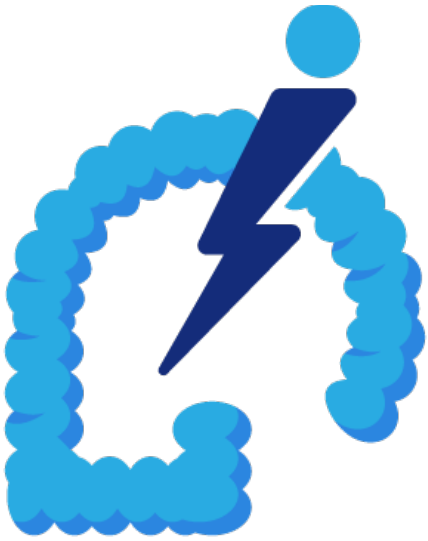


GI Bionics

Fecobionics™ Anorectal System

AR-100 Probe
DH-100 Data Hub
LT-100 Laptop with Fecotracker App

User Manual

Fecobionics Anorectal System User Manual

430-400 Rev N

> ⚠ **WARNING**:
>
> - Before using this system, carefully read through this manual in order to become familiar with its operation and warnings.
>
> - U.S. Federal Law restricts this device to sale by or on the order of a physician.

GI Bionics

Table of Contents

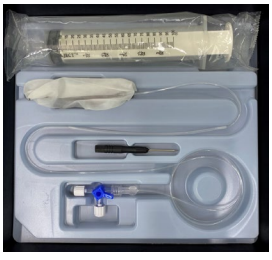
Introduction

The Fecobionics™ Anorectal System allows the remote measurement of several physical parameters related to defecation using a disposable device that closely mimics actual feces. A single-use probe transmits data wirelessly to a Data Hub, which sends the data to an App on a PC. The system provides real-time manometric data and geometric mapping information to clinicians in a single examination for improved efficiency with the fidelity of a probe that is defecated as an untethered free distensible mass. The measured parameters include:

- Rectal sensitivity as assessed by remotely filling the bag with saline until the patient reports an urge to defecate.
- Anorectal pressures are continuously measured at the front and rear of the probe and inside the bag.
- Motion sensors at the ends of the probe continuously indicate the orientation and bend of the probe in 3D space.
- Cross-sectional area (CSA) measurements are continuously made of the simulated mass at seven (7) planes along the length of the probe.

Package Contents

Probe (Ref 430-004)
The single-use non-sterile probe comes with an attached removable fill tube, 100mL empty syringe, small screwdriver, and User Manual.

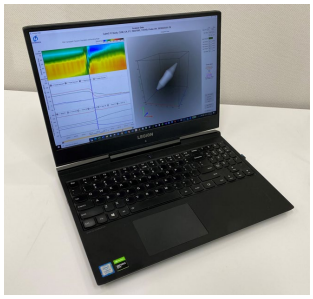
Included components: • Probe • Fill Tube • 100mL syringe • Screwdriver • System User Manual	

Data Hub (Ref 430-005)
The Data Hub includes an AC/DC power adapter with mini-USB cable. There are no data cables as all data is transmitted wirelessly.

Included components: • Data Hub • AC/DC power adapter • Data Hub information card	

Windows Laptop LT-100 (Ref 431-140) and Fecotracker App (Ref 432-024)

The Windows®-based laptop has an installed Fecotracker App, which manages data collection, annotation, local storage, display, and file organization.

Included components: • Laptop • External power supply • Mouse • Fecotracker App • Windows 11 operating system	

Descriptions

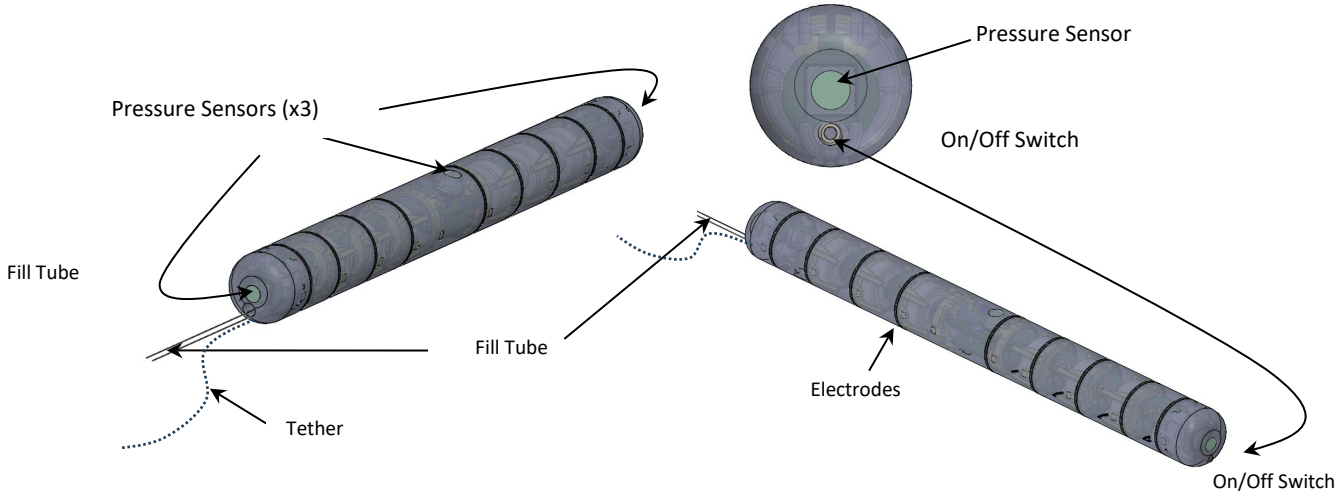
The Fecobionics Anorectal System is composed of a non-sterile single-use probe, a Data Hub, and a Fecotracker App running on a Windows PC laptop.

Probe

The probe has several sensors and an internal power supply that are embedded and sealed inside a silicone body (see below). An outer silicone bag (not shown for clarity) covers most of the probe length and allows the probe to assume the bulk of feces when remotely inflated via the fill tube. After the bag is filled, the fill tube is removed, leaving the probe where it was inserted to simulate actual feces without tubes or wires that might otherwise influence the patient's response.

Motion processor unit integrated chips (MPUs) at the ends of the probe allow the App to estimate the absolute orientation of the probe in space. These MPUs are calibrated to adjust for local conditions just before the App begins collecting data. An array of electrodes on the exterior of the probe body set up a small electrical field within the bag when it is inflated with normal saline. Seven pairs of electrodes positioned along the length of the probe provide cross-sectional area measurements of the inflated bag. The App fuses the orientation and cross-sectional data to display a 3-D geometric representation of the probe in real-time.

In case the patient is unable to naturally defecate the probe, a tether is provided to allow manually pulling it out. The probe is powered on by rotating a small screw at the end of the probe opposite the end from which the fill tube exits. Once powered on, the probe will be in an intermittent sleep state that allows it to listen for commands from the Fecotracker App via the Data Hub at 5 second intervals. After 5 minutes, the probe will switch to listening for commands every 300 seconds to conserve battery power. Powering the probe off and back on will restart this cycle.

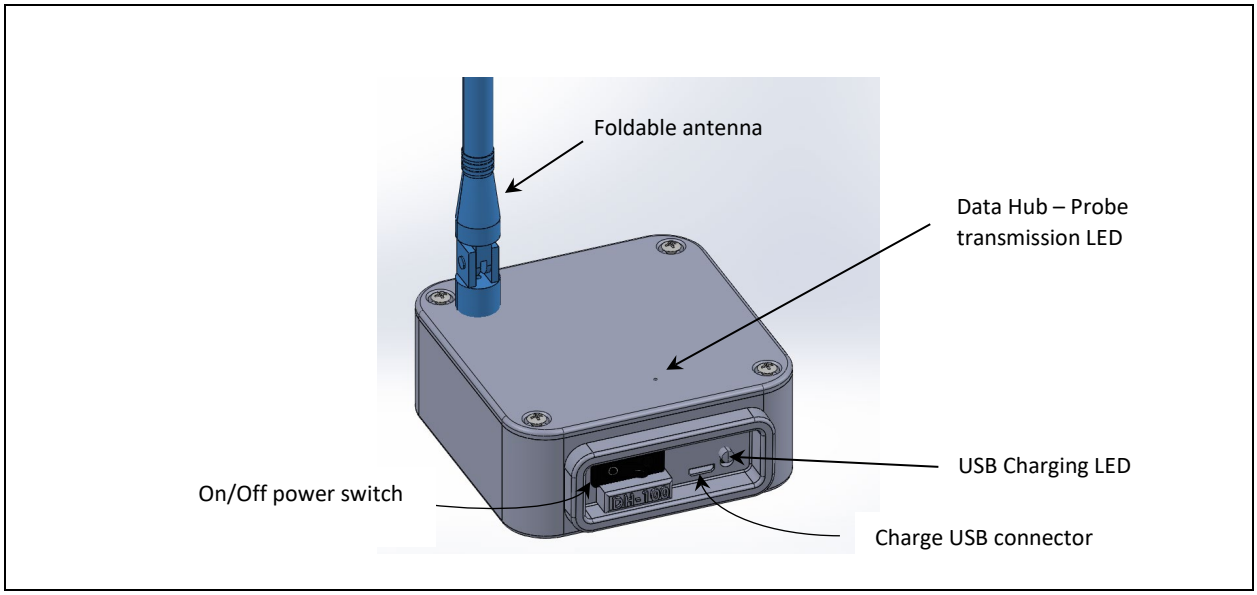


Detachable components:

1. The Fill Tube is connected to the probe with a friction fit. After the probe has been inserted and the bag filled to the desired volume, the Fill Tube is removed.
2. The screwdriver is used to rotate the screw switch to power the probe on or off.

