles). All users will see the following features shown in Figure 16.

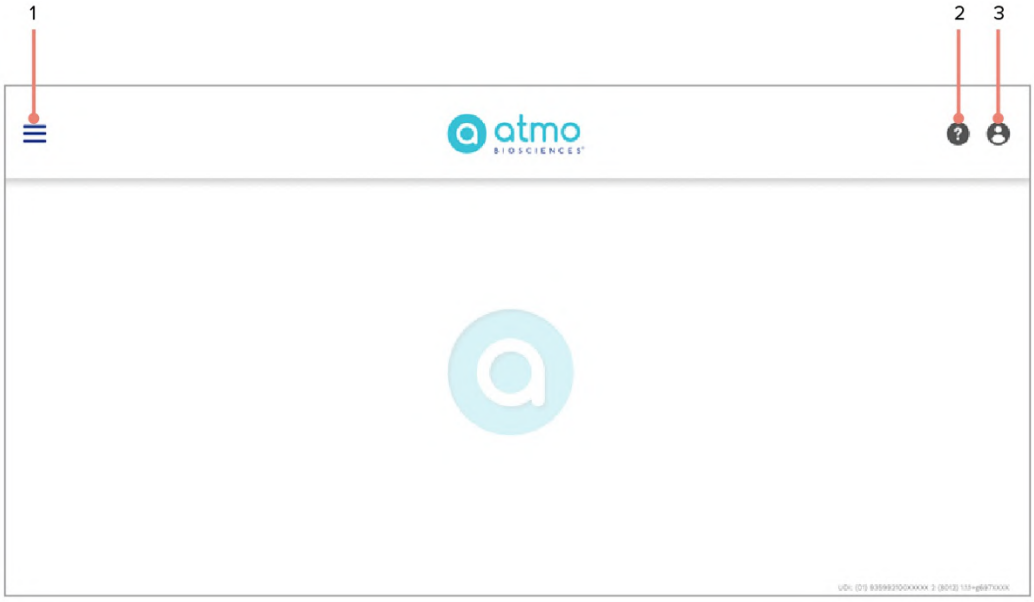


Figure 16. Clinician Portal page features that are common to all users after signing in

1. Navigation menu: click on the icon to navigate to different pages based on your user roles or to sign out.
2. User Manual icon: click on the icon and the User Manual will be displayed as a PDF file in a separate page.
3. My Profile icon: click to display 'My Profile' dialog to edit your personal details and change password. Please enter all required fields with '*' and click Save Changes to apply the update (see Figure 17).

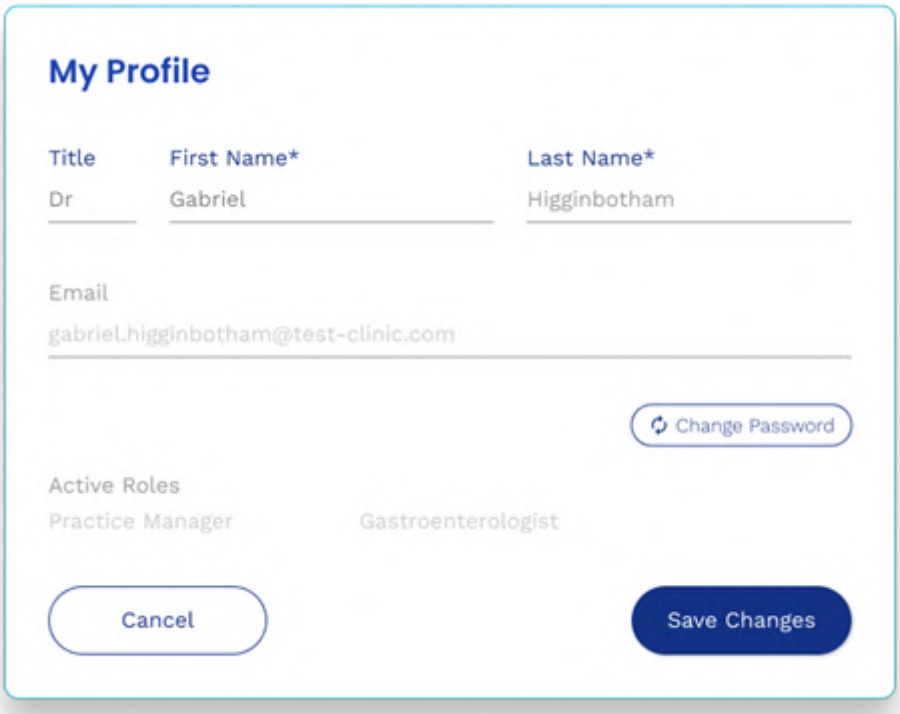


Figure 17. My Profile dialog that is common to all users

Practice Manager Settings

The Practice Manager will see the ‘Organization Users‘ page after signing in. This page is only accessible to Practice Managers (see Figure 18).

Figure 18. Organization Users page that the Practice Manager can access.

1. Navigation Menu icon: click to display the Navigation Menu and navigate to other pages.
2. User: the users in the organisation. A user's name is displayed as 'title, last name, first name.'
3. Email: the user's registered email address.
4. Roles: the assigned user roles. Each user can have multiple roles.
5. Practice Managers.
6. Gastroenterologists.
7. Capsule Administrators.
8. Search bar: use the search bar to search for users. Users can be searched by any of the column fields.
9. Status: the user’s account status.
10. Pending Invite: the user has received an email invitation but has not yet responded.
11. Active: the user can access the Clinician Portal.
12. Inactive: the user is denied access to the Clinician Portal.
13. Add User button: click to display ‘Add User‘ dialog and create profiles for new users.
14. User Manual icon: click on the icon and the User Manual will be displayed as a PDF file in a separate page.
15. My Profile icon: click to display ‘My Profile’ dialog to edit your personal details and change password.
16. User action menu: click to edit user settings and manage user access.
17. Navigation of the user list pages.
18. User list numbering.

Navigation Menu

Click on the ☰ icon to display the Navigation Menu. The Practice Manager can use the Navigation Menu to navigate to the Studies page, Organization Settings, Organization Users, or sign out (see Figure 19).

Figure 19. Navigation Menu based on the Practice Manager's role

Studies

In the Navigation menu, the Practice Manager can click on 'Studies' to navigate to the Studies page and view Studies List (see Study Analysis and Reporting).

Organization Settings

Figure 20. Organization Settings that the Practice Manager can access

1. Navigation menu.
2. Edit button: the Practice Manager can click on the button to open the 'Report Contact Details' dialog and edit the contact details for the Organization or Clinic they manage (see Figure 21). Please enter all required fields with '*.' Click **Save Changes** to apply the update.

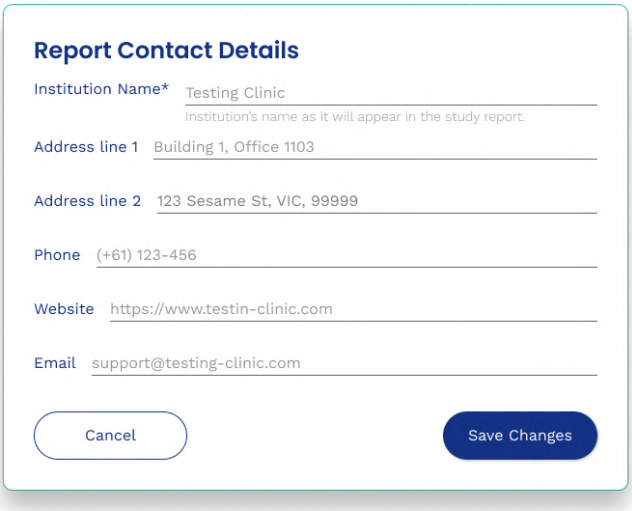


Figure 21. Report Contact Details dialog that the Practice Manager can access

3. Temperature Units: the Practice Manager can select and change the default Temperature Units.
4. User Manual icon: click on the icon and the User Manual will be displayed as a PDF file in a separate page.
5. My Profile icon: click to display 'My Profile' dialog to edit your personal details and change password.

Sign out

Click on **Sign Out** and you will be signed out from the Clinician Web Portal.

Add New User

The Practice Manager can add new users to the Organization. Click on the **Add User** button and the 'Add New User' dialog will be displayed (see Figure 22).

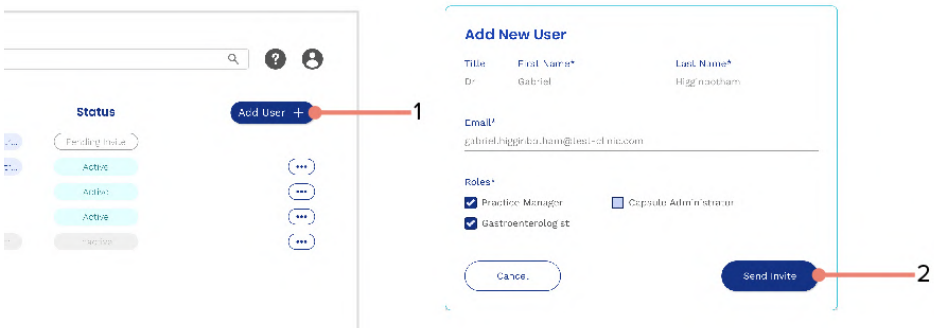


Figure 22. Add New User dialog that the Practice Manager can access

1. Add New User dialog: Please enter all required fields with '*.'
2. Click **Send Invite** to send an email invitation to the user. The user's status will be changed to 'Pending Invite.' Once they accept the invitation, their status will change to 'Active'.

User Action Menu

The Practice Manager can manage the users in the Organization. Click on the ••• icon and the 'User Action' menu will be displayed. If the user status is 'Active,' you can navigate to Edit User Settings, Reset User Password, or Deactivate User. If the user status is 'Inactive,' you can navigate to Reactivate User Account (see Figure 23).

Figure 23. User action menu that the Practice Manager can access

User Action menu:

- **Edit User Settings:** the Practice manager can click to display the 'User Profile' dialog. Please enter all required fields with '*'. Click 'Save Changes' to apply the update.
- **Reset User Password:** the Practice manager can prompt password reset for the user. A link will be sent to the user's registered email address.
- **Deactivate User:** the Practice Manager can click 'Deactivate User' to confirm and suspend the user's access to the Clinician Portal. The user's status will change to 'Inactive.' Click 'Cancel' to return to the Organization Users page.
- **Reactivate User:** Account: the Practice Manager can click 'Activate' to grant access to the Inactive user. The user's status will change to 'Active.'

Performing a Study

	**WARNING:** • The Capsule must not be used near sources of high magnetic force, such as MRI equipment. • Ensure the patient does not have an MRI procedure or goes near MRI equipment during the study. • The gastroenterologist must confirm the body exit of the Capsule using data displayed in the Clinician Portal (not just the end-of-study indicator) before an MRI can be performed. If there is any doubt, an abdominal X-ray should be performed.
	CAUTION: • Data transmission from the Capsule to the Receiver is impacted by the patient's Body Mass Index (< 40 BMI). Significant data dropout may occur in severely obese patients. • The Capsule and/or Receiver may cause electromagnetic interference with other electronic devices. If interference is noticed with the operation of essential equipment, move the Capsule or Receiver away from the equipment. (see Troubleshooting and Support).
	**NOTE:** • The end-of-study indicator on the Receiver is not to be used as a confirmation of body exit. • A patient with an active electronic implant should not ingest the Capsule. (See Contraindications).

Before the Day of the Study

Preparing a Patient

Prior to commencing the study, the patient must be fully informed about the procedure, including any associated risks, restrictions and required preparation. It is recommended that this information is also provided to the patient using the Pre-Study Information Template. This template can then be emailed or printed and given to the patient.

	**NOTE:** Patient compliance (especially relating to fasting) may be reduced if the patient is not given the pre-study information.

Pre-Study Checklist

✓	Ensure that the patient does not have any of the Contraindications.
✓	Ensure that the patient does not have any allergies to the contents of the bar (see Atmo Motility Bar for ingredients).
✓	Inform the patient of the benefits and risks of the study.
✓	Fill out the Pre-Study Information Template and go over it with the patient. The following points are of particular importance: • The patient must fast for eight hours prior to Capsule Ingestion. • The patient must refrain from tobacco smoke and e-cigarettes for eight hours prior to Capsule Ingestion. • The patient will not be able to eat for six hours after Ingestion of Motility Bar and Capsule. • The patient must refrain from tobacco smoke and e-cigarettes for six hours after Capsule Ingestion. • The patient will have to wear the Receiver for the duration of the study (approximately two days for normal transit). • The patient may have to restrict certain medications before the study (see Pre-Study Information Template). • Obtain written informed consent or give the patient the forms to be completed by the day of the study.

Fasting

Fasting Before Ingestion

Inform the patient that they must fast for eight hours prior to Ingestion of the Capsule.

This fasting includes:

- No food
- No carbonated (fizzy or soda) drinks
- No caffeine
- No alcohol or tobacco

Uncarbonated drinking water may be consumed.

	**NOTE:** Non-compliance to the fasting requirements may adversely impact results.

Fasting After Ingestion

Inform the patient that they must fast for six hours after Ingestion. They may drink small sips of uncarbonated (not soda water) water only during this period.

	**NOTE:** Non-compliance with the fasting requirements may adversely affect transit times.

Restricted Activities During the Study

During the study, it is recommended that the patient avoids the following activities:

- Drinking carbonated beverages as it may result in obscuring gastric emptying time, leading to misdiagnosis.
- Strenuous physical exercise, such as gym training, rock climbing or running.
- Operation of equipment with moving or rotating parts that could catch on the Receiver or the Belt.
- All non-essential activities that require the removal of the Receiver, such as swimming.

Scheduling a Follow-up Office Visit

Make arrangements with the patient to return the Receiver and note this down in the Pre-Study Information Template.

Pre-Study Information Template

Fill out the Pre-Study Information Template and give it to the patient (print it out or email it). The template can be found on the Atmo Resources Website: resources.atmobiosciences.com

Preparing the Receiver

Ensure Receiver is Charged

Ensure that the Receiver is fully charged prior to the day of the study and before supplying it to the patient. The Receiver can take up to five hours to fully charge.

A green light above the info button (***i***) button indicates that the Receiver has sufficient charge to begin a study. Receivers can be left on charge without damage to the Receiver battery.

Receiver Status when Unplugged

To check the status, press the info button. Expect a response within 3 seconds.

Standby mode.

Receiver battery charged.

Ready to pair.

Standby mode.

Receiver battery not fully charged.

Use a charged Receiver to pair.

Receiver Status when Plugged into Charger or Mobile Device

Standby mode.

Receiver battery charged.

Ready to pair.

Standby mode.

Receiver battery not fully charged.

A slow orange blink indicates charging.

Use a charged Receiver to pair.

Collecting data.

Study is complete.

Use the Mobile Device to upload data.

Initiating a Study

Required Product Items & Prerequisites Checklist

✓	Mobile device (fully charged)
✓	Receiver (fully charged) **NOTE:** Ensure the Receiver has been cleaned as per Section 8 Receiver Return, and does not contain any data from previous studies. (see Uploading Study Data, Ensure Receiver is Charged, Receiver).
✓	Capsule (still in packaging)
✓	USB Cable
✓	Motility Bar
✓	Belt (see Belt Reprocessing Instructions)
✓	Water to aid Motility Bar and Capsule ingestion
✓	Internet connection

Patient Arrival Checklist

✓	Ensure the patient has fasted for at least eight hours.
✓	Ensure the patient has followed the guidelines provided by the clinic in the Pre-Study Information Template.
✓	Ensure the patient has provided written informed consent.
✓	Ensure the patient has followed any medication restrictions.
✓	Ensure the patient has not had any tobacco or alcohol products for at least eight hours.
✓	Ensure the patient has followed any other instructions from the gastroenterologist.
✓	Ensure the patient does not have any condition that would preclude them from participating in the study (see Contraindications).
✓	Ensure the patient does not have any allergies to the contents of the bar (see Atmo Motility Bar for ingredients).

Powering on the Mobile Device and logging in

1. Power on the Mobile Device by pressing and holding the Power button.
2. The Clinic App Should start automatically upon bootup.
3. When requested, log into the App with your username and password (these will be the same as the Clinician Portal) (see Figure 24).

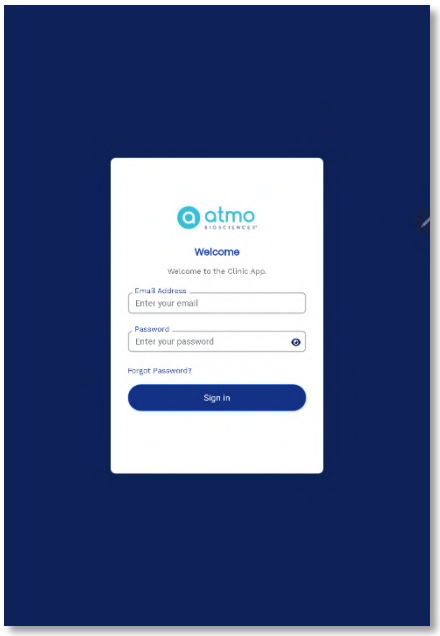


Figure 24. Clinic App sign in screen

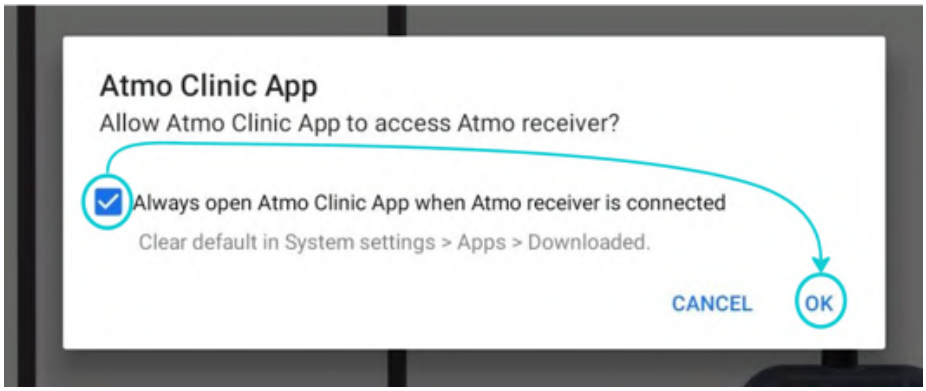
	NOTE: The Mobile Device needs to be connected to the internet (see Accessing the Clinician Portal)

1. When prompted, connect the Mobile Device to the Receiver using the supplied USB Cable. The Begin Study screen will be displayed (see Figure 25).

Figure 25. Clinic App begin study screen

NOTE:

If the Receiver has never been connected to this Mobile Device, it will request permission to access the Receiver. Tick the checkbox and press **OK**.



