DotSpace Inc.

# "PressureDOT®" GI Monitoring System

## PDT-001

## User Manual

For GI Motility Monitoring

V1.0

Doc ID: PDT001-MDF01

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## Copyrights



## Trademarks

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## Patents

Certain uses and features of the products referenced herein are protected by one or more United States and international patents or have pending patent applications.

## Federal Communications Commission (FCC)

15.105(a)
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.

15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user' s authority to operate the equipment.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

Limited Warranties

The PressureDOT GI Monitoring System

Dotspace Inc. warrants the system* for a period of one (1) year from date of purchase, and that the components of the system* have been designed, manufactured, packaged, and tested and, if properly used, are free from any defect of workmanship or materials that would materially and adversely affect their intended use. If any component of the system* fails during the period of this Limited Warranty for reasons covered by this Limited Warranty, Dotspace Inc, at its option, shall replace the specific failed component. This Limited Warranty does not cover failure occurring in connection with or arising out of uses not intended by Dotspace Inc, misuse, neglect, alteration, repair, improper installation, or improper testing. Without limiting the generality of the foregoing statement, this Limited Warranty shall be invalidated if any repairs, services, or modifications are made to any of the components by any person not explicitly authorized by Dotspace Inc. Dotspace Inc. is not liable or otherwise responsible for any loss, damage, or expense arising, directly or indirectly, from the use of the system* or PressureDOT capsule. Without limiting the generality of the foregoing statement, customers are liable for all matters beyond Dotspace Inc.' s control such as handling, storage, cleaning, misuse, treatment, and diagnosis.

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

Extended Warranty Options are available.

* Only the PressureDOT Capsule and reader of the PressureDOT GI Monitoring System are covered by this Limited Warranty:

**The PressureDOT Capsule**

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

If Dotspace Inc. verifies capsule failure during the warranty period for reasons covered by the Limited Warranty, Dotspace shall replace the failed capsule.

Additional Limitations

The Limited Warranty does not cover software or damages due to misuse, neglect, alteration, repair, improper installation, set-up, calibration, or improper testing. Dotspace Inc. is not liable for any incidental or consequential loss, damage, or expense arising, directly or indirectly, from the use of the system or capsule. Customers are liable for all matters beyond Dotspace Inc.' s control such as handling, storage, cleaning, misuse, treatment, and diagnosis. This warranty is in lieu of and excludes all other warranties whether expressed or implied warranties of merchantability or fitness.

DOTSPACE INC
1209 N ORANGE ST
WILMINGTON, DE, 19801, USA.

FCC ID: 2BBOEPRESSUREDOT001
This device complies with Part 15 of the FCC. Operation is subject to the following two conditions:

This device may not cause harmful interference.

This device must accept any interference received, including interference that may cause undesired operation.

# Table of Content

Recommended separation distance

DotSpace Inc.

# Introduction and Components


# Using this Manual

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

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

**Warning**

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

**Caution**

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

# System Components

## *PressureDOT Capsule Clamshell*

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

**Caution**

The capsule may shut down after being dropped or hit. You should always check the signal before swallowing or delivering, and if there is any abnormal connection, please try to restart the capsule.

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# *Capsule Operational Specifications*

| PressureDot | Specifications (PDT-001_Capsule) |
|---|---|
| Mechanical properties | ● Size: Height = 14.8 mm, Diameter = 10.3 mm,<br>● Weight = 1.6 g<br>● Bite force > 40 kg (or 130 kg/cm^2, or 1,850 psi) |
| Temperature and humidity | ● Operation temperature: 25 - 42 °C<br>Under ambient temperature 42 °C, the maximum capsule enclosure temperature is 42.5 °C.<br>● Storage temperature: 15 - 25 °C<br>● Operation humidity: 100% maximum<br>● Storage humidity: 90% maximum<br>● Operation atmospheric pressure: 666 - 1066 hPa |
| Material | ● Capsule material: Polycarbonate Makrolon® Rx2430 [5]<br>● Internal stand: PA66 (Nylon) + Glass fiber (35%)<br>● Sealing: Henkel Loctite EA M-31CL [6]<br>● Acid and alkali-resistance: pH1 to 13 for 24 hours<br>● Hermeticity: IP68<br>● Non-toxic material: Pass ISO 10993 Biocompatibility Study of Medical Device Services. |
| Wireless and control chip | ● Wireless communication: Bluetooth Low Energy (BLE) 5.0<br>● Wireless transmission (Tx) power = -1.66 dBm (measured)<br>● Frequency = 2402 - 2480 MHz<br>● Protocol: BLE 5.0 advertising mode<br>● Transmission rate: 0.2 Hz (every 5-second) |
| Antenna | ● Antenna type: inverted F antenna<br>● In the saline water, antenna efficiency < -25 dB |
| Sensors | **Pressure Sensor**<br>● Range: 500 to 800 mmHg (666 - 1066 hPa)<br>● Absolute accuracy over temperature: ±1.14 mmHg (1.52 hPa)<br>● Pressure senility: 4096 LSB/hPA<br>● Sampling rate: 0.2 Hz (every 5-second) |

| | |
|---|---|
| | **Temperature Sensor**<br>● Operating Temperature Range 25 - 42°C (Direct mode)<br>● Absolute accuracy: ± 0.5°C<br>● Temperature senility: 100 LSB/°C<br>● Sampling rate: 0.2 Hz (every 5-second)<br>**Magnetic Sensor**<br>● Sensitivity: 30 Gauss (3mT)<br>● Activation by trigger<br>● Sensing distance: < 5 mm |
| Battery/Power | ● Supply voltage: 3.0 V<br>● Battery: Two of 1.5V Silver Oxide, SR521SW, 16 mAh<br>● Operation for > 144 hours<br>● Standby current < 0.3 μA<br>● Operation current < 50 μA |
| Magnet<br>(In the clamshell) | ● Size: diameter = 5 mm, height = 2 mm<br>● Material: NdFeB magnet<br>● Surface magnetic flux density: 2000 Gauss (200 mT) |
| Operation and indication | ● Contactless switch with a latch function with LED indicator<br>● Turn on: three blinks.<br>● Turn off: one blink.<br>● The distance between activation magnet and the Capsule = 3 mm |


The activation magnet interacts with the capsule’ s internal power switch that turns the capsule on and off.

**Warning**

Individuals with pacemakers should not come within ten (10) cm of the PressureDOT activation magnet. The magnet could interfere with pacemaker operation.

**Warning**

Do not store the PressureDOT activation magnet in the same room with or a room adjacent to MRI equipment. The magnets could become a dangerous projectile.

**Caution**

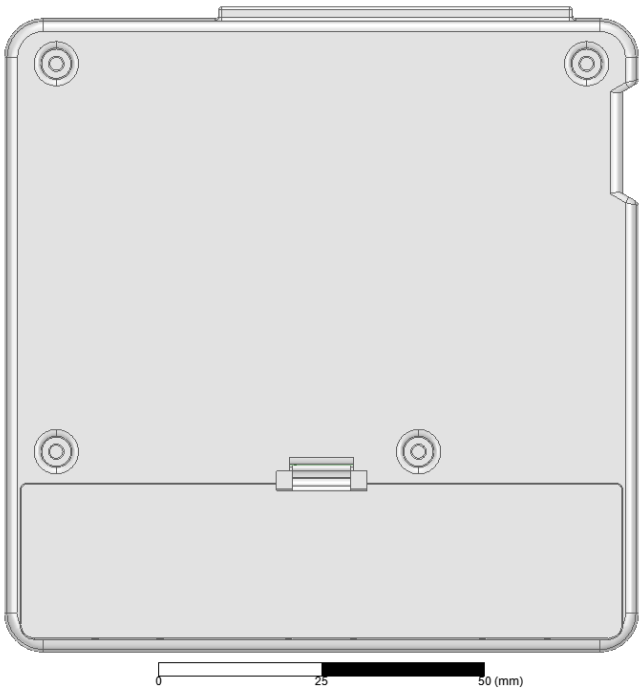
Keep the PressureDOT activation magnet more than ten (10) cm from magnetic media and computer monitors.

**Caution**

Do not store unused capsules within a strong magnetic environment. Stray magnetic fields may activate the capsule

## *Reader*

The reader records biomedical data sent by the capsule. It is placed or carried around the patient. The reader features an micro SD card slot to record the data. It will search the surrounding Bluetooth broadcasting signals automatically until you lock the target capsule. The reader weighs approximately 225g (0.5 lb) including four AAA batteries. To change the batteries, turn off the device and remove the battery cap from the back, then remove the old batteries. Insert new batteries and recycle the old batteries.