Data Hub

The user interface components of the Data Hub are shown in the image below. The Data Hub has an internal battery that is charged with the supplied AC/DC power adapter via a USB cable (not shown). When used with a patient, the Data Hub should be powered by the internal battery. The device communicates wirelessly with the probe on a sub-GHz ISM band and simultaneously to the Laptop using a standard PC wireless connection. The transmission to the probe is via the external foldable antenna. When commands or data are being transferred between the probe and device, a blue LED on the top cover will blink (e.g., approximately 5 Hz during data streaming). The charging LED shows amber when charging the battery and green when fully charged and plugged into the AC/DC adapter.

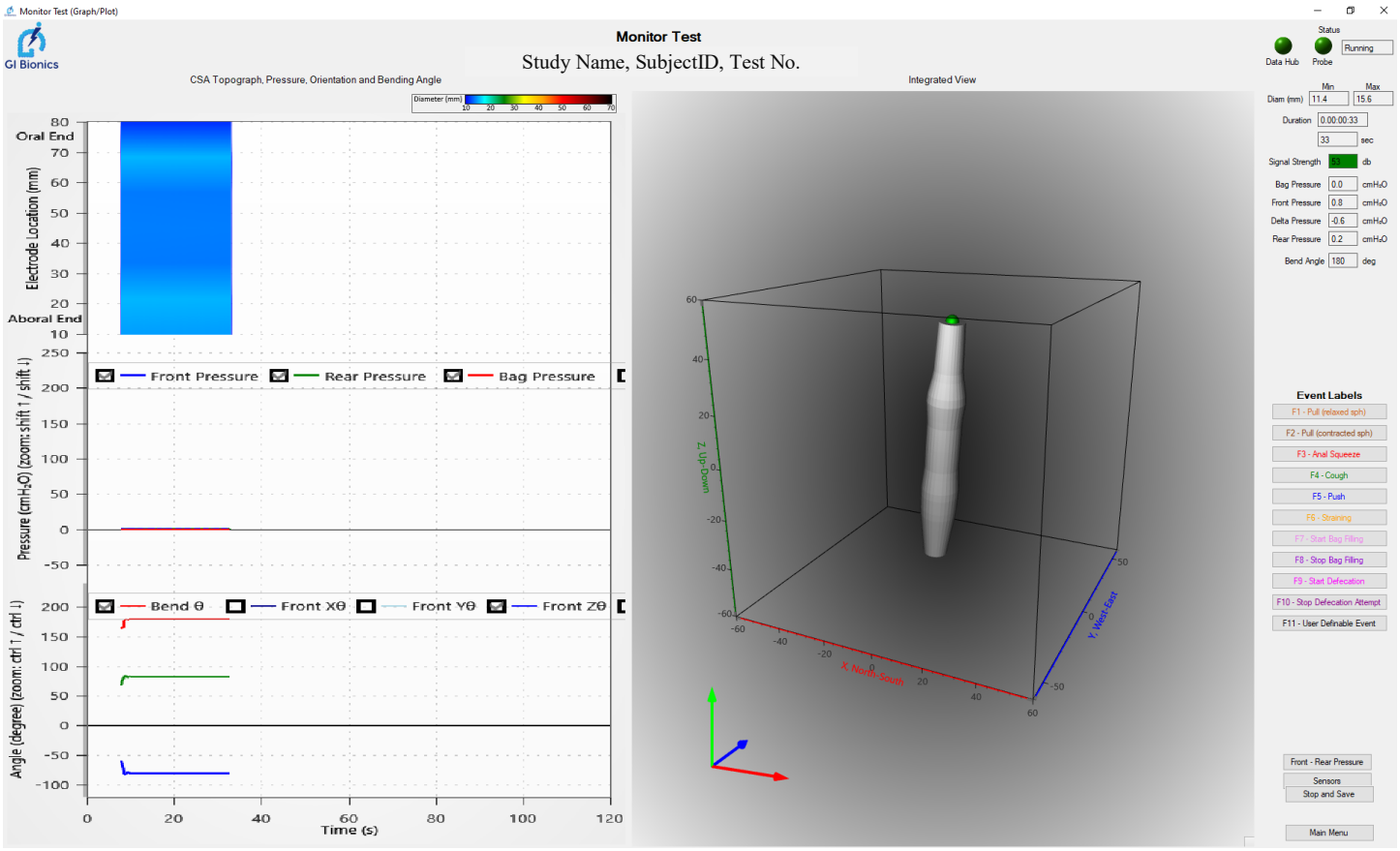


Detachable components:

1. The AC/DC adapter charging USB cable is detachable and should not be plugged into the Data Hub when taking measurements with a patient.

Fecotracker App on Windows Laptop

The Fecotracker App stores clinical measurements in user-generated Study and Subject (patient) categories. The data files are stored as Test numbers. A given subject could have many clinical measurement Test files (e.g. as treatment progresses), which are distinguished with a file name indicating the date and time of when the measurements were performed. After a study and subject have been created, a user initiates a patient measurement though the App by wirelessly connecting the Laptop to the Data Hub. The Data Hub issues commands to the probe and receives and stores measurement data from the probe. After entering the probe's lot number, the App will use the Data Hub to wake the probe and verify connectivity. Next the user is asked to calibrate the probe in the measurement environment through a series of physical maneuvers. When the App is satisfied with the calibration, it will display a screen of streaming data in real-time (see figure below). On the left-hand side from top to bottom are displays of the cross-sectional area as a heatmap, pressures as line graphs, and orientation angles as line graphs. The 3D graph shows a geometric representation of the probe in space and to the right are digital displays of various parameters.



Technical Data

Probe

General (Probe)	
Probe Manufacturer	GI Bionics, LLC San Diego, CA
Probe Model	AR-100
Dimensions	Diameter 10 mm Probe Length 100 mm Tether Length 400 mm Fill Tube Length 1000 mm
Weight	Probe 18 g Fill Tube 8 g
Power supply voltage	4.6 VDC
Max current	12 mA
Connection	Wireless sub–GHz ISM
Operating Environmental Conditions (Probe)	
Use	
Use environment	Gastroenterology lab, Out-patient clinic
Temperature	20º C to 40º C
Humidity	Max 10-100% RH
Pressure	75 – 126 kPa
Altitude	Less than 5,500 ft
Storage	
Temperature	10º C to 50º C
Humidity	10 – 70% RH, noncondensing

Operating Environmental Conditions (Probe)	
Electromedical characteristics	
Device type	NA
Applied part	Type BF
Insulation	Internally powered
Protection rating against liquids	IP35
Use in presence of inflammable gases	No
Mode of use	Continuous
Basic performance features	

Pressure range	265 – 1284 cm H2O
Pressure accuracy	± 5%
Max permissible pressure	1284 cm H2O absolute pressure
Bend angle	± 15º
Average diameter accuracy	± 20% for diameter values above 30mm excluding the outer 2 channels
Run time	50 minutes maximum

Data Hub

General (Data Hub)	
Data Hub Manufacturer	GI Bionics, LLC San Diego, CA
Data Hub Model	DH-100
Data Hub LiPo battery max output voltage	3.7 VDC
Data Hub LiPo battery max current	2.0 A
Data Hub LiPo battery max capacity	2000 mAh
Data Hub Dimensions	L x W: 93 x 85 mm H: 50 mm, 65 mm (antenna extended)
Data Hub Weight	160 g
Data Hub Connection	PC wireless: WIFI 802.11 B/G/N 2.4GHz Probe wireless: Sub 1 GHz ISM
AC/DC adapter Manufacturer	CUI, Inc 20050 SW 112th Ave. Tualatin, OR 97062
AC/DC adapter Model	SWM6-5-NH-C
AC/DC adapter power supply voltage	100-240 VAC, 50-60 Hz
AC/DC adapter max output voltage	5 VDC
AC/DC adapter max current	1.2 A
AC/DC adapter Output power	6 W
AC/DC adapter Dimensions	55 x 25 x 43 mm, cable 1500 ± 50 mm
AC/DC adapter Connection	Micro USB Type B, power only
AC/DC adapter Weight	65 g
Wi-Fi Power	17dBm, 2.4GHz
QoS	Fecobionics System meets IEC safety, emissions, immunity and compatibility requirements
Security	Password and WPA2-protected

Operating Environmental Conditions (Data Hub)	
Use	
Use environment	Gastroenterology lab, Out-patient clinic
Temperature	20º C to 30º C
Humidity	10 – 70% RH, non-condensing
Pressure	75 – 105 kPa
Altitude	Less than 5,500 ft
Storage	
Temperature	10º C to 50º C
Humidity	10 – 70% RH non-condensing
Pressure	75 – 105 kPa
Electromedical characteristics	
Device type	NA
Applied part	NA
Insulation	Internally powered (during patient use)
Protection rating against liquids	IP2X
Use in presence of inflammable gases	No
Mode of use	Continuous
Basic performance features	
Runtime	At least 4 hours
Battery recharge cycles	500

WARNING: this device may only be used by professional medical staff. This device can cause radio Interference and disrupt the operation of nearby equipment. It may be necessary to adopt measures to attenuate the signal. Such as facing the device in a different direction or relocating it or its cables or shielding the location.