If the Receiver still contains data from a previous study, or if it is still receiving data from a study, a different screen will be shown (see Uploading Study Data)

2. Tap **Begin Study**.
3. Enter Patient Information in the form provided (see Figure 26). This information will be saved to the Portal and will be displayed once the study data is uploaded.

Figure 26. Clinic App enter patient information screen

	NOTE: First Name, Last Name, Patient ID and Date of Birth are required fields.

Activating Capsule

Remove outer packaging and storage clip.

1. Follow prompts for Capsule activation, ensuring that the Patient Guide is also removed from the Capsule packaging (see Figure 27).

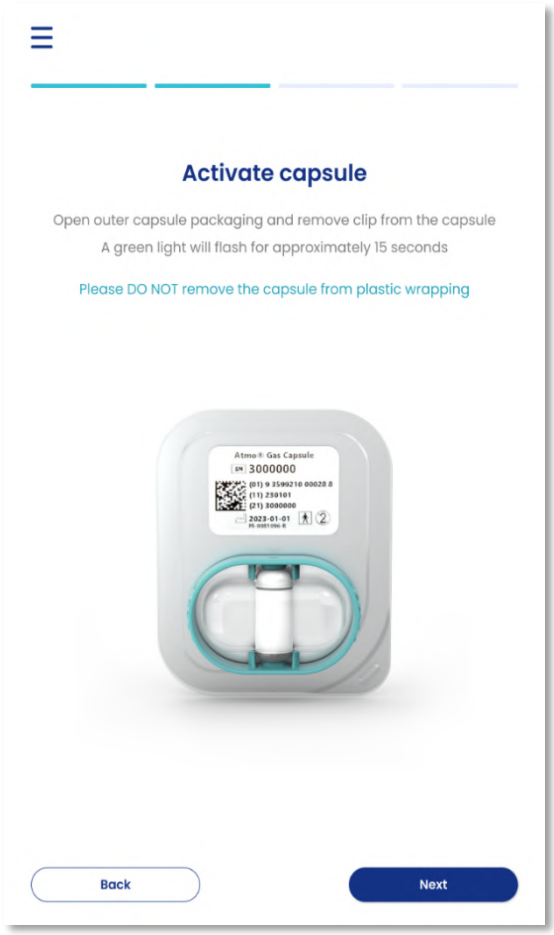


Figure 27. Clinic App activate Capsule screen and instruction

2. Once the storage clip has been removed, the top of the Capsule will blink green for 15 seconds. Once this has been confirmed, continue with the next step.

	NOTE: • Do not remove the Capsule from the blister pack until instructed. • Do not use if the top of the Capsule is not blinking green. If Capsule is not blinking green: re-attach the storage clip, put the unresponsive Capsule aside and use another Capsule (contact your Atmo Biosciences representative).

Pairing the Atmo Motility Capsule to the Receiver

Follow the onscreen prompts to enter the serial number manually using the onscreen keypad (see Figure 28).

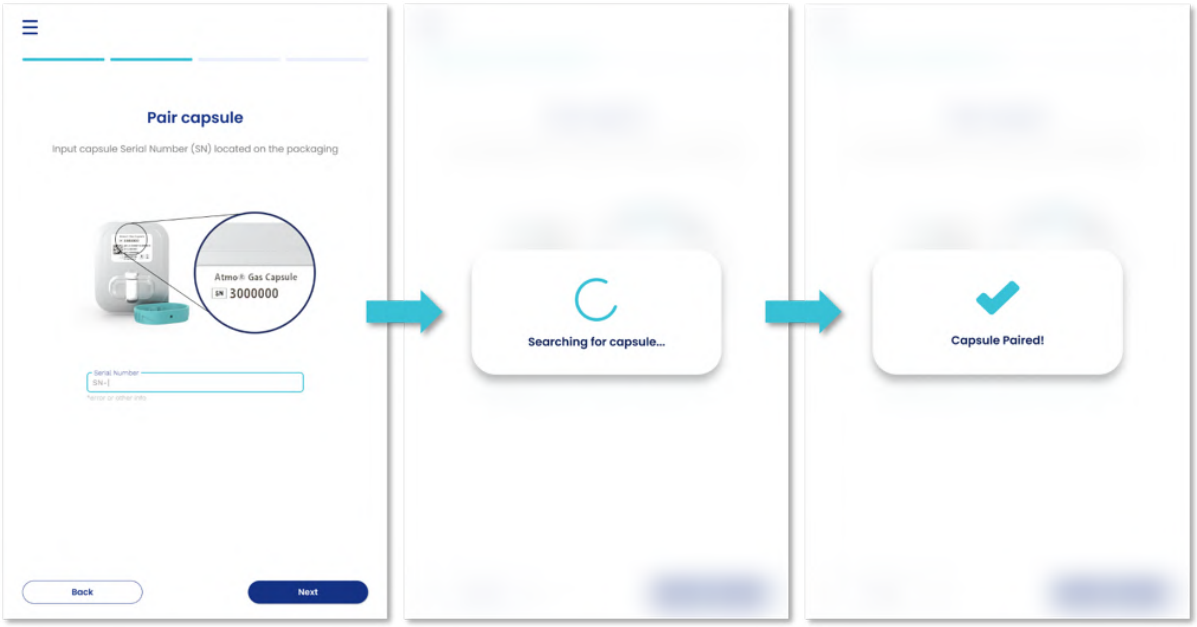


Figure 28. Clinic App pair Capsule screens

	NOTE: • If Capsule is erroneously unpaired, repeat step 4 to repair. • If paring is not successful see Troubleshooting and Support)

Ingestion of standardised meal

Provide the patient with the standardised meal (bar) and have them consume the meal.

	NOTE: The patient must ingest the Capsule within 15 minutes after consuming the meal.

Provide patient guidance

Give the patient the Patient Guide, and highlight the following:

- The patient must fast for at least six hours after Capsule ingestion.

	NOTE: Non-compliance of the fasting requirements may adversely affect transit times.

- The patient must wear the Receiver and Belt at all times, except when sleeping or showering.
- When sleeping or showering, the patient must remove the Receiver and Belt. They should be kept within arm's reach.
- The patient can press the info button (i) to check that the Receiver is operating correctly.
- The patient must record each bowel movement by pressing and holding the bowel movement button on the Receiver for 2 seconds. When a bowel movement is successfully recorded, the bowel movement indicator will light up blue and vibrate twice. For the following 5 minutes the blue LED will light up if the (i) button is pressed (see Figure 29).

Figure 29. Indicator when a bowel movement is successfully recorded

Explain the end-of-study alert to the patient. When the Capsule has exited the body, the Receiver will buzz three times and the end-of-study indicator will flash green for five seconds (see Figure 30).

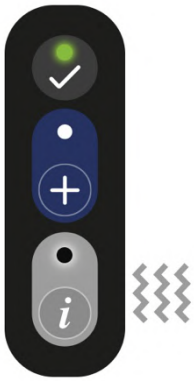


Figure 30. End-of-study Indicator when the Capsule has exited the body

	NOTE: Once the Receiver has alerted the patient that the Capsule has exited the body, they may remove the Receiver and Belt and return it to the clinic.

NEXT Tap **Next** once the patient has consumed the standardised meal.

Instructing patient to eat the Motility Bar

Instruct the patient to eat Atmo Motility Bar prior to ingesting the Capsule. Ensure the patient understands the instructional material (see Motility Bar).

Figure 31. Clinic App Instruct patient to eat food bar screen

Receiver Fitting

Disconnect the Receiver from the USB Cable and follow the onscreen prompts to fit Receiver on patient (see Figure 32)

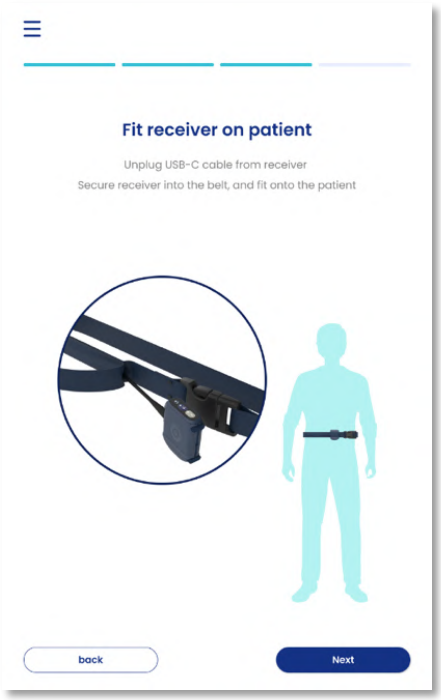


Figure 32. Clinic App Fit Receiver on patient screen

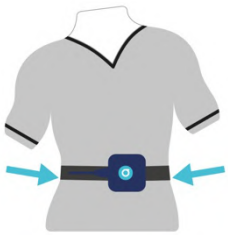
Securely insert the Receiver into the Belt (using the press studs on the Belt) (see Figure 33).

Figure 33. Insert Receiver to the Belt

	NOTE: Ensure the Receiver buttons and indicator LEDs are facing up.

Adjust the length of the Belt to suit the patient's waist ensuring that:

The Belt fits comfortably over the clothes.



The Belt is securely fitted above the hips and does not easily move up or down (including with patient movement).

The Receiver buttons and indicator LEDs are facing upwards and are visible to the patient.

	NOTE: The Belt length can be adjusted to suit the patient's waist using the Length Adjustment Buckle for coarse changes, and the Clip end for fine tuning the fit. To change between the shortest and longest Belt lengths, the Elastic Loop needs to be pulled past the Length Adjustment Buckle (see Figure 34).

Figure 34. Adjust the Receiver Belt

NEXT Tap **Next** once the patient has been fitted with the Receiver.

Administering Capsule

Follow the onscreen prompt (see Figure 35) and instruct patient to ingest Capsule with water. Ensure patient does not bite Capsule.

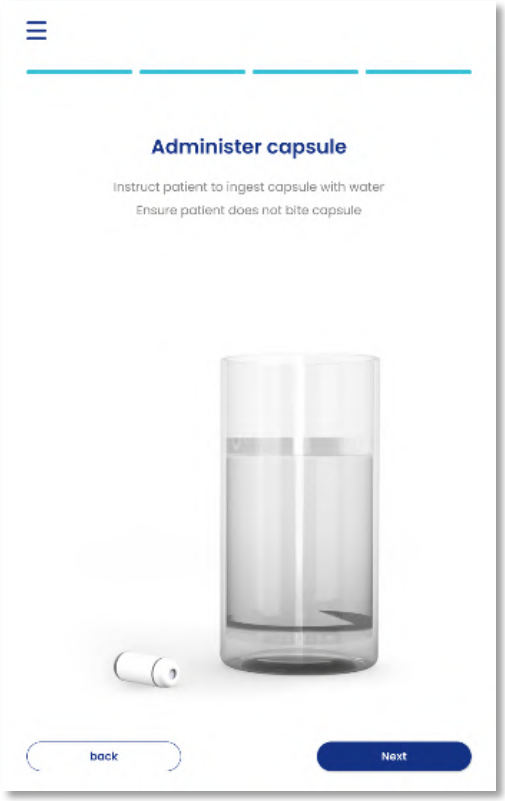


Figure 35. Clinic App Administer Capsule screen

Capsule Ingestion

1. Remove the foil seal from the back of the Capsule blister.

Figure 36. Remove the foil seal

2. Instruct the patient to carefully place two fingers underneath the Capsule to remove (see Figure 37).

Figure 37. Remove the Capsule

	CAUTION: • Ensure the patient does not drop the Capsule while removing from the blister pack. Do not use a Capsule that has been dropped. • Perform a visual inspection of the Capsule to ensure no signs of damage prior to the patient ingesting the Capsule. Do not use a Capsule that has been damaged.

3. Instruct the patient to inspect the Capsule for damage or visible contamination under the supervision of a nurse/capsule administrator.

	WARNING: If the Capsule has visible damage or contaminants, do not ingest, and contact Atmo Biosciences.

4. Instruct the patient not to bite or chew the Capsule when swallowing and that if they accidentally bite the Capsule, not to ingest it.

	NOTE: If accidental biting occurs, return the bitten Capsule into its packaging, replace the storage clip to deactivate it and restart the ingestion procedure with a new Capsule. Dispose of bitten Capsule.

5. Provide the patient with water to drink and ask them to swallow the Capsule, ensuring they do not bite or chew on the Capsule.

	**WARNING:** While rare, Capsule aspirations can occur. Ensure the patient is closely supervised while ingesting the Capsule.

6. Tap **Next** once the patient has swallowed the Capsule.

Post-Capsule Ingestion Instructions

Provide the patient with the following post-Capsule ingestion instructions:

1. Advise the patient to contact the clinic if they notice any new or unusual gastrointestinal symptoms or discomfort during the study.

	CAUTION: Acute pain, sudden nausea or vomiting beyond the patient's typical pattern within five days of Capsule Ingestion could indicate a bowel obstruction.

2. Follow the onscreen prompt and instruct the patient to fast for a period of six hours from the time of Capsule ingestion (see Figure 38).

Figure 38. Clinic App screen Instruct patient to fast for next 6 hours

3. Write the time when the patient may eat (six hours from time of Capsule Ingestion) in the space provided in the Patient Guide (see Figure 39).

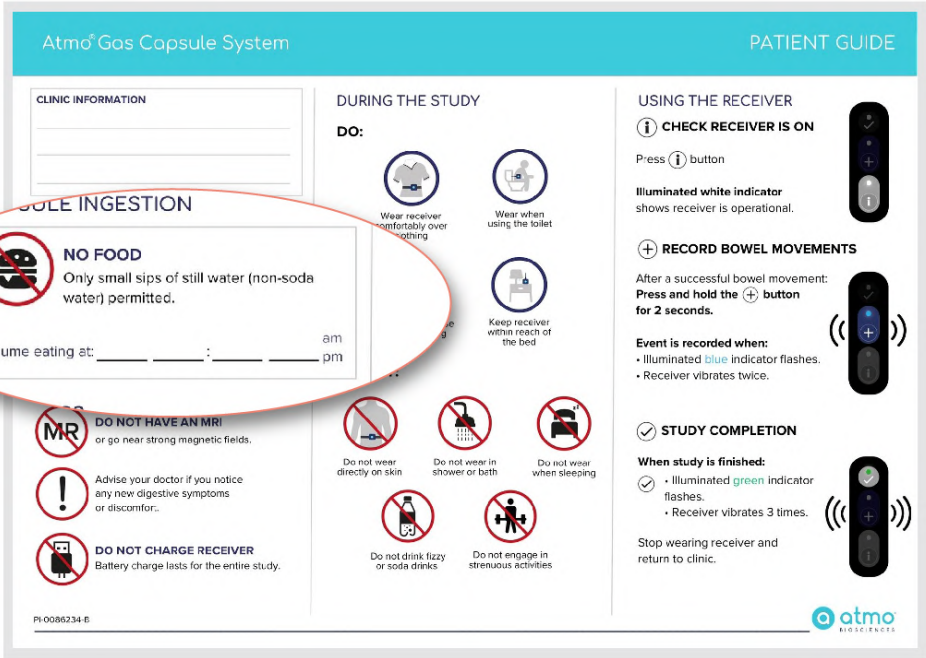


Figure 39. Patient Guide Resume eating time

4. Instruct the patient to record the date, time, and details of events such as bowel movements, meals, and other events in the Patient Diary, on back of Patient Guide (see Figure 40).

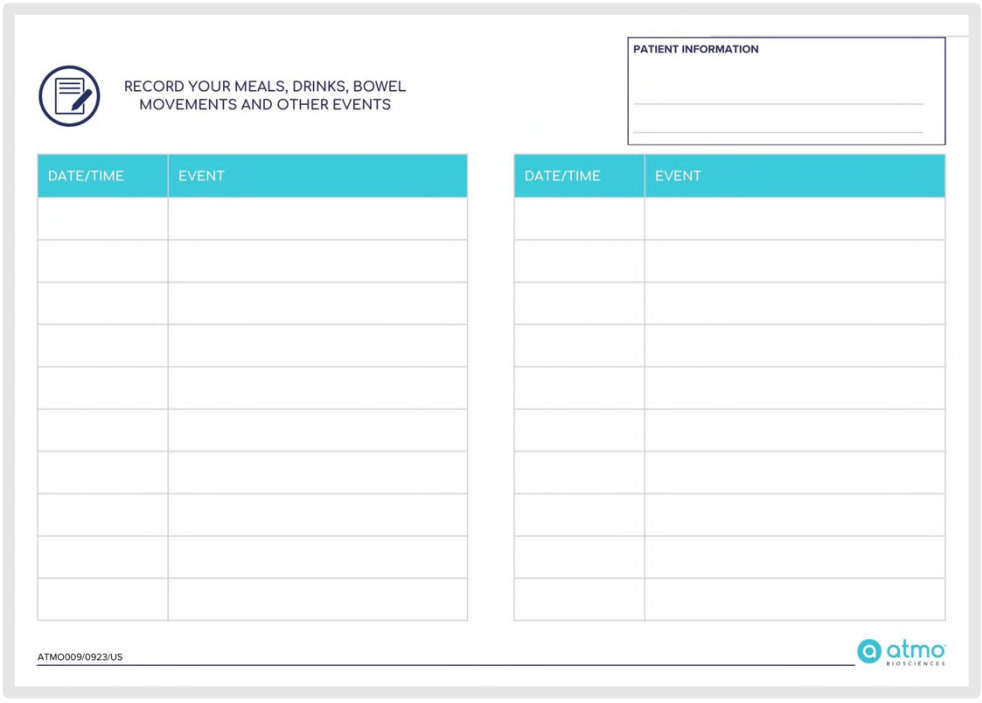


Figure 40. Patient Guide Patient Diary

5. Advise the patient not to recharge the Receiver during the study (see Figure 41).

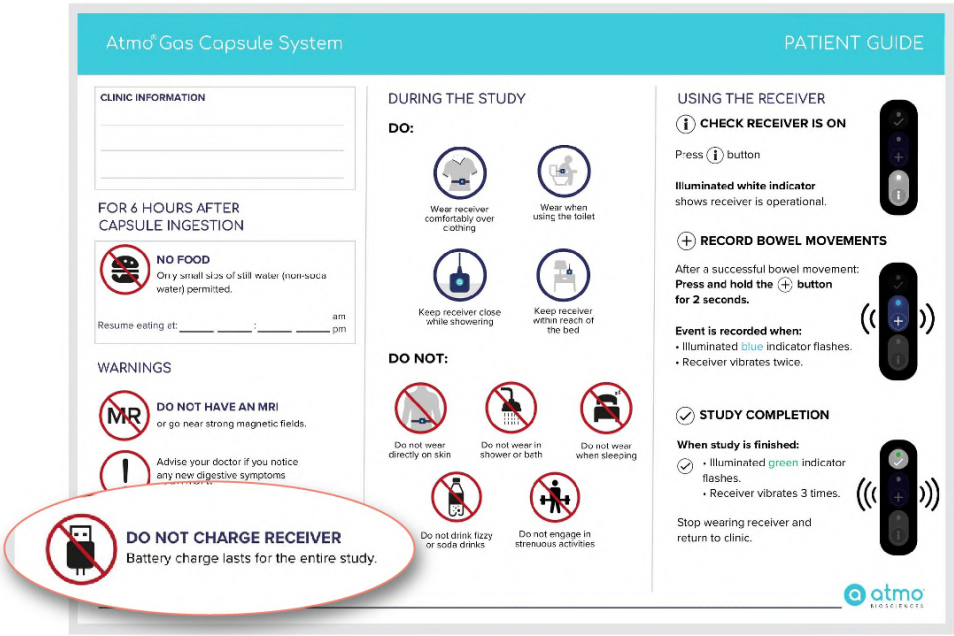


Figure 41. Patient Guide Do not charge Receiver

6. Confirm arrangements for the return of the Receiver and Belt (see Receiver Return).
7. Tap **Finish**.

	NOTE: Ensure the Mobile Device is placed back on the Charger after each use. The Mobile Device may lose charge quickly and cannot be charged while initiating a study.

