AiDEX™ Continuous Glucose Monitoring System

User Guide

CE 0197

MicroTech Medical (Hangzhou) Co.,Ltd.

Index

Important Safety Information

Indications for Use

The AiDEX™ 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 persons 14 years or older. It is intended for use by patients at home and in healthcare facilities.

Interpretation of the AiDEX™ CGM System results should be based on the glucose trends and several sequential readings over time. The AiDEX™ CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Measurements should not be used to make treatment adjustments, but rather as a reminder of when fingertip testing is required. The blood glucose detection module built into the Personal Diabetes

Assistant controller can be used in conjunction with MicroTech's Exactive EQ blood glucose test strips. It cannot be used for the diagnosis and screening of diabetes, nor as a basis for drug therapy decisions.

Patients

The blood glucose test function of the Personal Diabetes Assistant is suitable for measuring the blood sugar level of whole blood samples that meet the following requirements:

1. Hematocrit range of 30% to 55%.
2. Triglyceride concentration does not exceed 3,000 mg/dL or cholesterol concen tration does not exceed 500 mg/dL.
3. Non-critically ill patients (such as those with severe dehydration or ketoacidosis, etc.).

Contraindications

Patients who:

1. Suffer from alcoholism, drug abuse, severe mental disorders (such as depres sion,schizophrenia).

2. Are unconscious.
3. Unable to understand or master the usage of the device.
4. Have severe hearing or vision impairment.
5. Children too young to administer diabetes therapy themselves.

Precautions

- CGMS readings should only be used as a reference for the supplemental moni toring of diabetes mellitus and should not be used as a basis for clinical diagno ses.
- The CGMS should be completely removed before magnetic resonance imaging (MRI) and replaced afterwards.
- The CGMS contains many small parts that can be dangerous if swallowed.
- During rapid changes in blood sugar (more than 0.1mmol/L per minute), glucose levels measured in interstitial fluid by the CGMS may not be the same as blood sugar levels. When blood sugar levels drop rapidly, the sensor may produce a higher reading than the blood sugar level; Conversely, when blood sugar levels rise rapidly, the sensor may produce a lower reading than the blood sugar level. In these cases, the sensor readings are checked by using a blood glucose meter for a fingertip blood test.

- Severe dehydration or excessive loss of water may result in inaccurate results. If you think dehydration is occurring, consult a health care provider immediately.
- If the patient thinks the CGMS sensor reading is inaccurate or inconsistent with the way he feels, a blood glucose meter can be used to test the blood sugar lev el or calibrate the glucose sensor. If the problem persists, remove and replace the sensor.
- While extensive user testing was done on AiDEX TM CGMS in Type I and Type II diabetic patients, the study groups did not include women with gestational dia- be tes.
- The performance of the CGMS has not be evaluated when used in conjunction with another implantable medical device, such as a pacemaker.
- Only MicroTech Medical disposable supplies should be used with the CGMS.
- If the product is not working properly or has been damaged, cease using the product.
- When used in a medical facility, the operator should wear gloves to avoid the spread of infection.

BG Test Module Precautions

- This module should only be used in vitro and can only be used with MicroTech's Exactive EQ blood glucose test strips. Use of other brand test strips will result in incorrect test results.
- The blood glucose test function can only be used to determine blood glucose levels using whole blood samples. Do not use serum or plasma samples.
- The blood glucose test function is not intended for neonatal applications.
- Test results may not be accurate for blood hematocrit of more than 55% or be low 30%.
- Blood containing high levels of vitamin C or other reducing agents can lead to inaccurate results.
- The blood glucose meter test range is 1.1-33.3mmol/L (20-600 mg/dL).
- Triglycerides above 3,000 mg/dL and cholesterol above 500 mg/dL will lead to inaccurate test results.
- Patients with serious illness (such as severe dehydration or ketoacidosis) are not suitable for measuring blood sugar using the blood sugar test system.
- The blood glucose meter is only suitable for clinical screening tests or family self-monitoring. The test results cannot be referred to as confirmed cases. In order to ensure the accuracy of the results, the test results can be further con

firmed by other methods, such as biochemical methods.

- As with all diagnostic reagents, test results must be linked with a professional doctor’s diagnosis from the other clinical symptoms.
- Carefully process waste caused by blood glucose tests according to the relevant local laws and regulations, because blood samples are considered a biohazard.

Product Components

Name: Continuous Glucose Monitoring

System Product Configuration: This product includes a Personal Diabetes Assistant controller, a Transmitter and a Glucose Sensor.

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

The PDA and Transmitter Box includes:

- Personal Diabetes Assistant (Li-ion battery included)
- Transmitter
- PDA Charger
- PDA Charging Cable
- Quick User Guide