EMC Information (AC power)

The GI Bionics LLC Fecobionics System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GI Bionics LLC Fecobionics System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

WARNING: This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The GI Bionics LLC Fecobionics System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The GI Bionics LLC Fecobionics System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:

Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the GI Bionics LLC Fecobionics System or shielding the location.

Note:
This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1kV line(s) to line	±1kV line(s) to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GI Bionics LLC Fecobionics System requires continued operation during power mains interruptions, it is recommended that the GI Bionics LLC Fecobionics System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the GI Bionics LLC Fecobionics System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [3.5/10] √ P 80 MHz to 800 MHz d = [7/10] √ P 800 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recom-mended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GI Bionics LLC Fecobionics System is used exceeds the applicable RF compliance level above, the GI Bionics LLC Fecobionics System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GI Bionics LLC Fecobionics System.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity							
The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should assure that it is used in such an environment.							
Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment – guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	Portable and mobile RF communications equipment should be used no closer to any part of the GI Bionics LLC Fecobionics System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength In V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785 0.1342 13.56 0.030	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 2.1kHz 50kHz CW	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m 65 A/m 7.5 A/m 8 A/m	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785 0.1342 13.56 0.030	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 2.1kHz 50kHz CW	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m 65 A/m 7.5 A/m 8 A/m	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the GI Bionics LLC Fecobionics System.				
The GI Bionics LLC Fecobionics System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GI Bionics LLC Fecobionics System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GI Bionics LLC Fecobionics System as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz $d = [3.5/3] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9] \sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28] \sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

EMC Information (battery power)

The GI Bionics LLC Fecobionics System requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the GI Bionics LLC Fecobionics System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

WARNING: This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and manufacturer's declaration – electromagnetic emissions		
The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The GI Bionics LLC Fecobionics System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The GI Bionics LLC Fecobionics System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the GI Bionics LLC Fecobionics System or shielding the location.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GI Bionics LLC Fecobionics System is intended for use in the electromagnetic environment specified below. The customer or the user of the GI Bionics LLC Fecobionics System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the GI Bionics LLC Fecobionics System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [3.5/10] √ P 80 MHz to 800 MHz d = [7/10] √ P 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recom-mended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GI Bionics LLC Fecobionics System is used exceeds the applicable RF compliance level above, the GI Bionics LLC Fecobionics System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GI Bionics LLC Fecobionics System.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	Portable and mobile RF communications equipment should be used no closer to any part of the GI Bionics LLC Fecobionics System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	385	18 Hz	27 V/m	385	18 Hz	27 V/m	
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
	0.1342	2.1kHz	65 A/m	0.1342	2.1kHz	65 A/m	
	13.56	50kHz	7.5 A/m	13.56	50kHz	7.5 A/m	
	0.030	CW	8 A/m	0.030	CW	8 A/m	

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

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the GI Bionics LLC Fecobionics System.				
The GI Bionics LLC Fecobionics System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GI Bionics LLC Fecobionics System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GI Bionics LLC Fecobionics System as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz $d = [3.5/3] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9] \sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28] \sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Probe: FCC ID: 2BBFTAR100SG01

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including any interference that may cause undesired operation.

Data Hub: FCC ID: 2BBFTDH100SG01, Contains FCC ID: 2BBFTDH100WF01

You are cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including any interference that may cause undesired operation.

FCC RF Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions to satisfy RF exposure limits. This transmitter must not be co-located or operated with any other antenna or transmitter.

The module DH100WF01 is also certified for integration into the GI Bionics DH-100 Data Hub in Bud Industries plastic enclosure, Part# 377-1978-ND. No changes to this module are allowed without express written permission of GI Bionics

LLC. The DH100WF01 is certified by the FCC as a single-modular transmitter for mobile applications. The module is an FCC-certified radio module that carries a modular grant.

Indications For Use

The following statement describes the Fecobionics indications for use:

> The Fecobionics Anorectal System is for use on patients requiring anorectal pressure studies and testing of defecatory function. The Fecobionics System must only be used by appropriately trained clinicians. The Fecobionics System enables evaluation of rectal sensitivity, rectal volume and shape, rectoanal inhibitory reflex, anal diameter during defecation, defecatory push pressure, and anorectal angle changes. The Fecobionics device is only intended to be used in adult patients.

Contraindications and Warnings

Contraindications

Contraindicated for use in patients with a history of anorectal surgery (e.g., presence of staples, etc.).

General Warnings

1. Read this technical manual before carrying out any operation with the device.
2. Use this system in compliance with the instructions set out in this manual.
3. The system should only be used by appropriately trained and authorized staff.
4. The patient should normally be positioned on a horizontal bed with the part of the body to be examined in the field of vision of the operator during insertion.
5. Do not use high-frequency equipment (electronic instruments, cell phones, X-rays,
6. transmitters, etc.) or portable/mobile radio communication equipment near the device as this could result in its malfunctioning. Do not use the device near to or above other equipment. If the device must be used near other equipment, avoid moving the other equipment after the probe is calibrated and monitor the data closely to ensure proper functioning in the configuration in which it is being used.
7. After an electrostatic discharge event to the system that has resulted in either the probe or Data Hub status LED turning red, if the probe has already been inserted into the patient, turn the Data Hub off and then back on and go through the procedure of restarting a test (if the probe is still running, it is already calibrated). If the probe fails to respond, remove the probe and replace it with another device.
8. Be careful when handling the probe and fill tube so as not to pull the fill tube from the probe. They are connected by only a friction fit to allow remote separation once the probe has been inserted.
9. Do not inject liquids or gases other than 0.9% normal saline into the probe.
10. There are no parts inside the probe or Data Hub which can be repaired by the user: do not try to access internal parts for any reason as this will invalidate the warranty.
11. It is recommended to apply lubricant on the probe before inserting the device. It is necessary to lubricate the fill tube so that the outer tube can slide easily along it during separation of fill tube from probe.

12. The probe and fill tube are disposable: do not re-use the same probe/fill tube on different patients. If reused cross infection may occur.
13. If the probe or fill tube has touched an unclean surface, do not use.
14. Do not use solvents for cleaning purposes, except 70% Isopropyl alcohol.
15. Do not spray or pour Isopropyl alcohol onto the Data hub. Apply alcohol to cloth and then wipe Data Hub exterior.
16. Do not use abrasives on the Data Hub or probe.
17. The system should be used solely for the purposes for which it was designed. Be particularly careful in the event of a ruptured mucous membrane.
18. Do not use in oxygen enriched atmospheres.
19. The signal transmission from the probe to the Data Hub is influenced by many factors including room characteristics and patient size. Place the Data Hub as close to the patient as possible without letting it touch them and adjust the Data Hub orientation (e.g. rotate it) to increase the signal strength.

Specific Warnings

1. Be careful when manually retracting the probe too fast if the bag is filled.
2. Do not inflate beyond the threshold of urgency of the patient.
3. Do not exceed 100 ml of inflation. Or you risk bursting the bag which could risk harming the patient.
4. The Probe is disposable, non-sterile and cannot be sterilized.
5. Do not use beyond the expiration date.
6. If the bag accidentally breaks during the exam, do not reuse the probe, fill tube, and syringe on other patients.
7. Federal law (U.S.) restricts this device to sale by, or on the order of, a physician.
8. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. To minimize the risk of fire, use this device in well-ventilated areas away from flammable anesthetics.
9. Do not use this device near magnetic resonance imaging (MRI).
10. For accurate measurements, high-frequency devices such as electro-surgery or diathermy /cautery equipment should be deactivated.
11. Before use, inspect the probe assembly from end to end for breakage, occlusions, or debris. Do not use it if damage to the parts or packaging is evident, or if any portion of the probe packaging has been previously opened. Do not use any part after its expiration date or if the expiration date cannot be verified.
12. If the patient was defibrillated while the probe was inserted, remove the probe and repeat the measurements when patient is stable.
13. Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in these instructions for use.
14. Use the Fecobionics system only with parts and accessories approved by GI Bionics.
15. Take special care using the Feco probe where the mucous membrane is injured.

Potential Complications

1. Mild pain
2. Potential discomfort
3. Minor bleeding
4. Perforation

Cautions

Keep the probe stationary and straight until after the Fecotracker App monitor screen has started streaming data.

