

GutTracker

Instructions for Use



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BEFORE YOU BEGIN

1. Watch the GutTracker setup instructional video at <https://www.gtechmedical.com/trainingvideo/>
- 2a. If using a personal iPhone, download the "G-Tech-Patch-Monitor Gen 2" application from the App Store. Open the app and Select "Ok" to allow Bluetooth and push notifications.
- 2b. If using a provided iPhone, connect the iPhone to your password protected home Wi-Fi through the settings app. This allows real-time data collection during your test.

1

REMOVE PATCHES FROM FOIL POUCH

1. Remove the patch from the foil pouch by cutting open the pouch below the seal. Retain the foil pouches; the patient will return the patches in them.



2. On the patch, locate and remove the green sticker covering the battery, allowing the battery to be exposed to air.



3. Note the time. The battery needs to be exposed to air for at least 3 minutes before activating.



2

ENTER G-TECH PATIENT ID IN THE SET-UP TAB

1. On the iPhone, Select the G-Tech Patch Monitor icon to launch it.



2. From the Home tab, navigate to the Set-Up tab.



3. Enter the staff password "gutcheck" and select Done.

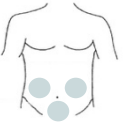
4. Select Enter Patient ID.

5. Enter the Patient ID and select Done.

3

PREPARE THE SKIN

1. Locate the approximate patch locations on the abdomen according to the diagram. The prep area should be larger than the patch.



2. Clip hairs if abdominal hair is present in the region that will interfere with patch contact with the skin.



3. Clean the skin thoroughly using alcohol pads and let dry.



4. Apply a pea size drop of NuPrep gel to the alcohol pad and rub gel onto skin in circular motions at each patch site. Pat dry.



4

ACTIVATE THE PATCHES

1. Make sure at least 3 minutes have passed since removing the patches from the foil pouches in step 1.



2. Locate the patch. Pull the tab (brown or white) horizontally outward, positioning the battery cover over the exposed battery. Peel the tab fully off and press firmly on the battery cover to ensure a tight connection. The patch is now "on".



Patch with tab (brown or white) attached



Pulling the tab, exposing the battery and battery cover



Tab removed, battery and battery cover connected

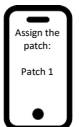
5

PAIR AND ASSIGN THE PATCHES

1. In the iPhone app, red text that begins with "Gtech_" will appear in the Set-Up tab when the patch is activated.



2. To pair the patch, select the red text and accept the patch assignment as Patch 1. Navigate back to the Set-Up tab and repeat for all patches to be paired.



3. Proceed when all patches are connected, displaying green text.



6

APPLY THE PATCHES

1. Find the positions on the body for each patch. Patch 1 will be on your left of midline, above the belly button, and inward from your ribs. Patch 2 position is similarly on your right side, and Patch 3 on the midline below your belly button.



- Orient the patches so the battery cover points towards your right.
- Remove half of the backing from the patch, being careful not to touch the adhesive. Place the exposed adhesive in its proper position on the body, and then remove the other half of the backing. Press firmly on the patch, especially around the edges.
- Repeat until all patches are placed.

7

START THE TEST

1. Select the Start Test button.



2. An End Test button replaces the Start Test button, and a Startup.XML file will appear. The system is now recording data.



8

REVIEW THE WEAR INSTRUCTIONS

1. Wear the patches for the prescribed duration.



2. You can go about your normal daily activities, however you should avoid activities that cause sweating, such as running, as this can cause the patch to become loose and end the test early.



3. Always keep the phone with you and do not let the battery die, charge accordingly.



4. Do not submerge the patch; take brief showers with your back facing the shower head.



5. Log events in the phone app; do not force quit the app.

a. Navigate to the Home tab.



b. Select the event you wish to log.



c. Select the logging option, change the time if needed and select Save.



6. Return the patches (and G-Tech iPhone) in the provided envelope. Do not throw away the patches.



9

END THE TEST

1. Navigate to the Patch Monitor tab in the app.



2. Select End Test.



3. Select YES, you are sure you want to end the test.



10

UPLOAD THE DATA

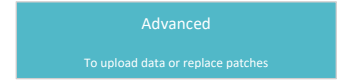
1. Make sure Wi-Fi is on and connected to a password protected Wi-Fi.