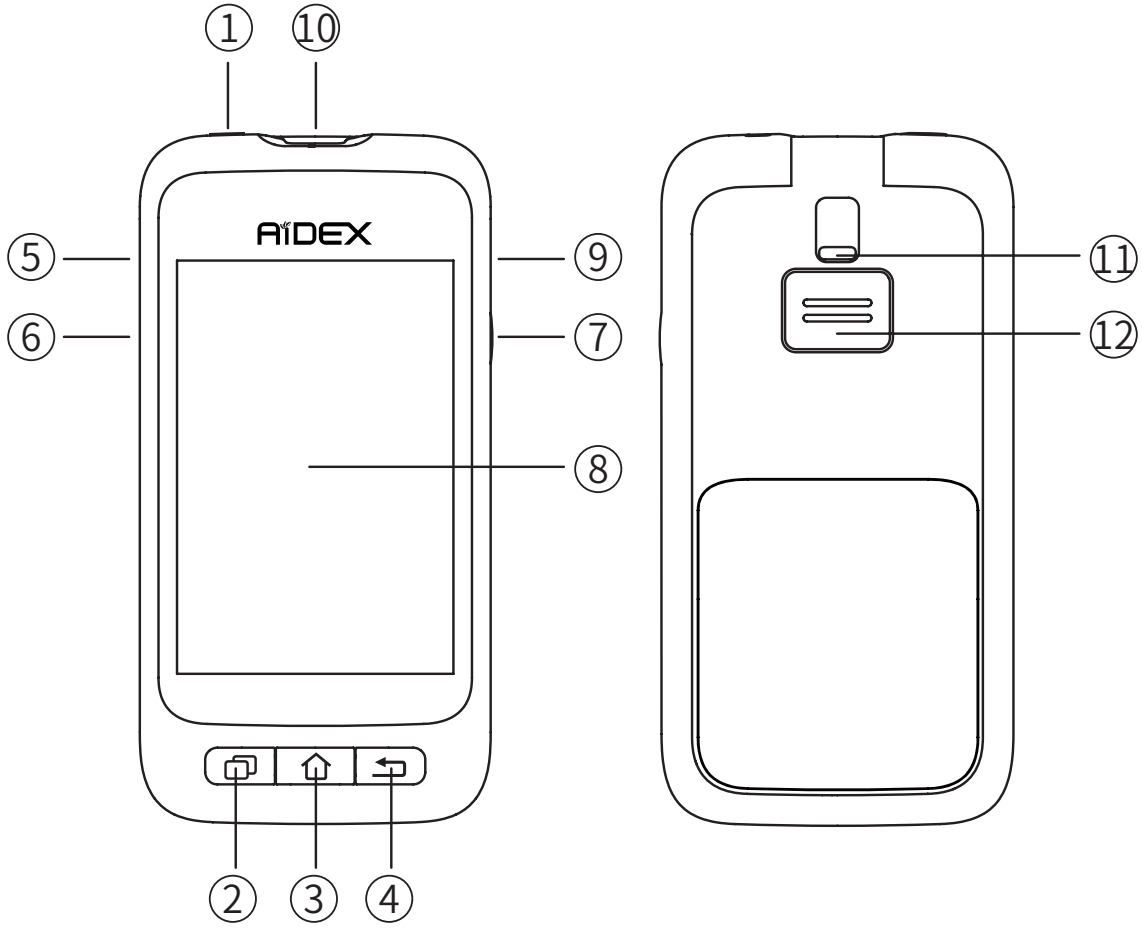
The Glucose Sensor Box contains:

- Sterilized Glucose Sensor package

Component Description

Personal Diabetes Assistant

When paired to transmitter that is attached to a glucose sensor, the PDA is used to display glucose readings and view historical data.



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.

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

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

Power off: While the display is on, press and hold the power button. A dialog box will open to confirm shutdown.

② **Help Button**

While using the PDA, use the Help Button to display helpful information when functions are not clear.

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 using the touchscreen.

⑧ **Display**

3.2 inch color display with touchscreen.

⑨ **Charging Port**

Connect the Charging Cable/Charger to the Charging Port to recharge the PDA battery.

⑩ **Blood Glucose Test Strip Port**

Insert a blood glucose test strip into this portand the PDA's blood glucose test function will be appear. For a more detailed description of the blood glucose test function, refer to the chapter "Using the Built-in Blood Glucose Meter".

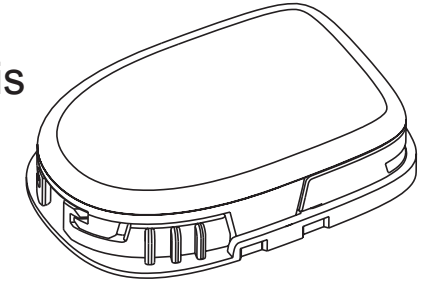
⑪ **Test Strip Ejector**

Used to eject used blood glucose test strips.