Receiver Return

WARNING:

- Ensure the Belt and Receiver have been cleaned as per Section 8.1 after each patient use, prior to uploading study data.
- The use of suitable safety gloves is recommended while cleaning the returned Receiver and Belt.

Clean Receiver and Belt

Inspect the Belt for any damage and ensure the clips and studs are working correctly.

Wipe down the surface of the Receiver and Belt using a soft cloth moistened with a solution of 70% isopropyl or ethyl alcohol. Ensure alcohol contact for at least 1 minute (for further information, see Receiver and Belt Reprocessing Instructions).

Inspect Receiver for Damage

Visually inspect the Receiver to ensure that it has not been damaged. Ensure that:

- The button and indicator light membrane is not damaged or peeling.
- The USB-C port is clean and free from dust or lint.
- There are no visible cracks.
- There are no visible signs of swelling.
- The antenna is still firmly screwed on and is not bent or broken

If there is any damage to the Receiver, contact Atmo Biosciences.

Check End-of-Study Status

Press and hold the info button on the Receiver for two seconds. If the study has been completed successfully, the end-of-study indicator will light up green and the status indicator will light up white (see Figure 42).

Figure 42. End-of-Study Status Indicator

NOTE:

If the end-of-study indicator does not light up green, see Managing a Study Still in Progress.

Uploading Study Data

Prerequisites

✓	Mobile Device (charged)
✓	Internet Connection
✓	Cleaned Receiver (returned by patient)
✓	USB Cable

Uploading Data

1. Power on the Mobile Device.
2. Ensure the Mobile Device is connected to an available Wi-Fi connection.
3. Log into Clinic App.

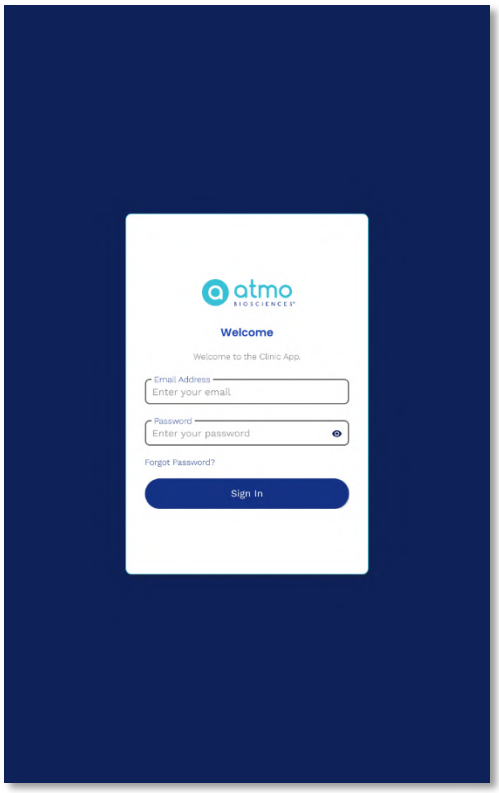


Figure 43. Clinic App Login Screen

4. Tap the App to open.
5. When prompted, connect the Mobile Device to the Receiver using the supplied USB Cable. The upload screen will be displayed (see Figure 44).

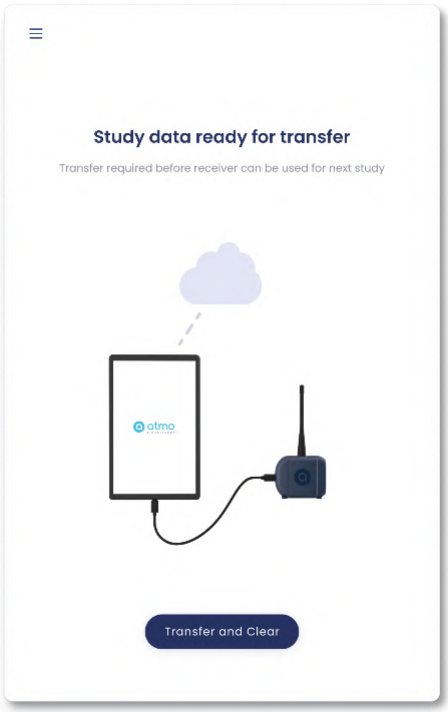


Figure 44. Clinic App Transfer Study screen

	NOTE: If the study is still in progress, for instance if Capsule exit has not been detected, the system will prompt you to end the study manually (see Managing a Study Still in Progress for details).

6. Tap **Transfer and Clear**. The transfer complete screen will be displayed when the data has successfully been uploaded.

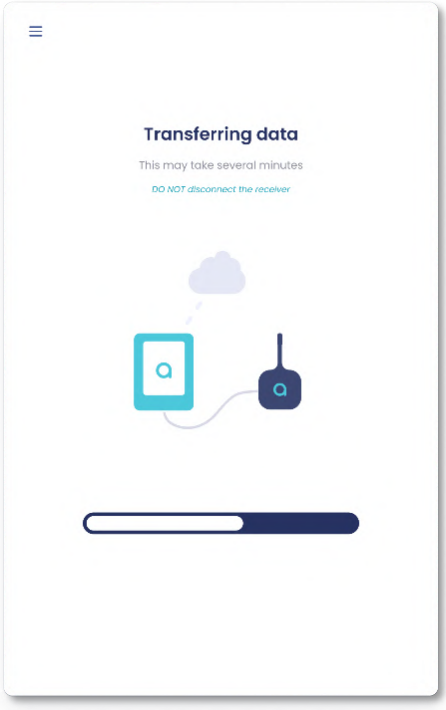
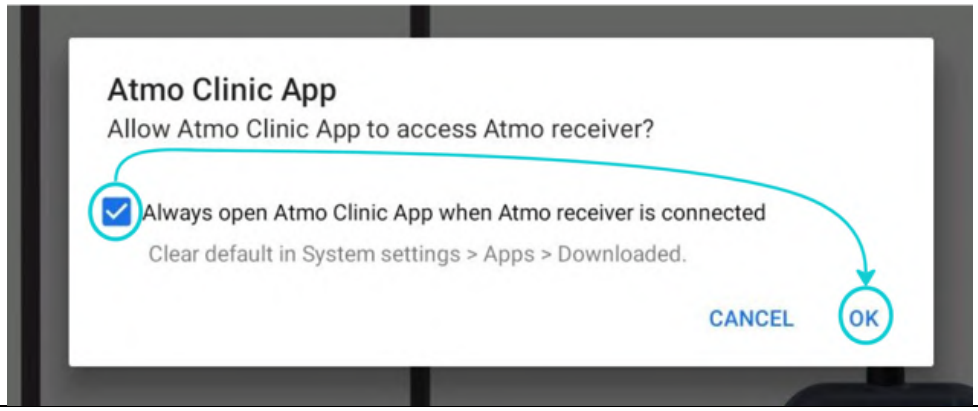


Figure 45. Clinic App Transfer Study in progress screen

NOTE:

- The data upload may take up to 10 minutes.
- The data upload clears all data from the Receiver. The end-of-study indicator will turn off when the upload is complete, and the Receiver will then be ready to receive data from a new study.
- If this is the first study wherethe Receiver has been used with this Mobile Device, it will request permission to access the Receiver twice during the upload process.
- Tick the checkbox and press OK when requested.



If the "Transfer complete screen" is not displayed, please refer to Troubleshooting and Support

1. Disconnect the Receiver and USB Cable from the Mobile Device.
2. Put the Receiver and Mobile Device back on charge (connect to the Power Supply via a USB Cable).

Managing a Study Still in Progress

The Receiver is designed to capture as much data as possible and may not trigger the end-of-study indicator before the patient returns the Receiver to the clinic. If a returned Receiver has not detected the end of study, the "Study in progress" screen will be displayed when the Receiver is connected to the Mobile Device (see Figure 46).

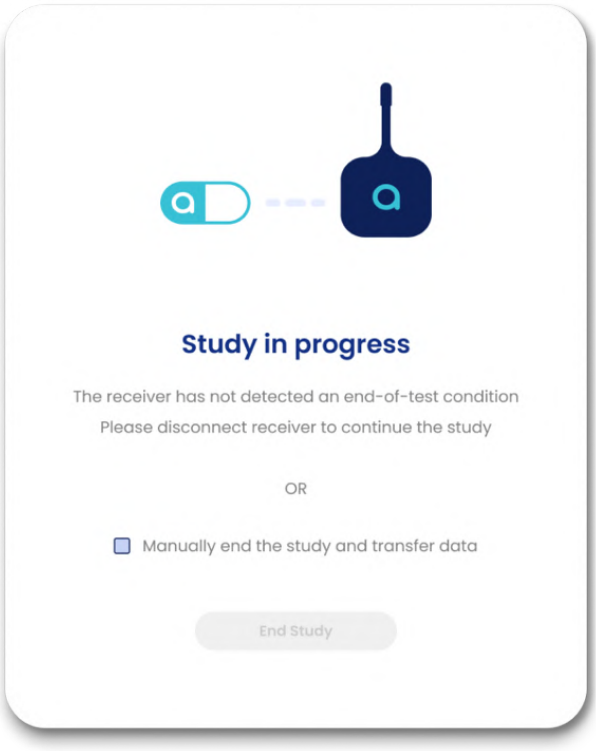


Figure 46. Clinic App Study in progress screen

If this occurs, a decision needs to be made whether to manually end the study or for the patient to continue wearing the Receiver and Belt. Ask the patient to share why they returned the Receiver before seeing the green LED light. This may occur if the patient has visually identified the Capsule in the toilet and returned the Receiver. Alternatively, request the patient to continue wearing the Receiver and Belt until the end of study is triggered.

See End-of-Study Indicator (Receiver) for more information.

If it has been deemed appropriate to end the study at this time, please follow the steps below:

1. Tap the **Manually end the study and transfer data** tick box on the Mobile Device screen (see Figure 27).
2. Tap **End Test**. The upload screen will be displayed. The data can now be uploaded (see Uploading Study Data).

Study Analysis and Reporting

Using the Clinician Portal, the gastroenterologist can:

- Analyse study data to place markers for Capsule ingestion, gastroduodenal junction, ileocecal junction, and body exit.
- Correlate changes or behaviours in the traces with events recorded by the patients in the Patient Diary during the study E.g. bowel movements or food intake.
- Enter annotations to study data.
- Generate and print study reports.

Accessing a Study Record

Once the data from the Receiver has been transferred to the Mobile Device, it will be automatically uploaded to the Clinician Portal, where it can be reviewed. If a completed and uploaded study is not shown on the Clinician Portal, please contact your Atmo Biosciences representative.

Having the following information available will assist you in quickly accessing a study record:

- Name of the organisation administering the study.
- Serial number of the Capsule used in the study (for example, SN-1234567).
- Date and time (if available) of Capsule ingestion.

Sign-In

1. Go to https://atmobiosciences.com/ and select **Login** tab in top navigation menu (see Figure 47).

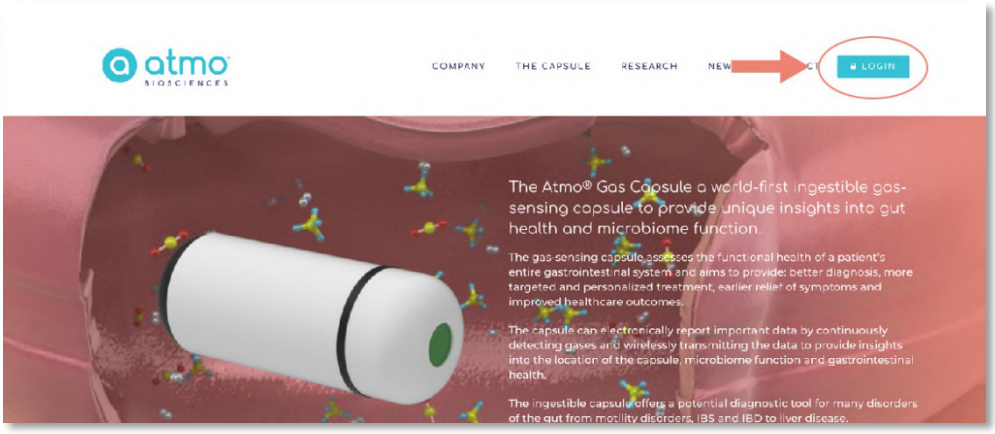


Figure 47. Clinician Portal Login from Atmo website

2. Enter your registered email address and password on the login screen and select **Sign-In**. The Capsule list screen will be displayed.

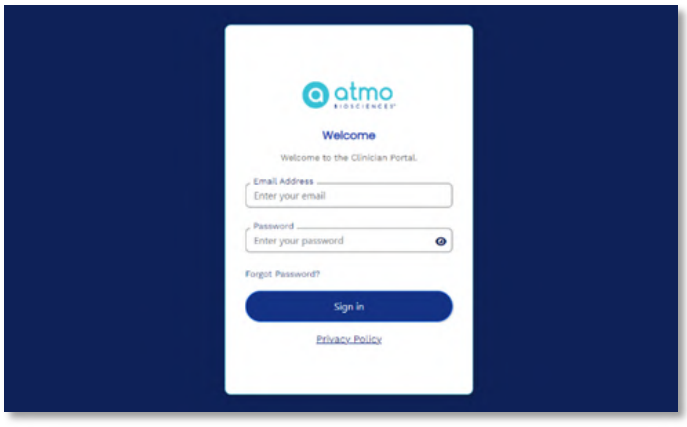


Figure 48. Clinician Portal Login Screen

Study List

The Studies screen lists the studies that can be selected for review (see Figure 49).

Figure 49. Studies screen interface

1. Navigation page.
2. Patient: the patient's name is displayed as 'last name, first name'.
3. Date of Birth: patient's date of birth.
4. Patient ID: the ID number assigned to the patient by the Capsule Administrator who started the study.
5. Referring Doctor: the doctor that initially ordered the study.
6. Study Start: the date the Capsule was administered.
7. Status:
   Data Processing: the study has been uploaded from a Receiver and is being processed for review.
   Ready for review: the study has been successfully processed and is awaiting review.
   In progress: one or more of the markers of the study have been reviewed, but there are still markers pending review.
   Reviewed: the study has been reviewed. Reviewed studies can be revised or revisited to generate new reports.
   Error: the study could not be processed for review. Hovering over the "i" icon may provide information about the error. Contact Atmo Support to request a reprocessing of the study.
8. Review Date: the date the last review of the study was completed.
9. Search bar: studies can be searched by any of the column fields.
10. Reviewer: physician in charge of the study review.
11. User Manual icon: click on the icon and the User Manual will be displayed as a PDF file in a separate page.
12. My Profile icon: click to display 'My Profile' dialog to edit your personal details and change password. Please enter all required fields with '*' and click 'Save Changes' to apply the update.
13. Go to study: opens the selected study for review.
14. Navigation of the study list pages.
15. Study list numbering.

Review Interface

Once a study is selected on the study list, the 'Study Overview' screen will be displayed (see Figure 50).

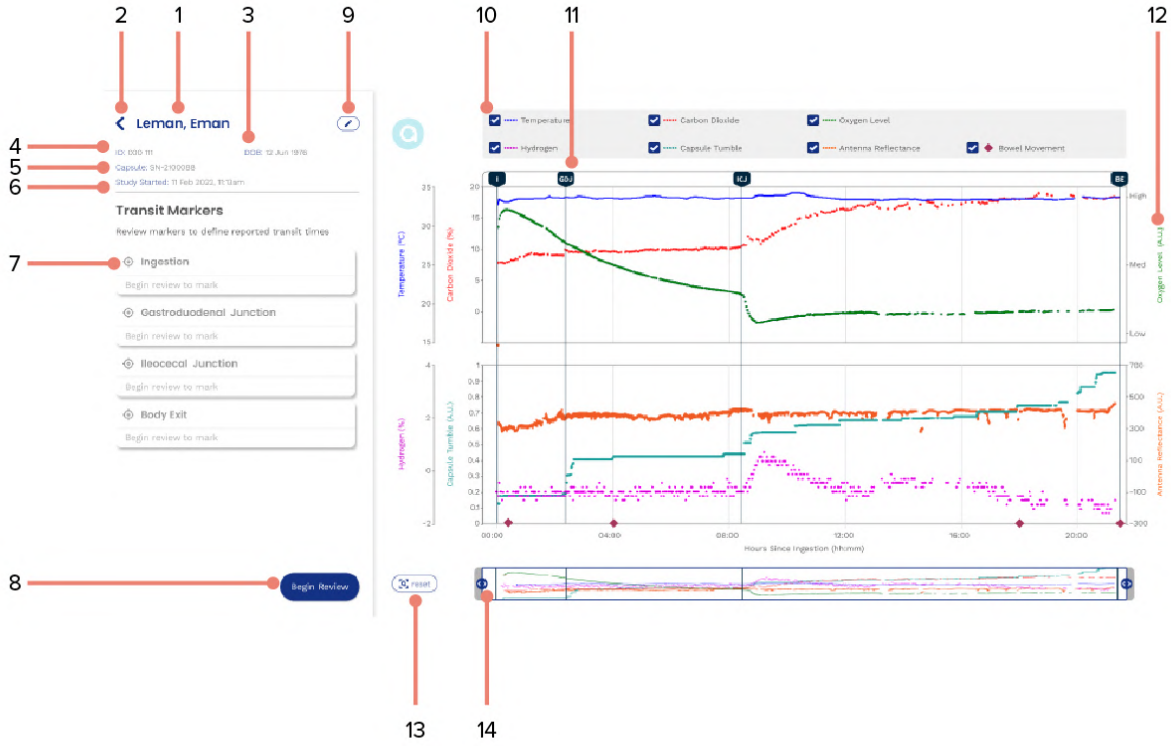


Figure 50. Study Overview screen interface

1. Patient Name.
2. Return to the study list.
3. Patient Date of Birth.
4. Patient ID.
5. Capsule serial number.
6. Study start date.
7. Transit Markers status.
8. Begin Review button. Clicking this button starts the process of placing the markers on the data traces.