Proceed with inserting the probe only after confirming that both probe and Data Hub status LEDs are green in the Fecotracker App monitor screen.

Instructions for Use

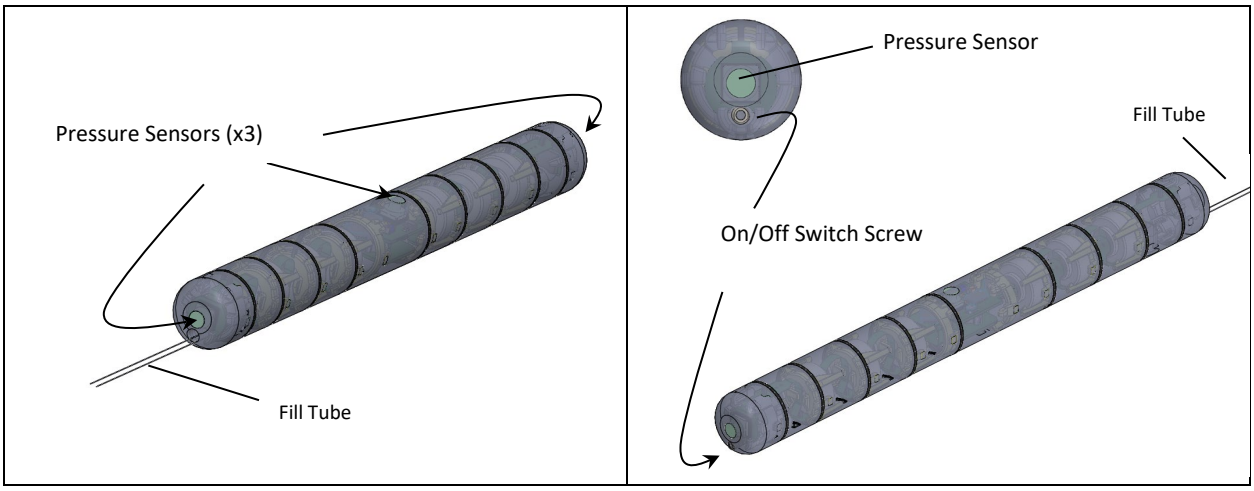
The user is expected to be a Gastroenterologist technician or physician with experience in performing tests related to investigating defecation abnormalities and assessing results of those tests.

Pre-test Preparation

1. Charge the Data Hub overnight using the micro-USB AC/DC power adapter. An amber LED on the faceplate of the Data Hub indicates that it is charging, and a full charge is indicated when that LED is green.
2. Obtain a 250mL bag of 0.9% normal saline and Surgilube™ lubricant.
3. Warm the above items and the shelf box containing the probe components as received in a medical IV bag warmer for about 2 hours before the test.

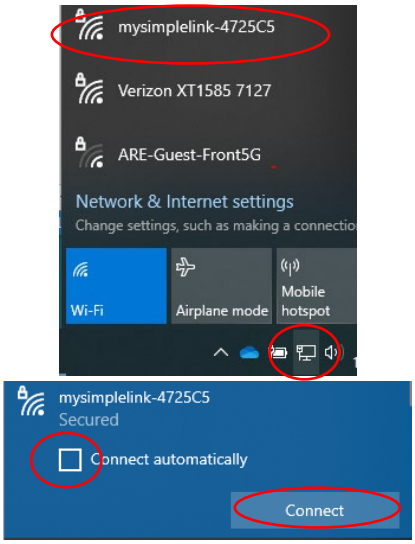
Prepare Fill Tube and Probe

1. Remove the shelf box top and tray cover to inspect the Fecobionics device. And make a visual check of the probe, filling tube, syringe, and Data Hub. If the probe or fill tube have visual damage, leaks, or any other abnormality, do not use the device and discard it according to institutional protocols. Do not move the probe or fill tube from their positions in the tray.

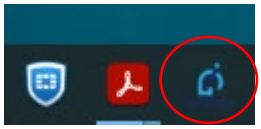


Connecting Laptop to Data Hub

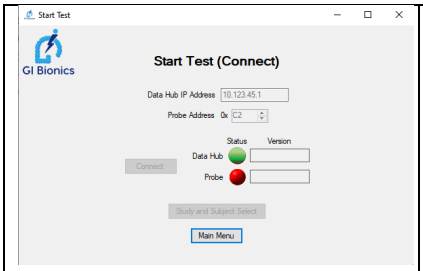
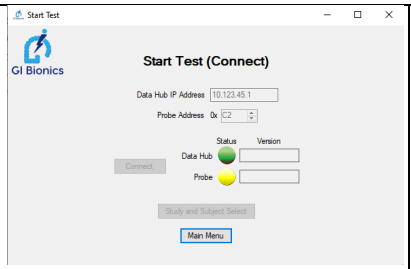
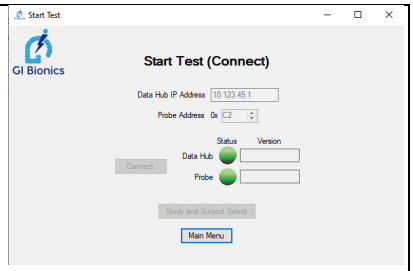
1. A fully charged Data Hub is indicated when it is connected to the AC/DC Adapter and the LED on the front bezel is green.
2. Disconnect the AC/DC Adapter from the Data Hub so that it is running on its internal batteries.
3. Arrange the Data Hub as close as possible but not touching the patient during the test.
4. Power on the Data Hub by pushing the switch to ON and identify its MAC number located on the housing label in the format MAC…xx:xx.
5. Find the Data Hub network in the PC's list of available networks. The Data Hub will be named *mysimplelink-yyxxxx* where *xxxx* are the last 4 alphanumeric characters of the MAC number. Select it and uncheck the option *Connect automatically* and then select *Connect*. If the system asks for a password, enter provided with the Data Hub. The Laptop will only require this at the first connection.



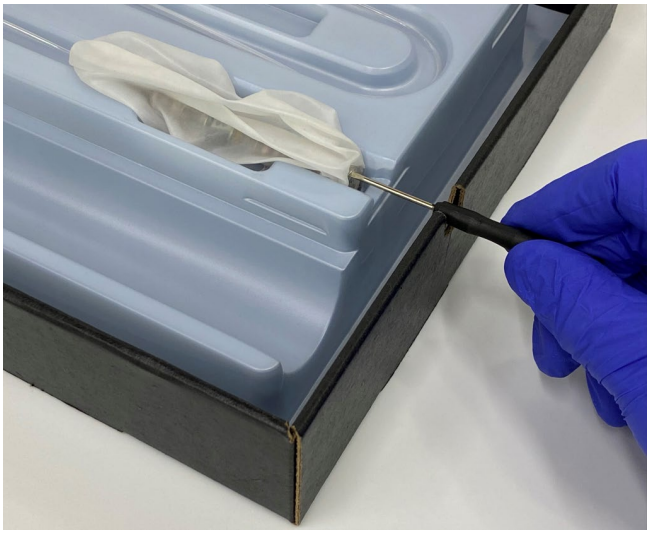
Starting the Fecotracker App and Data Collection

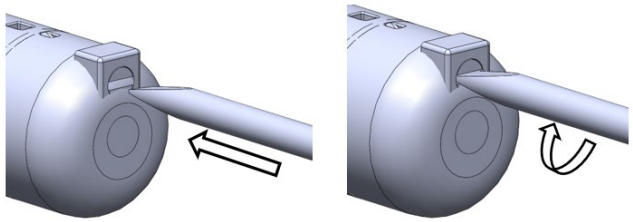


1. Start the Fecotracker App on the PC by selecting its icon in the taskbar.
2. To create a study, select the main menu item *Setup Study* and select *New…* in the drop-down menu. Enter the desired information. If a study has already been created, select it.
3. With the study selected in the *Study Setup* menu above, select *Add Subjects* towards the bottom of the screen and enter a SubjectID (e.g. a given patient), which as with all data entries, should not contain patient identifiable information. Note that multiple tests can be performed for a single subject, but it may be clearer to enter them as different subjects. An example might be, "FI_MJS_Day1", etc., for the first of several Fecal Incontinence studies for patient Mary Jane Smith. After entering an appropriate SubjectID add comments if desired and then click the *Add Subject* button.
4. The Test data files are differentiated by a date-time format to be explained in the *Analyze Data* module of the App.
5. If the patient is ready and it is desired to start a measurement, do so by selecting the *Start Test* button on the main menu.
6. If this Laptop has previously connected to the Data Hub, the IP address for the Data Hub will be automatically filled in. Otherwise, enter *10.123.45.1* in the *Data Hub IP Address* field. Place the Data Hub next to the probe.
7. Enter the probe lot number into the *Probe ID* field. The lot number can be found on the probe box label or on a small label surrounding the fill tube.
8. Press the *Connect* button to initiate communication between the App and the Data Hub. The Data Hub status LED should turn from red to green (left pane in table below), but the Probe status will remain red until the next step.