⑫ **Speaker**

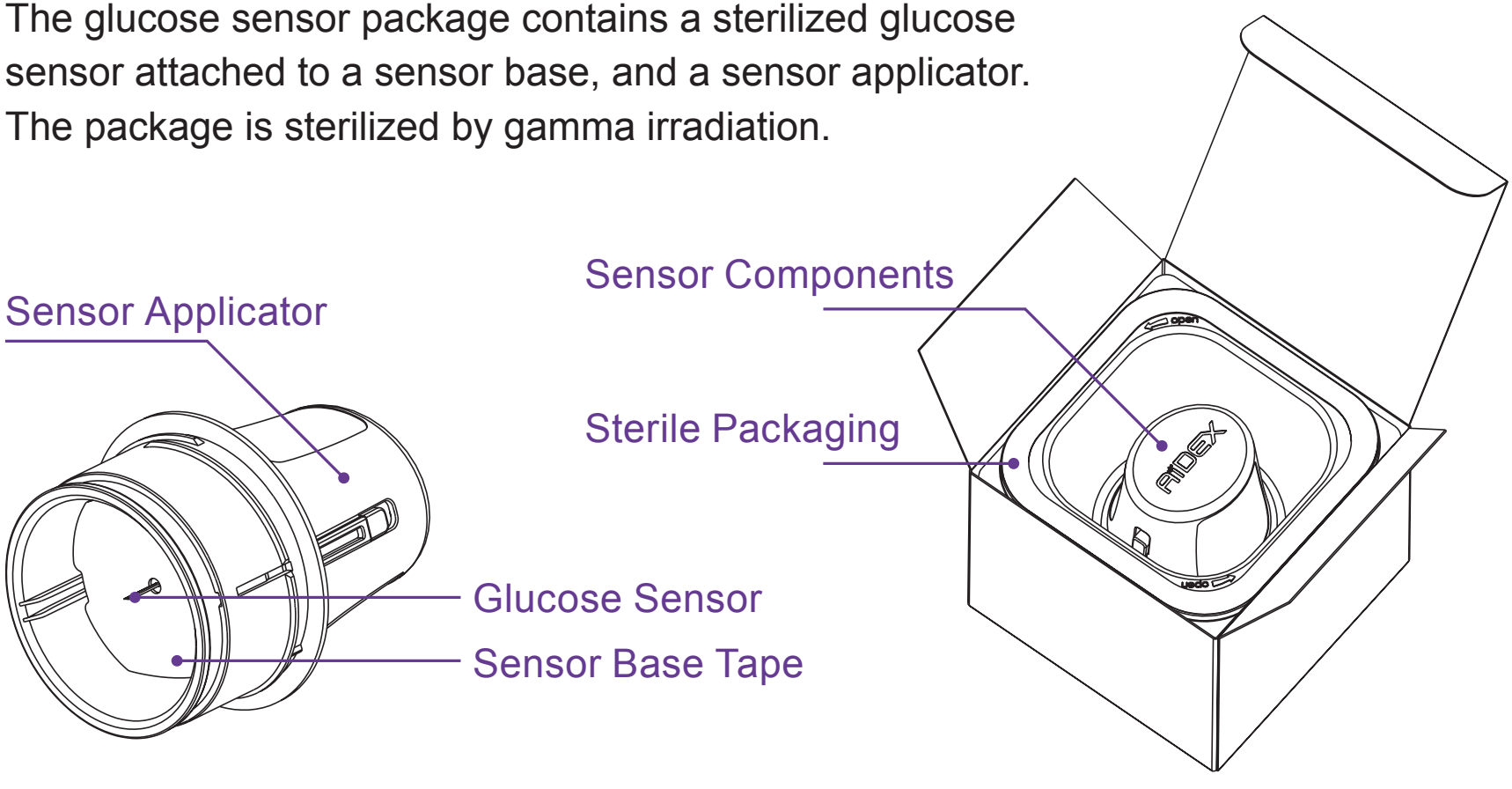
Transmitter

The Transmitter connects to the Glucose Sensor Base and is worn on the body to measure and store glucose readings.



Glucose Sensor Package

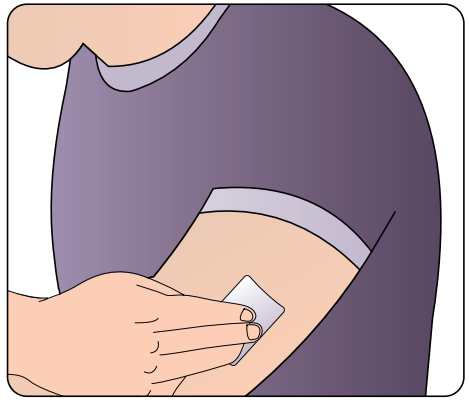
The glucose sensor package contains a sterilized glucose sensor attached to a sensor base, and a sensor applicator. The package is sterilized by gamma irradiation.

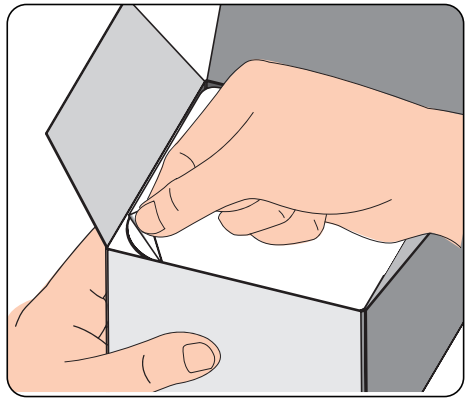


Starting a New Glucose Sensor

Applying a Sensor

- recommended to apply the sensor to the outside or back of the upper arm, or the abdomen. Avoid areas with scars, moles, stretch marks, or lumps.
- Before application, use alcohol pads to clean the skin where you want to place the sensor, wait for a minute to let the skin dry. To prevent discomfort or skin irritation, select a different location than the last place you wore a sensor.
- Open the sensor package.

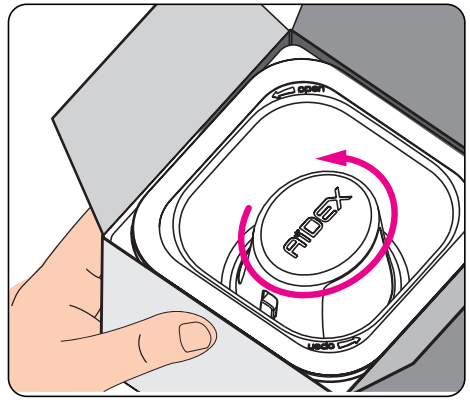




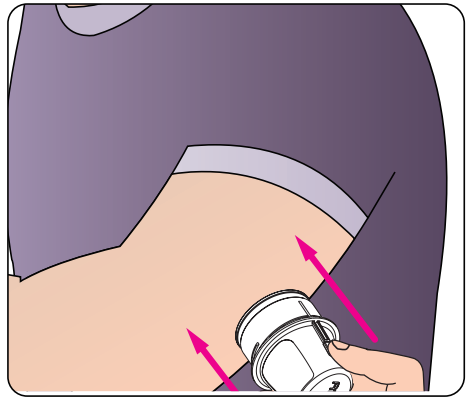
Note

Please check to be sure that the sensor is not beyond its expiration date. If the sensor is expired or the sterilized package is damaged.

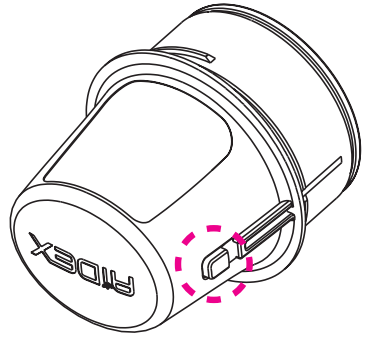
- Take out the sensor applicator by turning it anti-clock wise.



