AiDEX™ Continuous Glucose Monitoring System

User Guide

CE 0344

MicroTech Medical (Hangzhou) Co., Ltd.

Index

Important safety information

Indications for use

The Continuous Glucose Monitoring System (CGMS) is indicated for continuous or regular monitoring of glucose levels in subcutaneous tissue, and is used for daily detection and self-management of blood glucose levels in people 2 years and older. It is intended for use by patients at home and in healthcare facilities. Interpretation of the CGMS results should be based on the glucose trends and several sequential readings over time . The CGMS also aids in the detection of episodes of hyperglycemia and hypoglycemia, and facilitating therapy adjustments . The System is designed to replace fingerstick blood glucose (BG) testing.

Patients

This Continuous Glucose Monitoring System is suitable for patients with diabetes requiring regular blood glucose monitoring.

Contraindications

Patients who:

1. Suffer from alcoholism, drug abuse, severe mental disorders (such as depression, schizophrenia).
2. Are unconscious.
3. Are unable to understand or master the usage of the device.
4. Have severe hearing or vision impairment.
5. User below the age of 2 or are not capable of administering diabetes therapy themselves or who always

need to use Continuous Glucose Monitor under strict supervision of parents or qualified healthcare professionals.

Precautions

- CGMS readings should only be used as a reference for the supplemental monitoring of diabetes mellitus and should not be used as a basis for clinical diagnosis.
- The CGMS should be completely removed before Magnetic Resonance Imaging (MRI).
- The CGMS contains many small parts that can be dangerous if swallowed.
- During rapid changes in blood glucose (more than 0. 1mmol/L per minute), glucose levels measured in interstitial fluid by the CGMS may not be the same as blood glucose levels. When blood glucose levels drop rapidly, the sensor may produce a higher reading than the blood glucose level; Conversely,

when blood glucose levels rise rapidly, the sensor may produce a lower reading than the blood glucose level. When experiencing symptoms of hypoglycemic or hyperglycemic, the sensor readings are checked by using a blood glucose meter for a fingertip blood glucose test.

- Severe dehydration or excessive loss of water may result in inaccurate results. When you suspect you are dehydrated, consult a heathcare professional immediately.
- If you think the CGMS sensor reading is inaccurate or inconsistent, use a blood glucose meter to test your blood glucose level or calibrate the glucose sensor. If the problem persists, remove and replace the sensor.
- While extensive user testing was done on AiDEX™ CGMS in Type I and Type II diabetic patients, the study groups did not include women with gestational diabetes.
- The performance of the CGMS has not been evaluated when used with another implantable medical device, such as a pacemaker.

- Only MicroTech Medical consumables should be used with the CGMS.
- If the product is not working properly or has been damaged, stop using the product.
- When used in a medical facility, the operator should wear gloves while using.
- The CGMS can not be used in oxygen rich enviro-ment.
- Operator or the responsible organization shall read this instructions for use as the training or the knowledge required for using this equipment.
- Any serious injury or death that has occurred in relation to the device should be reported to the man-ufacturer and the competent authority of the Member State in which the user and/or patient is established.

Product components

Name: AiDEX™ continuous glucose monitoring system

System configuration: This product includes a Personal Diabetes Assistant, a Transmitter and a Glucose Sensor.

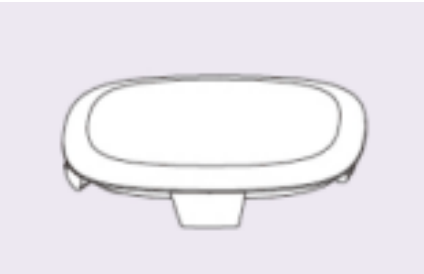
Personal Diabetes Assistant will be referred as PDA in the text below.

System	Sensor	Transmitter	PDA
G7	G7-S01	G7-T01	G7-P02 、 MTM-2
G7-A	G7-S01A	G7-T01A	
G7-B	G7-S01B	G7-T01B	

The PDA & Transmitter system consists of the following components:

- Personal Diabetes Assistant (Li-ion battery included)

- Transmitter



Warning :No modification of this equipment is allowed. Unauthorized modification of the equipment may cause the product to malfunction and become unusable.Replacement of a component could result in an unacceptable risk.

Warning :Remove the battery if not used for a long time ！

If the PDA battery charger does not work, do not try to repair it. Please contact your local supplier for a replacement.

Note:The device is intended to be transported and stored in waterproof case between use.Do not remove the waterproof case! Take it off, PDA waterproof performance is zero.

Warning :Using accessories, detachable parts and materials that are not specified in the instructions, or connecting the equipment to other equipment that is not specified in the instructions, may cause safety problems, such as hyperglycemia or hypoglycemia. Microtech Medical Ltd cannot be held liable for problems arising from the use of third party accessories.

WARNING: Use of accessories, cables, adapters, and chargers 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 : Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.

Warning :

Do not place CGMS in direct sunlight or dusty areas.

Always keep your PDA port free of debris and liquids,Lint,dirt, dust, and liquids can impair the functionality of your device or damage it.

Aovid storing CGMS components in a place where children, pets, or pests may access. Unintended access could result in damage to system parts or impact their sterility.

Warning:Use only batteries and chargers from MicroTech Medical. Use of third party accessories may cause unexpected behavior and will void your warranty.

Warning:DO NOT allow small children access to small parts, such as the sensor and its accessories. Small parts could be swallowed and pose a choking hazard. If ingested or swallowed, these small parts could cause internal injury or infection.

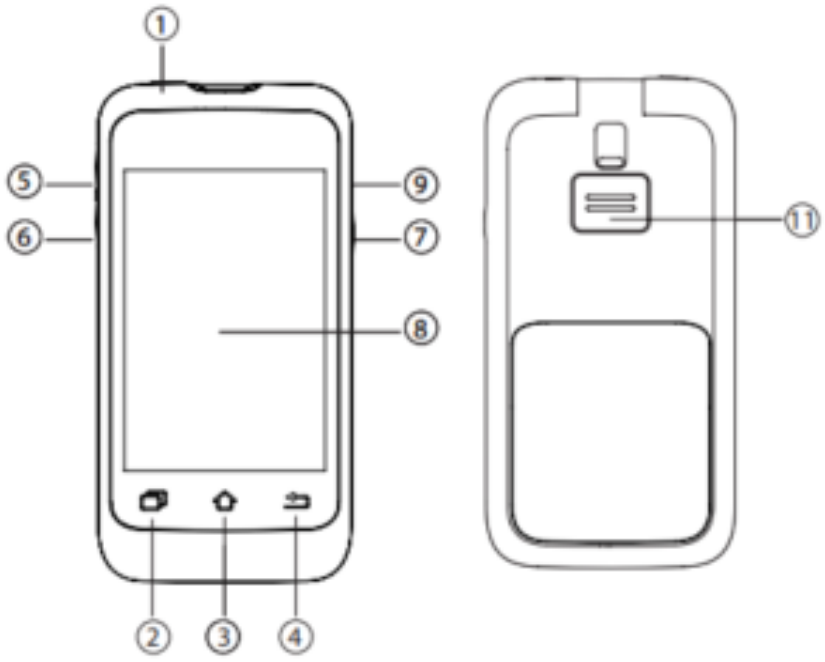
The glucose sensor system consists of the following components:

- Applicator with Built-in Sensor

Component description

Personal Diabetes Assistant

The PDA is used to display glucose readings and historical data when paired with an operational sensor transmitter set.



① Power button

Power on: Press and hold the power button, the PDA will vibrate indicating that the device is starting up. After about 30 seconds, it will enter the Home Screen.

Power off: Hold the power button until a confirmation notification appears . Confirm and shutdown the device.