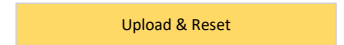
2. Navigate to the Set-Up tab.



3. Select Advanced.



4. Select Upload & Reset.



5. Select OK, you are sure.



11

REMOVE THE PATCHES

1. Gently peel the patch away from skin and place back inside the foil pouch.

2. Wash skin with mild soap, rinse with water, and pat dry.



12

RETURN THE PATCHES

1. Please return the used patches, as well as the iPhone and charger if provided.



2. Return in person, or place the items in a postage prepaid envelope provided by your healthcare provider.

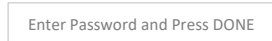


TROUBLESHOOTING: HOW TO REPLACE A PATCH

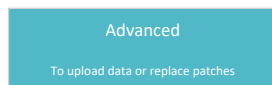
1. In the G-Tech app, navigate to the Set-Up tab.



2. Enter the Staff password "gutcheck" and select "Done".



3. Select "Advanced".



4. Below Individual Patch Data, scroll to highlight the patch that needs replacing.



5. Select "Configure".



6. Select "Un-Pair".



7. Return to the Set-Up tab and proceed to pair a new patch per the instructions in Step 4-6.

TROUBLESHOOTING: ADVANCED UPLOAD SUPPORT

1

1. Make sure Wi-Fi is on and connected to a password protected Wi-Fi.



2. In the Settings app, Navigate to "Display & Brightness".



3. Scroll to find "Auto-Lock" and change the selection to say "Never".

Auto-Lock

Never >

2

1. In the G-Tech app, navigate to the Set-Up tab.



2. Enter the Administrative password "Gtech1948" and select "Done".

Enter Password and Press DONE

3. Select "Advanced".

Advanced

To upload data or replace patches

4. Select "AWS Maintenance".

AWS Maintenance

5. Select "AWS Upload".

AWS Upload

A tab will appear like the one right.

Done AWS Upload

You will see files for numerous tests. A full test will contain hundreds of "Event" and "Data" files, starting with a "Startup file" and often ending with a "Log" file. The example below, TEST001, only contains 1 of each file described.

Release Keyboard

Account: gtech Group: default User: databucket
 Folder: Select First 0
 Folder: Select Second 27
 Select All
 Upload

TEST001-20240228-075632-Log.txt
 TEST001-20240228-075631-Event.XML
 TEST001-20240228-075631-Data.XML
 TEST001-20240228-075418-Startup.XML

TEST000-20240506-073219-Log.txt
 NoPatientID-20240402-064111-Log.txt
 NoPatientID-20240229-092344-Log.txt
 NoPatientID-20240229-092344-Log.txt

3

1. In the "Folder" window, type in the Patient ID for the patient you are uploading data for. In this case, it is TEST001.

Folder:

TEST001

2. Select "Release Keyboard" at the top.

RELEASE KEYBOARD

4

1. Scroll to find the Startup file for the relevant patient, select the file so it has a grey background, then "Select First". The text to the right of "Start First" will change from "0" to whatever # of file it is in the list, in this case it is "3".

Release Keyboard

Account: gtech Group: default User: databucket
 Folder: Select First 3
 TEST001 Select Second 27
 Select All
 Upload

TEST001-20240228-075632-Log.txt

TEST001-20240228-075631-Event.XML

TEST001-20240228-075631-Data.XML

TEST001-20240228-075418-Startup.XML

2. Scroll to find the last file for the relevant patient (Log or Event file). Repeat so the file is selected in grey text, and "Select" Second". In this case the "Log" file is the last file and "Select Second" changed from "27" to "0".

Release Keyboard

Account: gtech Group: default User: databucket
 Folder: Select First 3
 TEST001 Select Second 0
 Select All
 Upload

TEST001-20240228-075632-Log.txt

TEST001-20240228-075631-Event.XML

TEST001-20240228-075631-Data.XML

TEST001-20240228-075418-Startup.XML

5

1. Verify with your G-Tech contact that they have all the data.
 2. Change the "Display & Brightness" back to 2 minutes.

Auto-Lock

2 minutes >

DEVICE DESCRIPTION

The G-Tech Wireless Patch System (WPS) is a non-invasive wireless gastrointestinal monitoring system and consists of the G-Tech Patch and the G-Tech Patch Monitor, an iOS application. The G-Tech Patch is a single use, wearable electrode patch that reads the electrical signals of the gastrointestinal tract from the abdominal skin surface.