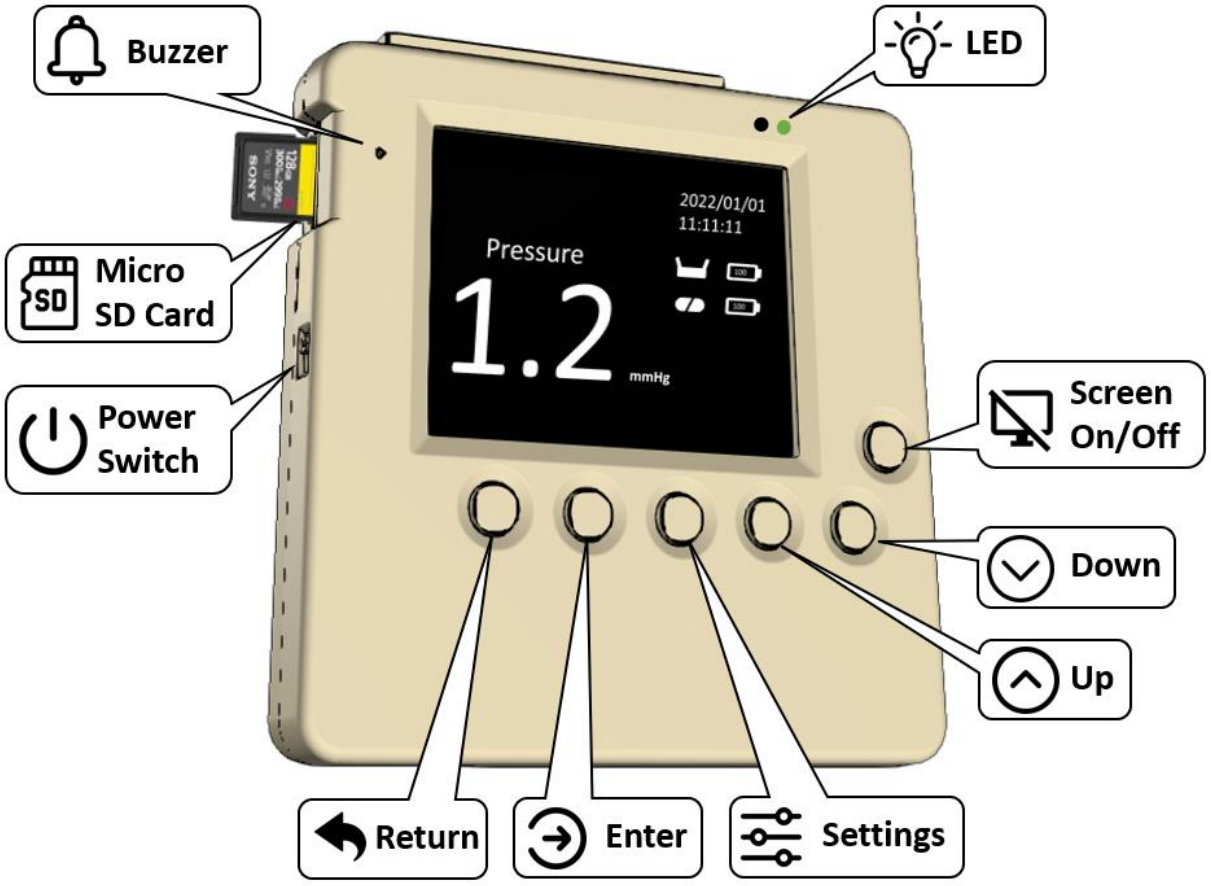

**Caution**

Use only the PDot_Plotter software to download data from the reader is highly recommended.

## *Reader Specifications*

| PressureDot | Specifications (PDT-001_Reader) |
|---|---|
| Mechanical properties | ● Size: Height = 99.8 mm, Length = 98.0 mm, Thickness = 16.4 mm<br>● Weight = 225 g |
| Temperature and humidity | ● Operation temperature: 20 - 45 °C<br>● Storage temperature: 0 - 40 °C |

| | |
|---|---|
| | ● Operation humidity: 90% maximum<br>● Storage humidity: 90% maximum<br>● Operation atmospheric pressure: 666 - 1066 hPa |
| Material | ● Material: Polycarbonate |
| Wireless and control chip | ● Wireless communication: Bluetooth Low Energy (BLE) 5.0<br>● Sensitivity = -95 dBm<br>● Frequency = 2402 to 2480 MHz<br>● Protocol: BLE advertising mode with AES-128<br>● Receiving rate: 0.2 Hz (every 5-second) |
| Antenna | ● Antenna type: F antenna<br>● Gain < -5 dB |
| Pressure Sensor | ● Sampling rate: 0.2 Hz (every 5-second)<br>● Range:  500 to 800 mmHg (666 - 1066 hPa)<br>● Absolute accuracy over temperature: ±1.14 mmHg (1.52 hPa)<br>● Pressure senility: 4096 LSB/hPA |
| Battery/Power | ● Supply voltage: 6.0 V<br>● Battery: Four of 1.5 V AAA Alkaline batteries, 1150 mAh<br>● Operation for > 48 hours |
| Operation and indication | ● Switch<br>● Notifying |




*Reader Features*

| Feature | Description |
|---|---|
| LCD screen | Data display |
| Screen On/Off | Whenever you are not watching the screen, you can turn off the screen for power saving, while it is still receiving data. |
| Settings and other control buttons | See **Reader Operation** for more details. |
| Power switch | Turn on/off the reader |
| MicroSD card slot | Insert MicroSD card to record the data. |
| Buzzer | Notify users according to settings. |
| LED | Indicates the state of the reader. See table below |

*Reader LED Status*

| LED | State | Action Recommended |
|---|---|---|
| Continuous Green | Searching for a signal. | If the green light stays on, it means the capsule and the reader are disconnected.<br>1. Try to put the reader closer to the capsule (patient body) and check the remaining battery.<br>2. If the problem remains, restart the reader.<br>3. If the problem is still there, you may activate the backup plan and contact our customer service. |
| Flashing Green | Data receiving. | N/A |

## *System Computer and PDot_Plotter Software*

PDot_Plotter software comes installed on the flash drive, and only limited PC models with specified operating systems are certified for this software. PDot_Plotter receives and processes data from the microSD card, provides data analysis tools, and graphically displays test results. PDot_Plotter features algorithms that calculate GET, SBTT, CTT, WGTT, and motility indices of the antrum and duodenum. An electronic copy of this user manual is included in the software.

**Caution**

Use PDot_Plotter only on the certified computer with specified operating system. Installing and operating PDot_Plotter on other computers is not recommended or supported by Dotspace Inc.

## *Minimum System Computer Requirements*

| Manufacturer | |
|---|---|
| Operating System | Compatible with x64 bits Windows, Linux, and MacOS. Launch the software with Chrome only. |
| Hard Drive | 100 megabytes of available space for the PDot_Plotter application and 100 gigabytes of available space for test files (recommended) |
| Communication Port | 1 open USB port for software installation,<br>1 SD card slot for data reading. |
| Peripherals | printer is optional |
| Processor | Intel(R) Core (TM) i7-8550U CPU @ 1.80GHz or higher |
| Memory | 8 gigabytes (GB) of RAM or higher |
| Display | 1920 x 1080 resolution<br>Widescreen aspect ratio (recommended)<br>96 dpi<br>32-bit color |

## *Accessories*

Your starter kit includes the accessories below:

| Accessory | **Description** |
|---|---|
| User manual | Complete the user training and read this manual before running the PressureDOT System. The user manual contains important safety information |

**Warning**

Do not try connecting items that are not part of the PressurDOT GI Monitoring System.

# Use and Care of the System

*Acronyms*

| | |
|---|---|
| GET | Gastric emptying time |
| SLBTT | Combined small and large bowel transit time |
| WGTT | Whole gut transit time |

## Intended Use/Indications for Use

The "PressureDOT" (PDT) GI Monitoring System is indicated for use in the continuous evaluation of patients with suspected delayed gastric emptying (gastroparesis).

The "PressureDOT" (PDT) GI Monitoring System measures pressure and temperature throughout the gastrointestinal tract and telemetrically transmits the continuous physiological measurement data. The measured gastrointestinal tract pressure and temperature are used to determine the gastric emptying time(GET), total transit time(TTT), and combined small-large bowel transit time(SLBTT) and pressure contraction patterns from the antrum and duodenum are used to calculate motility indices. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.

Not for use in pediatric populations.

| **Suspected disease or condition to evaluate** | **Indicated Measurement** | **Use** |
|---|---|---|
| Gastroparesis | GET | Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia. |

| | | |
|---|---|---|
| Chronic constipation | SLBTT | A surrogate measure of colonic transit in patients with chronic constipation when CTT alone cannot be determined. |

## *Contraindications for Use*

Do not use in patients with these diseases or conditions:

- History of gastric bezoar
- Swallowing disorders, patients with swallowing dysfunction may inhale the capsule into the bronchi or may have difficulty swallowing.
- Suspected or known strictures, fistulas, or physiological/mechanical GI obstruction.
- GI surgery within the past 3 months
- Severe dysphagia to food or pills
- Crohn' s disease or diverticulitis
- Implanted or portable electro-mechanical medical device such as a cardiac pacemaker, defibrillator, or infusion pump.
- Younger than 18 years old
- Female subjects who are pregnant, planning to become pregnant, or breastfeeding.
- Patients diagnosed with radiation enteritis.
- Data transmission from the capsule to the reader is influenced by patient BMI. Significant data dropout can occur in severely obese patients (>40 BMI).
- Any condition in which the subject is required to undergo an MRI within 7 days of ingestion of the capsule.

**Warning**

Individuals with pacemakers should not come within ten (10) cm of the PressureDOT activation magnet. The magnet could interfere with pacemaker operation.

**Caution**

Patients should be instructed to stay away from equipment that may generate strong electromagnetic fields (eg, MRI) between swallowing the capsule and expelling the capsule, which may cause damage to the body cavity.

**Caution**

This device should not be used adjacent to or stacked with other equipment.

**Caution**

Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.

**Caution**

If it is not possible to confirm whether the capsule has been excreted or not, an X-ray examination should be done about one week after swallowing to try to locate the capsule in the patient's body.

**Caution**

Any evidence of significant gastrointestinal obstruction or severe paralytic ileus may require immediate surgical intervention.

## Storage

Store PressureDOT GI Monitoring System components and capsules at ambient room temperature (15~25°C for capsule, 0~40°C for reader) and humidity (rH 30~90%).

**Warning**

Do not store the PressureDOT activation magnet in the same room with or a room adjacent to MRI equipment. The magnets and could become a dangerous projectile.

**Caution**

Keep the PressureDOT activation magnet more than ten (10) cm from magnetic media and computer monitors.

**Caution**

Do not store unused capsules within a strong magnetic environment. Stray magnetic fields may activate the capsule

### *Power Requirements*

| | |
|---|---|
| Capsule | 3.1 VDC self-contained batteries |
| Reader | 1.5 VDC AAA battery x 4 |

### *Recycling and Disposal Instructions*

1. Recycle the reader following the local, regional, and national regulations for electronic devices.
2. The capsule contains silver oxide batteries. Recycle unused capsules following the local, regional, and national regulations for electronic devices.
3. Dispose of used capsules following local, regional, and national regulations for disposing of human excrement.