Display on: While in stand by mode, press the power button and the display will show the lock screen.

Display off: When the display is on, press the power button once and the display will turn off. The PDA will enter standby mode.

② Help button

When certain functions are not clear, you can consult the Help-button to display helpful information.

③ Home button

Press the Home Button to return to the Home Screen.

④ **Back button**

Click this button to return to the previous screen or close a pop-up dialog.

⑤ **Up button**

⑥ **Down button**

The Up and Down Button can be used to adjust the brightness of the PDA screen dispaly.

⑦ **Enter button**

The Enter Button can be used to confirm entered information without touching the screen.

⑧ **Display**

3.5 inch color touchscreen.

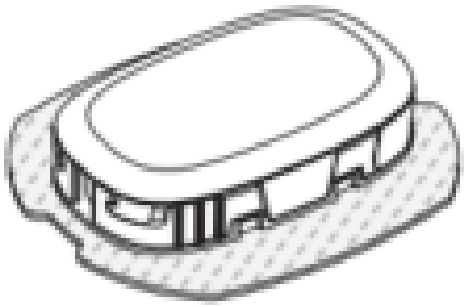
⑨ **USB port**

For PDA charging and USB data transmission.

⑩ **Speaker**

Transmitter

The transmitter is used together with the glucose sensor base.sensor and ransmitter set as applied parts. When the sensor and transmitter are ac- tivated on one's body, it measures and stores glucose readings as well as transmitting the readings to the PDA/the AiDEX ™ mobile App.

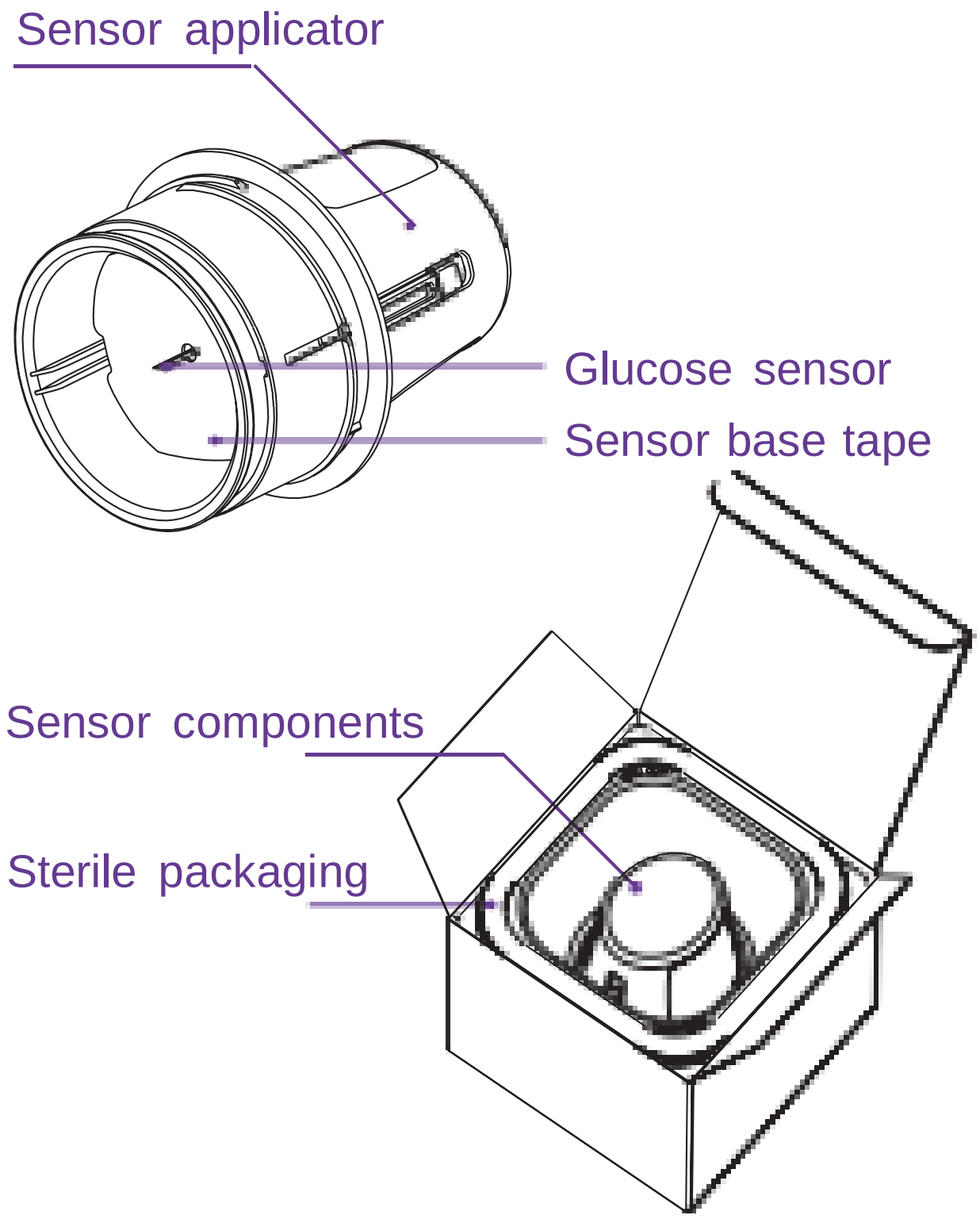


Glucose sensor package

The glucose sensor package contains a sterilized glucose sensor attached to a sensor base, and a sensor applicator.The package is sterilized by gamma irradiation.

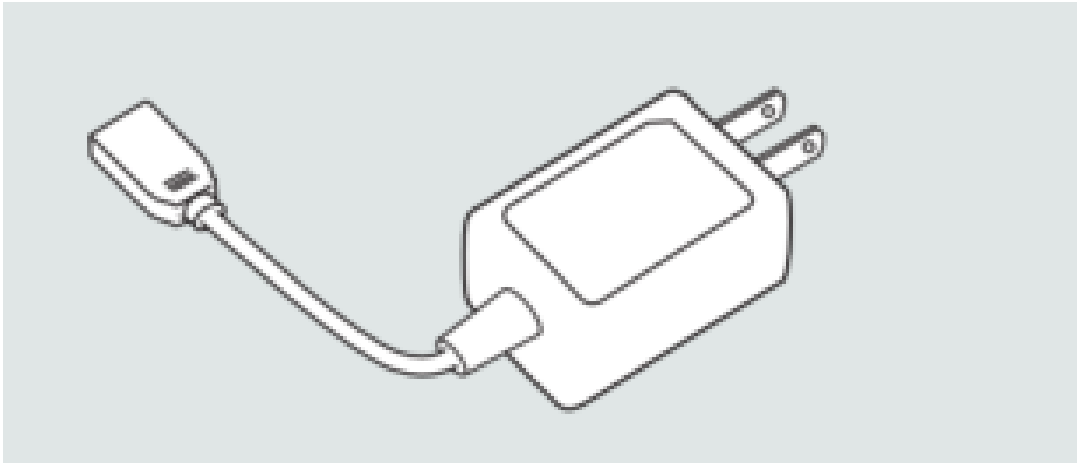
Note

General risks associated with Sensor base tape may include skin irritation or redness.