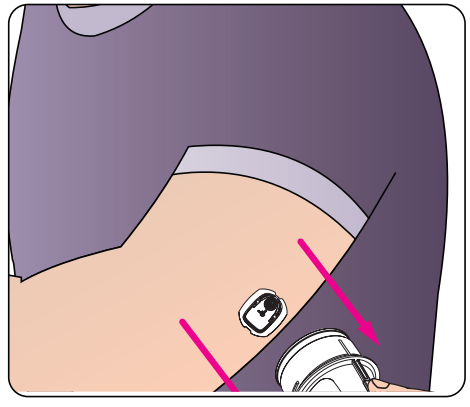
- Place the applicator on top of the desired sensor loca tion. Press it firmly against skin and press the button to launch the sensor applicator. Wait a few seconds after the sensor is inserted and let the sensor base patch stick to the skin.



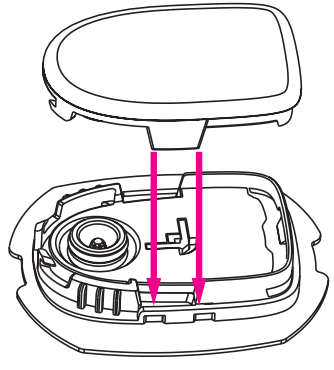
- Remove the applicator. The sensor should be applied successfully. Note: Applying a sensor may cause bruis ing or bleeding. If bleeding does not stop, remove the sensor and apply a new sensor to a different location.



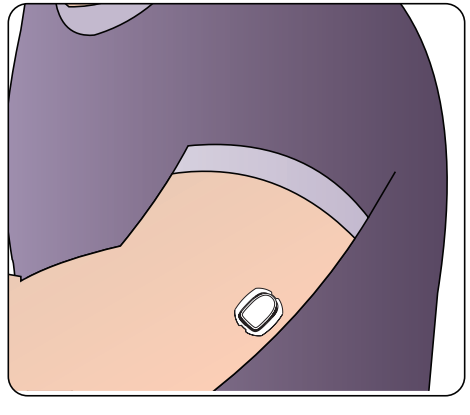
Align the transmitter to the sensor base and press the transmitter firmly onto the sensor base until it snaps onto the sensor base and attaches to it securely. Note: if the orientation of the transmitter and sensor base mismatch, the transmitter cannot be installed properly.



- The applicator is disposable and meant for single use only. Dispose of the used sensor package and sensor applicator according to your local regulations.
- Follow the steps described above carefully and be sure to only use components that are made by MicroTech Medi cal. Use of unapproved components can result in injury.



Setting up the PDA for the first time

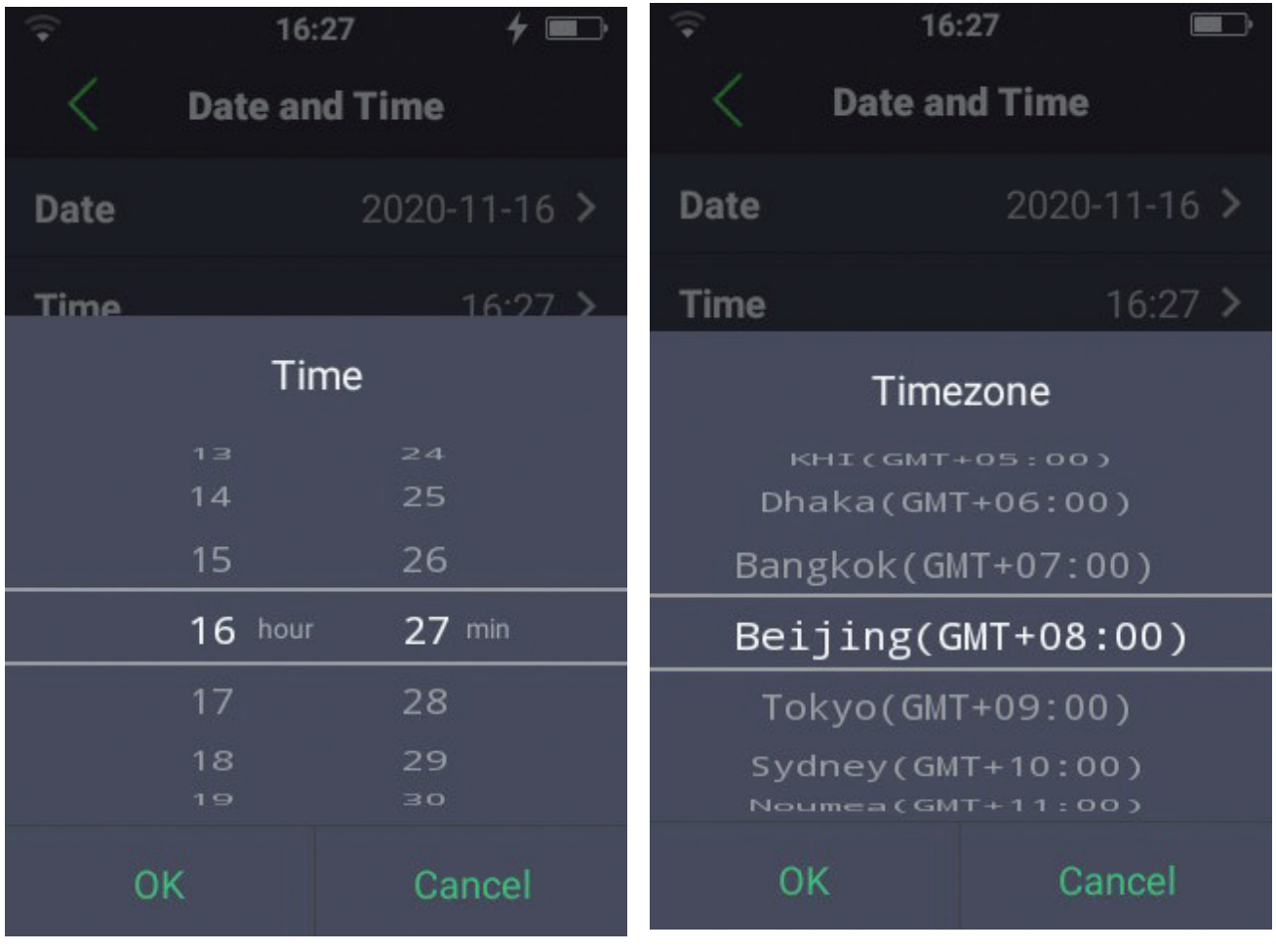


If you are using the PDA for the first time, the time needs to be set only.