## Device Marking

| | |
|---|---|
|  | Caution, consult accompanying documents. |
|  | Consult operator’ s manual. |
|  | Single use only. Do not reuse. |
|  | Type BF equipment. |
|  | The device has not been sterilized. |

| | |
|---|---|
|  | Date of manufacture. |
|  | Use by YYYY-MM. |
|  | Authorized representative. |
|  | Rx Only which means that the drug product is a prescription drug. |
|  | Keep dry. |
|  | MR unsafe, known to pose hazards in all MR environments. |
|  | Manufacturer. |
|  | US FCC compliance. |
| IP68 | IP (Ingress Protection) indicates how well a device is protected against water and dust. IP68 ratings occupy the very top of the IP rating scale. Both digits are at their maximum level:<br>• A **6** for total protection against solid ingress.<br>• An **8** for total protection against water ingress, up to and including complete submersion below one meter and for more than 30 minutes. |

# Risks and Safety

**Warning**

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

## *Non-Passage*

Risks associated with capsule ingestion and transit are minimal. The primary hazard is capsule retention. Retention incidence, as determined by a review of published studies of capsule endoscopy in adults, is estimated as 0.75% in patients without known stenosis and 21% in patients with known stenosis. Stenosis and strictures can be complications in inflammatory bowel disease. If you suspect a delay in passage and the Capsule is in the stomach, a pro-motility drug could be administered to assist in emptying the capsule from the stomach. Alternatively, endoscopy could be performed to retrieve the capsule. If located in the colon, laxative therapy could be administered to facilitate capsule movement, or a colonoscopy could be performed to retrieve the capsule.

## *Patient-Contacting Materials*

Patient-contacting materials include polycarbonate shield, pressure sensor, epoxy adhesive. All patient contacting materials have been tested for biocompatibility and have been found non-toxic, non-sensitizing, and non-irritating. The device does not contain natural rubber latex.

# Care, Cleaning and Maintenance

**Caution**

Do not reuse capsules. The capsule is a single-use, disposable item. The capsule may not be able to maintain performance on specification.

**Caution**

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

**Caution**

Do not store unused capsules within a strong magnetic environment. Stray magnetic fields may activate the capsule

**Caution**

The reader and capsule are not user serviceable

## *Reader*

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

1. Turn off the reader.
2. Wipe outside surfaces with a cloth dampened (not saturated) with a mild detergent and water. Suitable detergents include dishwashing detergent solutions, or laboratory glassware cleaners.
3. Wipe dry.
4. Disinfect by wiping outside surfaces with a cloth dampened (not saturated) with disinfectant. A solution of 10% household bleach can be used as a disinfectant.
5. Wipe dry.
6. Wait at least 5 minutes after cleaning and disinfection before turning the reader on.
7. Conduct a preventive maintenance inspection. Check for cracks or damage. Shake the reader and listen for detached batteries. Do not use the reader if the case is cracked or damaged, or a rattling can be heard.

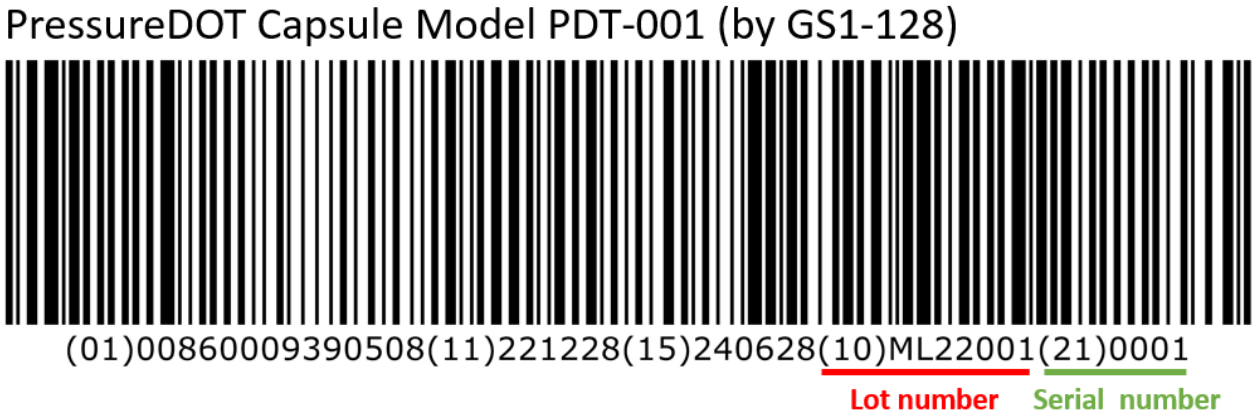
## Firmware Update

PressureDOT does not have a firmware updating plan, if you have any problem operating the device, please see the Troubleshooting and Support section of the user manual.

## Troubleshooting and Support

Contact technical support if you have a problem setting up or operating the system:
For swift and direct support, please be prepared to answer the following questions:

- What is the ID of the PressureDOT you are using?
  - Capsule: You can find the printed MAC number and the firmware version on the capsule, on the package, and on the reader (scanning mode)
- What operation or steps did you take before the problem occurred?
- What operations or steps did you take after the problem occurred?
- What is the exact error message that appeared?
- If you have trouble with a capsule or other hardware component, have the component' s lot and serial numbers ready. These numbers are on labels affixed to the hardware component or packaging. For example:



# Prepare for a Test

## Preparing the Patient

### *Before the Office Visit*

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

| Schedule | Restriction |
|---|---|
| 24 hours before the test | • Do not consume alcohol. |
| 8 hours before the start of the test | • Do not eat or drink.<br>• Do not use tobacco. |
| 6 hours after the start of the test | • Do not use tobacco.<br>• Do not eat.<br>• Do not sleep.<br>• Do not consume alcohol |

### *During the Office Visit*

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

| Schedule | Restriction |
|---|---|
| 6 hours after ingesting the capsule | • Do not use tobacco.<br>• Do not eat.<br>• Do not take medication. |

| | |
|---|---|
| During the entire test | • Do not consume alcohol.<br>• If you are diabetic, monitor glucose levels and follow your personal treatment plan. If you are unsure, contact the doctor who manages your diabetes.<br>• Avoid vigorous exercise such as sit-ups, abdominal crunches, and prolonged aerobic activity (greater than 15 minutes).<br>• Do not wear the reader while bathing or showering.<br>• Do not use laxatives, bowel cathartics, anti-diarrhea medications, alcohol and other drugs or medications that affect motility until after the capsule passes |

4. Instruct the patient to keep the reader as close to the abdomen as possible except while bathing or showering.
5. Instruct the patient on the use of the patient diary. The patient must record the time displayed on the reader and a brief description of the event or activity in the diary.
   - Marks bowel movements which are useful for verifying capsule exit.
   - Marks other events and symptoms which may be useful when reviewing test data.

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

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

## Resumption of Normal Routine

Review these instructions and warnings with the patient:

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

**Warning**

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

**Warning**

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

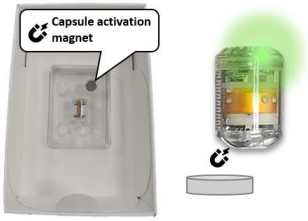
## Schedule a Follow-Up Office Visit

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

# Starting a Test

## Use Scenario

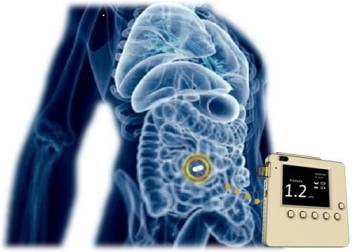
**Step1. Capsule Starting**




**Step2. Pair with the reader**


**Step3. Patient takes the capsule**

**Step4. Recording Pressure & Temperature**



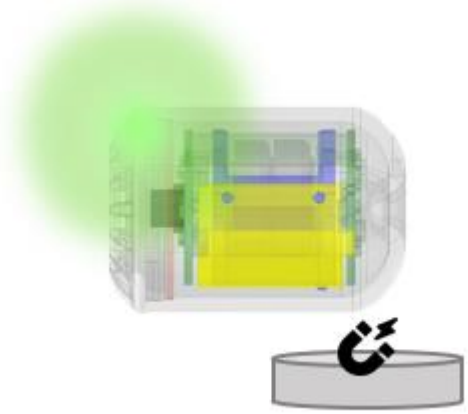

**Step5. Retrieve Physiological Measurements from the Reader for Professionals to Diagnose**



## Performing the Test

### *Step 1: Activate the Capsule*

1. Check the expiration date on the capsule packaging.
2. Remove the capsule from the case.
3. Take out the capsule and put the bottom close to the magnet on the blister to activate the capsule.

4. You will see the green LED flashes 3 times immediately to complete the boot process.
5. If you don’ t see the LED flashes after the activation process, follow the instructions in the Troubleshooting and Support section.

## *Step 2: Connect to the Reader*

1. Turn on the power switch of the reader and display the waiting search screen. When the capsule signal is found, the capsule's MAC and signal strength will be displayed.
2. If there are multiple capsules nearby, you can double check the MAC on the capsule or its package and select the right one on the reader.
3. If you cannot find the signal coming from your capsule or connection errors, follow the instructions in the Troubleshooting and Support section.
4. Detailed reader instruction is described below.
5. Place the reader within reach and observe the screen for at least 30 seconds. When the message "Locked on Capsule" and the serial number of the capsule appear, it is connected and starts recording.

## *Step 3: Ingestion*

1. Wipe outside surfaces with alcohol pads.

2. The capsule is swallowed by the patient or introduced into the patient's gastrointestinal tract by a medical practitioner.
3. After 3 days, if no signal is received or the temperature signal drops to 25 degrees Celsius, the monitoring will be completed.