Sensor applicator
Glucose sensor
Sensor base tape
Sensor components
Sterile packaging

Accessories

- **PDA Charger**（Use only with AiDEX™ continuous glucose monitoring system packaging）

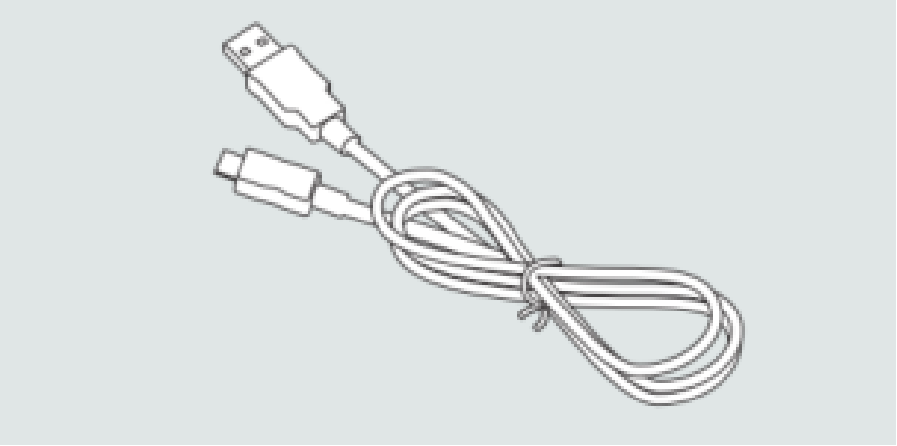


Waring: The included charger can be used in wall outlets rated at AC 100-240V ～50/60Hz. Connection to outlets that are outside this range can cause damage.

Power Supply/Charger Specifications

Input	5 V DC, 1A USB A to USB micro B
DC Output	5V DC, 1A
Use life	5 years

- **PDA Charging Cable（Use only with AiDEX™ continuous glucose monitoring system packaging）**



Warning: Please keep the charging cable away from children, the charging cable may wrap around the neck and cause strangulation

USB Charging/Download Cable Specifications

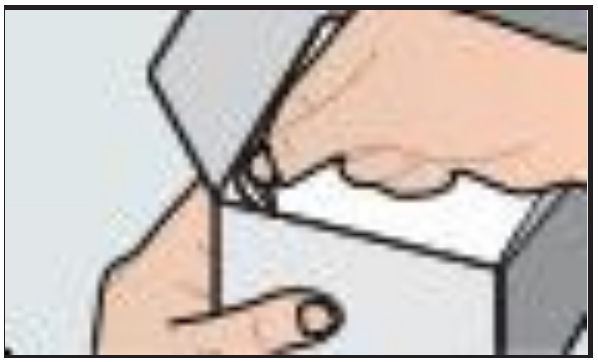
Input/Output	5 V DC, 1A
Type	USB A to USB micro B
Length	3 feet
Use life	5 years

Using a new glucose sensor

Applying a sensor

- Recommended areas for sensor application includes the abdomen, the outside and the back of the upper arm . For best performance, avoid excessive motion which may weaken the sensor and its adhesive tape. Avoid accidental knocking off the sensor. It is strongly recommended to put sensor on your abdomen rather than arms or other areas.
- Before application, use alcohol pads to disinfect your select-

ed skin area and wait for a minute to let the skin dry. Change your sensor sites regularly to avoid discomfort or skin irritation.

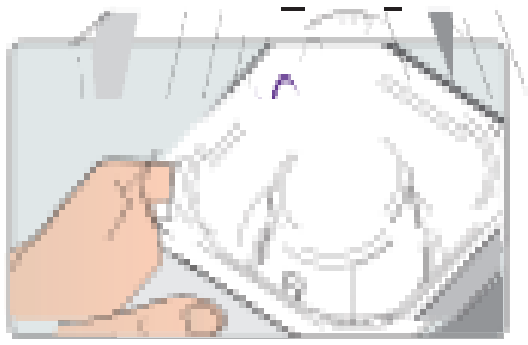


- Open the sensor package.

Note

Ensure the sensor is not expired by checking its expiration date. If the sensor is expired or the sterilized package is damaged, please do not use it,,which may result in no glucose readings and infection.

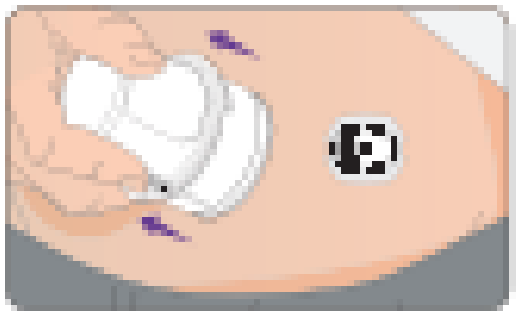
- Take out the sensor applicator by turning it anti-clock wise.



- Place the applicator on the top of the desired sensor site. Press it firmly against skin and press the button to launch the sensor.

After inserting the sensor, wait a few seconds to allow the sensor base patch to adhere to the skin.

- Remove the applicator. The sensor should be applied successfully.



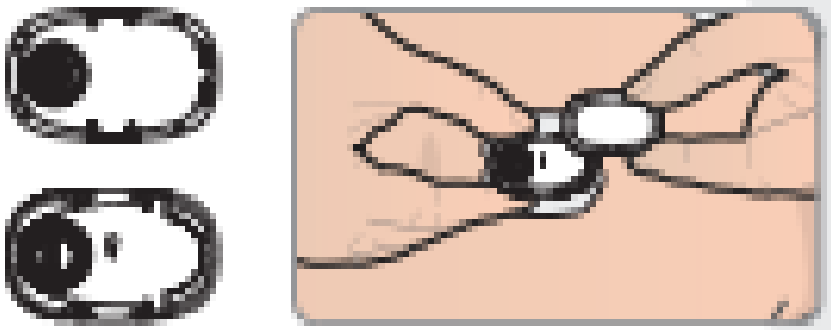
Note

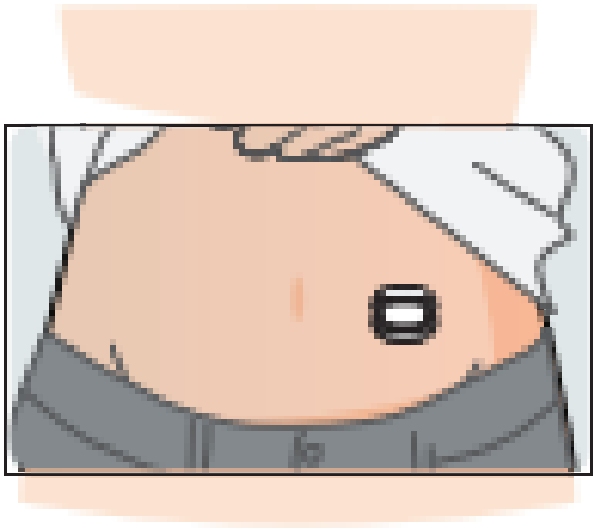
Applying a sensor may cause bruising or bleeding. If bleeding does not stop, remove the sensor and apply a new sensor to a different location.

Note

The sensor and sensor applicator are designed for single use. Reuse may result in no glucose readings and infection.

Align the transmitter to the sensor base and press the transmitter firmly onto the sensor base until it snaps onto the sensor base and attaches to it securely.





Note

If the orientation of the transmitter and sensor base mismatch, the transmitter cannot be installed properly.

You won’t get s or CGMS readings during the 1-hour warmup or after a sensor session ends.Sensor coming out of body.

- The recyclable applicator is meant for single use only. Dispose the used sensor package and sensor applicator according to your local regulations.

Note

The applicator contains a needle, please dispose of it properly to avoid any possibility of injury to others.

- Follow the steps described above carefully and be sure to only use components that are made by MicroTech Medical . Use of unapproved components can result in injury.