- **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.

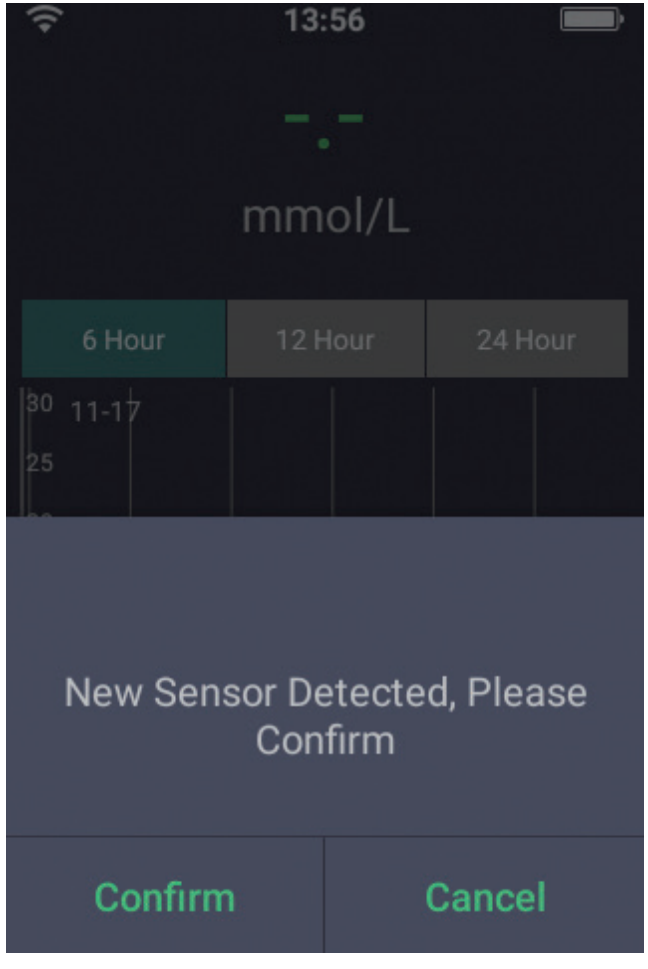
Basic Settings

- After entering the setup wizard, the first screen is the time setting. Set the correct date, time, timezone and click OK.