The G-Tech Patch transmits the acquired electrical signals via Bluetooth to the G-Tech Patch Monitor. The Patch Monitor receives the raw data and periodically uploads it to a secure cloud server. Additionally, the Patch Monitor has a patient interface to allow the patient to manually enter events such as meals, bowel movements, pain or the taking of medications. Data analysis algorithms running on the cloud server process the uploaded data to measure and report myoelectrical motor activity levels for the stomach and intestines. These measurements are made available to physicians for aid in clinical evaluation of their patient. Patients do not have independent access to either the raw data or calculated results except as shared with them by their physician.

INTENDED USE

The intended use for the G-Tech WPS is to serve as a tool that provides gastrointestinal myoelectrical activity measurements to be used by the Physician or Clinical User as an aid in the diagnosis and evaluation of gastrointestinal disorders.

INTENDED USE POPULATION

- Infants, pediatrics, and adults.

CONTRAINDICATIONS

- Do not use the G-Tech Patch in combination with high frequency surgical equipment near strong magnetic fields or devices such as MRI as it may disrupt the quality of data.
- Do not use the G-Tech Patch on patients who do not have the competency to wear the WPS for the prescribed monitoring period.

WARNINGS

- The information from the G-Tech WPS does not replace current standard of care or treatment practices. Information from the WPS is not intended to replace or override other clinical signs or symptoms.
- Patients may experience adverse skin reactions due to the nature of the adhesive used on the patch. Healthcare providers should advise patients to seek medical attention if they experience allergic skin reaction or rash.
- Users should not modify the G-Tech Patch or the G-Tech Patch Monitor iOS Application as it can result in erroneous measurements and unsafe conditions.
- User should not service or attempt maintenance the patch while the WPS is in use.
- The patch should not be placed on an open wound or broken skin.
- The patch should be removed prior to an MRI scan or if the patient will be in a location exposed to strong electromagnetic forces.
- Safety and effectiveness of the G-Tech Patch has not been established for pregnant women.

PRECAUTIONS

- Do not use the patch if it appears used or damaged, as the WPS may not perform as intended.
- Remove any significant body hair prior to the application of the patch.
- The G-Tech Patch has an IP23 rating which means it is protected from touch by fingers and objects greater than 12 millimeters. The rating also indicates that it is protected from water spray less than 60 degrees from vertical. It is advised to take short 5-minute showers with back facing shower head.
- Avoid activities that involved submerging the patches such as swimming or immersion in a bathtub.
- Avoid activities that cause active sweating such as moderate or higher levels of exercise.
- Avoid activities that involve high levels of repetitive flexing of the abdominal area, such as sit-ups or other abdominal exercises.
- Remove the patches if significant discomfort or irritation occurs at the skin.
- Dispose of the G-Tech Patches per local laws, care facility laws or hospital laws for routine/non-hazardous electronic waste.

STORAGE AND HANDLING

- Storage temperature range: 0 – 40° C
- Storage relative humidity range: 10 – 95% RH
- Ensure your hands are clean and dry before handling the G-Tech Patches. Gloves are recommended.

G-TECH WPS ANALYSIS

Data recorded by the G-Tech WPS are automatically uploaded to a cloud server where they are analyzed by proprietary algorithms developed by G-Tech Medical, Inc. Results of the study are reported to the prescribing physician.

NOTICE OF PRIVACY PRACTICES

G-Tech Medical is committed to upholding patient privacy and protecting personal information, in particular health information collected and processed in conjunction with our G-Tech WPS. We commit to complying with all applicable privacy laws and allowing patients to exercise their rights.