Setting the Personal Diabetes Assistant (PDA) for the first time

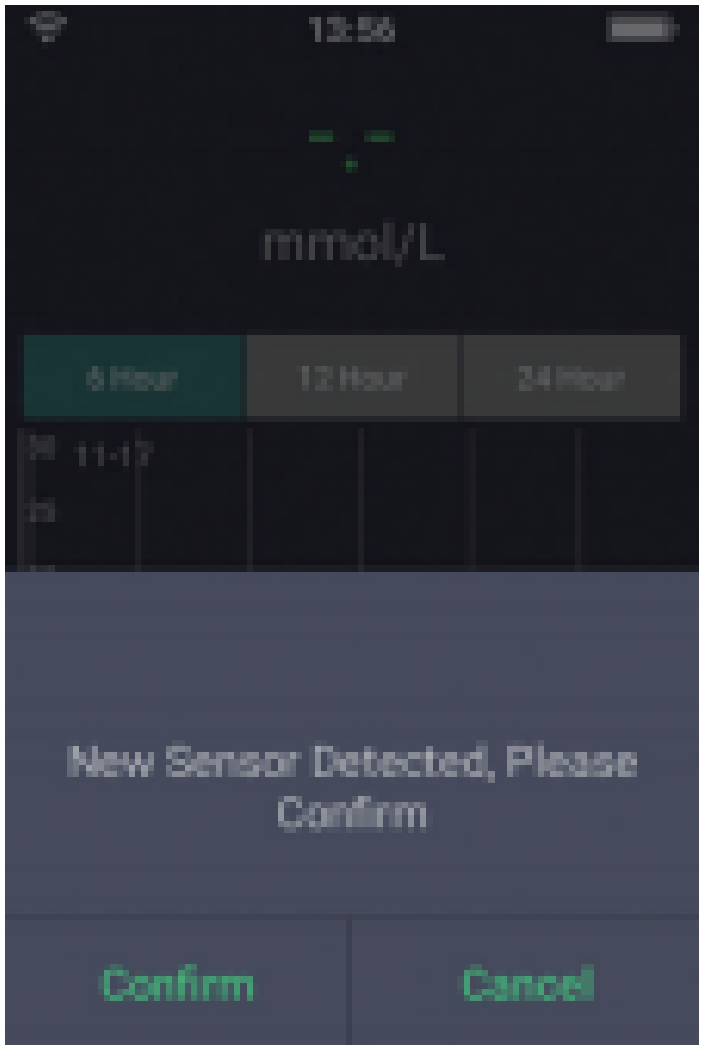
When using the PDA for the first time, set the date and time.

- **First time start up:** Press and hold the power button, the PDA will vibrate, indicating that the PDA is powered on. After about 30 seconds the Setup Wizard will appear and guide you through entering basic settings.

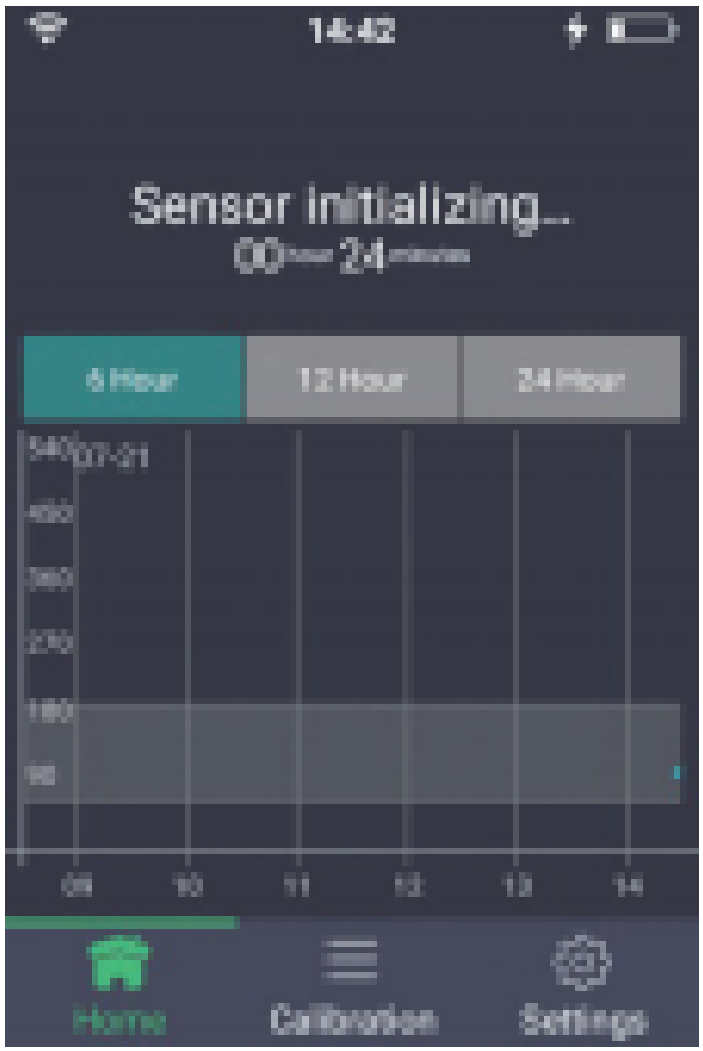
- When you open the installation wizard, the first thing you will see is the date and time setting. Set the correct date, time, timezone and click OK.

Sensor start-up

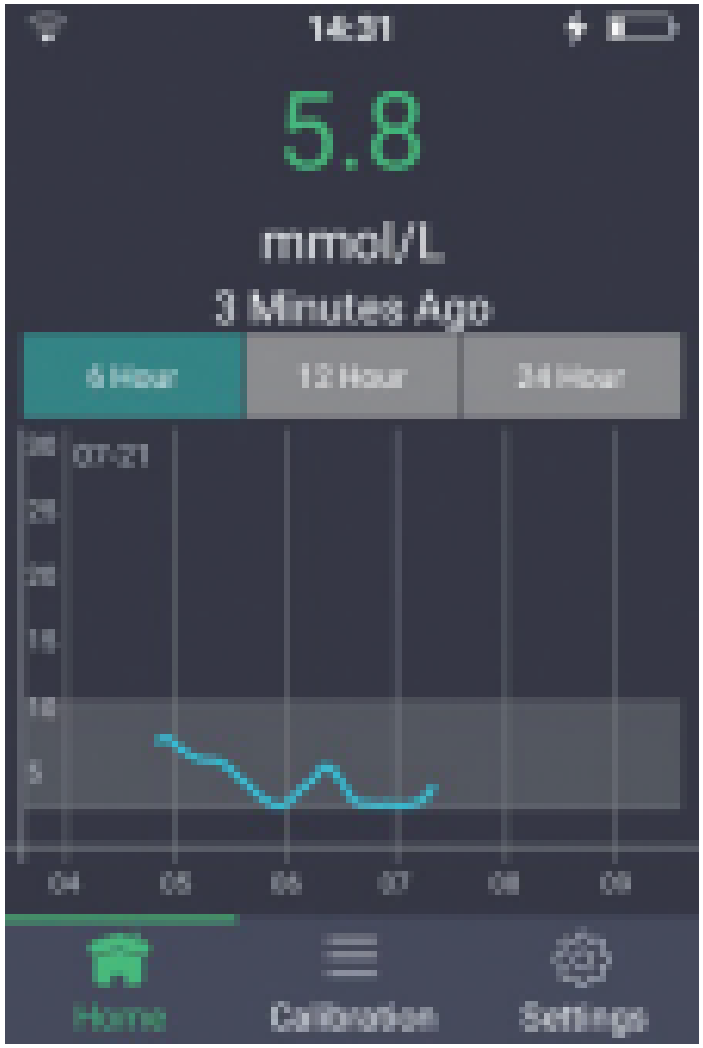
- After the sensor is successfully applied to your body and connected to the transmitter, the paired PDA will display “New sensor detected, please confirm.” Press the “Confirm” to continue.