		
Data Hub Connected (Green) Probe Off (Red)	Data Hub Connected (Green) Probe **Acknowledges Data Hub (Yellow)**	Data Hub Connected (Green) Probe Awake & Running (Green)

9. With the probe box and tray covers removed and the probe and fill tube still in the tray, remove one of the stopcock's white luer caps and open the stopcock so that the probe bag is open to atmospheric pressure. Power the probe on by placing the supplied screwdriver into the small screw near the pressure sensor through the opening in the box as shown below. The screw is small and recessed, but once the screwdriver is engaged, turn it clockwise until a stop is felt (about 180º). At this point, the Probe status LED should turn from red to yellow and then about 5 seconds later it should turn to green (middle and right panes in the table below respectively). The probe is now fully powered on, and its battery life will be approximately 50 minutes. Replace the tray cover





⚠ **WARNING**:

Do not put the screwdriver into the pressure sensor.

Make sure the probe is straight throughout the calibration procedures that follow.

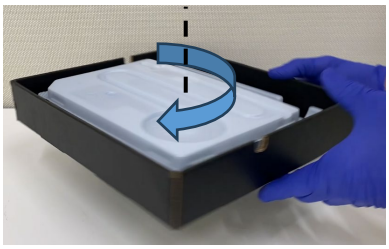
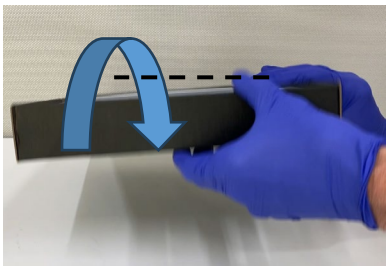
⚠ **WARNING**: If the probe LED does not turn yellow and eventually green after rotating the screw clockwise to the stop, be sure the data hub antenna is within a few feet of the probe and check that the probe lot number is correct. The most important are the last 2 digits (*ID (hex)*), which can assume values comprising: 0 – 9, a,b,c,d,e, or f. If the probe LED is still not yellow or green, turn the Data Hub off and then on again and close the App and start over. If more than 5 minutes has transpired since the probe screw was turned clockwise and the probe status LED is still not yellow or green, rotate the screw counterclockwise to the stop and then again clockwise to the stop. This resets the probes sleep-wake interval back down to 5 seconds.

10. After the status LEDs for both the Data Hub and Probe turn green, select a study and subject by clicking on the *Study and Subject Select* button and selecting the items corresponding to the current patient.
11. The App will now present a screen for calibrating the probe. Follow the steps described in the App and in the sections below.

Probe Calibration

1. **Magnetometer** – Nearby structures and objects in the test area that contain either steel or iron or that might generate a magnetic field (e.g. motors) can affect the magnetometer measurements and must be compensated for by a series of calibration maneuvers just before the measurements begin. Try to distance these objects from the test area by at least 30cm. It is best to perform these calibration maneuvers near the test area (e.g. commode) rather than the examination bed, etc. Place the Data Hub and probe near the test area and near to each other.

> ⚠ **WARNING**: Try to keep all metallic and electronic objects at least 30cm away from the probe during calibration and use. It is preferable to perform the calibration over the commode or where the patient will be defecating the device.

a. As described in the embedded videos accompanying the Fecotracker App, rotate the box containing the tray and probe a full 360º about a vertical axis. Rotate back 360º to the starting orientation.	
b. Next, rotate the box a full 360º about a front-rear axis and then rotate back 360º to the starting orientation.	
c. Finally, rotate the box a full 360º about a side-to-side axis and then rotate back 360º to the starting orientation. **Note**: These rotations do not need to be performed in the order presented, but performing all of them is required. Further rotations can improve the calibration after the status LED has turned green.	

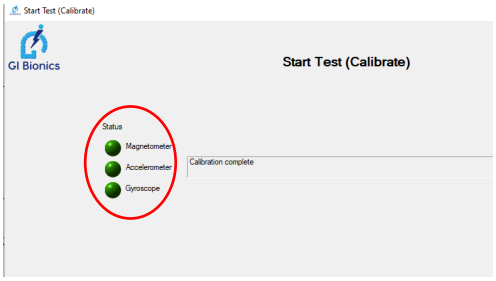
2. Accelerometer – The accelerometer sensors are calibrated by exposing their axes to the direction and magnitude of gravity from several directions as shown in the following steps.

a. Using a flat horizontal surface, place the box on the edge as shown in the picture at right. Ensure that it is motionless and wait 3 seconds. **Note**: The exact edge that you begin with is not important, but cycling through all four edges is required.	
b. Rotate the box 90º counterclockwise ↺ as shown in the picture at right and leave it motionless for about 3 seconds.	
c. Rotate the box 90º counterclockwise ↺ as shown in the picture at right and leave it motionless for about 3 seconds.	
d. Rotate the box 90º counterclockwise ↺ as shown in the picture at right and leave it motionless for about 3 seconds.	

e. Finally, place the box on a flat surface with the open face up and leave it motionless for about 25 seconds, after which the accelerometer and gyroscope status LEDs should have turned from red to green.	

3. **Gyroscope –** Th probe must be left motionless to calibrate the gyroscope sensors. Leave the box motionless from the position of the last accelerometer calibration step for approximately 25 seconds. The Gyroscope indicator LED will change from red to green when calibrated. Avoid doing this on a surface that might be moving, vibrating, etc.

At this point, the device should be fully calibrated as indicated by the three green status LEDs in the *Start Test (Calibrate)* screen.



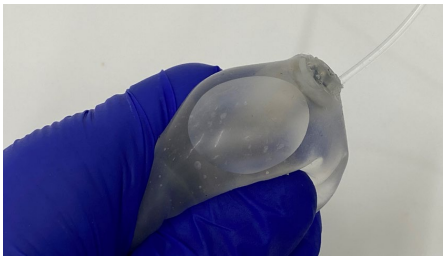
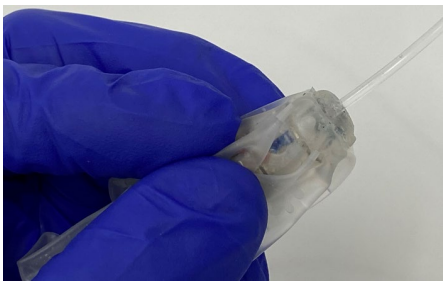
Keep the probe stationary while the Fecotracker App automatically zeroes the pressure sensors and calculates an initial orientation for the probe. After a few seconds, the App will then display a screen of graphs showing real time sensor data while it is simultaneously being stored on the Data Hub.

Prepare Probe for Insertion

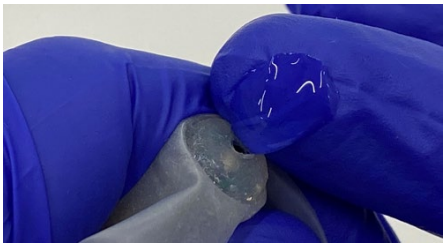
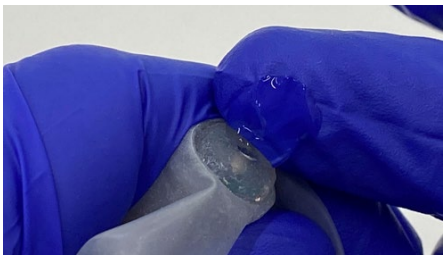
1. Remove the probe from the tray being careful not to pull the fill tube from the probe. It is connected to the probe via a friction fit so that the fill tube can be remotely removed from the probe after insertion into the patient.

⚠ **WARNING**: Do not accidently dislodge the fill tube from the probe. The fill tube is connected to the probe by a friction fit that allows it to be removed remotely from the probe. Be careful not to snag the fill tube on objects as it can be separated from the probe or pulled part way causing an obstruction to the fill lumen.

2. Connect the syringe to the fill tube stopcock and pull the air out of the probe bag by pulling back on the syringe plunger until all air is removed and a vacuum is created in the bag. Close the stopcock to prevent air from going back in the bag.	

3. Draw up about 20mLs of warmed 0.9% normal saline into the syringe, connect it to the stopcock, open the valve and inject the saline into the bag. An air bubble will be present in the bag that needs to be removed. Squeeze the bag at the opposite end from the fill tube to corral the saline and air to the other end. The outlet into the fill tube is about 0.5cm toward the probe center from where the bag is connected to the probe. Use the syringe to draw out the saline and air as you manipulate the bag to force the contents out of the outlet.	
4. Use your fingers to urge the bag down onto the probe body near the outlet taking care to not occlude the outlet. This will force the air out of the outlet. The bag membrane can become sucked down over the outlet and may need to be massaged away from it to allow further emptying of the bag. Any air or saline left in the probe bag in the end will make it difficult to insert the probe into the patient.	