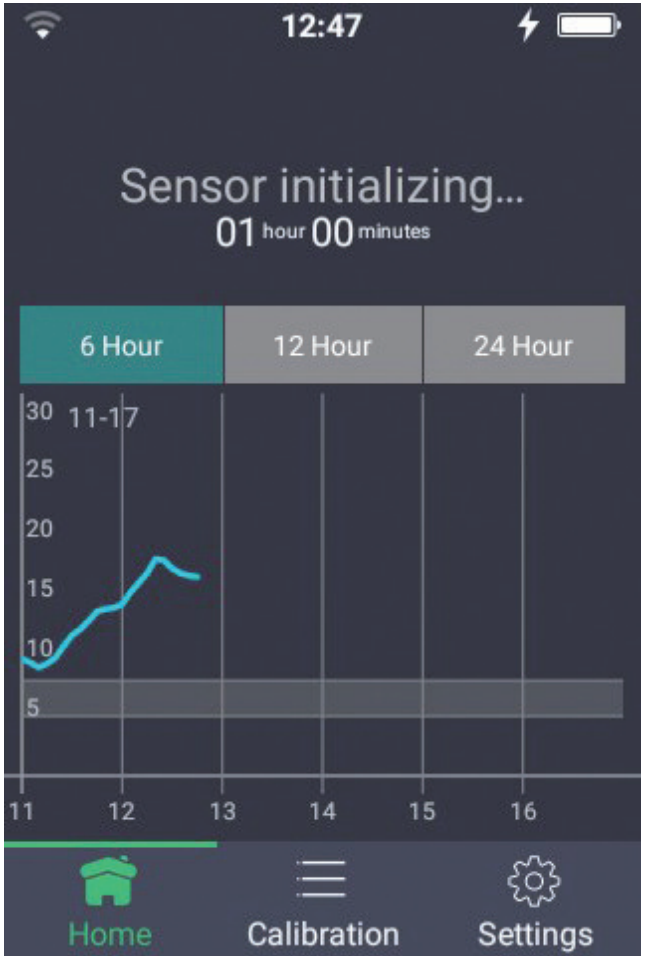


Sensor Startup

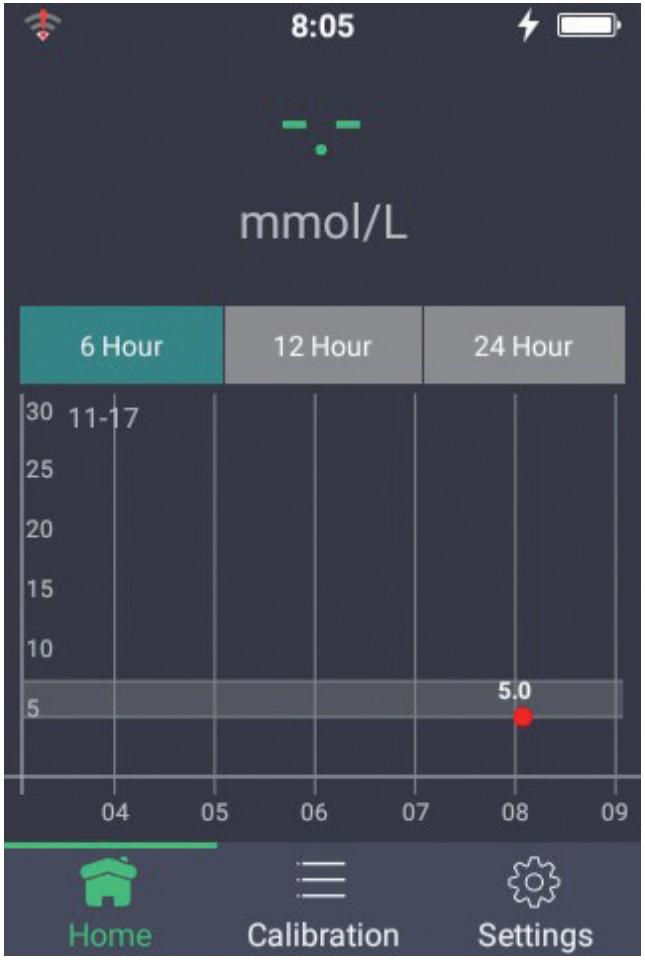
- After the sensor is successfully applied to your body and connected to the transmitter, the paired PDA will display “New Sensor Detected, Please Confirm” Press the “Confirm” to continue.



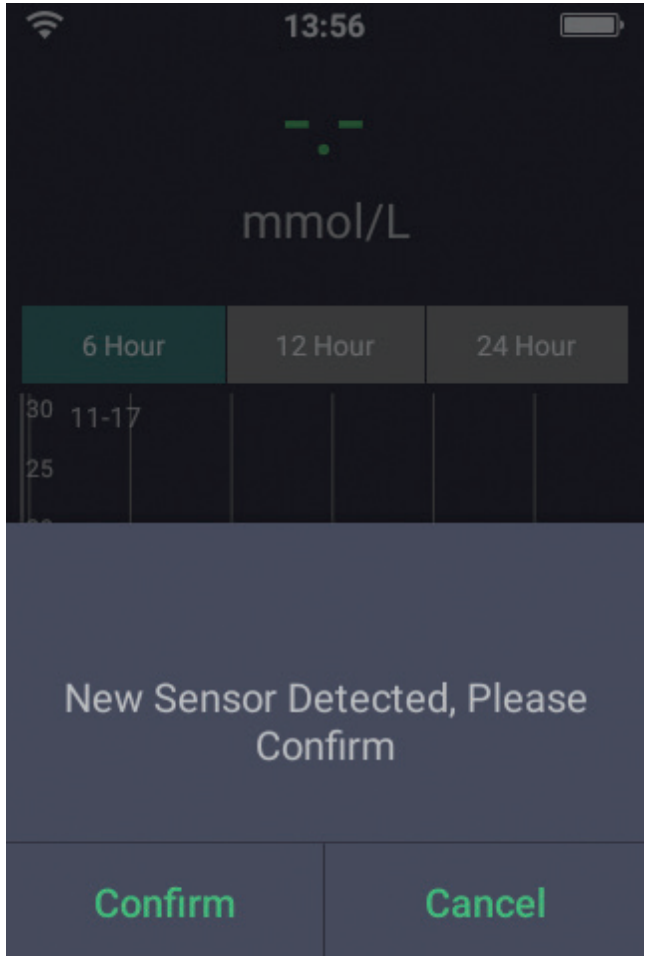
- Now the PDA will display “Sensor Initializating”. Sensor Initialization typically takes about 1 hour to complete.



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



- If the sensor has previously been implanted and connected to the signal trans mitter for a period of time, after disconnecting and reconnecting with the signal transmitter, click the “Cancel” button when the PDA prompts “New Sensor De-tected, Please Confirm”.
- At this point, the PDA skips initialization and starts displaying the current blood sugar value directly.



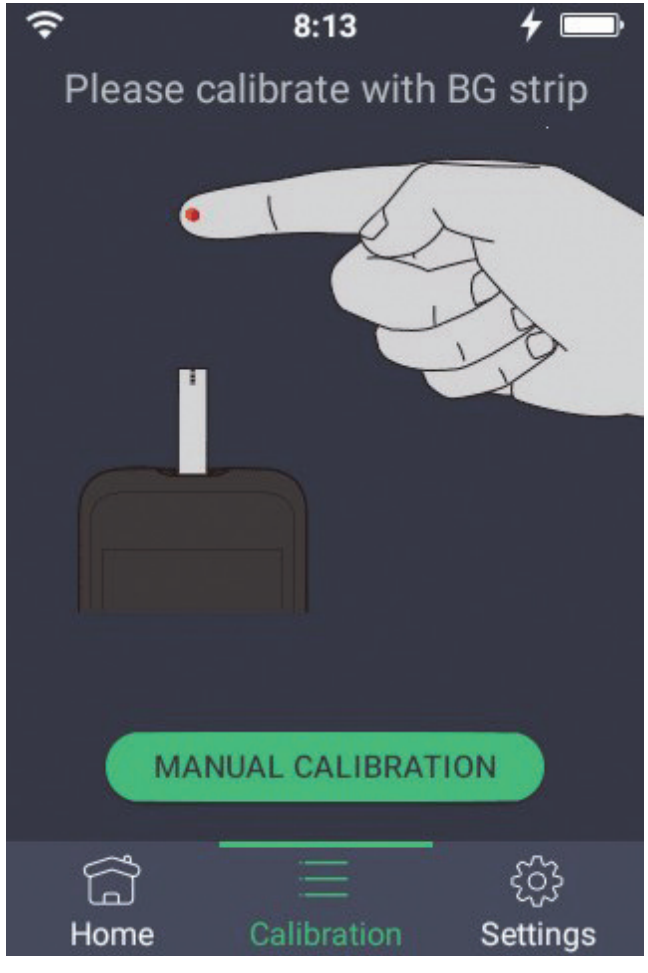
Note

Do not cancel the initialization process when using the new sensor. Skipping the initializa tion of the new sensor may cause the system to display incorrect glucose concentration values.