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Warning

Do not operate the system in the following situations.

- High oxygen concentration
- There are flammable anesthetics in the air

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**Caution**

To avoid loss of data during Step 3, avoid separating the capsule and reader by more than 1 meter.

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**Caution**

Please be sure to instruct patients that if they need to take medicine before or during the diagnosis, they should follow the instructions of the physician or medical personnel, otherwise the diagnosis may fail.

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**Caution**

Do not open the pressure capsule within 1 meter of another patient who has swallowed the pressure capsule for examination. At the same time, do not allow the patients under examination to approach each other, which may cause the pressure capsule to fail to start.

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**Caution**

The pressure capsule contains a radio transmitter, so the patient cannot travel by air until the end of the consultation.

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**Caution**

Although it is rarely possible that you receive signals not coming from the capsule in Step 2, you should always make sure you select the corresponding MAC address of the capsule you wanted. You may not use the device normally by connection with unexpected devices.

---

**Caution**

The capsule may shut down after being dropped or hit. If there is an abnormal connection, please try to restart the capsule.

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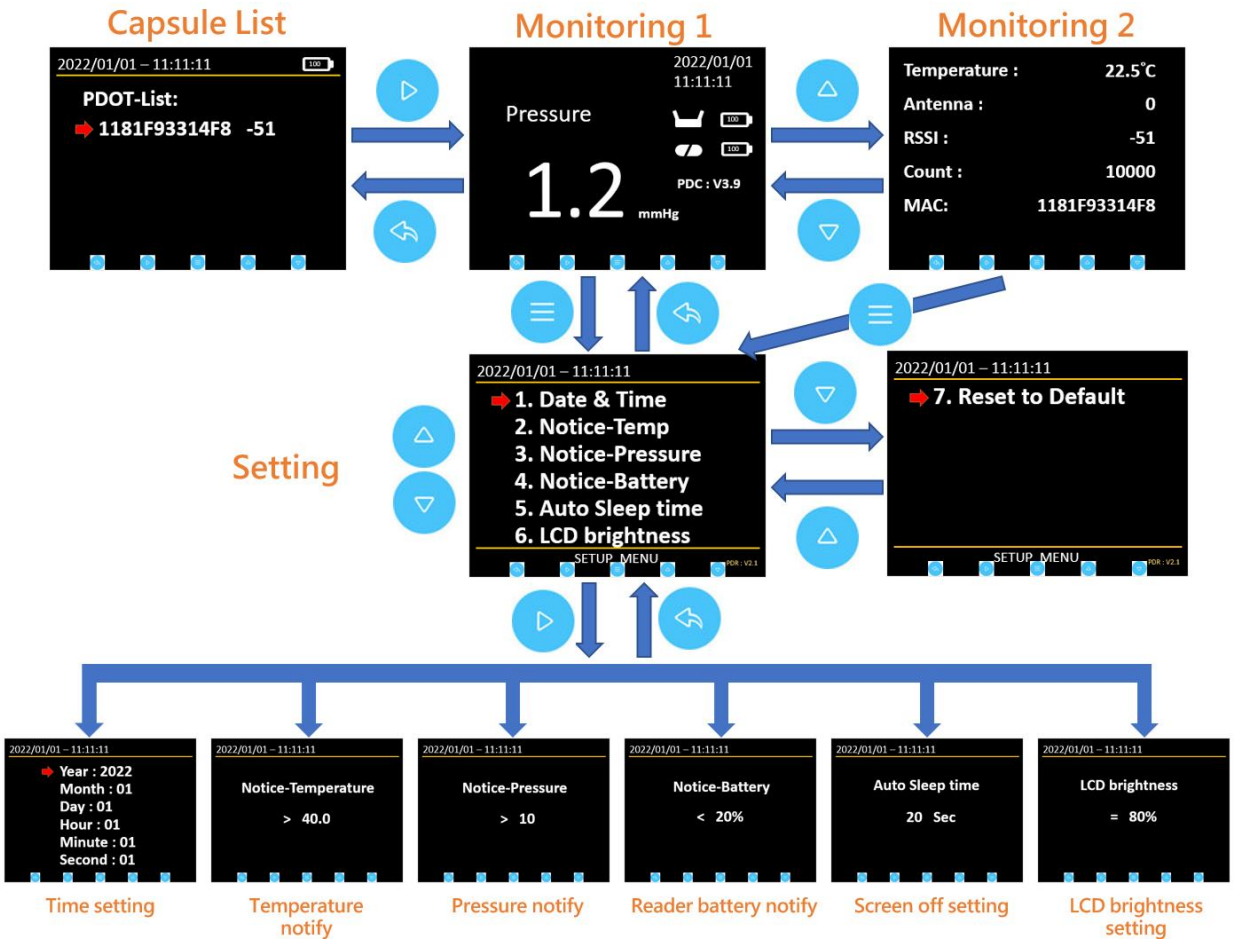
# Reader Instruction




*The Reader’ s user interface.*

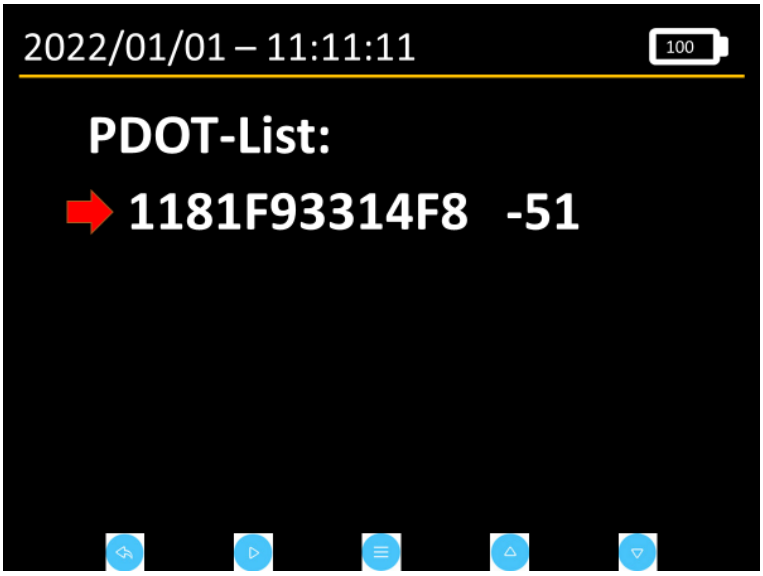
1. Boot

   1.1 Turn on the "power switch" to display the waiting search screen. The capsule's MAC and signal strength will be displayed when the capsule signal is found. (If multiple capsules are found at the same time, they will be arranged from top to bottom according to the signal strength.)

   1.2 The top of the search screen displays the date, time, and reader power in sequence from left to right.

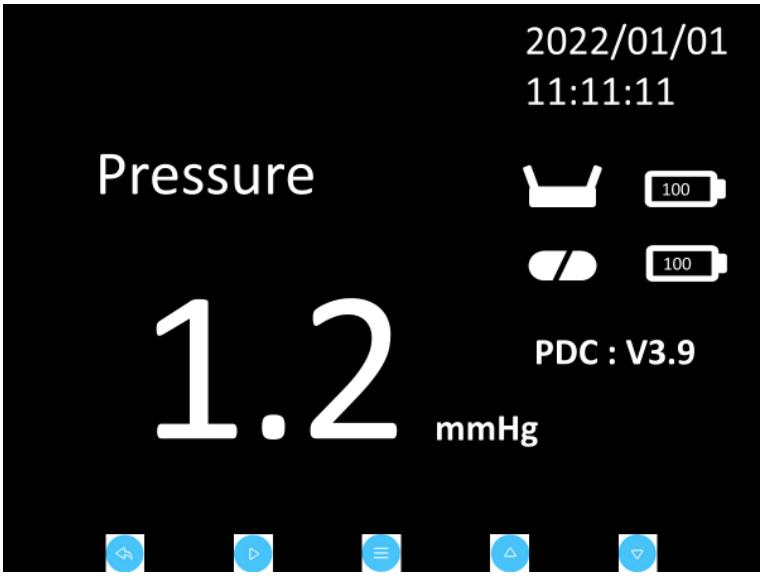
2. **Monitoring page**

   2.1 After the capsule to be monitored appears, press the "OK" button to lock the capsule and enter the monitoring page. (If there are multiple capsules, press the "Up" or "Down" button to move the red cursor to the capsule to be monitored.)



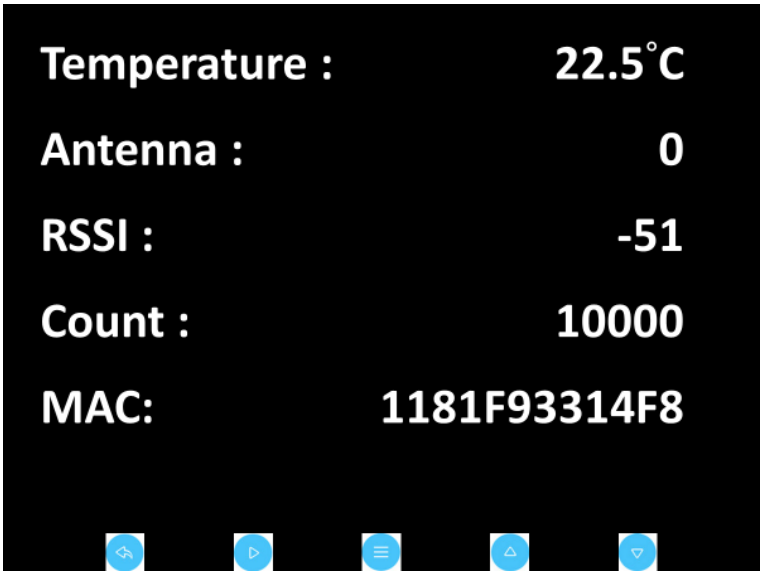

*The screen shot of the Reader: the reader shows the capsule' s MAC with RSSI.*

2.2 The left half of the monitoring page on the first page displays the pressure difference between the capsule and the Reader, and the right half displays the date, time, reader power, and capsule power sequentially from top to bottom.