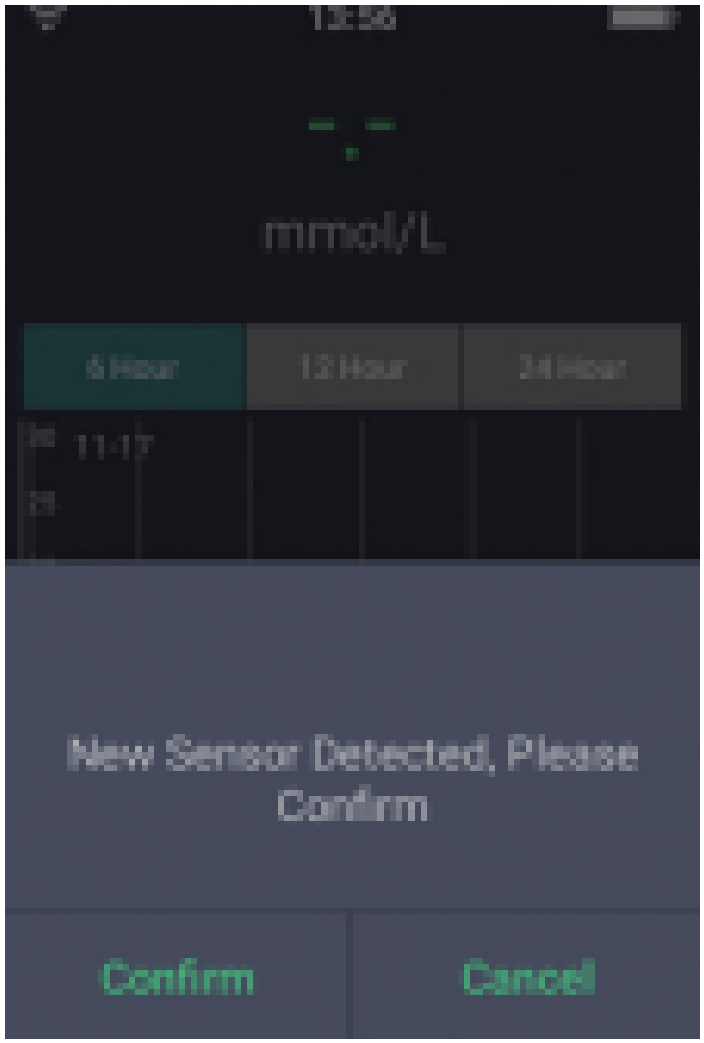
• Now the PDA will display “Sensor initializing” . Sensor initialization typically takes about 1 hour to complete.



- When the sensor initialization is complete, the PDA will begin to display the current blood sugar value.



- When the transmitter loses the connection with the sensor and reconnects, the PDA will ask you to confirm. Please press “Cancel” if you already completed the initializing process. The PDA will skip initialization and starts displaying your current blood glucose value immediately. If you press “Confirm”, the sensor will start initializing again.
- At this point, the PDA skips initialization and starts displaying the current blood sugar value directly.



Note

Do not cancel the initialization process when using a new sensor. Skipping new sensor initialization may make the system display incorrect blood glucose values.

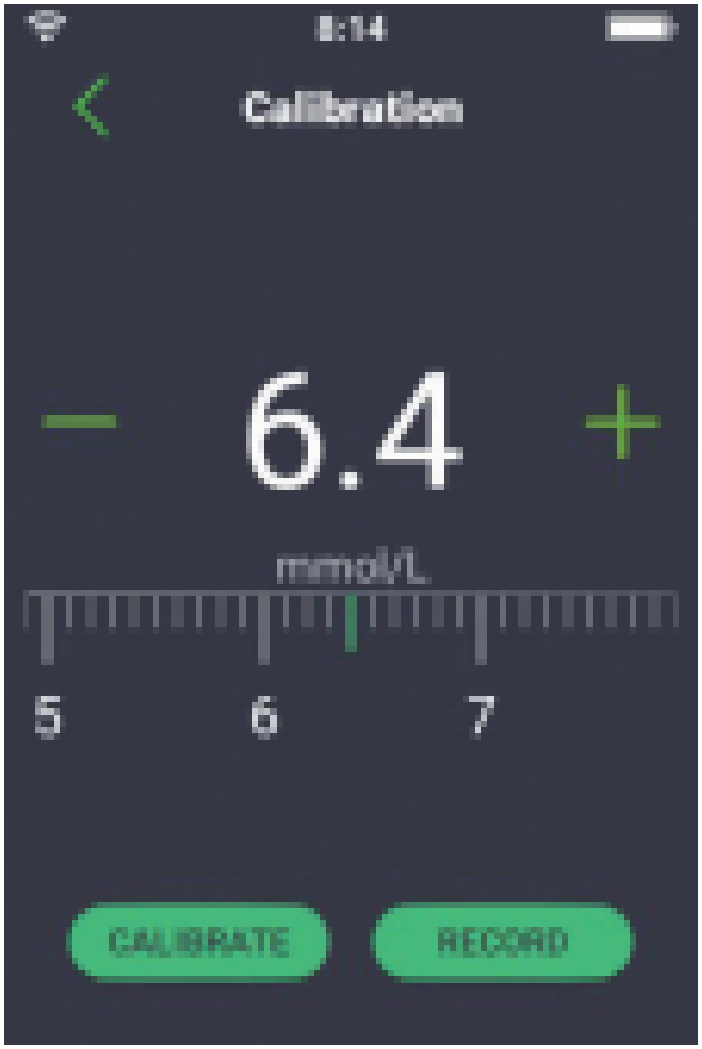
Sensor calibration

After a new sensor is initialized, you can calibrate the CGMS as needed. Please calibrate the system only when blood glucose is relatively stable - the interstitial glucose has a physiological lag compared to capillary blood glucose so calibrate the CGMS when blood glucose is rapidly changing may cause the CGMS to be less accurate.

Please calibrate the system only using reliable blood glucose test values - Use certified BG meter and test strips that are within expiration date; ensure the BG meter readings are consistent by performing two or three repeating tests; make sure the finger is cleaned with alcohol wipes and dried before the finger prick.

Avoid any calibrations in the first 6 hours after the sensor warming-up, which might affect the CGM accuracy afterwards.

- If you want to use the measurement from a different blood glucose meter for calibration, press “ Manual Calibration” when the PDA shows “ Please insert blood glucose test strip” . Enter the value manually and press “Calibrate” to finish the calibration.



- If you doubt that the glucose level displayed by the CGMS is correct, you can use the calibration function to confirm the performance. However, do not abuse the calibration. i.e. No more than once every 6 hours.

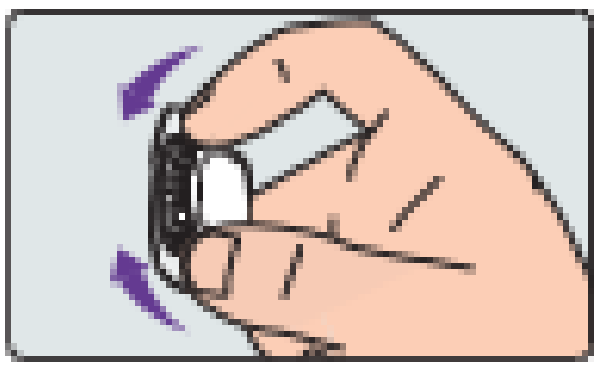
Important

Do not calibrate more than once every 6 hours.

Removing a sensor

Remove the old sensor when the PDA indicates that the sensor has expired or if you feel any site irritation or discomfort.

- Carefully pull the tape that holds the sensor to the skin from the edge and slowly uncover it until the entire sensor is removed. You can use warm soapy water to remove any remaining sticky residue.
- Press the two locking arms on one side of the sensor base, pull the transmitter away from the sensor base, and then remove the transmitter so that it can be used again.
- The sensor is meant for one-time use only. Dispose the used sensor according to your local regulations.