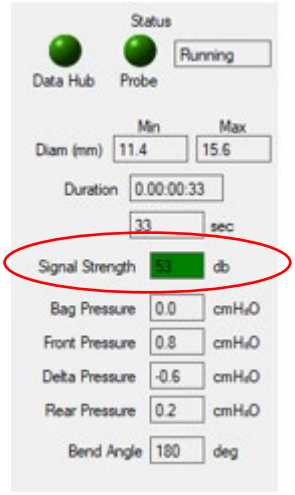
5. Use Surgilube to thoroughly lubricate the probe and fill tube along about 20-30 cm of the exposed length as it emerges from the probe. The fill tube includes a short external tube used to apply a counter force to hold the position of the inserted probe when the inner fill tube is pulled out of the device. Without lubrication, the outer tube will stick to the inner tube preventing it from being used to keep the probe in position.

6. Carefully fill the pressure sensor housings with Surgilube at both ends of the probe being careful not to put too much pressure on the sensors nor to entrap air in the housings.	
7. Rolling a small amount of Surgilube with your finger into the housing starting at the edge is effective.	

8. The probe is now ready for insertion into the patient.

⚠ **WARNING**: Avoid pushing your finger against the probe pressure sensor when inserting the probe. Excess pressure can damage the sensor.

9. After insertion is complete, assess the strength of the radio signal from the probe to the Data Hub to ensure maximum data transfer. At the upper right of the *Monitor Graph/Plot* screen there is a data display labelled Signal Strength. A strong signal is indicated with a green field, marginal strength with yellow, and poor strength with red. Reposition the Data Hub as close as possible, but not touching, the participant and try to rotate the Data Hub about a vertical axis to see if the signal is improved. If the signal is really weak (red) for a few seconds, the probe status LED may turn red in the upper right section of the *Monitor Graph/Plot* screen. This should return to green if the Data Hub is repositioned fast enough to regain data transmission.



10. Measurements may now begin, and event markers related to certain typical assessments can be inserted into the data record using the color-coded buttons to the right of the *Monitor Graph/Plot* screen or the corresponding Function keys on the keyboard. A small window will open allowing additional event comments to be entered, but if none are needed, just press the return key to quickly dismiss them. Double clicking on the event marker allows the event notes to be edited.
11. After the probe has been filled to the desired volume and no further volume changes are required, remove the fill tube by advancing the outer tube on the fill tube until it contacts the probe in the patient and continue to advance it while simultaneously pulling on the fill tube until it pulls away from the probe. The goal is to remove the fill tube without moving the probe inside the patient. With the probe isolated from tubes, etc. it can more closely simulate feces for a more realistic defecation.
12. After the test with the patient has finished (e.g., the patient has defecated the probe), it is advantageous to hold the probe in a vertical position over the commode with the bag pressure sensor pointing toward the front of the commode (fill tube hole/tether toward the rear of the commode). This will provide a means to orient the probe to the patient's position during defecation. This can be done after the patient has dressed and left the room. The probe has the capacity to run for about an hour.
13. After all data has been collected, click on the *Stop and Save* button and then select the *Finish Test* menu item. This will cause the data from the Data Hub to be downloaded to the appropriate subject folder on the PC. Prior to this, the data has only been stored on the Data Hub and will be overwritten if another test is started before it is downloaded.

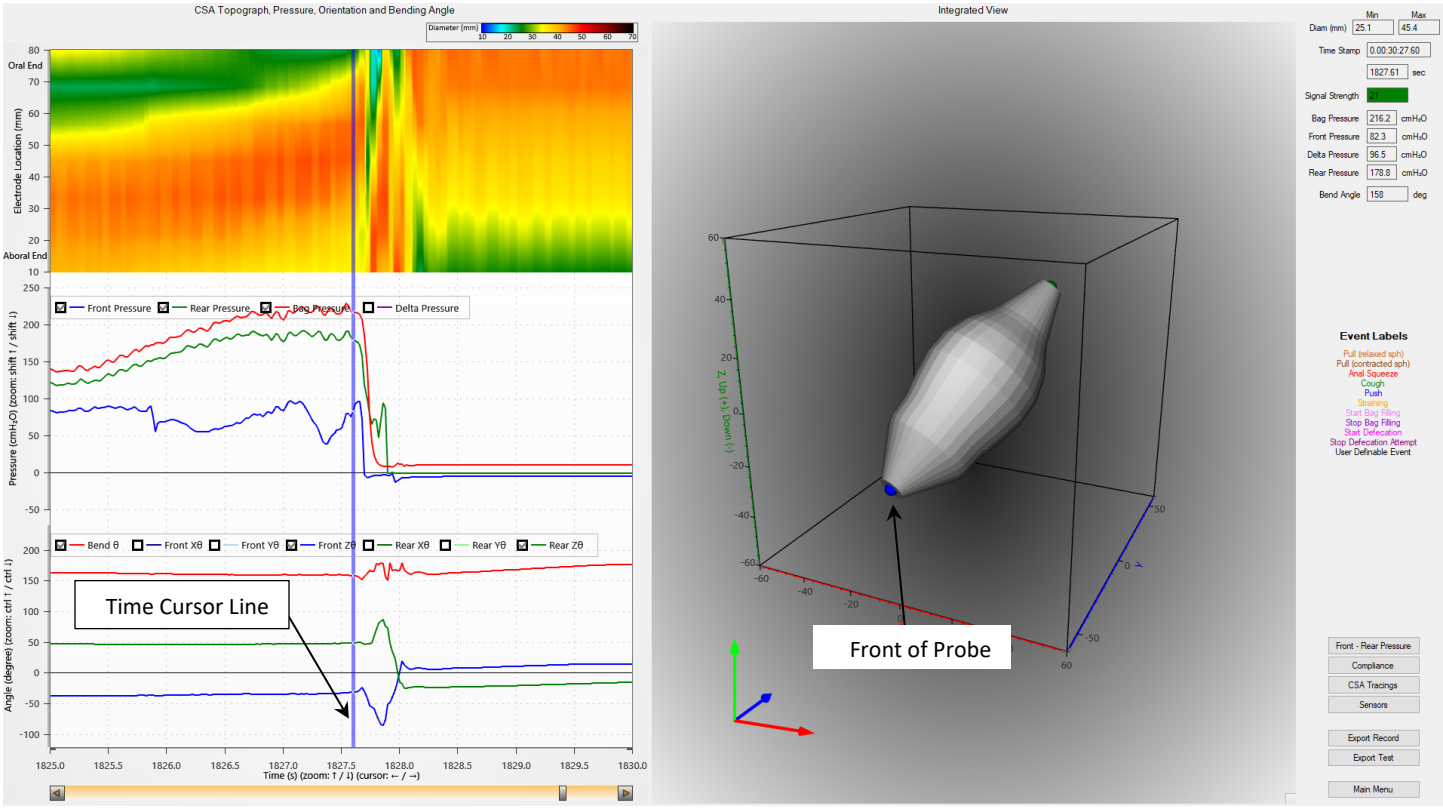
Viewing, Exporting, and Transferring Data Files

Once the data is downloaded to the PC, it can be viewed by selecting the *Analyze Data* button on the main menu. The *Analyze Data* screen will open with the complete time course of the test shown in the left-hand graphs against the collective time axis at the bottom. Zooming into a region of time is accomplished by pressing the up-arrow key (↑) on the keyboard. A time cursor or vertical blue line traversing all three graphs can be moved to a particular point in time, which will determine the time at which the digital displays of sensor data on the right of the screen were recorded. It also determines the focal point in time for the zoom-in (↑) and zoom-out (↓) functions.

The vertical axes of the bottom 2 left graphs can be moved up or down by clicking on the vertical axis and moving the mouse up or down. The scales can be changed with the designated control or shift keys plus the up or down arrows as indicated in the labels for the vertical axes.

The 3D graph showing the probe orientation has a Z-axis that represents the direction away from the earth's center. The X-axis represents the North-South direction, and the Y-axis represents the West-East direction. The front of the probe is the side that the fill tube is connected to and is represented by a blue hemisphere in the 3D graph and blue lines in the graphs. The other end of the probe, which is usually the first end inserted and the closest to the oral end of the alimentary tract, is represented by a green hemi-sphere and green lines in the graphs.

The CSA Topology graph at the upper left of the screen displays colors representing the diameter of the bag along the length of the probe. The bottom of the vertical axis represents the front (Aboral) end and the rear end of the probe is at the top of the axis. The horizontal axis reflects a point in time according to the time scale at the bottom of the screen.



The sensor data from a complete test file can be exported as a csv file from the *Analyze Data* screen using the *Export Test* button. One or more slices of data taken at the time indicated by the vertical blue line in the main graphing area can be placed into a csv file using the *Export Record* button. Repeated pressings of the *Export Record* button at different time points will add those records to the same csv file. The csv files have a name format and location indicated in the following table.

	File Name Format (*date_time* = the date and time when the test was performed)
Export Test	*AllSamples_date_time.csv*
Export Record	*SelectedSamples_date_time.csv*
Export File Directory	*C:\ProgramData\CMII\DCD\Output\Studies\{Study_Name}\{Subject_Name}*

If event markers have been recorded during the measurement, then they appear as vertical-colored lines at the appropriate time in the graphs on the left. Hovering the mouse over the triangle at the base of the event lines will reveal any comments entered for that event.