	NOTE: This review process must be completed before a Motility Study Report can be generated.

9. Patient information edit button. Display the patient information for review and editing.
10. Study legend. The toggle switches on each trace name will show or hide the traces on the graphs underneath.
11. Transit Markers for Ingestion (I), the Gastroduodenal Junction (GDJ), Ileocecal Junction (ICJ) and Body Exit (BE). If the system cannot suggest a marker placement for any markers, they are not displayed in the initial overview.
12. Trace axes: The traces are displayed in a graph containing two scatter plots. The trace colours follow the legend at the top of the graph, the axis names and units on the sides.

	NOTE: Hovering over the axis displays vertical zoom and pan controls for the specific traces (see Figure 51).

13. Time-axis zoom and pan reset button.
14. Time-axis zoom and pan control. Drag the handles of the blue frame around the minimap to select the area for the graphs displayed.

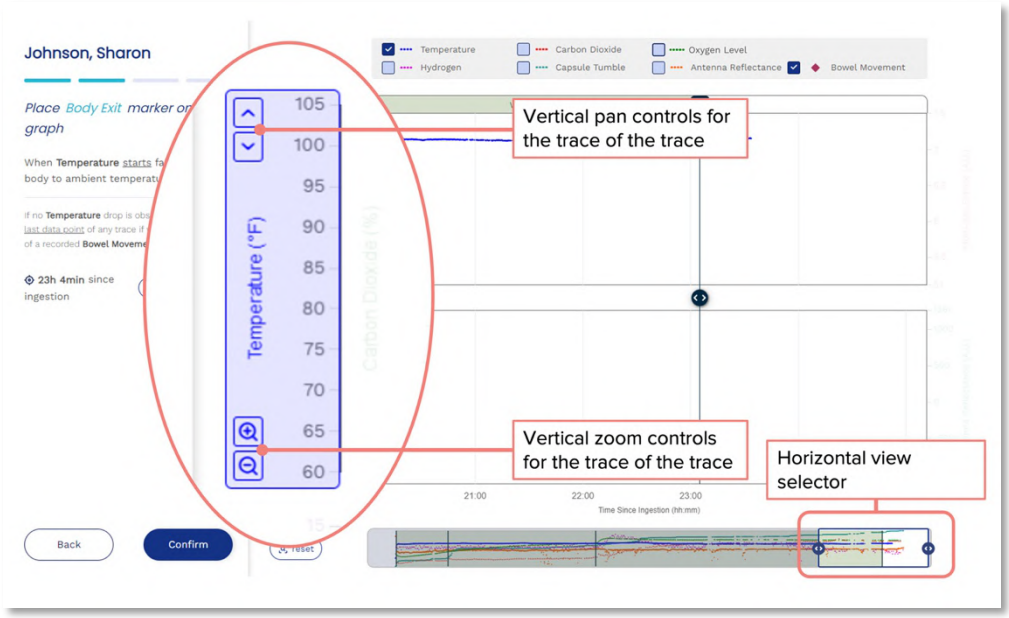


Figure 51. Example of view and zoom controls on the study review interface

Motility Study Data

The Atmo Gas Capsule System is designed to determine transit times between the major anatomical landmarks of the gastrointestinal (**GI**) tract: Ingestion (**I**), Gastroduodenal Junction (**GDJ**), Ileocecal Junction (**ICJ**) and Body Exit (**BE**). These landmarks are derived from Capsule Measurement or Indicator traces and the Bowel Movement Event Marker.

Figure 52 shows the "Primary Indicators" typically sufficient to identify each landmark and the "Secondary Indicators", which can provide supporting information if the Primary Indicator is unclear. Each of these traces is described in this section (see below).

Detailed information about interpreting each trace to identify the landmarks is presented below.

GI Landmark	Primary Indicator(s)	Secondary Indicator(s)
Ingestion	Temperature	NA
GDJ	Carbon Dioxide	Capsule Tumble Antenna Reflectance
ICJ	Oxygen Level	Hydrogen and Carbon Dioxide Antenna Reflectance
Body Exit	Temperature	Bowel Movement

Figure 52. Specific data traces analysed for each anatomical landmark

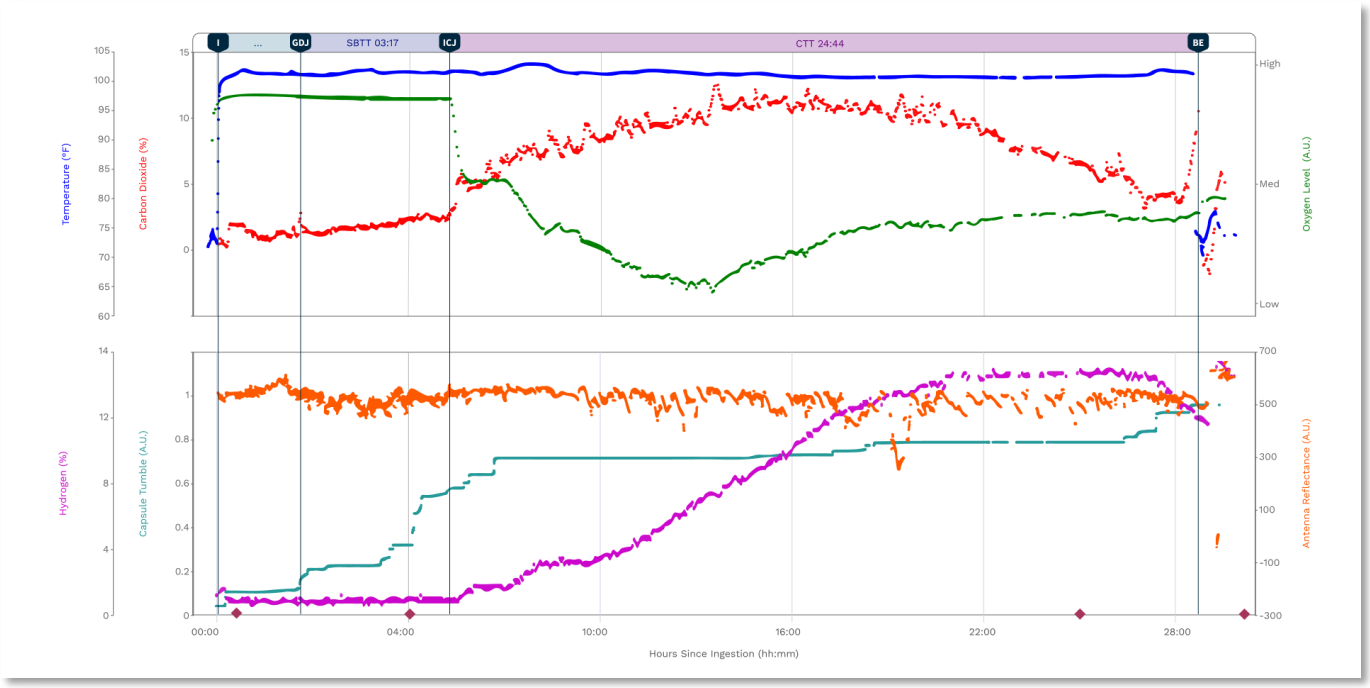


Figure 53. Example of Motility Study traces graph

Temperature Trace

The temperature sensor measures the Capsule's internal Temperature (see Figure 54). The temperature trace is primarily used to determine Ingestion time (see Marking Ingestion), where it rises to body temperature and Body Exit (see Marking Body Exit (BE)), and where it falls from body temperature.

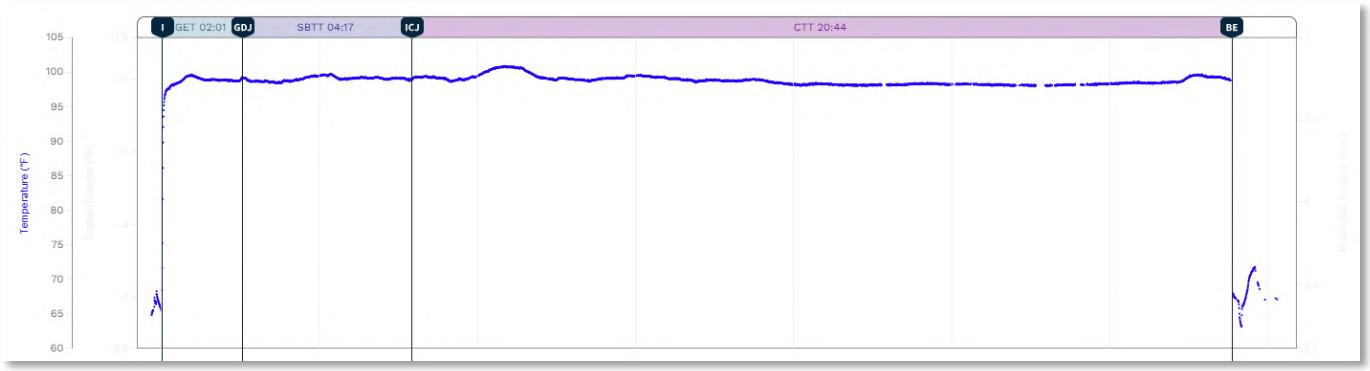


Figure 54. Example of the Temperature Trace

	NOTE: Temperature can fluctuate with hot or cold food or drink consumption while the Capsule is in the stomach (see Figure 64 and 65).

Carbon Dioxide Trace

This trace displays the percentage concentration of Carbon Dioxide from the environment around the Capsule (see Figure 55). It is used as the primary indicator to determine GDJ (see Marking Gastroduodenal Junction (GDJ)). When the Capsule is emptied from the stomach, released Hydrochloric acid mixes with bicarbonate excreted from the pancreas to produce a measurable spike in Carbon Dioxide. This trace is also used as a secondary indicator for ICJ (see Marking Ileocecal Junction (ICJ)) where a marked change in its output can often be observed as the Capsule enters the colon.

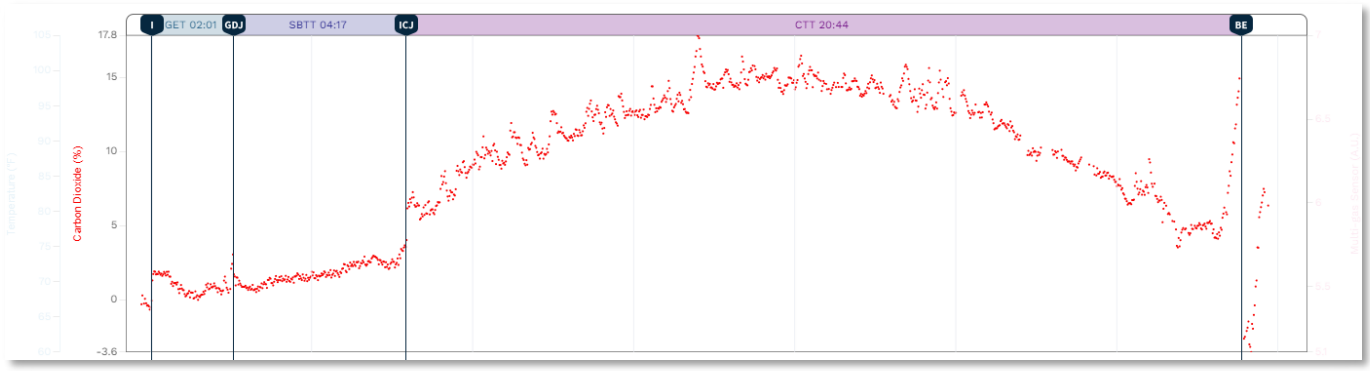


Figure 55. Example of Carbon Dioxide Trace

NOTE:

This trace should not be used for purposes other than identifying GDJ and ICJ, as the Carbon Dioxide trace has cross-sensitivity with Hydrogen and Methane, which can be present in large concentrations in the colon.

Hydrogen Trace

This trace displays the percentage concentration of Hydrogen from the environment around the Capsule (see Figure 56). It is used as the secondary indicator for ICJ (see Marking Ileocecal Junction (ICJ)). Typically, no measurable Hydrogen is detected in the small bowel before rising in the colon.

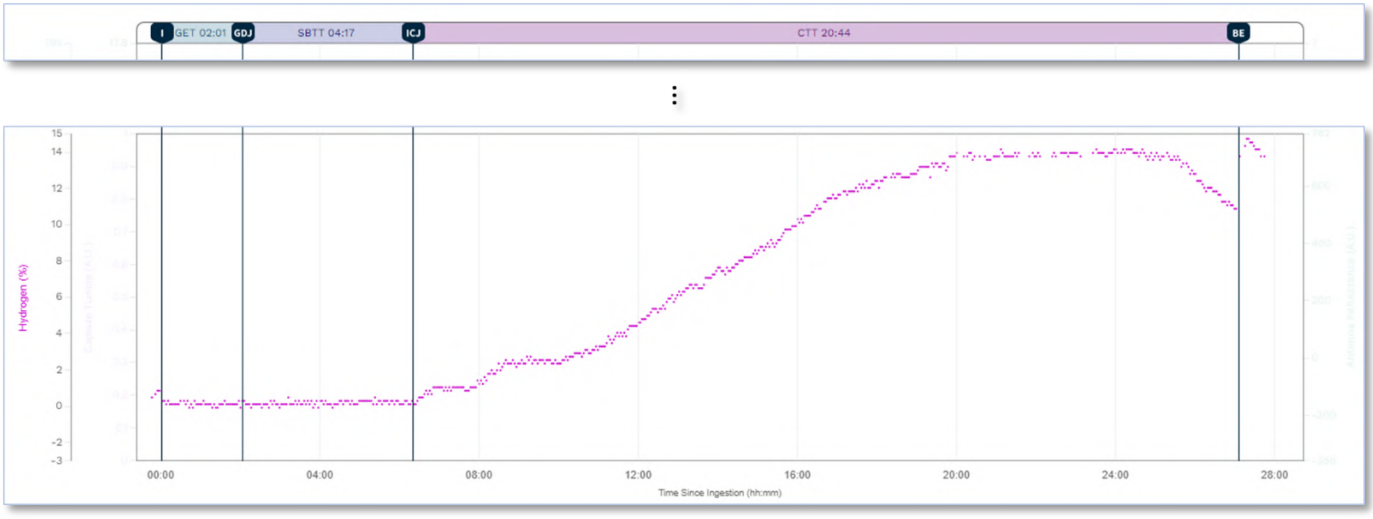


Figure 56. Example of the Hydrogen trace

NOTE:

This trace should not be used for purposes other than identifying ICJ; it has insufficient sensitivity to detect the small Hydrogen concentrations found in the small bowel.

Some patients may show no measurable hydrogen in the colon.

Oxygen Level Trace

This trace displays an indication of Oxygen Level from the environment around the Capsule. It Is expressed from Low to High in arbitrary units (A.U.) (see Figure 57). It is used as the primary indicator for ICJ (see Marking Ileocecal Junction (ICJ)), as it has a marked decrease in output as the Capsule enters the anaerobic environment of the colon. This change is accentuated due to the sensors inverse sensitivity to increased concentrations of Hydrogen and Methane found in the colon.

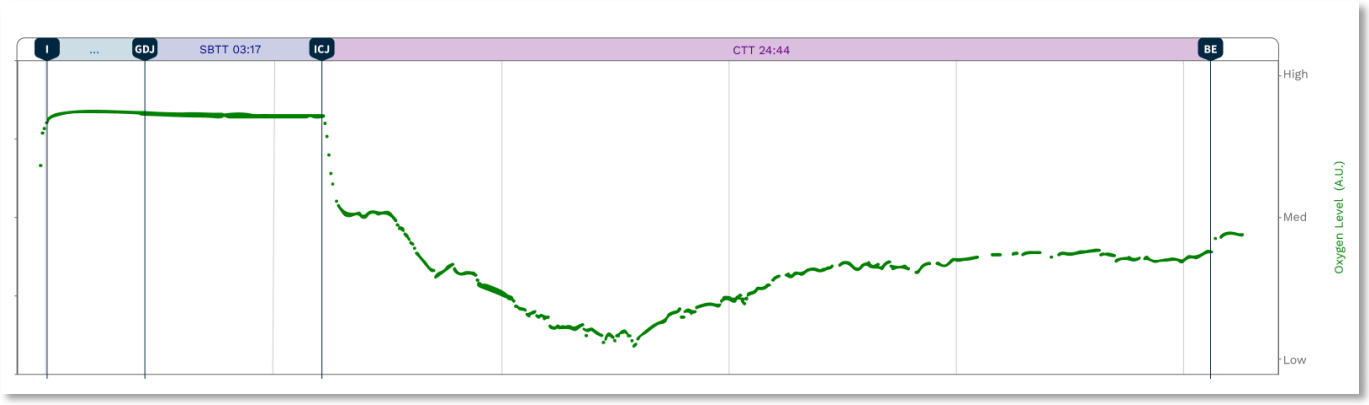


Figure 57. Example of the Oxygen Level trace

Capsule Tumble Trace

The Capsule Tumble trace indicates how much the Capsule's tilt angle (end-over-end rotation) has changed beyond a threshold angle. It is expressed in arbitrary units (A.U.) (see Figure 58).

Capsule Tumble is used as a secondary indicator for GDJ (see Marking Gastroduodenal Junction (GDJ)). The Capsule typically settles to the bottom of the stomach, so the tilt angle rarely exceeds the threshold, and the trace remains relatively flat. By comparison, as the Capsule follows the twisting path of the small bowel, the threshold is exceeded, which causes the trace to rise.

Figure 58. Example of Capsule Tumble trace

	NOTE: Physical activity or food and drink consumption can cause the Capsule tilt angle to exceed the threshold while in the stomach.

Antenna Reflectance Trace

The Antenna Reflectance trace indicates changes in the Capsule's surrounding environment (see Figure 59). A visual change in this trace can result from the Capsule transitioning from being surrounded by gastric fluid in the stomach, to tissue in the small bowel and faecal matter in the colon. This marker acts as a secondary indicator for GDJ (see Marking Gastroduodenal Junction (GDJ)) and ICJ (see Marking Ileocecal Junction (ICJ)). It is expressed in arbitrary units (A.U.).

Figure 59. Example of Antenna Reflectance trace

Bowel Movement Event Marker

The Bowel Movement Event marker (◆) is displayed on the chart to indicate when the patient recorded bowel movements by pressing the "+" button on the Data Receiver (see Figure 60). This marker can be used as a secondary method of confirming Body Exit (see Marking Body Exit (BE)).