*The screen shot of the Reader: the reader shows the pressure difference between the capsule and the Reader.*

2.3 Press the "Up" key or the "Down" key to enter the second monitoring page. Temperature value, antenna number, signal strength, count, and MAC are displayed sequentially from top to bottom.

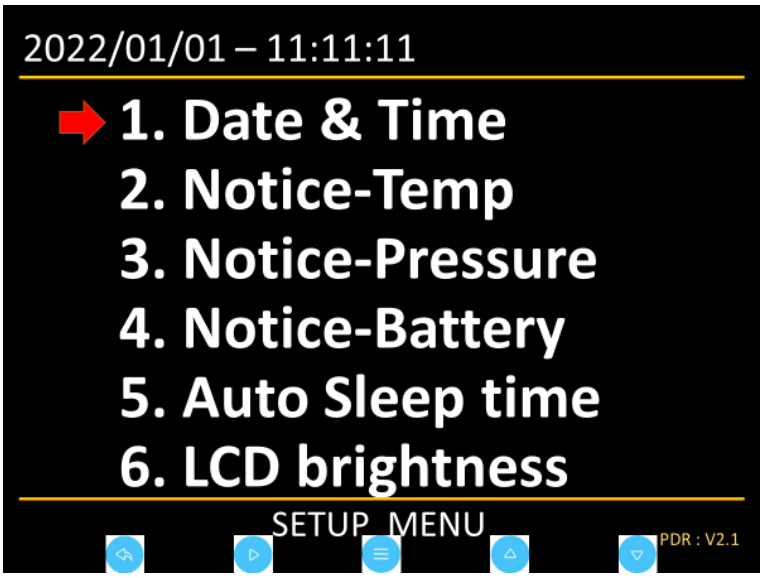


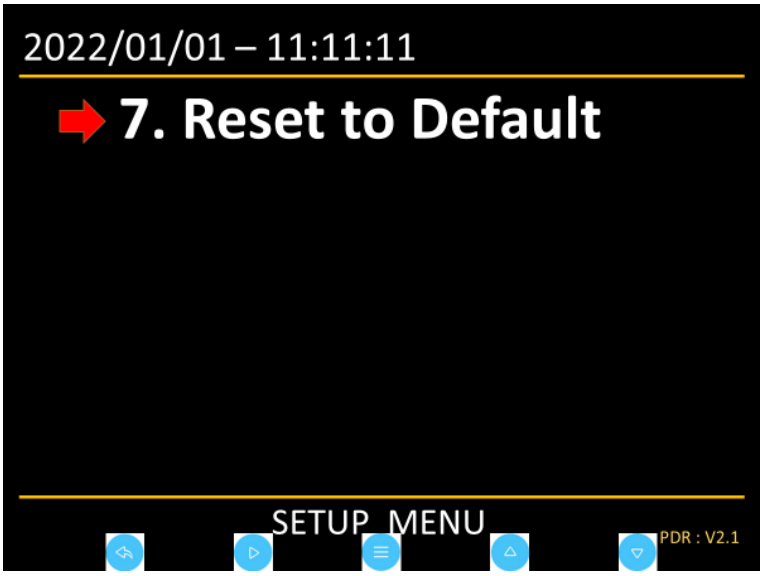

*The screen shot of the Reader: the reader shows capsule’ s information.*

## 3. Settings page

3.1 This page can modify the date and time, temperature, pressure, capsule battery notification, and screen sleep time.

3.2 Press the "Settings" button on any page to enter the setting page. Press the "Up" key or the "Down" key to move the red cursor to the option to be modified, and then press the "Confirm" key to enter the option.

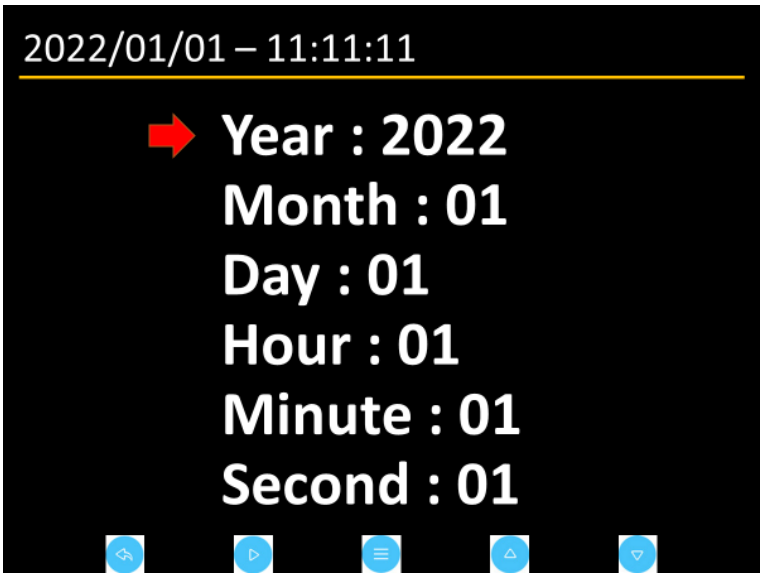





*The screen shot of the Reader’ s setup page.*

3.3 Date and time settings:

After entering the date and time setting page, move the red cursor to the option you want to modify (year, month, day, hour, minute, second) and press the "OK" button, the value will be reversed to blue and then press the "Up" button or "Direction" button. Press the "Down" button (press and hold the value to scroll quickly) to modify the value. After modification, press the "Enter" button to save the value. Press the "Back" button to return to the setting page.

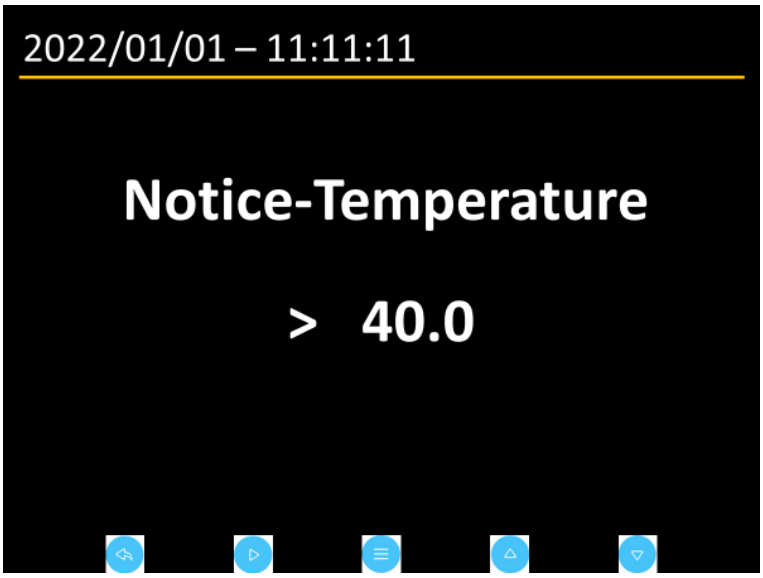



*The screen shot of the Reader’ s time setup.*

3.4 Temperature notifying value setting:

After entering the temperature warning value setting page, you can press the "Up" key or the "Down" key (press and hold the value to scroll quickly) to modify the

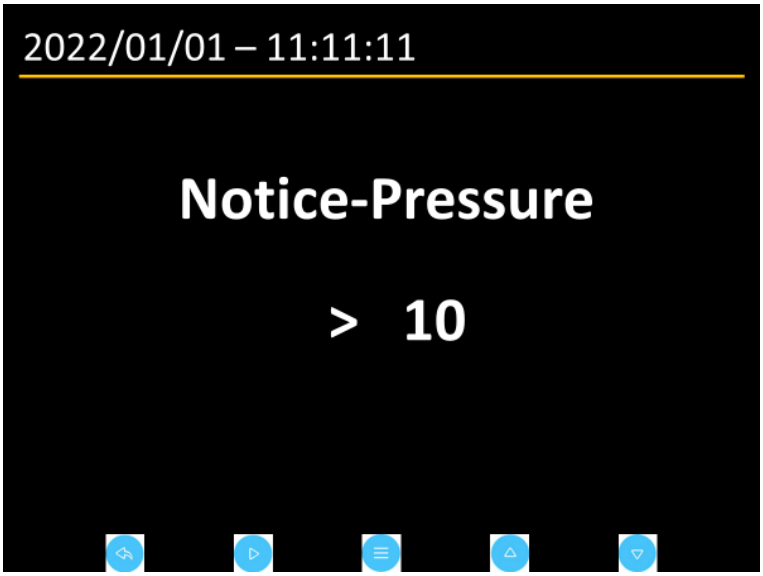
value and press the "Confirm" key to save the value after modification. Press the "Back" button to return to the setting page.




*The screen shot of the Reader’ s notice-temperature.*

3.5 Pressure notifying value setting:

After entering the pressure notifying value setting page, you can press the "Up" key or the "Down" key (press and hold the value to scroll quickly) to modify the value and press the "Confirm" key to save the value after modification. Press the "Back" button to return to the setting page.