Sensor Calibration

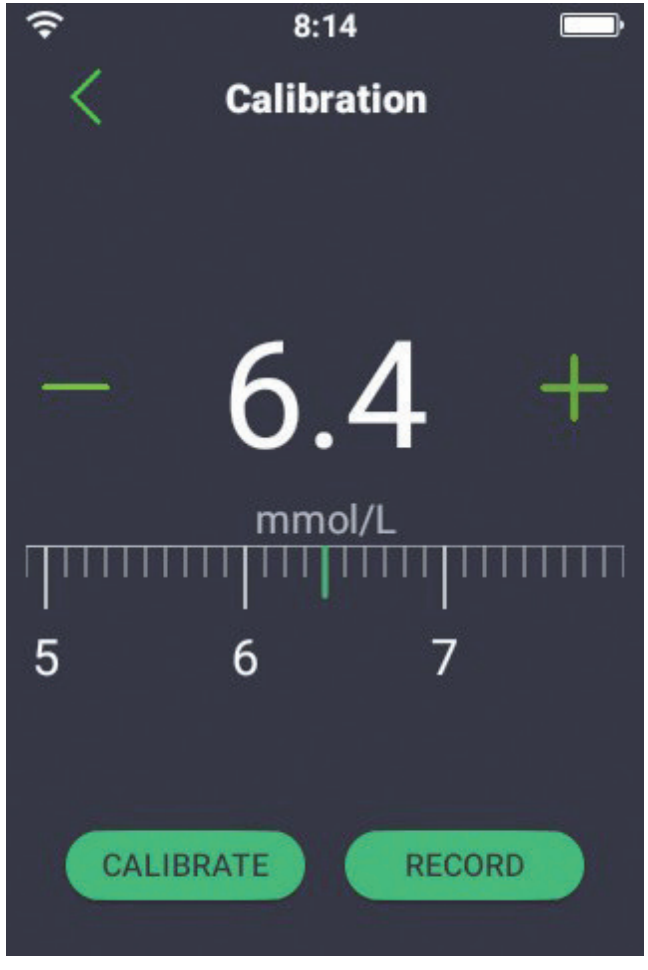
After a new sensor is initialized, you can calibrate the CGMS as needed.

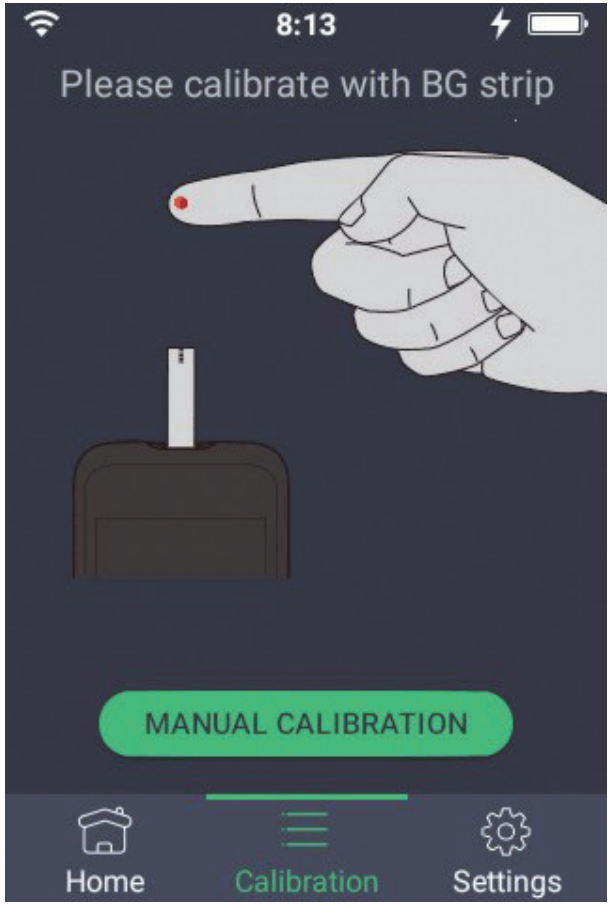
- Click the“Calibration”menu on the PDA’s home screen.
- The PDA will prompt “Please calibrate with BG strip”.
- Insert a blood glucose test strip into PDA’s the test strip port, and the display will automatically open the blood glucose test page.
- Follow the instructions in the “Using the Built-in Glucose Meter” section for fingertip blood collection tests.

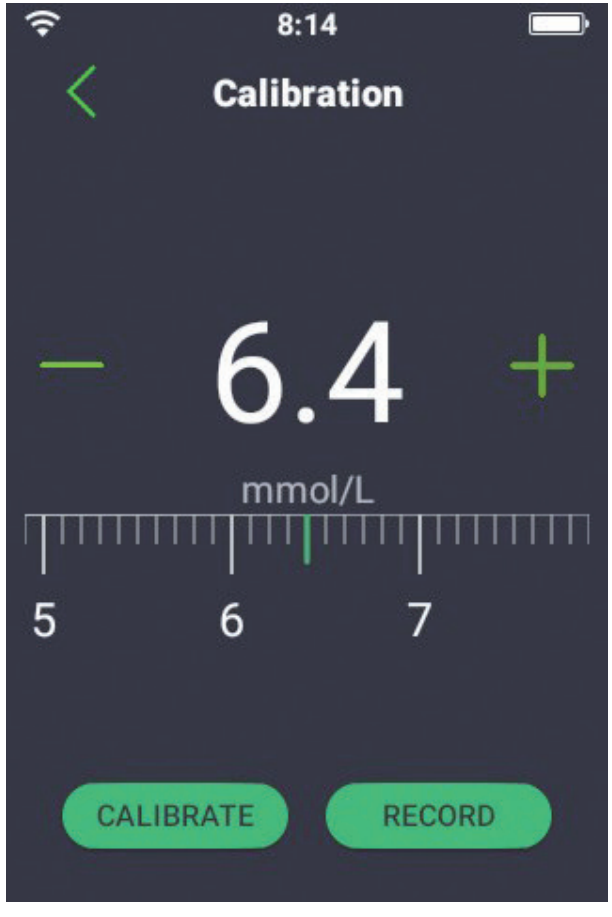


- After the test results are displayed, click on the “Calibrate” button to complete the calibration of the CGMS.