PRODUCT SPECIFICATIONS

MEASUREMENTS		BATTERY	
Gastrointestinal activity frequency range	1 to 40 cpm (cycles per minute)	Battery Type	Zinc Air
Measurement Range	-78mV to + 78mV	Battery Voltage	DC 1.4V
Precision (Resolution)	0.09 µV	Battery Life	Up to 6 days
COMMUNICATIONS		OPERATING, STORAGE & TRANSPORT CONDITIONS	
Bluetooth (BT 4.2)	Max. 10 Meters (30 Feet Line of Sight)	Ambient Temperature	0 – 40° C
Radio Modulation	FSK (Frequency Shift Keying)	Humidity	10 -95% RH
Radio Frequency	2.402 – 2.481 GHZ	Barometric Pressure	70-106 kPa
Transmit Power	4dbm		

ENVIRONMENT USE GUIDANCE AND WARNINGS

SUITABLE ENVIRONMENT FOR USE OF EQUIPMENT

The use of the G-TECH GEN 2 PATCH is suitable in both a PROFESSIONAL and a HOME healthcare environment.

The following exclusions apply:

- Near active HF SURGICAL EQUIPMENT and the
- RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

Table 2: Guidance and manufacturer's declaration – electromagnetic immunity (HOME HEALTHCARE ENVIRONMENT)

The G-TECH GEN 2 PATCH is intended for use in the electromagnetic environment specified below. The customer or the user of the G-TECH GEN 2 PATCH 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical residential environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical residential environment. If the user of the G-TECH PATCH SYSTEM requires continued operation during power mains interruptions, it is recommended that the iOS DEVICE be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
Power frequency magnetic field (50/60 Hz) 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the G-TECH PATCH SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√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 recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the G-TECH GEN 2 PATCH is used exceeds the applicable RF compliance level above, the G-TECH GEN 2 PATCH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 3: Recommended separation distances between portable and mobile RF communications G-Tech Patch Gen 2 and the G-Tech Patch Monitor iOS Application (For ME equipment ME system that are not life-supporting) (HOME HEALTHCARE ENVIRONMENT) (Valid for test levels: 3V for 150 kHz to 80 MHz; 10V for 80 MHz to 2700 MHz)

The G-TECH GEN 2 PATCH is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the G-TECH GEN 2 PATCH can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the G-TECH GEN 2 PATCH SYSTEM as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80MHz to 800 MHz	80 MHz to 2.7 GHz
	d = 1.2√P	d = 1.2√P	d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23



DEVICE PERFORMANCE

- The G-TECH GEN 2 PATCH must be capable of measuring the activity of the gastrointestinal tract over the course of multiple days. The ability of the device to measure the activity of the gastrointestinal tract may be lost or degraded due to EM DISTURBANCES.

USE ENVIRONMENT GUIDANCE AND WARNINGS

- 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. The use of the G-TECH GEN 2 PATCH is suitable in both a PROFESSIONAL and a HOME healthcare environment.
- 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.
- 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 G-TECH GEN2 PATCH SYSTEM, including the IOS device and accompanying charging cable specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

ELECTRICAL SAFETY AND COMPATIBILITY

Table 1: Guidance and manufacturer's declaration – electromagnetic emissions
(For ME equipment ME system that are not life-supporting)
(HOME HEALTHCARE ENVIRONMENT)

The G-TECH PATCH SYSTEM GEN 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the G-TECH PATCH SYSTEM GEN 2 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The G-TECH GEN 2 PATCH 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 B	The G-TECH GEN 2 PATCH is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

















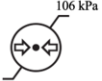
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

Table 4: Immunity to RF Wireless Communications Equipment
(HOME HEALTHCARE ENVIRONMENT and PROFESSIONAL HEALTHCARE FACILITY)
(Valid for test levels: 3V for 150 kHz to 80 MHz; 10V for 80 MHz to 2700 MHz)

Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

SYMBOLS

 Prescription Only	 Manufacturer	 Date of Manufacture	 Read Usage Instructions	 Lot Number
 Serial Number	 Magnetic Resonance (MR) Unsafe	 Use-By Date	 Do Not Reuse	 Do Not Use if Package is Damaged
IP23 Protected from touch by fingers and objects greater than 12 millimeters. Protected from water spray less than 60 degrees from vertical.	 Non-ionizing Radiation	 Contents (Numeral represents quantity of units inside)	 Type BF Applied Part	 Properly Dispose of EEE (Electrical and Electronic Equipment)
 Temperature Limits (Storage)	 Humidity Limits (Storage)	 Atmospheric pressure limits (Storage)		