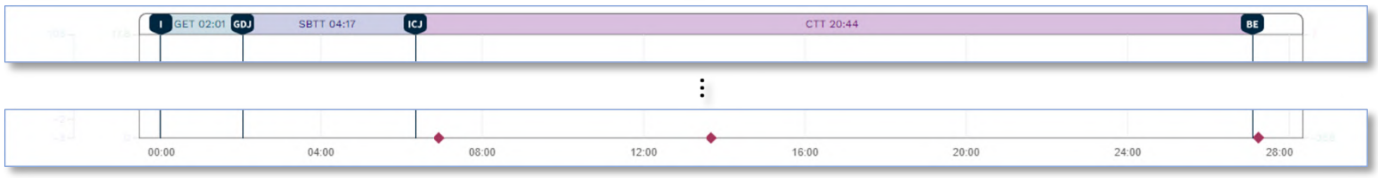


Figure 60. Example of the Bowel Movement markers (◆)

Motility Study Review

The following sections illustrate how to review a study.

Begin Study Review

Clicking **Begin Review** from the Study Overview screen begins the marker placing process. A screen will be displayed for each GI landmark in sequence. Each screen presents the information necessary for placing each marker, including a graph showing relevant traces and cropped areas of the study, along with guidance on how to interpret the data to place the marker.

	NOTE: Once the review is complete, the process of placing markers can be repeated by clicking **Edit Markers.**

Transit Marker Interface

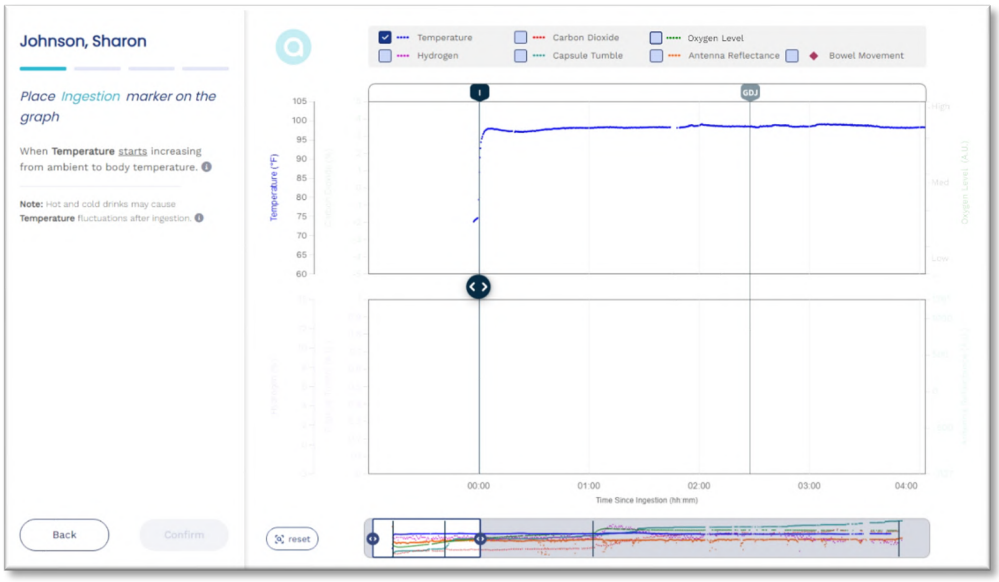


Figure 61. Example of the Review Screen for the first marker, i.e. Ingestion

	NOTE: Physical activity or food and drink consumption can cause the Capsule tilt angle to exceed the threshold while in the stomach.

1. To move the marker, click on the handle in the middle of the marker ( ) and drag it horizontally until it is in the desired position.
2. If no marker movement is required, confirm the current placement by clicking on the marker ( ).
3. If you do not believe a motility marker can be placed based on the data and guidance provided, click the tick box labelled 'Unable to determine marker time' (Figure 62).
4. Once the marker placement has been reviewed and/or adjusted, click **Confirm**. The Summary Data Review screen will be displayed.

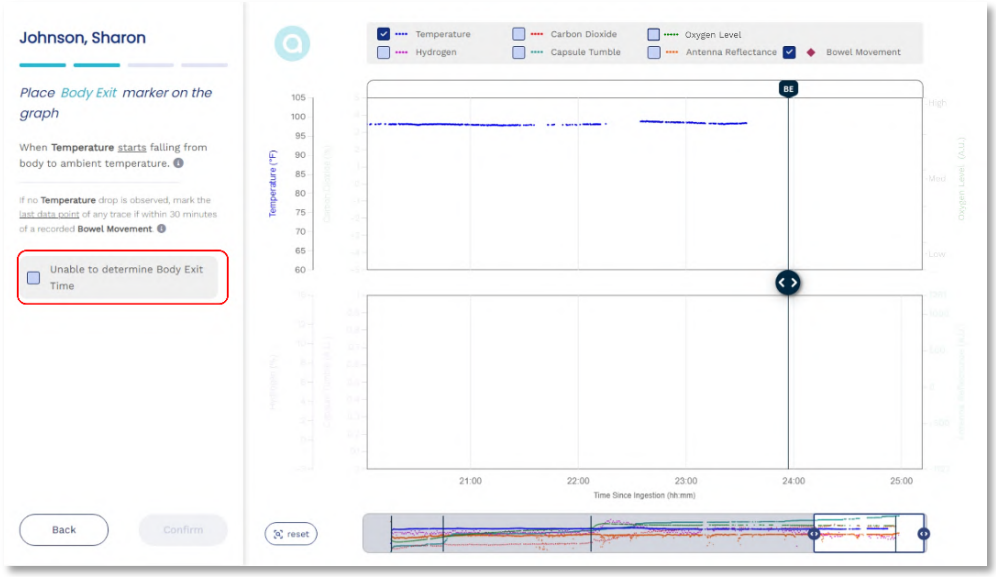


Figure 62. Example of the 'Unable to determine' marker checkbox on the Body Exit Review Screen

	NOTE: The placement of each marker must be reviewed and confirmed before a Motility Study Report can be generated. The application prompts the user to review the study in the following order: Ingestion, Body Exit, ICJ and GDJ. This order aids usability as GDJ is easier to identify after ICJ has been marked.

Marking Ingestion

Guidance:

The marker should be placed when **Temperature** starts increasing from ambient to body temperature.

	NOTE: Hot and cold drinks may cause temperature changes after Ingestion (see Figure 64 and 65).

Ingestion Primary Indicator - Temperature

Ingestion is marked when Temperature rises from ambient room temperature to human body temperature (see figure 63).

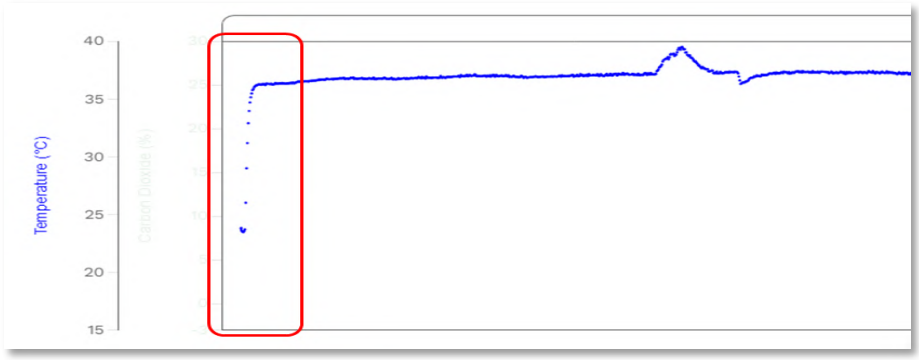


Figure 63. Example of Ingestion with the corresponding rise in Temperature

Temperature Fluctuations

The consumption of hot or cold drinks after Ingestion may result in temperature changes (see Figure 64 and Figure 65), which the Capsule may detect while in the oesophagus or stomach. Temperature changes due to hot and cold drinks are unlikely to occur after the Gastroduodenal Junction.

Figure 64. Example of temperature fluctuations due to Ingestion of cold drinks

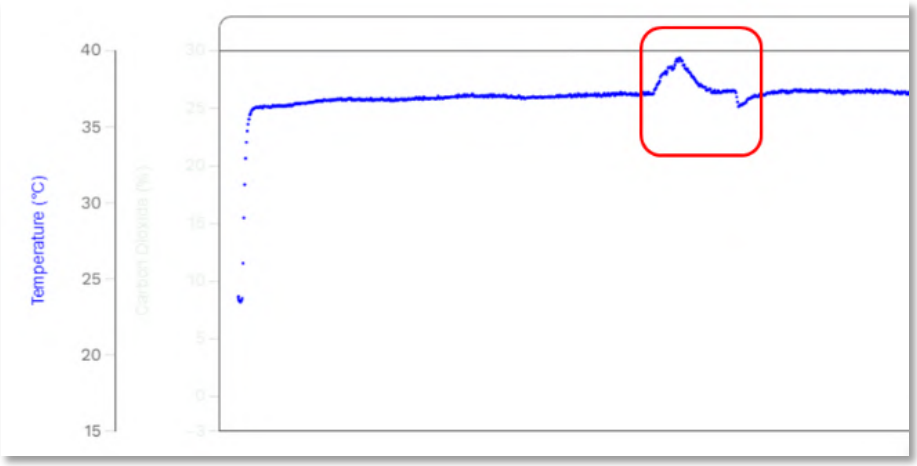


Figure 65. Example of temperature fluctuations due to Ingestion of hot drinks.

There may also be temperature changes before Ingestion if the Capsule is activated but not immediately ingested by the patient (see Figure 66).

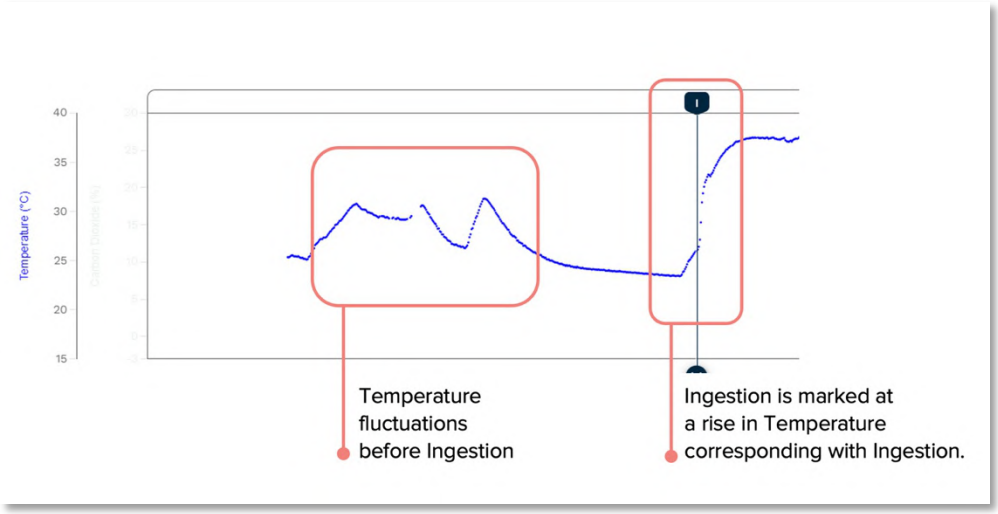


Figure 66. Example of temperature fluctuations before Ingestion

Marking Body Exit (BE)

Guidance

The marker should be placed when **Temperature** starts falling from body to room temperature.

Or, if no Temperature drop is observed, mark the last data point of any trace if within 30 mins of a recorded Bowel Movement.

BE Primary Indicator – Temperature

Body Exit is marked when **Temperature** falls from human body temperature to ambient room temperature (see Figure 67).

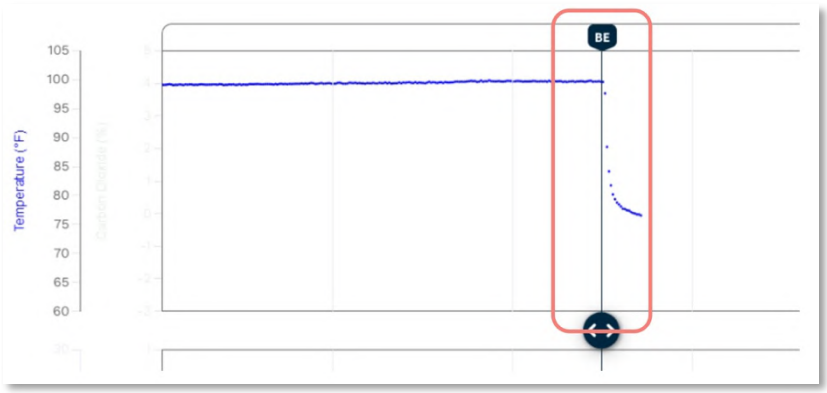


Figure 67. Example of Body Exit with the corresponding temperature drop

BE Secondary Indicator – Corresponding Bowel Movement

If no temperature drop is observed, Body Exit can be marked at the last temperature data point, provided it is within 30 minutes of a recorded bowel movement (see Figure 68).

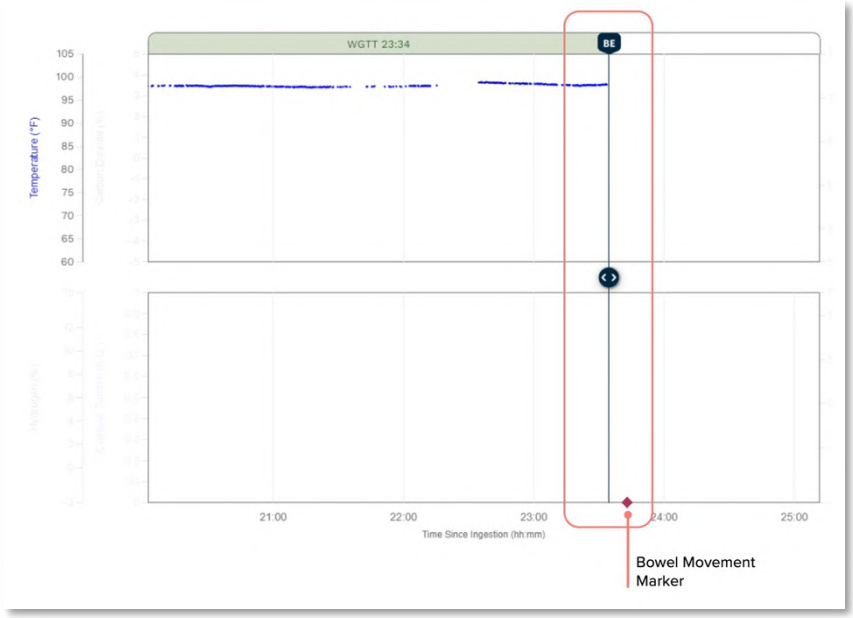


Figure 68. Example of Body Exit marked at the last temperature point within 30 minutes of a recorded bowel movement

BE – Unable to Determine

If there is no temperature drop and no recorded bowel movement within 30 minutes of the last temperature data point (see Figure 69), the 'Unable to determine Body Exit' checkbox should be checked, and the patient should be managed for suspected Capsule retention.

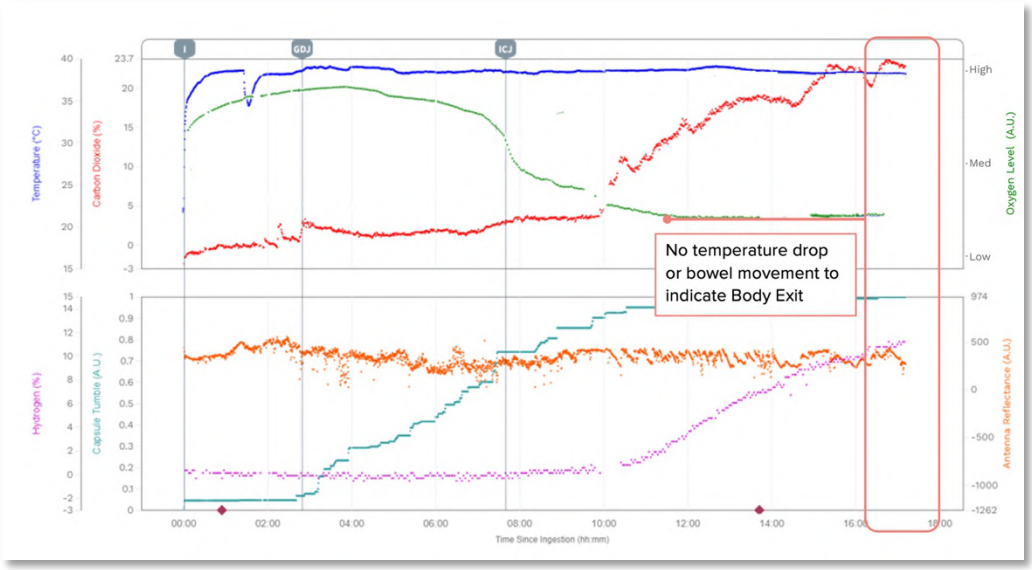


Figure 69. Example of where Body Exit is unable to be determined

Marking Ileocecal Junction (ICJ)

Guidance

The marker should be placed at the start of a steep drop in the **Oxygen Level Indicator**.

If unclear, look for a corresponding change in **Carbon Dioxide**, **Hydrogen**, or **Antenna Reflectance**.

	NOTE: The Oxygen, Carbon Dioxide and Hydrogen levels change significantly in the colon.

ICJ Primary Indicator – Oxygen Level Indicator

The Oxygen Level Indicator is most sensitive to Oxygen and inversely to Hydrogen and Methane. The Oxygen Level Indicator is used as the primary indicator for ICJ, as it has a marked decrease in its output as the Capsule enters the anaerobic environment of the colon. This change is accentuated due to the sensors inverse cross sensitivity to increased concentrations of Hydrogen and Methane found in the colon (see Figure 70).

Figure 70. Example of ICJ shown by a steep decrease in the Oxygen Level Indicator

ICJ Secondary Indicator – Hydrogen and Carbon Dioxide

Hydrogen and Carbon Dioxide are secondary indicators for ICJ, as these gases may be present in different concentrations in the colon. Therefore, ICJ can be associated with a sudden rise in the Hydrogen and Carbon Dioxide concentrations (see Figure 71).