Data files can be shared as needed by selecting the *Transfer Data* main menu item and selecting the appropriate Study and Subject. Click on the *Export Subject* button and save the zipped folder to a convenient directory on the PC.

A user wishing to receive the data must first create a study using the App. Afterwards they can receive the zipped folder from above and use the *Import Subject* on the *Transfer Data* screen to import it into the chosen study.

Positioning the Fecobionics System and Patient

The probe is typically inserted into the patient while they are in the left lateral decubitus position on an examination bed. Afterwards the patient is helped over to a commode where they ideally remain relatively motionless and minimally conversational to reduce aberrations in the data caused by trunk motion or thoracic pressure changes.

Ensure that the patient is not sitting on the fill tube at the commode. It is deliberately soft and may cause the bag to be difficult to inflate. It may be best to inflate the bag from behind the patient to prevent additional sensory input for patient's self-reported urge volume. If necessary, run the fill tube toward the back between the patient's glutei maximi while they are seated on the commode.

At all times, the Data Hub should be kept as close to the probe as possible to ensure a strong signal between the probe and Data Hub; however do not allow the Data Hub to come in contact with the patient. Monitor the signal strength in the upper right corner of the Monitor Test screen and reposition or rotate the Data Hub to improve the signal strength. Data loss is likely if this indicator turns red.

Trouble Shooting Guide

Wireless Connections

If a Data Hub status LED has turned red, check the laptop's connection to the Data Hub in the Windows wireless network selector. If the Data Hub was not recharged before a test, there is some chance the red LED is caused by loss of battery power, in which case the data will probably be lost and Data Hub must be recharged and the test repeated.

If the probe status LED has turned from green to red, try to move the Data Hub closer to the probe and ensure there is nothing between them except the patient's body, however, do not let the Data Hub be in contact with the patient. Also try rotating the Data Hub while monitoring the signal strength to determine an optimal orientation. If a probe has been connected and transmitting data, the blue LED on the top surface of the Data Hub should be flashing at 5Hz. The connection can be permanently lost if a prolonged period of weak signal strength persists.

If there is a long delay connecting to the probe after the Data Hub has registered a green LED, make sure the probe is next to the Data Hub. If no connection is made within 30 seconds, try turning the probe power screw off (counterclockwise) and then on (clockwise). The probe will enter into a longer interval of sleep (300 seconds) after 5 minutes of being turned on but not connected, making it unresponsive to the connect command between intervals. The probe can be reset to the shorter sleep interval (5 seconds) by power cycling the screw switch, which resets the 5-minute timer.

Probe Calibration

The magnetometer calibration requires that the probe be rotated through most conceivable spatial rotations. The prescribed rotations should accomplish this, but further waving/rotating the box in space may help if the magnetometer calibration has not turned green. The magnetometer calibration will continue to compensate after the status LED has turned green, so additional sweeps can help improve the orientation.

The gyroscope calibration requires that the probe be held absolutely still for a period of about 20-30 seconds. Surfaces that are vibrating or fill tubes that are swinging can cause delays in calibration.

Difficulty Inserting the Probe

The lubed probe can be difficult to insert. Make sure the patient's sphincter has been relaxed prior to insertion and that the rectum has been confirmed to be reasonably empty. If the probe bag was not completely emptied prior to insertion, the excess bag volume will accumulate at the near end of the probe making it very difficult to insert the final end of the probe.

Excess Curvature of the Probe

During insertion the probe can appear excessively bent according to the App's 3D representation of the probe. It is possible that the patient has anal rectoceles into which the leading end of the probe has become engaged causing the bending. If this is noticed during insertion, it may help to withdraw the probe slightly and retry while rotating the probe. Distorted orientations can also be caused when testing near electronic or iron-containing objects. There should be at least 30 cm between the probe and Laptop, cell phones, etc. An exception is the Data Hub, which should be near to the probe. The magnetometer calibration continues to improve with probe motion after the initial calibration, so performing additional sweeps in the test area will improve the orientation. It's also important to perform the calibration near the commode and to not move electronic or metal objects in the area once the calibration is complete. Examination beds are often a source of distortion, which will be temporary after the patient moves to the commode if the original calibration was performed near the commode.

Filling the Probe Bag

The fill tube is deliberately small requiring a modest amount of force at the syringe plunger to fill the bag. If the force is excessive, a lack of flow can be caused by the stopcock being closed between the syringe and fill tube. Check the stopcock handle orientation if flow is absent. Also make sure the patient is not kinking or sitting on top of the fill tube.

Abnormal Probe Pressures

The probe pressure sensors are zeroed against the atmospheric pressure at the very start of data collection. If the bag interior is under a slight vacuum from when the bag was primed an incorrect offset will affect all bag pressure measurements. This situation can be discerned at the end of the test if the defecated probe shows pressures that are not close to zero (the bag's saline content can exert a normal small 2-6 cm of H2O offset).

Patient Unable to Defecate the Probe

Certain patients may have difficulty defecating the probe. If so, the tether can be used to gently urge the probe out through the anus.

Gaps in the Data During a Test

Occasionally the Windows operating system will cause gaps in the data displayed on the App. When the data is reviewed later, the gaps should not be there. If they are, then it is probably due to momentary poor signal strength between the probe and Data Hub during the test.

Cleaning, Storing, Transport, Disposal

The Data Hub should be wiped down with 70% isopropyl alcohol before each use at the point-of-use. Make sure the AC/DC charging cable is not connected to the Data Hub when doing so. Do not spray or pour Isopropyl alcohol onto the Data Hub. Apply alcohol to cloth and then wipe Data Hub exterior. Visually inspect the exterior for areas that are unclean and repeat the process until it can be visually confirmed that all surfaces are clean.

The cleaning frequency should be at least before each use.

Do not use abrasive materials to clean the Data Hub.

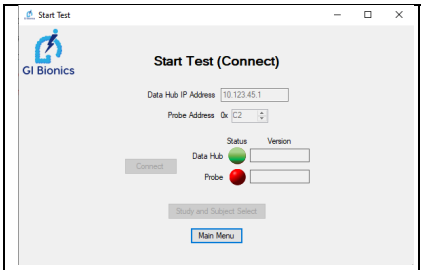
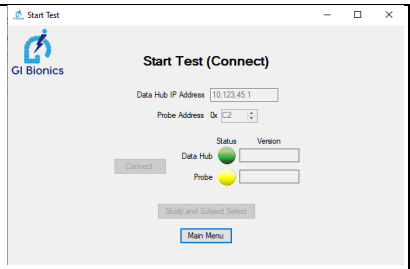
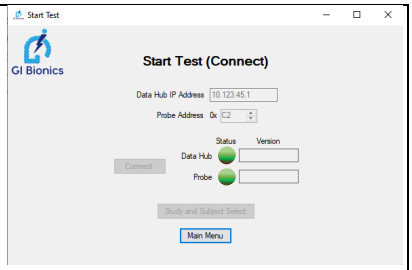
The probe and Data Hub are susceptible to ESD damage and should be transported in their original respective shipping containers.

Both the probe and Data Hub should be disposed of in compliance with the institution's procedures for medical and electronic waste.

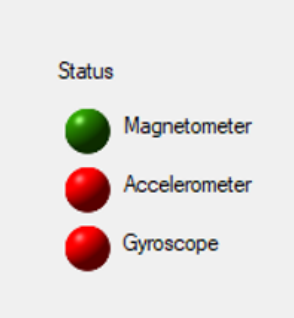
Operator Messages

Fecotracker App Messages or LED Indicators

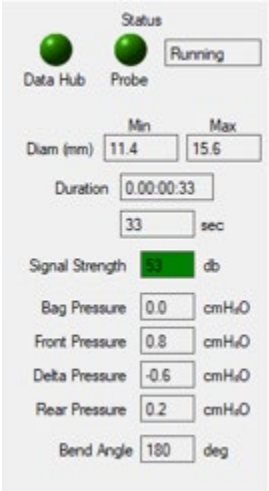
When wirelessly connecting to a Data Hub and probe, the following LEDs are present in the Fecotracker App Start Screen. A green status LED indicates that a connection has been successfully achieved. After the Data Hub has been connected (red LED turns green), the probe can attain a yellow LED when the Data Hub and probe have made a preliminary connection and a pending command is to be sent on the next transmission cycle. A green LED for the probe indicates that it has been woken and is fully powered. Red LEDs indicate that a connection has not been established or was lost.

		
Data Hub Connected (Green) Probe Off (Red)	Data Hub Connected (Green) Probe **Pending command to be sent on next transmission cycle (Yellow)**	Data Hub Connected (Green) Probe Awake & Running (Green)

After establishing a connection, the App presents the following calibration status LEDs for the magnetometer, accelerometer, and gyroscopes. Once the physical motions and orientations that are described in the directions have been successfully achieved, the LEDs for each sensor turn from red to green. They can be satisfied in any order even though the directions imply an order, however during the gyroscope calibration, the probe must be kept still for up to 30 seconds.