WARNING

Wire Breaks Off

Don’t ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can’t see it, don’t try to remove it. Please contact your local dealer.Also seek professional medical help if you have symptoms of infection or inflammation – redness, swelling, or pain at the insertion site.

PDA settings

Target glucose range

You can change the thresholds for high glucose and low sensor glucose . These settings change the normal range of sensor glucose concentrations displayed on the home page and when high/low glucose s are triggered.

- Before setting the target glucose range, please make sure that the transmitter is connected to the sensor base, and that the PDA and transmitter have a good wireless connection.
- Press “Settings” on the PDA’s home screen to enter the settings menu.
- Press “Hi BG Threshold” to enter the desired sensor blood glucose threshold. The threshold range is 8.0-25.0 mmol/L (144-450 mg/dL)(default value is 12.0 mmol/L).

- Press “Lo BG Threshold” to enter the desired low sensor glucose threshold. The threshold range is 2.2 -5.0 mmol/L (39.6 mg/dL – 90 mg/dL) (default value is 3.5 mmol/L).
- Add “Press “OK” to confirm” .

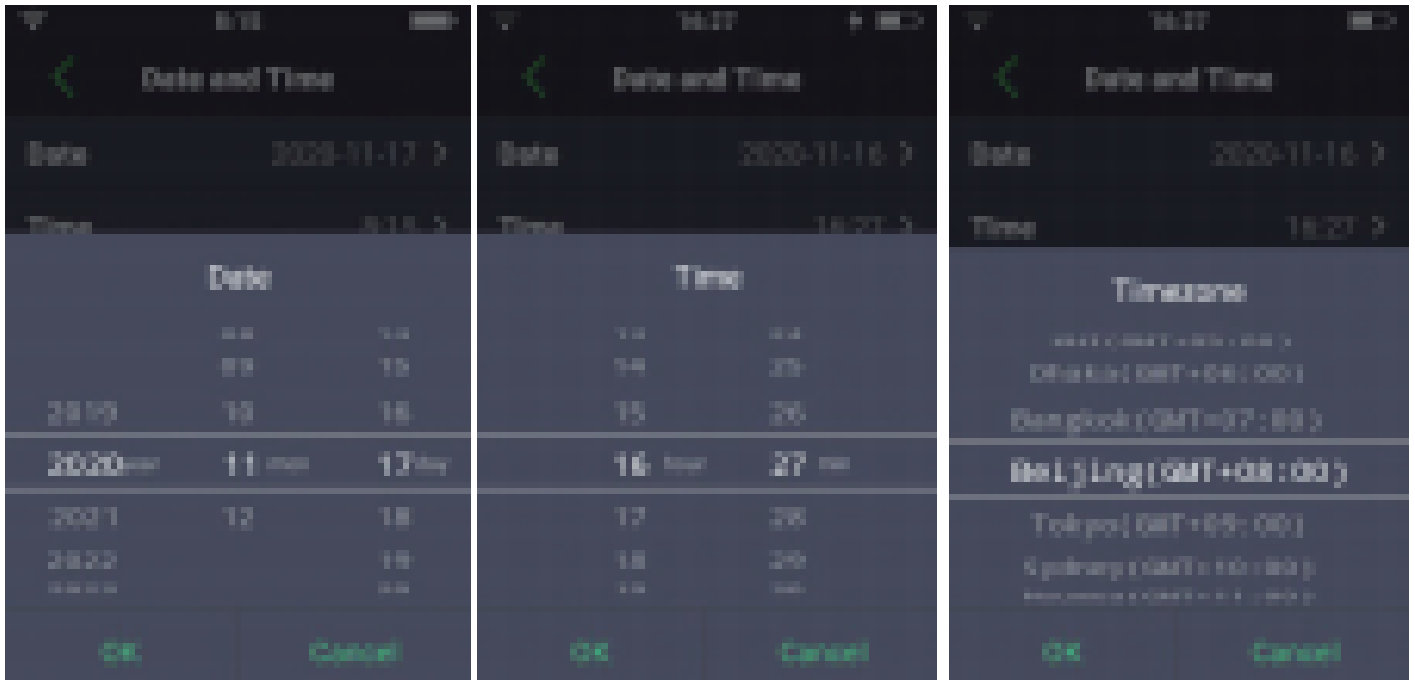
- After entering the preferred threshold values the PDA will update the system settings. After updating, the

PDA will display “settings changed successfully” .

- When the PDA and the transmitter are not within the communication range, the PDA will show “settings change failed” . Make sure that the PDA and transmitter are within communication range and try again.

Date and time settings

- Press “Settings” on the PDA’s home screen to enter the Settings menu.
- Press the “Date” or “Time” or “Time zone” option.
- Set the correct date, time and timezone and click “OK” .



Using the PDA

Pairing with a new transmitter

Note

For safety reasons, the PDA can only be paired with one transmitter at a time.

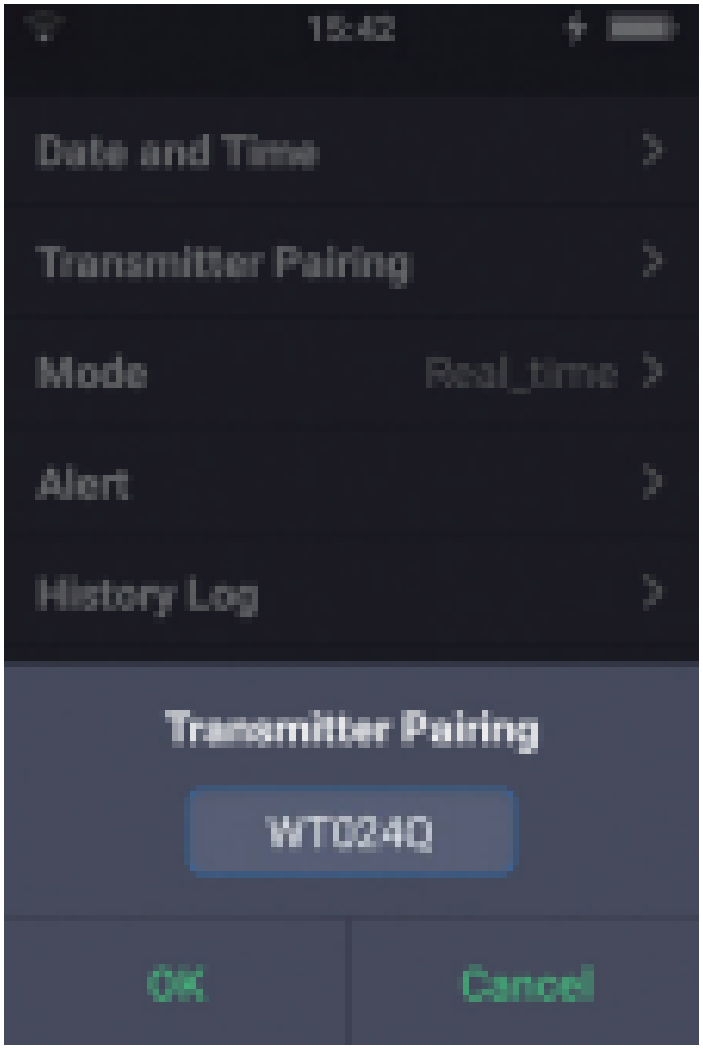
- Before pairing, please find your transmitter serial number on the transmitter box . Make sure the new transmitter is assembled to the sensor base.
- Press “Settings” on the PDA’s home screen to enter the Settings Menu.
- Press “Pair transmitter” .