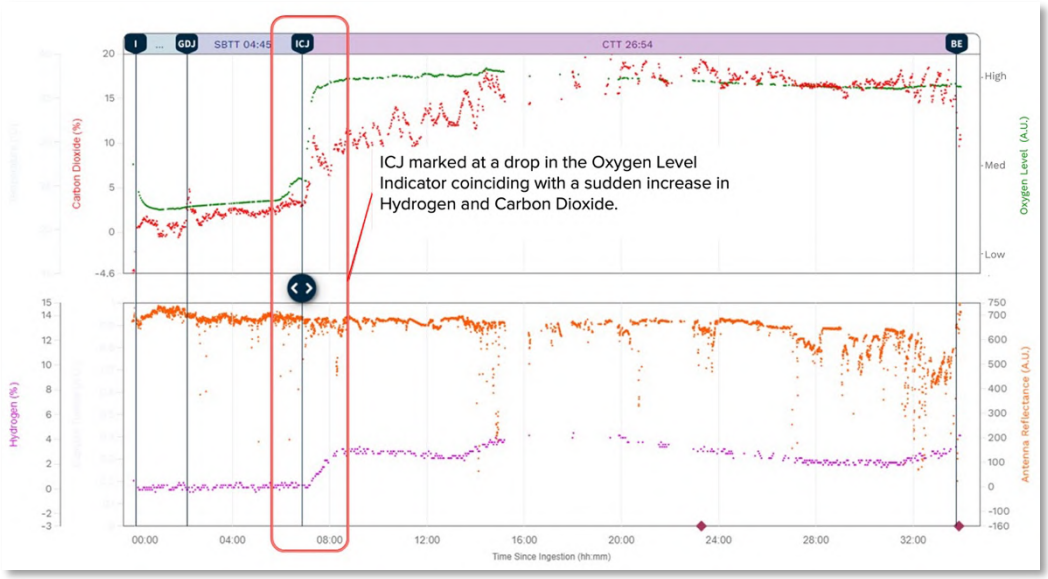


Figure 71. Example study with ICJ marked at the start of a steep decrease in the Oxygen Level Indicator, corresponding with a rise in Hydrogen and Carbon Dioxide concentrations

If multiple steep decreases exist for the **Oxygen Level Indicator**, select the one coinciding with the first of a sudden rise in the concentration of either of Hydrogen or Carbon Dioxide (see Figure 72).

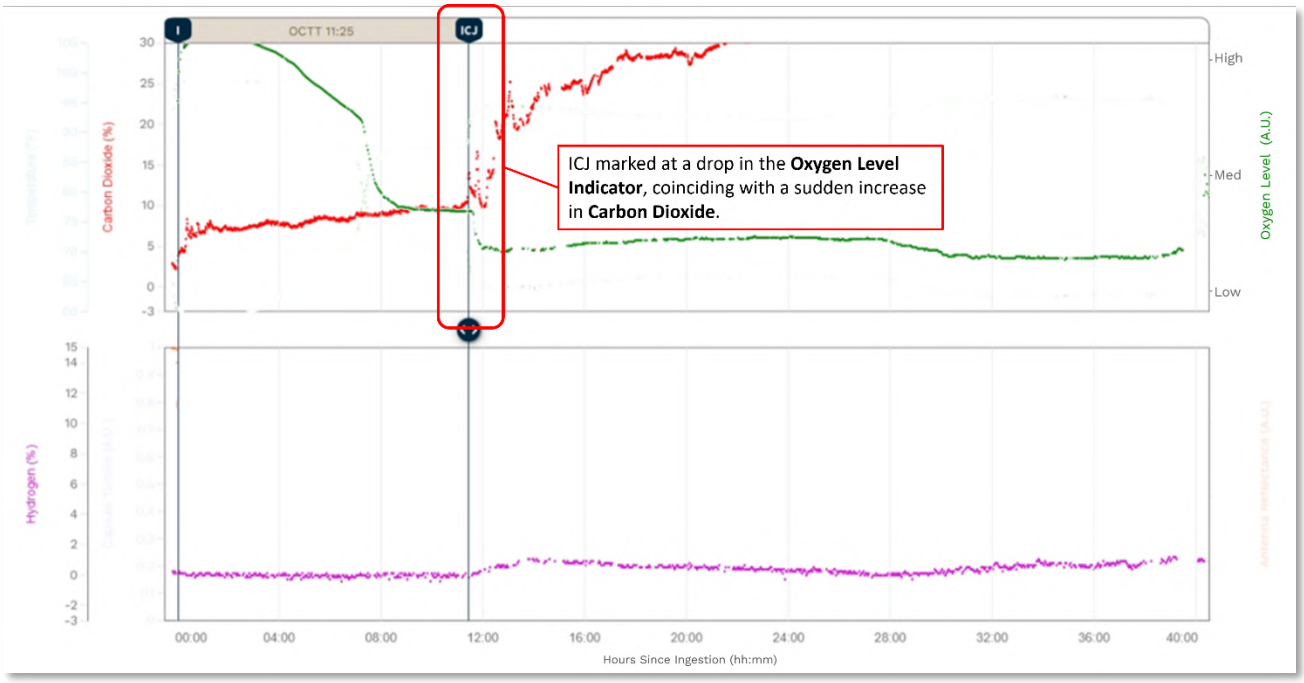


Figure 72. Example where the Oxygen level has two steep decreases. ICJ is marked at the second steep decrease, corresponding with an increase in Carbon Dioxide and a slight increase in Hydrogen

ICJ Secondary Indicator – Antenna Reflectance

Antenna Reflectance is also a secondary indicator for the ICJ, identified by a sudden change in the pattern of this trace. This change often presents as a change in noise or a step change (either a rise or fall) (see Figure 73).

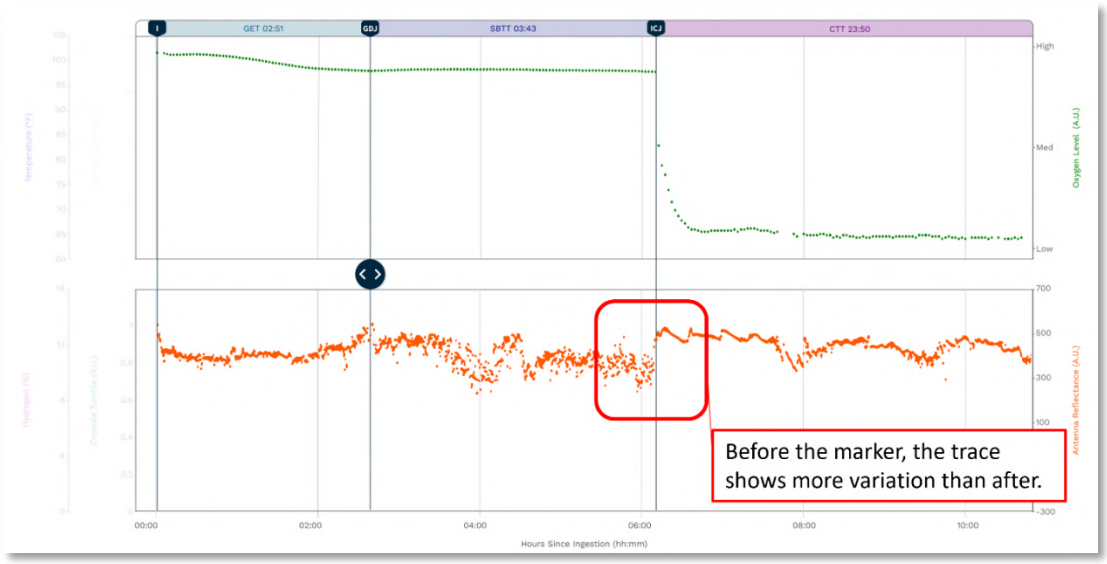


Figure 73. Example of ICJ, where a sudden change in Antenna Reflectance accompanies a steep decrease in the Oxygen level

ICJ – Unable to Determine

If there is no steep decrease in the Oxygen Level, you may be unable to place the ICJ marker (see Figure 74). If this occurs, tick the box to indicate that you were 'Unable to determine Ileocecal Junction time'. As a result, transit metrics requiring ICJ: Small Bowel Transit Time, Colonic Transit Time and Orocecal Transit Time will not be reported.

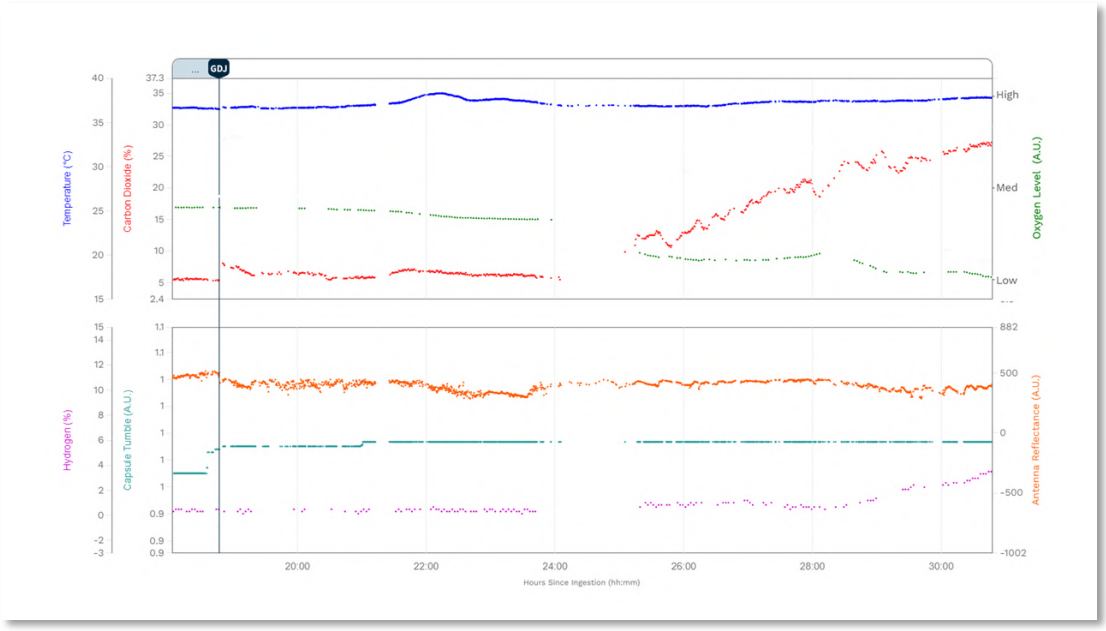


Figure 74. Example where ICJ could not be marked due to lack of a steep decrease in the Oxygen level

	NOTE: If there is minor data loss around the ICJ, then ICJ may be marked using discretion.

Marking Gastroduodenal Junction (GDJ)

Guidance

The Marker should be placed at the beginning of one of the last spikes in **Carbon Dioxide** before the Ileocecal Junction, corresponding with a sudden change in **Capsule Tumble** or **Antenna Reflectance**.

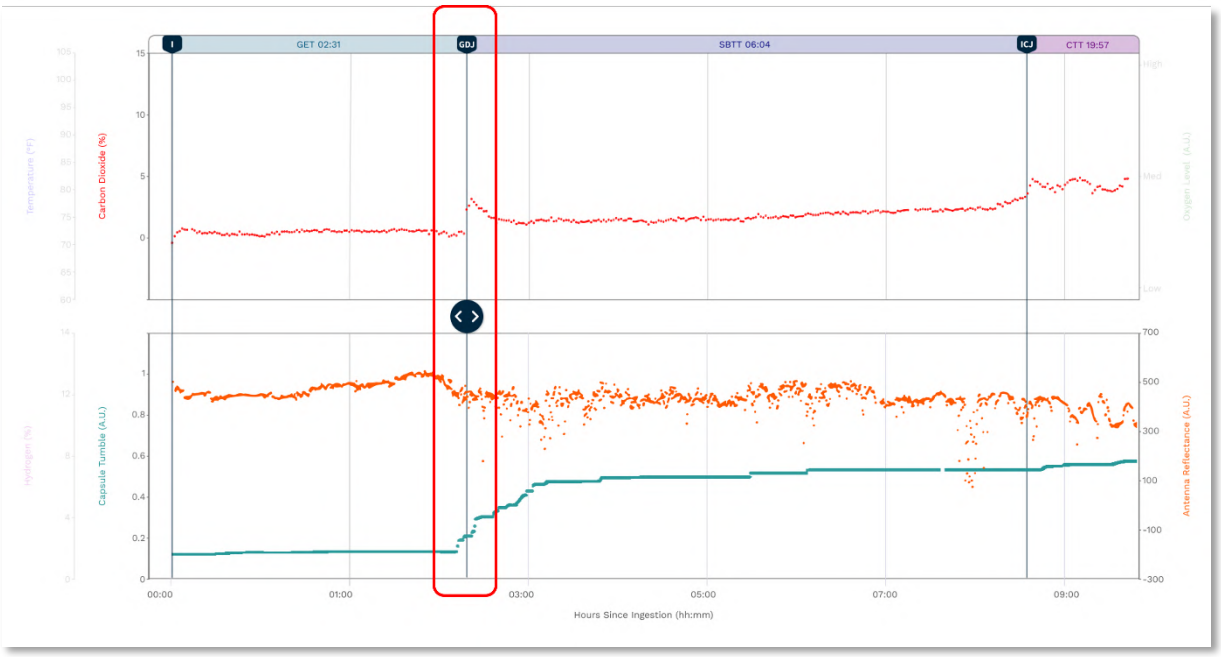


Figure 75. Example of GDJ Traces

	NOTE: Temperature fluctuations due to food or drink are unlikely to occur in the small bowel.

GDJ Primary Indicator – Carbon Dioxide

Carbon Dioxide is the primary indicator for the GDJ, as it is a gaseous by-product of the neutralization reaction that occurs when the Capsule passes through the pylorus and hydrochloric acid from the stomach reacts with bicarbonate excreted from the pancreas. Therefore, the last spike or a step increase in Carbon Dioxide before the ICJ indicates the GDJ (see Figure 76).

Figure 76. Example of GDJ, marked at the last spike in Carbon Dioxide before the ICJ

If the spike or step increases in Carbon Dioxide is unclear, a corresponding steep increase in Capsule Tumble or sudden change in Antenna Reflectance can help you to mark the GDJ (see Figure 77).

GDJ Secondary Indicator – Capsule Tumble

Capsule Tumble is a secondary indicator for GDJ. The Capsule Tumble trace remains relatively flat while the Capsule is settled on the bottom of the stomach. The Tumble indicator increases when it travels through the twisting path of the small bowel. (see Figure 77).

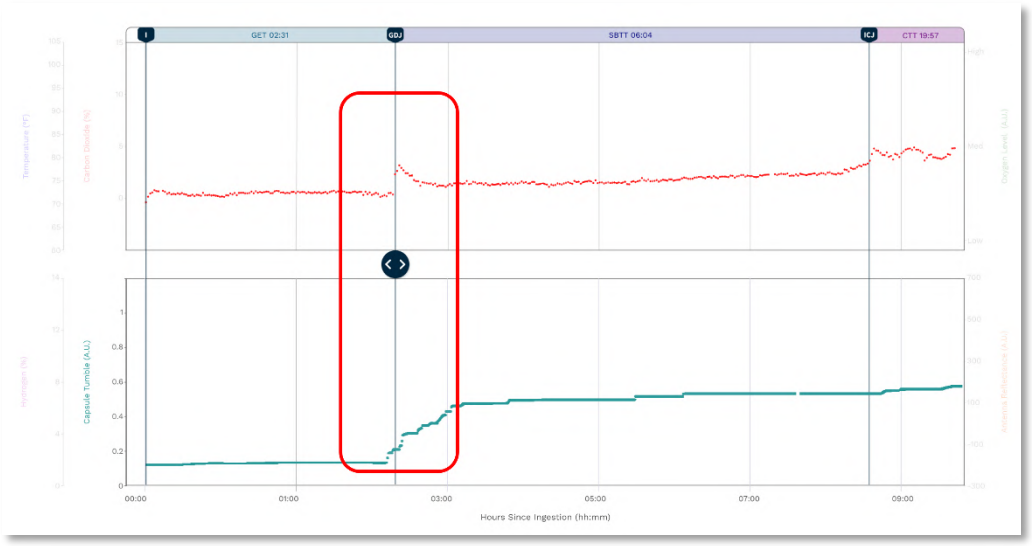


Figure 77. Example of GDJ, marked at the last spike in carbon dioxide before the ICJ, which also corresponds with a steep increase in Capsule Tumble

GDJ Secondary Indicator – Antenna Reflectance

Antenna reflectance is also a secondary indicator for the GDJ, as a sudden change in this trace can occur when the Capsule moves from the predominantly liquid environment of the stomach to the surrounding tissue environment of the small bowel (see Figure 78).

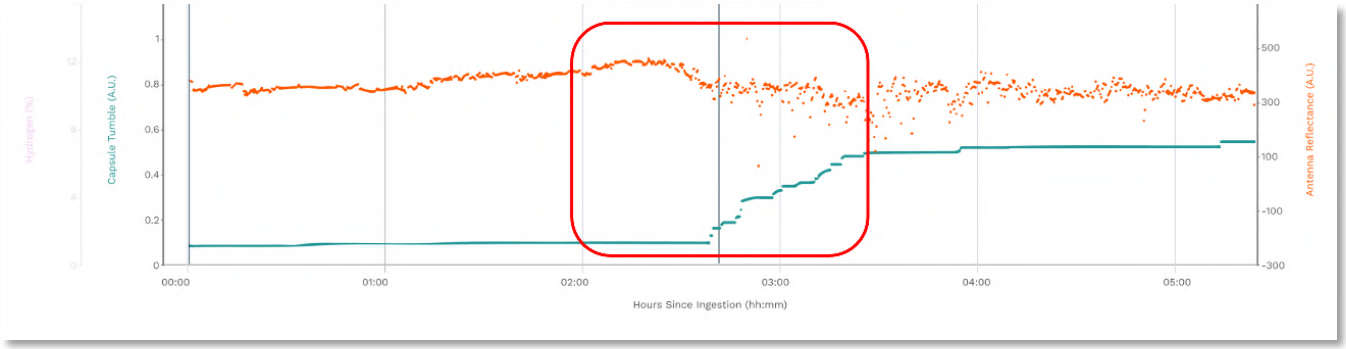


Figure 78. The graph above highlights the steep increase in Capsule Tumble and sudden change in Antenna Reflectance that have aided the placement of the GDJ marker

GDJ – Unable to Determine

If the GDJ landmark cannot be identified. Tick the box to indicate that you were 'Unable to determine Gastroduodenal Junction.' As a result, transit metrics requiring GDJ: Gastric Emptying Time, Small Bowel Transit Time and Small-Large Bowel Transit Time will not be reported. (see Figure 79 and Figure 80).