After a probe has begun streaming data, the Monitor Test screen shows the following LEDs in the upper right-hand corner. Green LEDs for the Data Hub and probe indicate that their wireless connections are working. A red LED means that the connection has been lost. If the Data Hub LED turns red, check the WiFi connection between the laptop and Data Hub and re-establish it if disconnected. Otherwise suspect that the Data Hub battery was not fully charged. If the probe LED has turned red, see the Trouble Shooting section.



If during a during a measurement or when opening a past measurement, if the system detects that the probe experienced a failure of an internal check related to the diameter data, which would include the cross-sectional area, the following message will be presented to the user indicating that all or part of this data may be inaccurate.

> *Probe failed diameter and cross-sectional area output self-test. Caution: the diameter and cross-sectional area data may be inaccurate.*

If the entry for a diameter or cross-sectional area reading is absent from a digital display or exported csv file, it means the output was invalid (e.g. out of range).

Probe Messages or LED Indicators

There are no messages or LEDs displayed on the probe.

Data Hub Messages or LED Indicators

The charging LED on the front of the Data Hub will be on when the AC/DC power adapter is plugged into the device. Otherwise, the LED will be dark. It is amber when the internal battery is still charging and green when it has reached full charge.

A blue LED at the top of the enclosure indicates that the Data Hub and probe are transmitting. It will blink at approximately 10 Hz when sensor data is streaming from the probe to the Data Hub after connecting.

Chronological Checklist of Steps

Participant / Subject ID Code: _____

Date: _____

Day-Before Procedure Preparation

1. Charge the Data Hub's internal battery overnight using the supplied AC/DC adapter plugged into the micro-USB power port on the front panel. ☐

3-Hours Before Procedure Preparation

1. Several hours before the start of the test, begin warming a bag of normal 0.9% saline, Surgilube, and the shelf box containing the probe and fill tube and 100mL syringe. ☐
2. Establish an anonymous Subject ID code to ensure participant privacy. ☐
3. Place the commode in the room at least 40 cm away from potential magnetic disturbances (steel/iron objects, electronics, etc.). ☐

Participant Preparation

1. Qualify and approve the prospective patient against the contraindications. ☐
2. Allow the patient to empty their rectum if desired. ☐
3. Explain procedure to patient and how to do anal squeezes, strains, pushes, etc. as appropriate. ☐
4. Ask patient to lay on the bed in a left lateral position.
5. Evaluate anorectum for pressure, length, abnormalities, presence of feces, etc. ☐

Device Preparation

1. Remove the tray cover, inspect the probe and fill tube for damage. Discard if found. ☐
2. Connect the Laptop to the Data Hub wireless network (*mysimplelink-yyxxxx*) using the PC's wireless network access feature. ☐
3. Start the App and select/create the appropriate study and Subject ID for the current patient. ☐

4. If the patient is ready, select *Start Test* at the main menu and enter the probe lot number. Then select *Connect* and confirm that the Data Hub LED has turned green. ☐
5. Turn the probe on with the screwdriver and wait for the probe connect status LED to turn green. ☐
6. Select the study and subject. ☐
7. Calibrate the probe near the test area following the indicated motions and keeping the probe motionless and straight until the App displays sensor data. ☐

⚠

a. If the probe status LED does not turn yellow and green, check that the probe lot number is correct.
b. If the lot number is correct, restart the program and turn the Data Hub off and then on and reconnect to the PC's wireless.
c. Note: if more than 5 minutes has elapsed since the screw switch was turned on, turn it counterclockwise 180º and then turn it clockwise to the stop to reset the wake-sleep interval to 5 seconds. The probe listens briefly at 5 second intervals to conserve battery power for the first 5 minutes after power-on. Afterwards it will listen every 5 minutes, which is too long to wait. Turning the probe off and then back on will restart this 5-second listening cycle making it more responsive.

☐

8. Remove air from the probe bag with the syringe and then close the stopcock.
9. Apply Surgilube to the probe body, distal end of fill tube, and pressure sensor housings at the end of the probe. ☐
10. Once the probe LED is green, click the *Study and Subject Select* button and select the appropriate options. ☐
11. After the probe has been inserted, check the check the signal strength and try to reposition/rotate the Data Hub to improve it if necessary. ☐
12. Record event markers as needed. ☐
13. After the probe has been filled to the desired volume, remove the fill tube. ☐
14. When testing is complete, allow the patient to defecate the probe. ☐
15. Click on the *Stop and Save* button and then select the *Finish Test* menu item. ☐
16. Finally, select the *Analyze Data* menu item and let the App process the data for review. ☐

Meaning of Symbols

Symbol	Meaning	Symbol	Meaning
	Model Number		Catalog Number
	Serial Number		Unique Device Identifier
	Date of Manufacture		Legal Manufacturer
	Use By		Prescription use only.
	Consult Instructions for use		Do not use if package is damaged
	Magnetic Resonance (MR) unsafe		Electrostatic sensitive devices
	Non-ionizing electromagnetic radiation		Electronic waste
	Rechargeable battery (Data Hub)		Do not reuse (Probe)
	Non sterile		Product is not made with natural latex
	Non-pyrogenic (Probe)	**IP2X**	Ingress Protection levels (Data Hub)
	TYPE BF APPLIED PART (Probe)	**IP35**	Ingress Protection levels (Probe)
	Refer to instruction manual/ booklet		UN3481 Lithium-ion battery contained in equipment

⚠ **WARNING:** Cancer and Reproductive Harm - www.P65Warnings.ca.gov.

Service and Maintenance

There are no serviceable parts within the Data Hub or probe.

The probe has a shelf life as indicated on the packaging. The unit is not drawing power until the user rotates the power screw switch clockwise as indicated in the directions. Once it is powered on, the probe is in a sleep mode that allows it to respond to connection requests only every 5 seconds for the first 5 minutes after the screw was turned on. After this it will respond to request only every 300 seconds to conserve battery power. To restart this cycle, turn the screw off (counterclockwise to the stop) and then back on. A measurement should be started shortly after powering on the device to ensure the runtime of 50 minutes maximum.

The battery within the Data Hub should be able to sustain 300-500 charging cycles before its capacity drops significantly depending on the historical discharge-recharge cycle. The Data Hub will need to be sent back to the manufacturer when it is unable to hold a charge for the duration of the measurement episode after being fully charged.

The laptop Windows operating system may need occasional updating as with any Windows computer. Follow your IT administrator's policy for performing these updates.

Contact the manufacturer to arrange a return of any product that is malfunctioning.

Contact Information

Manufactured by: **GI Bionics, LLC**
11107 Roselle St., Suite 213, San Diego, CA 92121
USA Customer Service (858) 249-7400

Limited Warranty

GI Bionics guarantees the Fecobionics system against manufacturing defects and will fix or replace any component within the warranty period.

The Fecobionics System warranty is for a duration of 12 months from the date of purchase.

Rev	Description	Originator	CO #	Release Date
A	Initial release	F Field		
B	Adding switch to probe	F Field	2023-012	3-28-23
C	Various updates	F Field	2023-029	8-28-23
D	Updated according F2Labs IEC Safety feedback and to reflect FecoTracker App v45	F Field	2023-041	10-24-23
E	Modified calibration procedure to incorporate new packaging, various clarifications	F Field	2023-060	12-15-23
F	Adding FCC ID no.'s, correcting IP ratings, applied part symbol	F Field	2024-020	2-26-24
G	Correcting Rev callouts	F Field	2024-029	3-07-2024
H	Adding Prop 65 warning, alcohol spraying warning, lithium battery symbol, various corrections	F Field	2024-043	4/29/24
I	Corrected accuracy for bend angle and CSA, maximum fill volume warning from 120 to 100mL, battery recharge cycles, and contraindication language to replace "canal" with "anorectal"	F Field	2024-049	5-16-24
J	FCC requested change to " Contains FCC ID: 2BBFTDH100WF01 ", changed Lot No. to Serial Number symbols	F Field	2024-050	5-17-24
K	Adding FCC-requested language	F. Field	2024-084	6-24-24
L	Adding Natalie's suggestions for power, QoS, and security labeling for data hub based WC email, adjusted spelling of recto anal to rectoanal in indications to match 510k submission sec 15, changed probe 60 minute runtime to 50, and Data Hub run time to 4 hrs to match DI, DV test results might allow an adjustment of these later, changed the Data Hub PW to reflect current security plans and PW format, removed p/n 430-006 near the first mention of Fecotracker as I'm not sure what it references (not in QMS) and replace it with Laptop LT-100 and it's p/n 431-140, clarified meaning of blank data readings.	F. Field	2024-084	9-2-24
M	Changed the wording of the diameter accuracy statement	F. Field	2024-085	9-3-24
N	Added frequency and point-of-use cleaning information on page 35.	F. Field	2024-102	12-13-24
O	Added FCC 15.21 and other language on ~ pg 20 and FCC 15.105 language on ~ pg 11.	F. Field	2025-003	3-18-25

Design Verification Protocol Approvals:	
Name / Title	**Signature / Date:**
Project Engineer:	3/19/25
Quality Designee:	3/28/25
Project Manager:	3/19/25