- If the PDA is already paired with a transmitter, click “ Transmitter Pairing” and a pop- up window will appear. It shows “ The PDA already had a transmitter paired to it. Unpair the old transmitter, Press OK to unpair the old transmitter and pair a new one.

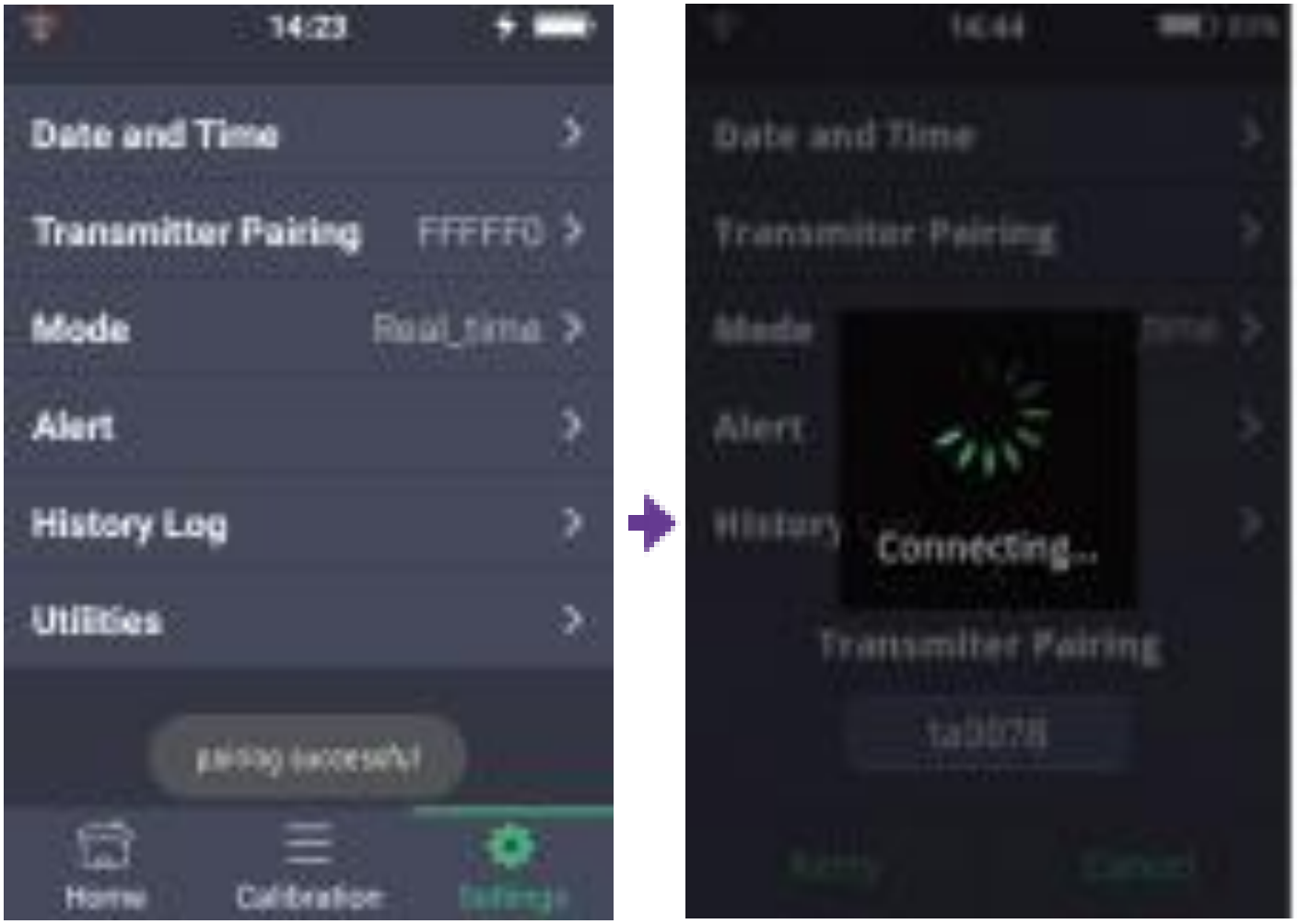
Note

When unpairing an expired transmitter, make sure that the PDA and transmitter are within communication range and have good connection. If the connection is lost during unpairing, the transmitter may encounter difficulties re- pairing to PDA in the future.

• Enter the transmitter’s serial number when prompted.



• Click “Confirm” . The PDA will search for a connection and show “Pairing successful” when the connection has been made.



PDA Cautions

caution description	Solution/Action
Low Blood Glucose	Perform a finger- tip glucose measurement using an approved glucose meter to confirm the sensor glucose reading. If the measure- ment indicates low blood glucose, please take actions to raise blood glucose immedi- ately and call for medical assistance
High Blood Glucose	Perform a finger- tip glucose measurement using an approved glucose meter to confirm the sensor glucose reading. If the measure- ment indicates high blood glucose, please take medicine or inject appropriate amount of insulin according to doctor's prescription.
Sensor Expired	Remove the current glucose sensor and replace it with a new sensor.
Sensor Error	Check if the current sensor has peeled off or partially peeled off from the skin. If yes, please remove the current sensor and re- place it with a new sensor. If the sensor is still firmly attached to the skin, but the Sensor Error message continue to appear for more than 30 minutes, Please remove the current sensor and replace it with a new sensor.
Other Unspecified Errors	Please switch off the PDA and restart it. If the error message continue to appear, please contact our customer service.

Charing the Personal Diabetes Assistant (PDA)

A fully charged PDA should last up to 4 days. Battery life may vary depending on your usage . When the remaining battery power is about enough for one day, the PDA will give a low battery warning.

- Insert the PDA charging cable into the PDA charger. Plug the other end of the charging cable into the PDA's charging port.
- Insert the PDA charger into a power outlet.
  - A battery charging animation will be displayed if the PDA is off.
  - When the PDA is on, the battery icon will change to the charging icon.
- It may take up to 2 hours to fully charge the PDA's battery.
- Batteries generally have a service life of about 4 years, but may vary depending on your usage.

- When the battery needs replacement, please contact our customer service staff to obtain a new one.

Note

Be sure to use batteries and chargers provided by MicroTech Medical. Use of unapproved components can result in injury.

Warning： The included charger can be used in wall outlets rated at AC 100-240V ～50/60Hz. Connection to outlets that are outside this range can cause Damage.

Caring for your Continuous Glucose Monitoring System (CGMS)

Cleaning the PDA and transmitter

1. Use alcohol wipes to clean the pump outer surface thoroughly until there are no obvious dust particles and stains left by visual inspection.

2. It is recommended to clean every 3 days.

Note

Do not immerse the PDA or transmitter in water or other liquids. Avoid dust, dirt, blood, chemicals, water, or other substances on the PDA's test strip and charging ports.

Equipment shall not be serviced or maintained while in use.

No cleaning methods are recommended or tested for the PDA. Only wipe with a clean, dry cloth.

Disposal

Dispose PDA, transmitters and sensors that you do not use any more in compliance with local regulations for electronic devices, batteries, sharps, and biohazard materials. Please do not discard old products or accessories directly. For further information on how to dispose of system components, please contact customer service.

Do not discard the battery if it is damaged or expired. Please recycle batteries in accordance with local battery disposal regulations.

Note:

1. At the end of service life or scrap of the device, remove the batteries and send batteries and device to the corresponding designated recycling locations separately.
2. The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.
3. Please dispose according to the local laws or consult with dealer from whom you purchased it about waste disposal.

Transportation

Avoid placing heavy weight on top of the PDA and transmitter. Avoid direct sunlight and rain.

Storage

If you are temporarily not using the PDA, transmitter, or sensor system, store the components in a cool, dry, clean and well-ventilated area. If you decide not to use the PDA for a prolonged period, the battery should be stored separately.