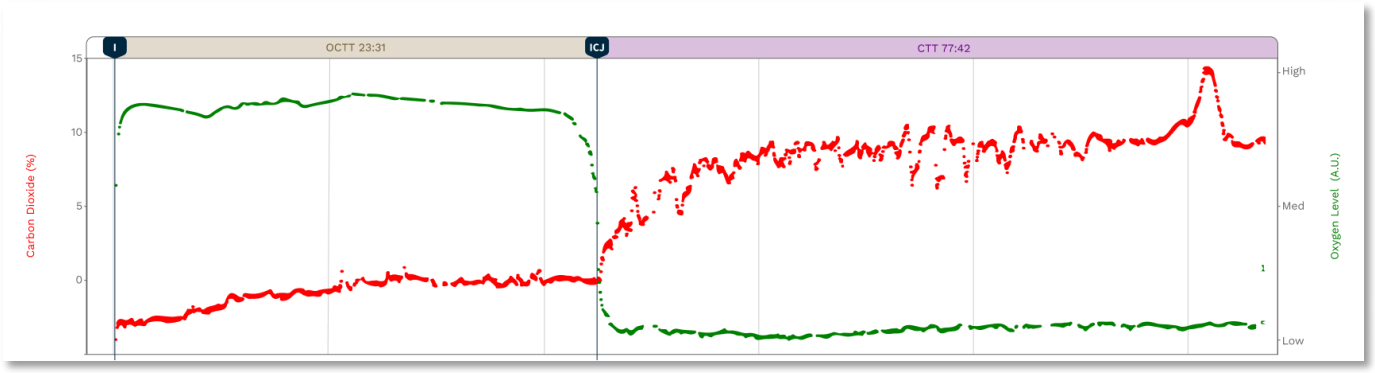


Figure 79. Example where GDJ could not be determined due to a lack of spikes or a steep increase in Carbon Dioxide. Since ICJ was determined, OCTT is reported as a proxy metric

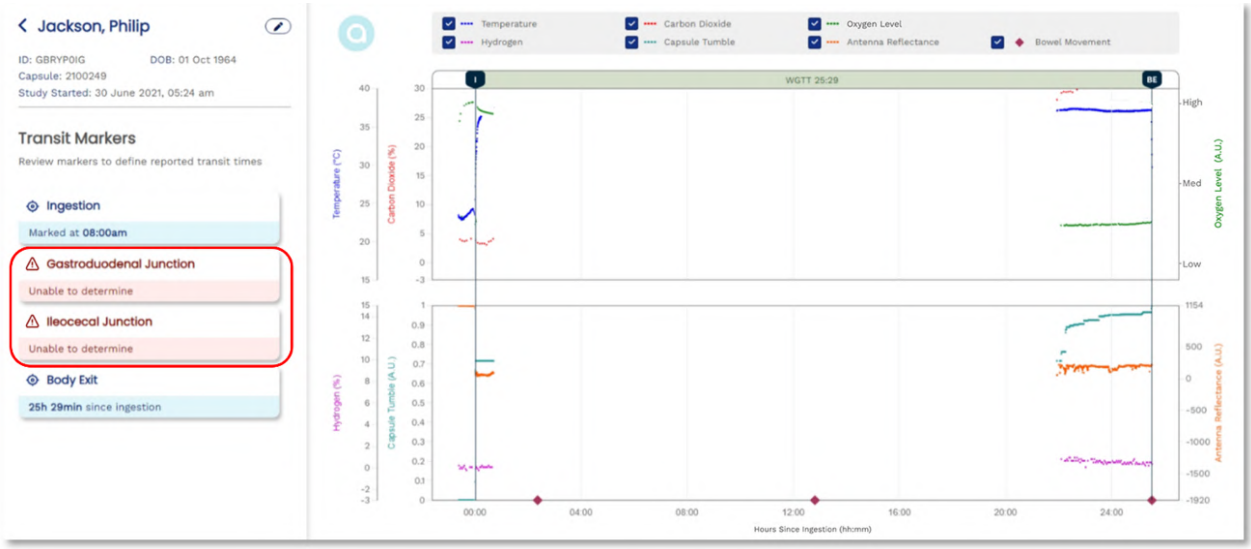


Figure 80. Example where both GDJ and ICJ could not be determined. Whole Gut Transit Time would be the only transit metric reported in such a case

Generating a Study Report

A study report can only be generated once all motility markers have been reviewed and confirmed (see Figure 81). This report can be viewed electronically or printed to share. Study reports are generated from the Summary Data Review Screen.

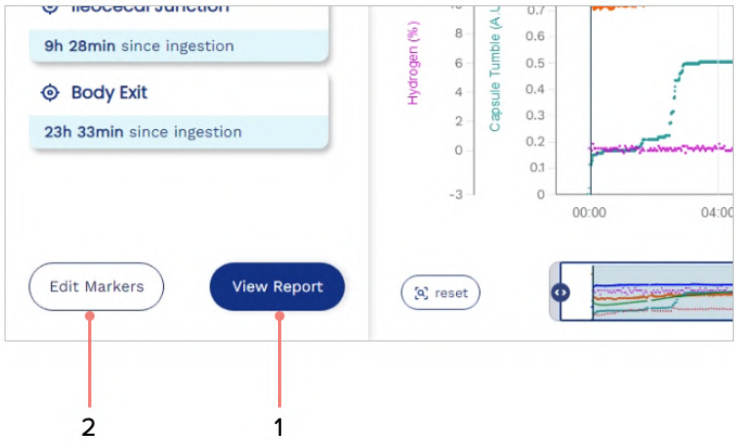


Figure 81. Controls for editing the transit marker placement or generate report that appear after a study has been reviewed

1. View generated Motility Study Report.
2. Edit Markers button (restart the marker placement process).

Study Report

Clicking **View Report** from the Summary Review screen will generate a PDF report (see Figure 82), which can be saved and printed.

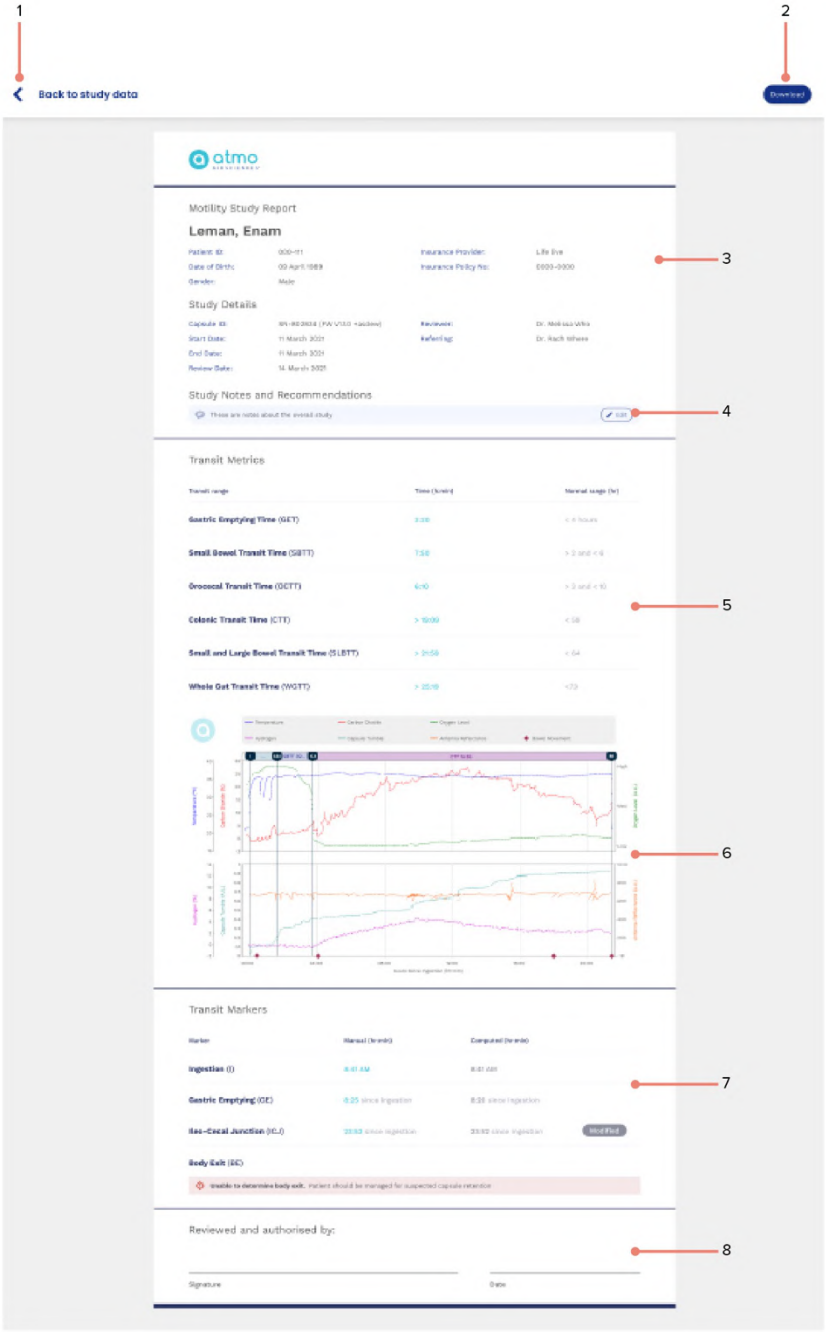


Figure 82. Study Report Interface

1. Navigation button.
2. Download Button (prints to PDF or printer).
3. Study Identifier and Other Details.
4. Study Notes Entry Box.
5. Study Transit Metrics.
6. Study Graph.
7. Transit Markers Summary.
8. Reviewer signature space.

Study Identifier

Figure 83. Motility Study Identifier

1. Patient Details.
2. Study Details.
3. Study Notes: notes to the study report can be added by clicking the **Edit** button.

Motility Transit Metrics

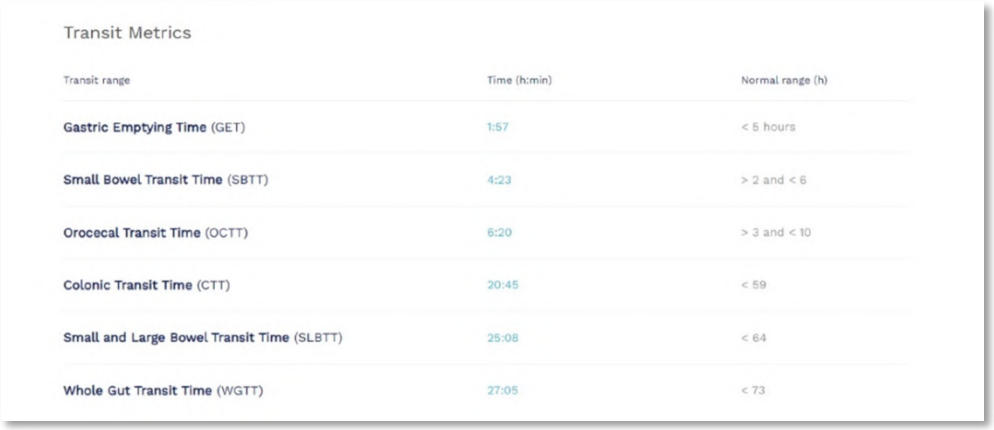


Figure 84. Motility Transit Metrics

Motility Transit Markers

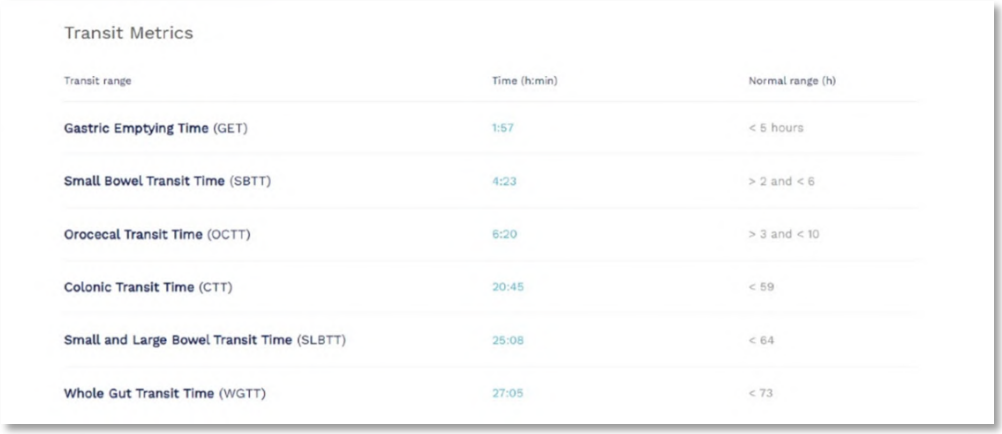


Figure 85. Motility Transit Markers

Device Limitations

Food Ingestion

Food eaten during the period between Ingestion and gastroduodenal junction (GDJ) can delay gastric emptying.

Signal Loss

Signal loss at critical periods can result in:

- Inability to make a conclusive diagnosis.
- Inability to determine Capsule body exit.

Signal loss can be caused by:

- Patient not wearing the Belt during the study.
- Receiver placed too far away from the patient.
- Patient physiology (high BMI is correlated with signal loss).
- Technical problems.

End-of-Study Indicator (Receiver)

The Receiver end-of-study indicator will light up once it has determined that there is no longer any need to gather data. The following circumstances may cause the end-of-study indicator to light up prematurely, leading to a possible data loss:

- Toilet water that is close to body temperature or a toilet that does not use water.
- The recording of a bowel movement that coincides with a loss of signal.
- Patients that have a long transit and body anatomy that completely attenuates the signal.
- The Receiver is paired with an incorrect Capsule.

Non-compliant behaviour:

- Not wearing the Receiver in the prescribed manner.
- Not taking the Receiver to the toilet.
- Not pressing the event button at the time of a bowel movement.

Accuracy of CO_2 after Gastric Emptying

The measurement of CO_2 levels can be affected by the presence of H_2 and CH_4, which are expected to be elevated in the colon. This reduces the accuracy of the displayed CO_2 while in the colon.

Differentiation of Slow Motility from Functional Obstruction or Defecation Disorder

The system measures CTT by the difference in time from ICJ to body exit. A large CTT could be caused by several things, including slow motility and functional obstruction/defecation disorder. As such, additional factors should be taken into consideration before making a diagnosis of slow motility.

Safety

Adverse Events

Potential adverse events associated with the use of this device may include delayed body exit or retention of the Capsule, aspiration, obstruction, perforation and mucosal injury or bleeding. In some instances, intervention may be required to remove the Capsule.

Non-Passage

All Capsules carry some minimal risk with regards to failed exit (retention). The common definition of retention is non-passage of greater than 14 days[1]. Comparable wireless motility devices with similar indications for use and similar contraindications to the Atmo Gas Capsule System have an expected retention rate of about 0.33%.

Patient Management Protocol for Unconfirmed Capsule Body Exit

If Body Exit cannot be confirmed using the Atmo Gas Capsule System, then the patient should be managed for potential Capsule retention. If the Atmo Gas Capsule fails to pass after 14 days, then it can be considered retained. An abdominal X-ray should be taken to confirm its location and managed accordingly.

1. Cave D, Legnani P, de Franchis R, Lewis BS; ICCE. ICCE consensus for Capsule retention. Endoscopy. 2005 Oct;37(10):1065-7. doi: 10.1055/s-2005-870264. PMID: 16189792

Troubleshooting and Support

If any problems arise while using the Atmo Gas Capsule System, try the following solutions. If the problem persists, contact your sales representative or Atmo Biosciences. Please do not attempt to open or repair any system components.

Error	Possible Cause	Possible Solution
Capsule		
The Capsule light did not flash when the clip was removed.	• Flashing occurred but was not seen by user. • Capsule malfunctioned.	• Replace the clip, wait 20 seconds, and then try again. • Dispose or quarantine the Capsule.
The clip was already removed when the packaging was opened.	Clip was inadvertently removed during prior handling.	Dispose of the Capsule.
The blister pack was already open.	Packaging was damaged during prior handling.	Dispose of the Capsule.
Motility Bar		
The Use By date has been exceeded.	The bar was not used in a study.	Dispose of the bar.
The bar packaging is torn or already open.	Packaging was pierced/torn during prior handling.	Dispose of the bar.
Receiver		
The Receiver is not responding.	• The Receiver requires charging. • The Receiver software may have frozen. • The Receiver may have malfunctioned.	• Charge the Receiver. • Reset the Receiver by using a pen or pencil to press the reset button on the bottom of the Receiver. • Contact your Atmo Biosciences sales representative.
The Receiver will not charge (The Receiver battery indicator light is still blinking orange after 24 hours connected to the Power Supply).	• The cable used for charging Receiver is not the cable supplied with the system. • The cable is damaged. • There is an internal problem with the Receiver/Power Supply requiring service.	• Use the USB Cable supplied with the Atmo system. • Dispose of the damaged cable and contact your Atmo Biosciences sales representative for a replacement cable. • Contact Atmo Biosciences sales representative for a replacement Receiver and/or Power Supply.
Mobile Device		
The Mobile Device is not detecting the Receiver.	• The USB Cable used is not the USB Cable supplied with the system. • The cable is damaged. • The Receiver software may have frozen and needs to be reset. • There is an internal problem with the Receiver requiring service.	• Use the USB Cable supplied with the Atmo system. • Dispose of the damaged cable and contact Atmo Biosciences sales representative for a replacement cable. • Reset the Receiver by using a pen or pencil to press the reset button on the bottom of the Receiver. • Contact your Atmo Biosciences sales representative.

Error	Possible Cause	Possible Solution
The Mobile Device will not turn on.	The Mobile Device does not have enough charge to turn on.	Charge the Mobile Device.
The Mobile Device will not charge.	• The USB Cable used for charging is not the cable supplied with the system. • The USB Cable used for charging is damaged. • There is an internal problem with the Mobile Device or Power Supply requiring service.	• Use the USB Cable supplied with the system. • Dispose of the damaged cable and contact Atmo Biosciences for a replacement cable. • Contact your Atmo Biosciences sales representative.
Cannot find the Clinic App.	The App has been deleted from the Mobile Device.	The App and Mobile Device are managed by Atmo Biosciences. Please contact your Atmo Biosciences sales representative or technical support to have the App reinstalled.
Study data is not being uploaded from the Mobile Device to the Clinician Portal.	The Mobile Device is not connected to Wi-Fi.	Check the Mobile Device settings to ensure the Mobile Device is connected to Wi-Fi.
Belt		
The Belt buckle will not remain secure during normal use.	The Belt buckle is deformed/damaged.	Replace the Belt.
The Receiver will not remain securely encased by the Belt during normal use.	The press studs on the Belt detach during wear.	Replace the Belt.
Capsule Pairing Errors		
Capsule pairing failed due to **Capsule Not Found.**	Incorrect Capsule serial number was entered.	Re-attempt the Capsule activation and pairing process entering all 7 digits exactly as found on the Capsule packaging.
	Capsule is too far away from the Receiver.	Move the Capsule to within 30cm of the Receiver and reattempt the Capsule activation and pairing process.
	Capsule has not been properly activated.	• Replace the clip on the Capsule and wait 20 seconds before reattempting the Capsule activation and pairing process. Ensure that the Capsule flashes green several times.
	Multiple Capsules present in immediate environment.	• Multiple Capsules or other Capsules that transmit on the same RF band 433MHz can interfere with each other. This usually only occurs if their transmission schedules align. • To de-synchronize them, replace the clip on the Capsule, wait 20 seconds and reattempt the Capsule activation and pairing process.