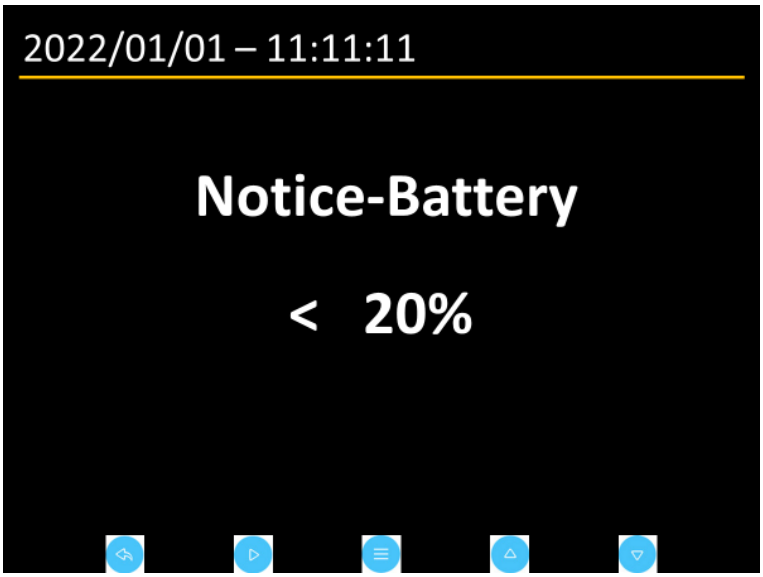

*The screen shot of the Reader’ s notice-pressure.*

**Caution**

PressureDot system Model-001 is for GI motility monitoring only, if the user receive pressure notifying information outside of clinic, we suggest you reach out to the health care professionals for further investigation.

### 3.6 Capsule battery power notifying value setting:

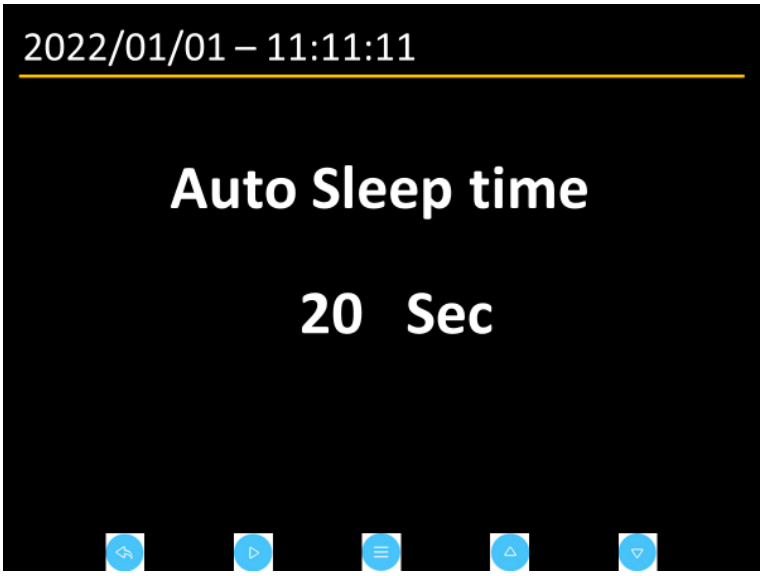
After entering the setting page of the battery level warning value of the capsule, you can press the "Up" key or the "Down" key (press and hold the value to scroll quickly) to modify the value and press the "Confirm" key to save the value after modification. Press the "Back" button to return to the setting page.




*The screen shot of the Reader’ s notice-battery.*

### 3.7 Screen sleep time setting:

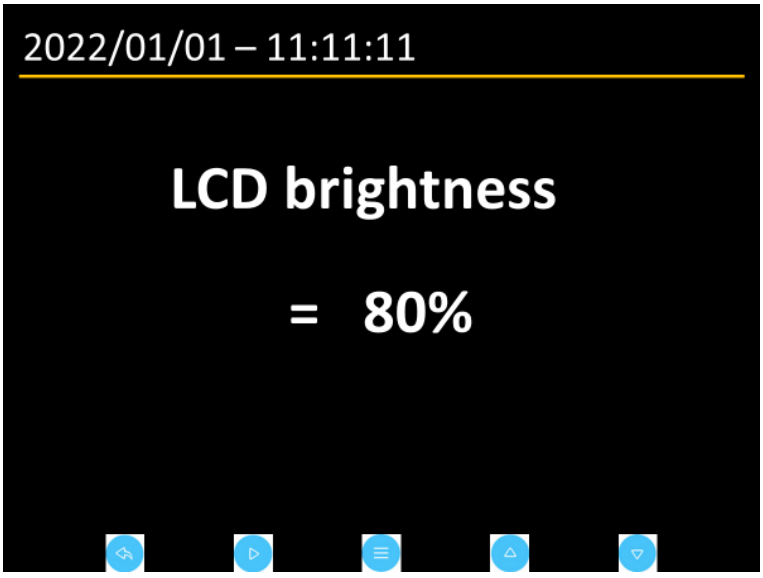
After entering the screen sleep time setting page, you can press the "Up" key or "Down" key (press and hold the value to scroll quickly) to modify the value and press the "Enter" key to save the value after modification. Press the "Back" button to return to the setting page.




*The screen shot of the Reader’ s auto sleep time.*

3.8 LCD brightness setting:

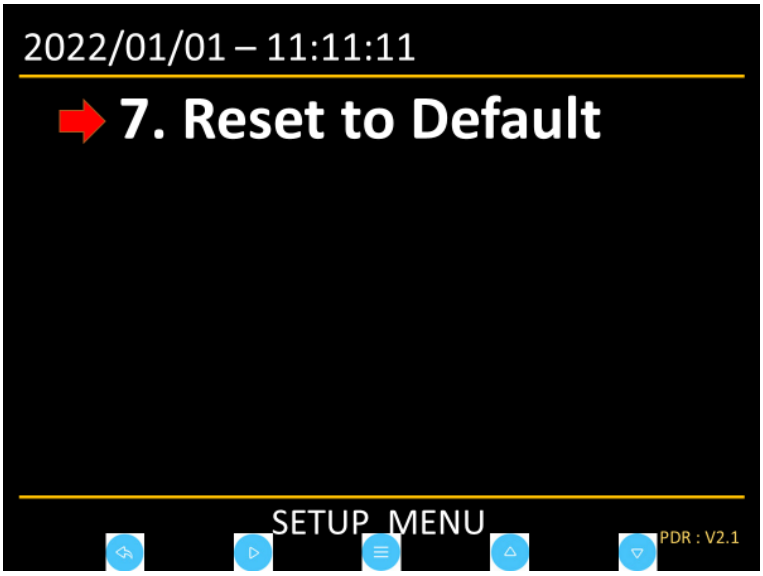
After entering the LCD brightness setting page, you can press the "Up" key or "Down" key (press and hold the value to scroll quickly) to modify the value and press the "Enter" key to save the value after modification. Press the "Back" button to return to the setting page.




*The screen shot of the Reader’ s LCD brightness.*

3.9 Reset to default setting:

After entering the reset to default setting page, you can press the "Enter" key to reset the settings to initial value. Press the "Back" button to return to the setting page.




*The screen shot of the Reader' s Reset function.*

4. Other button description

"Screen switch" button to manually turn the screen on or off.

## Data Collected During Capsule Low Voltage

**Caution**

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

If the PressureDOT software detects a low voltage condition in the capsule, a notice appears.

# Setting-Up the Pdot_Plotter Software

## Ending a Test

To determine capsule exit, you can observe the data display on the reader for at least 2 minutes. If the reader is receiving data from the capsule, the Green LED light on the reader will flash continuously. You can also check the second monitoring page, if the RSSI value and the MAC address display, it confirms that the capsule is still in the patient. If the Green LED light is always on and does not flash within the 2-minute observation is presumptive evidence of capsule exit. Actual passage can only be confirmed clinically by examination of the graph or physical examination.

### *Confirming Capsule Exit*

**Caution**

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

Use one of these methods:

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

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

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

If the capsule is in the colon, consider:

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

## Getting Started for data reading

1. Find the flash drive inside the package.
2. Prepare the specified PC model with a certain operating system for PressureDOT use only.
3. Plug in the flash drive to the computer and open the folder.
4. Remove the SD card from the reader and plug into the computer.

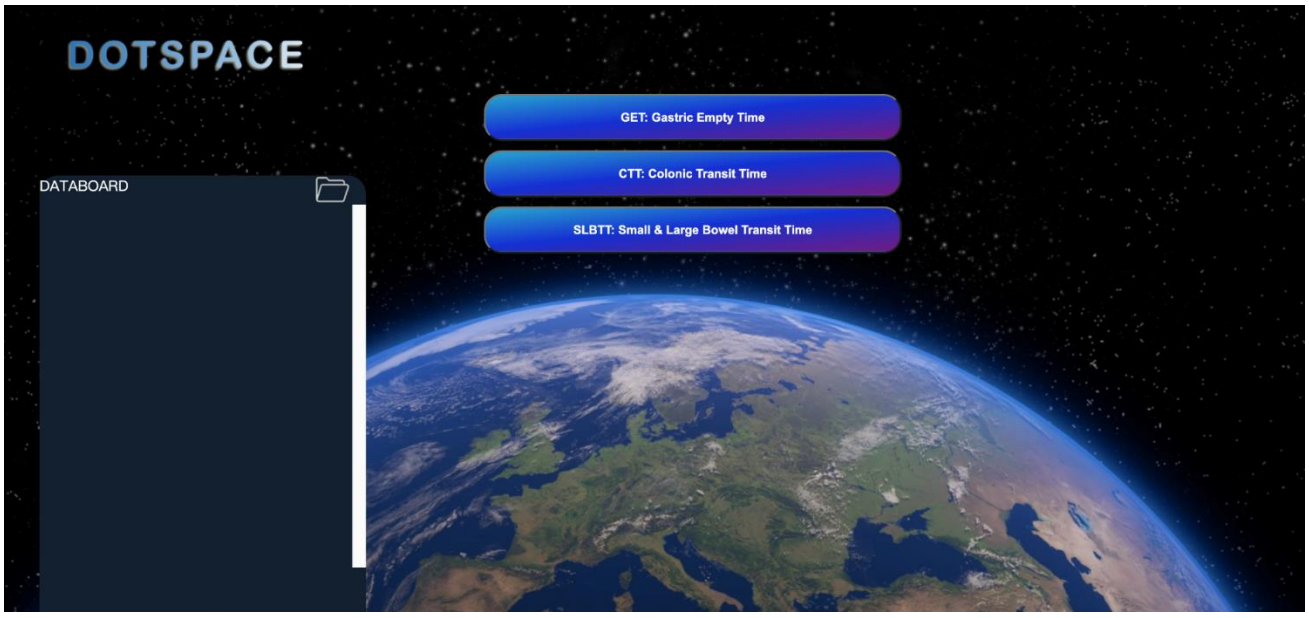
## Suggested Supporting Software Setting-Up

This is a plotting software that we suggested, supporting you to easily understand the data. It does not influence the PressureDOT system and its data even if you don’ t use the software.