The PDA, transmitter and sensor are precision instruments . If they fail, they can only be returned to the manufacturer to repair. No third- party individuals or organizations are allowed to perform repairs. Circuit diagrams and component lists are not provided in the manual.

Warning:Please strictly follow the instructions to perform adjustment, cleaning, sterilization, and disinfection procedures.

Warning:Avoid exposing the Transmitter and PDA to temperatures above 60℃ and below 20℃.The time required from extreme storage temperature to normal

infusion status is : 8mins from 60 ℃ to 20 ℃,1min from -20℃ to 20℃.

Specifications

Item	Subcomponent		
	Transmitter	Sensor	PDA
Model number	G7-T01 G7-T01A G7-T01B	G7-S01 G7-S01A G7-S01B	G7-P02、MTM-2
Operating temperature	5-40℃(41-104 ℉)		
Operating humidity	10-93% (non-condensing)		
Operating pressure	700hpa~1060hpa		
Storage and transporta- tion temperature	-20℃ -60℃	4℃ -30℃	-20℃ -60℃
Storage and transporta- tion humidity	5-95% (non-condensing)		
Storage and transporta- tion pressure	700hpa~1060hpa		
Ingress protection level	IP48(combination)		IP20(without waterprof IP02)
Battery	40mA		2100mA
Use life	4 Years	G7-S01: 14 days G7-S01A: 10 days	4 Years

		G7-S01B: 7 days Shelf life: 1 year	
Detection range	2.0mmol/L-25.0 mmol/L		
Measurement accuracy	When the glucose concentration >4 .2mmol/l (75mg/dL), the accuracy deviation of the sensor does not exceed ±20%; when the glucose con- centration ≤4.2 (75mg/dL), the accuracy deviation does not exceed ±1mmol/l (18mg/dL).		
Wireless frequency and bandwidth	Frequency: 2.402GHz ~ 2.48 GHz Bandwidth: 1Mbps		
Wireless frequency	2402MHz~2480MHz		2402MHz~2480 MHz
Wireless modulation	GFSK		GFSK
Conducted output power	-2.34dBm		-3.42dBm

Security Measures

The CGMS System is designed to transmit data between the transmitter and designated display devices in accordance to the industry standard BLE protocols. It will not accept radio frequency (RF) communications using any other protocol, including Bluetooth classic communication protocols.

In addition to the security provided by the BLE connection, communication between the CGMS transmitter and the CGMS receiver

and mobile applications is protected by additional levels of security and safety mitigations using an encrypted and proprietary data format. This format embeds various methods to verify data integrity and to detect potential instances of data tampering. While the format is proprietary, industry standard encryption protocols (e.g., RSA and AES) are used in different parts of this proprietary data format. Unless disabled, the CGMS mobile application regularly communicates with Servers. Communication between the CGMS applications and Servers is protected by a number of mechanisms, designed to safeguard against data corruption. This includes industry standard JWIT token based authentication and authorization. All such communication takes place exclusively over encrypted data path using industry standard SSL format.

Electromagnetic compatibility

These devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Portable and mobile RF communication interference may have an impact on the device.

Please use the cables and accessories provided. The cable information is as follows:

#	Item	Length(m)	Shielded	Notes
1	PDA charging cable	1.0m	Yes	EUT DC 5V

The use of accessories other than those specified for the device is not recommended . They may result in increased emissions or decreased immunity of the device.

The device should not be used adjacent to or stacked with other equipment . If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic interference can still occur in the home health care environment as control over the EMC environment cannot be guaran-teed. An interference event can be recognized by gaps in CGMS readings or gross inaccura-cies. The user is encouraged to try to mitigate th-ese effects by one of the following meas-ures:

• If your symptoms don’t match your CGMS readings, use your BG meter when making treatment decisions. If your CGMS readings don’t consistently match your symptoms or BG meter values, then talk to your healthcare professional about how you should be

using the CGMS to help manage your diabetes. Your healthcare professional can help you decide how you should best use this device.

The basic performance is described in the table below:

Performance	Description
Measurement accuracy	When the glucose concentration is >4 .2mmol/L (75mg/dL), the sensor accuracy deviation does not exceed ±20%; When the glucose concentration is ≤4.2mmol/L (75mg/dL), the accuracy deviation does not exceed ±20mg/dL

IEC60601-1-2 Table 201

Guidance and manufacturer' s declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage power supply.
Harmonic emissions IEC 61000-3-2	Class A	Move to a place within the normal operating temperature range and repeat the test.
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	Repeat test. If you see the same result, contact your healthcare professional immediately.

IEC60601-1-2: Table 202

Guidance and manufacturer' s declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC 60601-4-2	±6KV contact ±8KV air	±6KV contact ±8KV 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	±2KV power cord ±1KV input/output	±2KV power cord ±1KV input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1KV line to GND ±2KV line to GND	±1KV line to GND ±2KV line to GND	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	<5% UT for 0.5 weeks (>95% dip in UT) 40% UT for 5 weeks (60% dip in UT) 70% UT for 25 weeks (30% dip in UT) <5% UT for 5s (>95% dip in UT)	<5% UT for 0.5 weeks (>95% dip in UT) 40% UT for 5 weeks (60% dip in UT) 70% UT for 25 weeks (30% dip in UT) <5% UT for 5s (>95% dip in UT)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field should have the characteristics of power frequency magnetic field level at atypical place in a typical commercial and hospital environment

IEC 60601-1-2: Table 204

Guidance and manufacturer' s declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure 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 Radiated RF IEC 61000-4-3	3V(Vrms) 150kHz~80MHz 10V(engineering medical frequency band) 150kHz~80MHz 3V/m 80MHz~2.7GHz	3V(Vrms) 10V (engineering medical frequency band) 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, 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 80MHz~800MHz d=2.3 √P 800MHz~2.5GHz 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).Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol: 

IEC60601-1-2: Table 206

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Maximum rated output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
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

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.

FCC Statement：

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

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

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

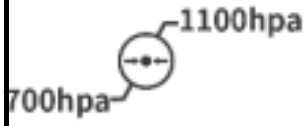
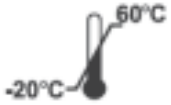
—Consult the dealer or an experienced radio/TV technician for help.

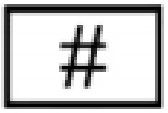
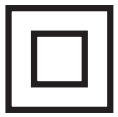
This device complies with FCC radiation exposure limits set forth for an uncontrolled environment.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference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

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

Appendix

Symbols

Atmospheric pressure limitation		Humidity limitation	
Do not re-use		Temperature limitation	
Protected from tools and small wires greater than 1 millimeter. Protected from long term immersion up to a specified pressure.	IP48	Protection against solid particle of diameter greater than 12.5 mm	IP20
Protected from touch by fingers and objects greater than 12 millimeters. Protected from immersion between 15 centimeters and 1 meter in depth.	IP27	Medical Device	MD

Consult Instructions for Use		Type BF Applied Part	
Use by date		Modle Number	
Manufacturer		Date of manufacture	
Lot Number		Handle With Care	
Serial Number		Do Not Dispose with Household Waste	
Sterilized by EO		Class 2 Equipment	
Biohazard		Keep Dry	

Non-Ionizing Radiation		Recyclable	
See Instructions for Use		Refer to Instruction Manual	
Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.	**IP21**	Protected from touch by fingers and objects greater than 12 millimeters.Protected from water spray less than 15 degrees from vertical.	**IP22**
Not protected from solids. Protected from water spray less than 15 degrees from vertical.	**IP02**	Protected from touch by fingers and objects greater than 12 millimeters. Protected from long term immersion up to a specified preasure.	**IP28**

MicroTech Medical

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