Error	Possible Cause	Possible Solution
	RF Interference.	• If pairing is consistently failing with multiple Capsules and within 30cm of the Receiver, it is possible that RF interference is present on the band that the Capsule transmits. • Reattempt the Capsule activation and pairing process in a different location (preferably a different room) and with the Capsule very close to the Receiver.
Capsule pairing failed due to **Capsule Error.**	The system has detected an internal error in the Capsule. Error codes: • 103 • 104	Dispose of the Capsule and try the Capsule activation and pairing process with a new Capsule.
	The system has detected an internal error on the Receiver. Error codes: • 101 • 105 • 106	Please disconnect the Receiver, press the Reset button with a ball point pen and reattempt the Capsule activation and pairing process. If the error persists, try using another Receiver.
	The Receiver was unplugged during the pairing process. Error code: • 107	• Please plug the Receiver in and reattempt the Capsule activation and pairing process. • Do not unplug the Receiver until instructed.
Data Transfer		
Data Transfer Fails.	Receiver unplugged during transfer. Error code: • 401	• Keep Receiver plugged in and reattempt a data transfer. • Do not unplug the Receiver until instructed.
	Problem with cloud connection. Error codes: • 404 • 405	Ensure the Mobile Device is connected to Wi-Fi. Check your connection to the internet by attempting to view google.com in the Mobile Device web browser.
	Problem with Transfer. Error code: • 400 • 402 • 403 • 409	Contact your Atmo Biosciences representative. Retain the Receiver containing patient data.
	Problem with Receiver. Error codes: • 402 • 403 • 406 • 407 • 408 • 410 • 411	• Please disconnect the Receiver, press the Reset button with a ballpoint pen and reattempt the Capsule activation and pairing process. If the error persists, contact Technical Support. • Retain the Receiver containing patient data.
Clinician Portal		
Cannot log in to the Clinician Portal.	• The URL entered is incorrect. • The email address and/or password details entered are incorrect.	• Ensure the URL is correct: https://www.atmobiosciences.com. • Check login details and retry. If issue persists, reset password.

Error	Possible Cause	Possible Solution
Cannot locate patient data for review.	• Study data has not been uploaded from the Receiver to the Clinician Portal. • Study data has not been fully processed.	• Ensure that the study data has been successfully transferred. The Clinic App (found on the Mobile Device) will not allow the study data to be deleted from the Receiver until it has successfully been transferred to the cloud. • Wait for data to be processed. It can take up to 10 minutes for the Clinician Portal to fully process the data.

Maintenance

Receiver and Belt Reprocessing Instructions

Wipe down the surface of the Belt and Receiver using a soft cloth moistened with a solution of 70% isopropyl or ethyl alcohol. Ensure alcohol contact for at least 1 minute.

Other Device Cleaning Instructions

Wipe down the Mobile Device, Power Supply and USB Cable with a soft cloth moistened with a solution of 70% isopropyl or ethyl alcohol. Do not immerse in liquid.

Transport / Storage and Operating Conditions

The Atmo Gas Capsule and other components of the Atmo Gas Capsule System should be transported and stored at ambient room temperature of between -10 to +45°C and between 30% to 90% relative humidity.

For operating conditions see the technical specifications of the Capsule and Receiver.

Software & Firmware Updates

Atmo Biosciences manages all the software within the Atmo Gas Capsule System including the Clinician Portal, Mobile Device, Atmo Clinic App, and Receiver firmware. Atmo Biosciences maintains and updates these components as required. The Capsule firmware is programmed at the factory.

Occasionally, the Atmo Clinic App will update the Receiver firmware which may cause a one or two minute delay in the initiation of a study.

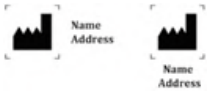
The current version and Unique Device Identifier (UDI) of the Atmo Clinic App and Clinician Portal can be found in the 'About' page.

Disposal

- The Capsule is intended to be disposed of via the local human waste processing system.
- The Receiver and Mobile Device should be disposed of as per local regulations.

	**NOTE:** Both the Receiver and Mobile Device contain a non-removable lithium-ion battery.

Table of Symbols

Label	Explanation	Label	Explanation
	Atmo Gas Capsules are MR unsafe		Do not tumble dry
	The Atmo Capsule is single-use only		Do not dry clean
	Consult the provided Atmo Biosciences documentation		Do not iron
	Temperature limits (operational or storage)		Serial Number
	Type BF (Body Floating) equipment		Manufacturing Date
	FCC compliance		Prescription only
	Expiration Date		Manufacturer Name and Address
	Lot Number		Fragile, handle with care
IP22	Ingress protection		DC Power Input Rating
	Double Insulated		

Technical Specifications

Device Classifications

	Atmo Gas Capsule	Atmo Data Receiver	Atmo Mobile Device
Power:	Internally Power Equipment.	Internally Power Equipment.	Internally Power Equipment.
Electric Shock Protection:	Type BF Applied Part.	Type BF Applied Part.	Ordinary Equipment.
Harmful Ingress Water:	Watertight Equipment (IP57).	Protected from touch by fingers (IP22).	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.

Sensors and Outputs

The Atmo Gas Capsule System uses the following sensors in the Capsule to produce the traces as displayed on the Clinician Portal graph.

Capsule Onboard Sensors	**Traces (as displayed on Clinician Portal)**
Thermal Conductivity Detector (TCD)	Hydrogen (%) Carbon Dioxide (%)
Volatile Organic Compound (VOC)	Oxygen Level (Low/Med/High, A.U)
Temperature Sensor	Temperature (°C) or (°F)
Triaxial Accelerometer	Capsule Tumble (A.U)
Antenna Reflectometer	Antenna Reflectance (A.U)

Gas Sensor Performance Specifications

The Atmo Gas Capsule System displays Hydrogen and Carbon Dioxide data traces. The trace performance was derived from bench testing (as part of the Atmo Gas Capsule System product development) which simulates a subset of gas states seen within the human gut.

The limit of detection is the smallest gas percentage change that can be detected by the sensor.

These performance metrics are valid for the specified ranges for each gas type.

Data Trace*	Range	Limit of Detection	Gas Trace Sensitivity*	Gas Trace Sensitivity 95% Confidence Interval*
Carbon Dioxide	0-27%	1.1%	0.9	(0.6, 1.2)
Hydrogen	0-50%	0.6%	1.1	(1, 1.2)

* Change in reported concentration (%) per change in actual gas concentration (%)

Temperature Sensor Performance Specifications

The Atmo Gas Capsule System displays a Temperate data trace. The trace performance has been derived from bench testing (as part of the Atmo Gas Capsule System product development).

The limit of detection is the smallest temperature change that can be detected by the sensor. The trace accuracy describes how close the reported temperature is to the actual temperature.

Data Trace	Limit of Detection	Trace Accuracy
Temperature	0.11°C	+0.49 (-0.2, +0.7)°C

At body temperature, 37°C

Capsule Specifications

Category	Attribute	Specification
Physical	Length	27.8 mm
	Diameter	11.2 mm
	Weight	3.8 g
	Capsule Outer Material	Biocompatible Plastic
	Capsule Battery	Silver Oxide Batteries, Mercury Fee
Operational Properties	Shelf life	6 months
	Battery Life (Total)	10 days
	Battery Life (Gas Sensing), Full Sensing Capabilities	4 days
	Battery Life (Temperature-Only)	6 days
	Max Operating Temperature (sensing performance)	41 / 106 °C / °F
	Min Operating Temperature (sensing performance)	33 / 91 °C / °F
	Max Operating Temperature (pairing with Receiver)	40 / 104 °C / °F
	Min Operating Temperature (pairing with Receiver)	18 / 64 °C / °F
	Max Operating Humidity (sensing performance)	100% RH
	Max Operating Humidity (pairing)	90% RH
	Min Operating Humidity	30% RH
	Min pH	1
	Max pH	8
	Min Operating Pressure	700 hPa
	Max Operating Pressure	1910 hPa
Communication	Transmission Frequency	433.92 MHz
	Modulation	Frequency Shift Keying (FSK)
	Data Transmission	Every 20 seconds

Receiver Specifications

Category	Attribute	Specification
Physical	Length	85.5 mm
	Width	25.0 mm
	Height	247 mm
	Weight	148.76 g
	Receiver Outer Material	Chemical Resistant Plastic
	Capsule Battery	Lithium-Ion Polymer
	Ingress Protection	IP22
Operational Properties	Operational Lifetime, Total	3 years
	Battery Life	10 days
	Max Operating Temperature (on Patient)	50 / 122 °C / °F
	Min Operating Temperature (on Patient)	5 / 41 °C / °F
	Max Operating Temperature (in Clinic)	40 / 104 °C / °F
	Min Operating Temperature (in Clinic)	18 / 64 °C / °F
	Max Relative Humidity	90% RH
	Min Relative Humidity	30% RH
	Min Operating Pressure	700 hPA
	Max Operating Pressure	1060 hPA
Communication	Receiving Frequency	433.92 MHz
	Modulation	FSK
	Wired Communication	USB 2.0
	Wired Port	USB-C
Power/Charging	Charger circuit	Receiver internal, fully managed
	Power Connector	USB-C
	Power Management	USB-C PD, non-negotiated (pull-down resistor 5.1k)
	Power Voltage	5 V
	Max Current Draw	1.5 A

Power Supply Specifications

Attribute	Specification
Power Connector	USB-C socket
Input Voltage	100-240 VAC
Input Frequency	50-60 Hz
Output Current	3.0 A
Output Voltage (Nominal)	5 V
Output Voltage Variation	+-8 %
Certification	IEC 60601
Mode	Continuous

Only use supplied Power Supply.

Appendix

Atmo Privacy Policy

Purpose

Atmo Biosciences Limited (ACN 626 053 183) and its subsidiary Atmo Biosciences Inc. ("Atmo", "we", "our" or "us") values privacy and is committed to the appropriate handling and protection of personal information consistent with relevant privacy law.

This Policy describes how we collect, hold, use, disclose or otherwise handle personal information. This policy also explains our commitment to data management in general, our approach and responsibilities to support the compliant handling of Atmo data.

Overview

We are a digital health business commercializing a world-first ingestible gas-sensing Capsule for gut health (Atmo Capsule). Our information processing activities are related to advancing product development of the Atmo Capsule. Our core business and work in digital health is pursued with regard for and in alignment with applicable privacy laws, appropriate information handling and data protection practices.

Atmo is committed to personal information handling practices in accordance with the Australian Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs), and other applicable privacy laws relevant to our functions and activities in all locations. This Policy outlines our approach to privacy and is modelled on Australian and international requirements.

A copy of the Australian Privacy Principles may be obtained from the website of The Office of the Australian Information Commissioner at www.aoic.gov.au

Information we collect

In the course of undertaking and completing our business functions and activities, the type of personal information we collect may vary depending on how individuals engage with us. We may collect and hold personal information about current and prospective investors, shareholders, suppliers, clients and prospective clients, contracted service providers, clinical trial and research partners, candidates for employment and employees, and other members of the public who interact with us.

The type of personal information we collect may include:

a) name
b) personal contact details including email, address and phone number
c) business contact details including email, job title and company
d) date of birth
e) tax file number (TFN) or social security number
f) banking details
g) marketing preferences
h) any other information provided to us or authorised by individuals for us to collect as part of their interaction with us.

We will always collect information directly from the individual where it is reasonable and practicable to do so. We may also collect information about individuals from other sources such as contracted service providers who assist us to operate our business, or when the individual has consented to sharing information with us through a third party. Where Atmo receives personal information about an individual that is unsolicited or not reasonably necessary for one or more of our functions or activities, it will be deleted or de-identified, or Atmo will notify the individual of its collection, its use, and their rights. Individuals can choose to remain anonymous or use a pseudonym where practicable, but this may limit our ability to engage with individuals for the purpose intended.

Sensitive information

Atmo generally only collects sensitive information or sensitive personal information if we are authorised to or it is required by law.

If Atmo requires sensitive information for one or more of our functions or activities, we will only collect it from the individual for a specific purpose.

Use of Information

Our position is that we work with anonymised or de-identified data wherever possible and in pursuit of the principle of data minimisation.

Atmo will only use and share personal information for the purpose for which we have collected it.

This includes:

a) to perform the functions and activities related to advancing product development and commercialization of our Atmo Capsule
b) establishing and managing the relationship with our employees and contractors
c) administering our relationship with our shareholders
d) administering our relationship with clinical trial and research partners
e) responding to expressions of interest, information requests and inquiries
f) managing our contracted service providers
g) managing our operations including transacting between Atmo entities named under this Policy
h) to comply with industry standards, our legal and regulatory requirements.

We may also use and share personal information for a related secondary purpose where the individual reasonably expects, as required by law, or other lawful basis for processing under applicable privacy laws, such as providing information to government departments or agencies.

Disclosure to others

Atmo does not sell, rent or trade personal information to, or with, third parties.

Where necessary and appropriate, we share personal information with third parties including:

a) financial institutions
b) regulatory agencies or government bodies (such as the Therapeutic Goods Administration in Australia, Australian Security and Investments Commission or the Australian Tax Office)
c) our contracted service providers (e.g., Planet Innovation Pty Ltd) who provide us with a range of professional and business services
d) information technology vendors
e) professional advisers (such as recruitment advisers, auditors, accountants, insurers, and lawyers)
f) externally hosted applications and software subscriptions (for example, for recruitment and onboarding of employees)
g) as required or authorised by law
h) or, otherwise where we have consent from individuals.

Rights of individuals

Individuals have a right to contact us about their privacy concerns or about personal information we may hold about them. Depending on the location of residence and how individuals engage with us, Atmo recognises a range of rights available to individuals under applicable privacy law, including the right to:

a) to access and correct their personal information
b) request information about what personal information we hold and any third parties we share their personal information with where it is necessary to fulfil the collection purpose or is otherwise authorised or required by law
c) request the erasure of personal information in certain circumstances
d) restrict or object to the use or sharing of personal information
e) receive personal information in a commonly used, and machine-readable format or to request the transmittance of personal information to another person, entity, agency or other body
f) withdraw or opt-out at any time where our use or disclosure relies on consent as a lawful basis.

Individuals can contact us at any time using the details below (see Contacting Us).

Employees have direct access to their personal information via our human resources platform and can contact the Chief Financial Officer for advice on how to access and correct their personal information.

Storage and protection

Atmo holds and stores data in hard copy documents or as electronic data in our software or systems, including cloud or other types of electronic storage. We use physical and technical safeguards to protect data from interference or unauthorised access, modification, use or disclosure. These include managed access controls to our systems and network, and security measures for access to premises.

Personal information may be disclosed to third parties in Australia and overseas (such as the United States, New Zealand and countries in the European Economic Area) where it is necessary to perform our core business functions and administer services consistent with this Policy. We take reasonable steps to maintain the integrity and security of any data and personal information to prevent interference, misuse, unauthorised access or loss, such as implementing technical measures for data storage and protection and entering into contractual arrangements with third parties that cover data authorised processing activities, including any cross-border transfer of data, consistent with applicable privacy law.

Website privacy

Our website (https://atmobiosciences.com) is managed by our service provider, Planet Innovation Pty Ltd. We will only collect personal information through our website if it is provided by an individual to respond to an information request or inquiry.

Information recorded when users interact with our website includes:

a) IP address
b) location data (where available and not disabled by the user)
c) the type of web browser used
d) dates, times, and other user activity.

In most cases, we will not be able to reasonably identify a visitor to our website from the information collected. However, if cookies or similar technologies are linked with personal information we hold about a user, this cookie information becomes personal information and will be treated in the same manner as the personal information to which it has been linked. A 'cookie' is a small text file that is sent to a device by the user's web browser which then stores a record of the visit in the web browser used. Cookies enable the proper functioning of our website and assist us to improve our website browsing experience. Users can manage their cookie settings via their web browser privacy settings.

Our website also uses interfaces with social media sites such LinkedIn, and links to third party websites. Atmo is not responsible for the protection of personal information provided to third parties where individuals choose to navigate to them via our website. We recommend users review the privacy policy applicable to the website visited.

Data Management Approach

Atmo takes a risk and value-based approach to data management to direct our resources and attention. Our high-value information includes any data that:

a) is critical to product development and commercialization of our Atmo Capsule
b) affects the rights and entitlements of our employees and stakeholders
c) is subject to a high level of scrutiny or has a high likelihood of legal action if not appropriately handled (e.g. data privacy)
d) involves funding.

Any compromise of high-value business information will be taken seriously.

Contacting us

All privacy related inquiries or complaints should be directed to the contact details below:

Privacy Officer

Atmo Biosciences Ltd

Ground Floor, 436 Elgar Road, Box Hill

Victoria, 3128

Email: info@atmobiosciences.com

We will endeavour to respond to all requests within 30 days and may require individuals to verify their identity as part of our management of their request. If a compliant remains unresolved or our response is not considered satisfactory, individuals may apply to the Office of the Australian Information Commissioner (OAIC) at www.oaic.gov.au to have the complaint heard and determined, or in some circumstances, the relevant supervisory authority or agency in the country or state in which the individual resides.

Policy Updates

This policy will be reviewed every two (2) years or more frequently if operational changes impact privacy and data management compliance. Updates may be published on our website without notice. By continuing to use Atmo's services and our website, individuals are deemed to have accepted any changes to our Privacy Policy.

This policy was last updated on 13th November 2023.

The latest version of this policy is available on our website: https://atmobiosciences.com

Glossary

Physiology

There are many ways of describing the physiology of the gastrointestinal tract (GI). Outlined below are the preferred terms with acceptable alternatives. The alternatives should only be used in limited circumstances (see table below).

Preferred Name	Abbreviation	Acceptable Alternative
Gastrointestinal tract	GI	Gut
Stomach	-	-
Small Bowel	SB	Small Intestine
Colon	-	Large Bowel or Large Intestine

Motility Transitions

The motility product is designed to identify four major transitions as the Capsule transits through the GI tract.

Term	Abbreviation	Meaning
Ingestion	-	Entry into the body via the oral route
Gastroduodenal junction	GDJ	Transition from the stomach into the duodenum
Ileocecal junction	ICJ	Transition from the small bowel into the colon
Body exit	BE	Exit from the body via the anus

Transit Metrics

The four transitions are used to calculate the following transit metrics.

Term	Abbreviation	Meaning
Gastric Emptying Time	GET	Ingestion to GDJ
Small Bowel Transit Time	SBTT	GDJ to ICJ
Orocecal Transit Time	OCTT	Ingestion to ICJ
Colonic Transit Time	CTT	ICJ to Body exit
Small and Large Bowel Transit Time	SLBTT	GDJ to Body exit
Whole Gut Transit Time	WGTT	Ingestion to Body exit

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Final Audit Report 2023-12-21

Created:	2023-12-21
By:	Ian Sohn (ian.sohn@atmobiosciences.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAasvWwIvIx6bvy6rJT5fCkas1dnRtAnS7

"515_2032_01_Atmo Motility Gas Capsule System User Manual NZ English_Final (1)" History

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2023-12-21 - 4:47:26 AM GMT

Document emailed to Ian Sohn (ian.sohn@atmobiosciences.com) for signature
2023-12-21 - 4:49:47 AM GMT

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