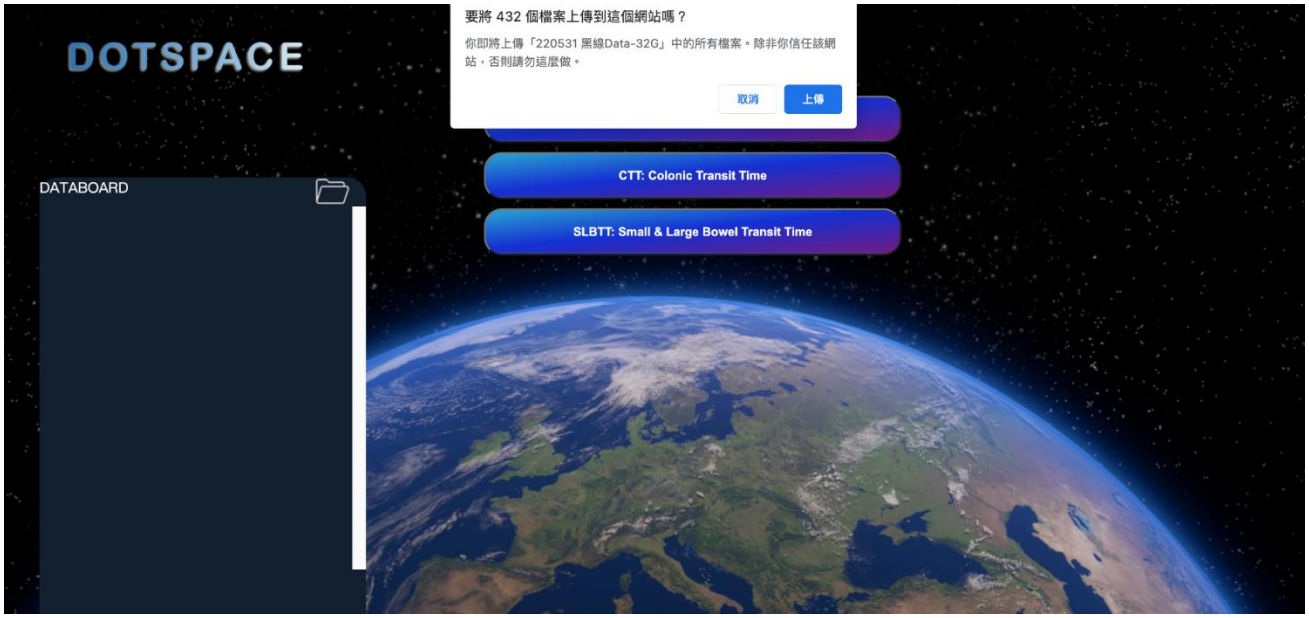
1. You will see a SW folder and an e-copy of the user manual in the flash drive.
2. Open the SW folder and find the “login.html” file.
3. Open the file with Chrome browser to begin the login process.
4. To login to the System Computer, enter the information below.

| | |
|---|---|
| ID | admin1234 |
| Password | admin1234 |

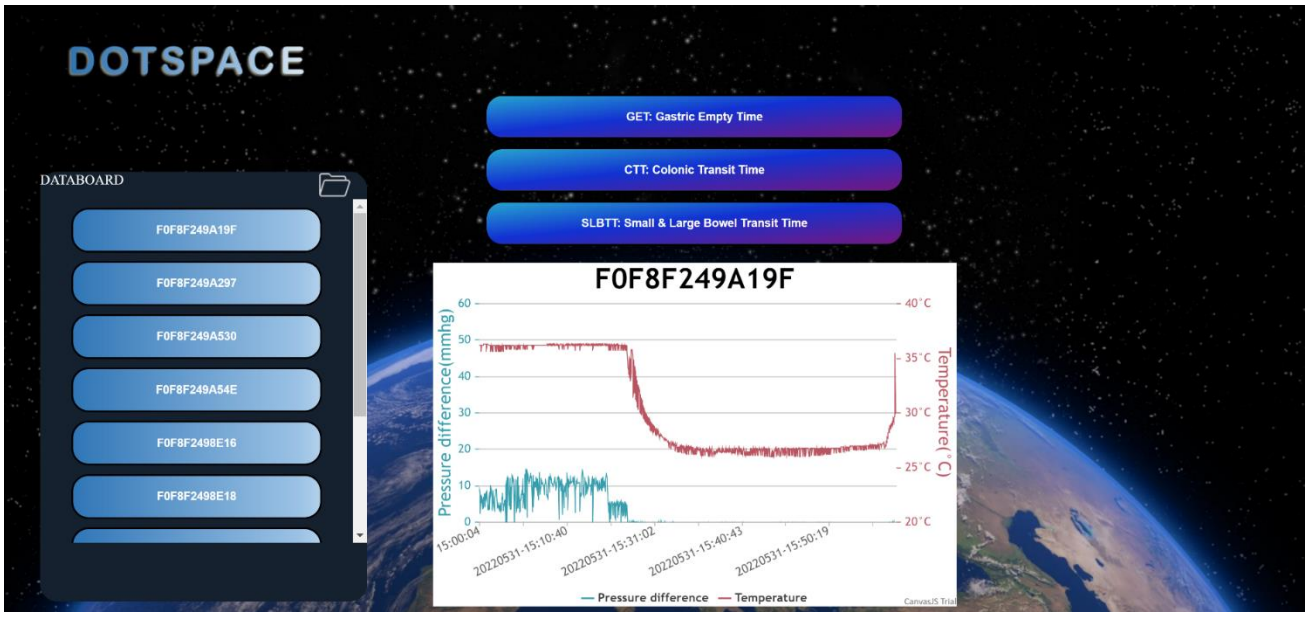
5. Click the file icon to browse the SD card folder



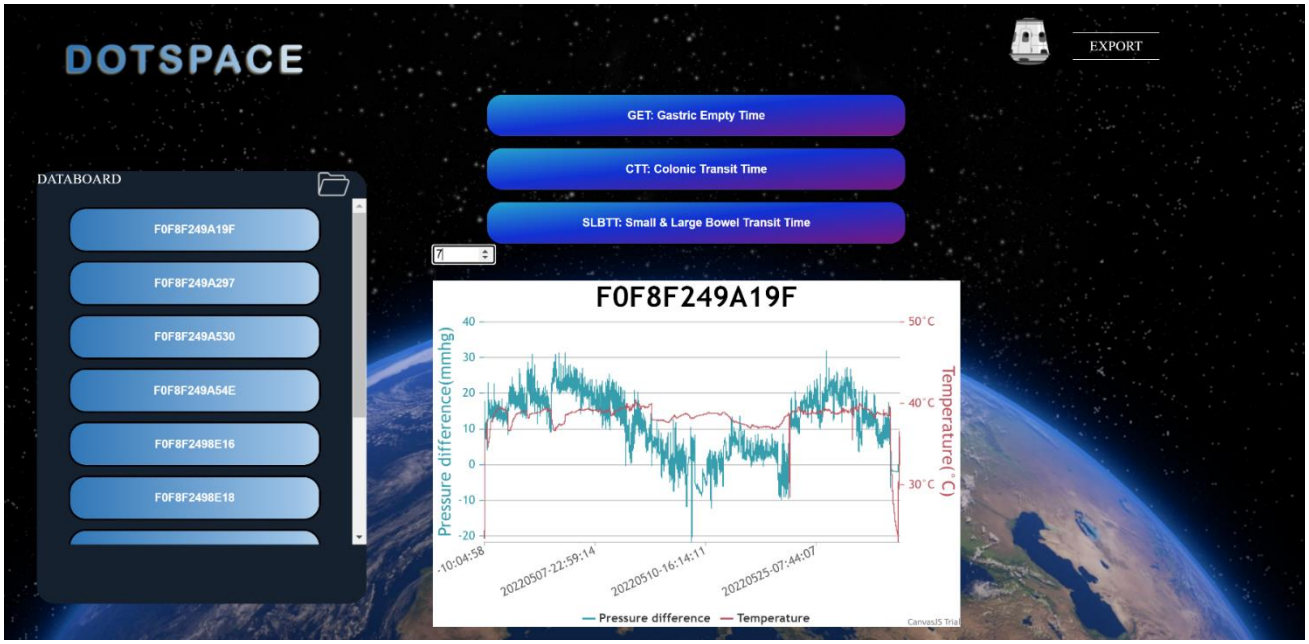

6. Select the SD card folder and click “upload”



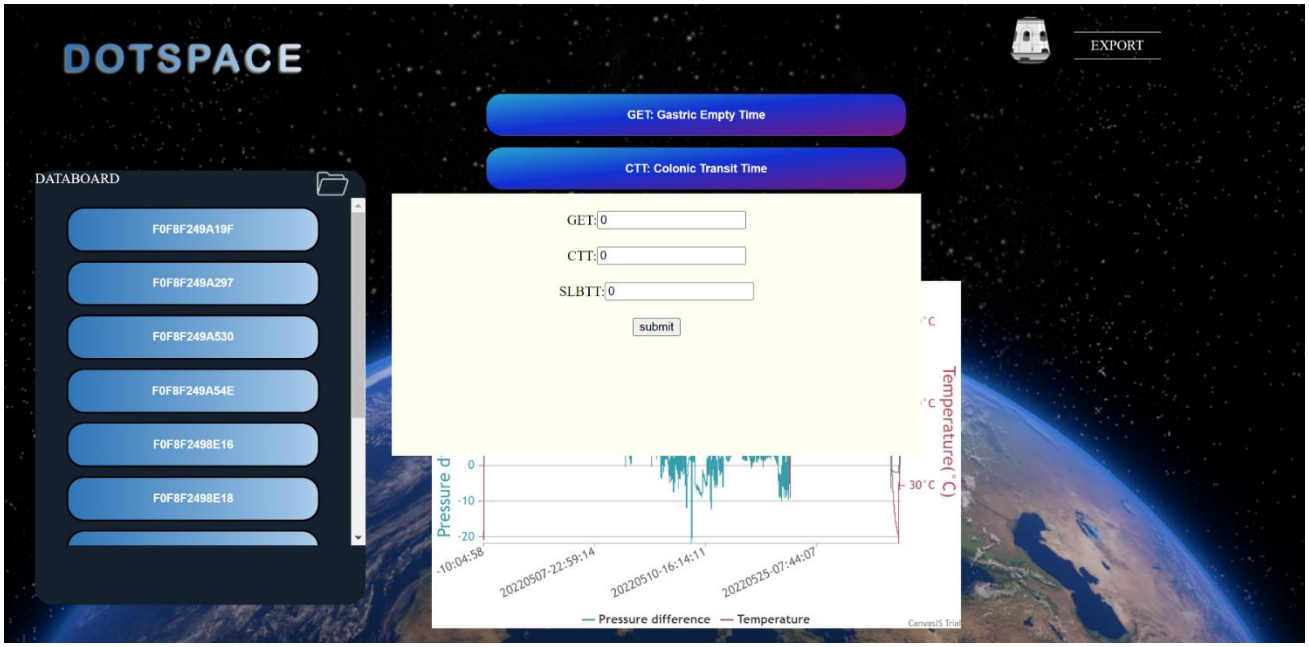

7. Select the MAC number corresponding to the capsule then the Pressure-Time and Temperature-Time diagram will be plotted automatically.




8. You can tune the curve by inputting the moving average number in the small window from 1 to 99.




9. Select the GET button to label the gastric empty time, same to the other two buttons.




10. You can export your result to a PDF file by clicking the "EXPORT" button.

**Caution**

You can also download the latest version of the software on our website: http://www.Dotspaceinc.com/

**Caution**

This software can only be launched by Chrome browser, and it does not manipulate any data. It only helps visualizing the data into line charts for better understanding,

all clinical diagnosis or judgment should be done by the medical staff, and you can always check out the raw data and make your own analysis.

# Aborting a Test – Deactivating the Capsule

**Caution**

If a test is aborted before ingestion, the capsule may be deactivated but must be used within one month or before its expiration date is reached, whichever is sooner. Otherwise discard the capsule (refer to Recycling and Disposal Instructions)

1. Placed the bottom of the capsule on top of the activation magnet to deactivate.
2. The green LED light will flash once when deactivated.
3. Put the capsule back into the blister and the package.

# System Administrator Tools

## Password Management

### *Logging into the Pdot_Plotter software*

The user ID and the password will be supplied by the Technical Support.

Since the plotter software only works on local server, the password management only provides simple protection, and the user should only use it on authorized computer only.

## Security of PressureDOT GI Monitoring System

1. The capsule only broadcasts signals by Bluetooth LE advertising without receiving data, and the data are all encrypted by AES-128.
2. The reader scans specific frequencies that are different from most of the commercial electronic devices.
3. The reader only receives the data from the capsule signal you selected and displays the value on the LCD panel while recording into the microSD card.
4. The reader could only write data into the microSD card, it cannot read data from it.
5. Only specified PC and operating environments are allowed to run the PDot_Plotter software and read the SD card.

6. The Pdot_Plotter software works on the local end, which means the PC doesn’ t need internet connection, and all data is preserved on the PC.
7. All data is de-identified, only the MAC address and the corresponding sensor value and tags are recorded, no patient information.

# Declaration

## Electromagnetic emissions

<table>
<tr><th colspan="3">Manufacturer’s declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The PDT-001 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.<br>The customer or the user of the PDT-001 should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance (for home and professional healthcare environment)</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The PDT-001 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 B</td><td rowspan="3">The PDT-001 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations /flicker emissions IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

# Electromagnetic immunity

| **Manufacturer's declaration-electromagnetic immunity**<br>The PDT-001 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.<br>The customer or the user of the PDT-001 should assure that it is used in such an environment. | | | |
|---|---|---|---|
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment-guidance (for home and professional healthcare environment)** |
| Electrostatic discharge(ESD)<br>IEC 61000-4-2 | Contact:±8 kV<br>Air±2 kV,±4 kV,±8 kV,±15 kV | Contact:±8 kV<br>Air±2 kV,±4 kV,±8 kV,±15 kV | 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<br>IEC 61000-4-4 | ± 2kV for power supply lines<br>± 1kV for input/output lines | Not applicable<br>Not applicable | Mains power quality should be that of a typical home and professional healthcare environment. |
| Surge<br>IEC 61000-4-5 | ± 0.5kV, ±1kV line(s) to line(s)<br>± 0.5kV, ±1kV,± 2kV line(s) to earth | Not applicable<br>Not applicable | Mains power quality should be that of a typical home and professional healthcare environment. |
| Voltage Dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | Voltage dips:<br>0 % $U_T$; 0,5 cycle<br>0 % $U_T$; 1 cycle<br>70 % $U_T$; 25/30 cycles<br><br>Voltage interruptions:<br>0 % $U_T$; 250/300 cycle | Voltage dips:<br>Not applicable<br>Not applicable<br>Not applicable<br><br>Voltage interruptions:<br>Not applicable | Mains power quality should be that of a typical home and professional healthcare environment. If the user of the PDT-001 requires continued operation during power mains interruptions, it is recommended that the PDT-001 be powered from an uninterruptible power supply or a battery. |
| Power frequency(50, 60 Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50 Hz or 60 Hz | 30 A/m<br>50 Hz and 60 Hz | The PDT-001 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

| Manufacturer's declaration-electromagnetic immunity | | | |
|---|---|---|---|
| The PDT-001 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.<br>The customer or the user of the PDT-001 should assure that it is used in such and environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment-guidance (for home and professional healthcare environment)** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms:<br>0,15 MHz – 80 MHz<br>6 Vrms:<br>in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br><br>80 % AM at 1 kHz | Not applicable<br><br>Not applicable | **Portable and mobile RF communications equipment should be used no closer to any part of the** PDT-001 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance:**<br>$d = 1,2\sqrt{P}$<br>$d = 1,2\sqrt{P}$ 80MHz to 800 MHz<br>$d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz<br>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 metres (m).<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Radiated RF<br>IEC 61000-4-3 | 10 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | 10 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | |
| NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

## Manufacturer's declaration-electromagnetic immunity
## Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The PDT-001 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.
The customer or the user of the PDT-001 should assure that it is used in such an environment.

| **Test frequency** (MHz) | **Band** [a] (MHz) | **Service** [a] | **Modulation** [b] | **Maximum power** (W) | **Distance** (m) | **IMMUNITY TEST LEVEL** (V/m) | **Compliance LEVEL** (V/m) (for home and professional healthcare) |
|---|---|---|---|---|---|---|---|
| 385 | 380 –390 | TETRA 400 | Pulse modulation b) 18 Hz | 1,8 | 0,3 | 27 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM c) ±5 kHz deviation 1 kHz sine | 2 | 0,3 | 28 | 28 |
| 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation b) 217 Hz | 0,2 | 0,3 | 9 | 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 | 28 |
| 870 | | | | | | | |
| 930 | | | | | | | |
| 1 720 | 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 | 28 |
| 1 845 | | | | | | | |
| 1 970 | | | | | | | |
| 2 450 | 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 | 28 |
| 5 240 | 5 100 – 5 800 | WLAN 802.11 a/n | Pulse modulation b) 217 Hz | 0,2 | 0,3 | 9 | 9 |
| 5 500 | | | | | | | |
| 5 785 | | | | | | | |

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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.

**Manufacturer's declaration-electromagnetic immunity**
**Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields**

The Model is intended for use in the electromagnetic environment (for home healthcare) specified below.
The customer or the user of the Model should assure that it is used in such an environment.

| Frequencies | Test Level [A/m] | Modulation | Dwell time [s] | Compliance LEVEL [A/m] (for home healthcare) |
|---|---|---|---|---|
| 30 kHz (a) | 8 | CW | 3 | 8 |
| 134,2 kHz | 65 | Pulse modulation (b) 2,1 kHz | 3 | 65 (c) |
| 13,56 MHz | 7,5 | Pulse modulation (b) 50 kHz | 3 | 7,5 (c) |

Note:

(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

(c) r.m.s., before modulation is applied.

# Recommended separation distance

**Recommended separation distance between portable and mobile RF communications equipment and the** PDT-001

The PDT-001 is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the PDT-001 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PDT-001 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** $d = 1{,}2\sqrt{P}$ | **80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$ | **800 MHz to 2,7 GHz** $d = 2{,}3\sqrt{P}$ |
| 0,01 | N/A | 0,12 | 0,23 |
| 0,1 | N/A | 0,38 | 0,73 |
| 1 | N/A | 1,2 | 2,3 |
| 10 | N/A | 3,8 | 7,3 |
| 100 | N/A | 12 | 23 |

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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Factory name: DOTSPACE INC.

Factory Address: 4F, no.118, Gongye 9th Rd, Dali District, Taichung 41280, Taiwan

Name of drug dealer: DOTSPACE INC.

Pharmacy Address: 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware 19801, United State.

Tel: 1-919-4577577

E-mail: service@dotspaceinc.com