- If you only intend to use the blood glucose meter and do not want to calibrate the CGMS, press “Record” after the test result is displayed. Your blood glucose reading will be recorded to history, but not used to calibrate the real-time glucose monitoring system.
- You can also choose to press “Manual Calibration” when “Please insert blood glucose test strip”appears. This allows you to input a reference blood glucose value from a different blood glucose meter. Press“Calibrate” to complete the calibration.
- If you do not wish to calibrate the CGMS, you can click “Record” to enter a blood glucose reading into history. The system will only record the current blood glucose value and measurement time, but it will not calibrate the CGMS.





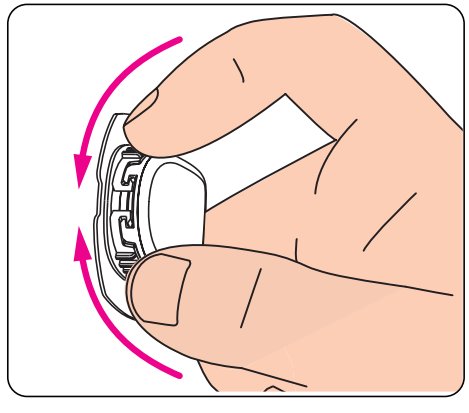


- The blood glucose test interface will appear any time you insert a blood glucose test strip, even when the PDA is active and on the home screen.
- It is recommended to perform a calibration as soon as possible after the sensor is initialized to confirm the performance of the sensor.
- If you doubt that the glucose level displayed by the CGMS is correct, you can use the calibration function to confirm the performance. However, do not cali brate the system frequently within a short period of time.

Removing a Sensor

Remove an 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.

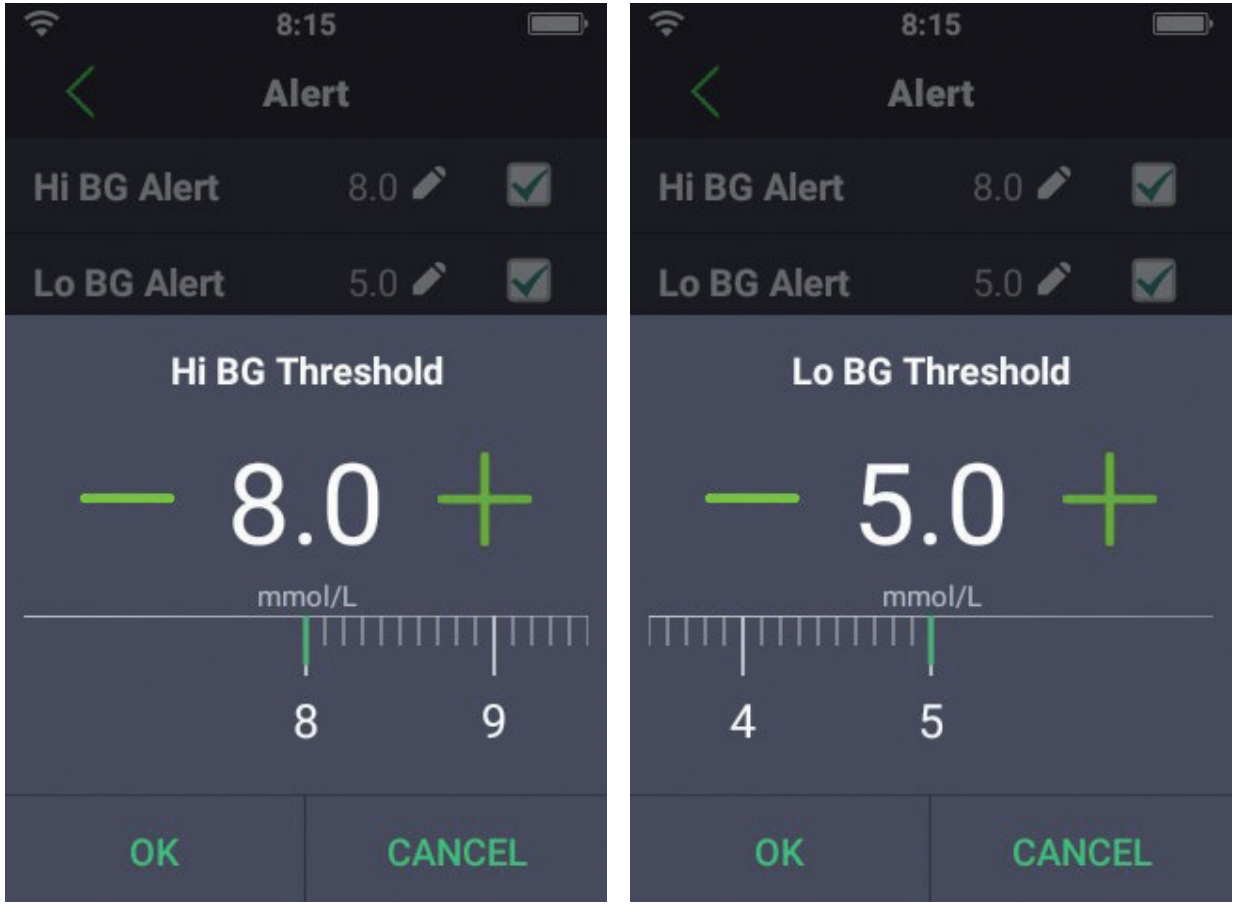


PDA Settings

Target Glucose Range

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

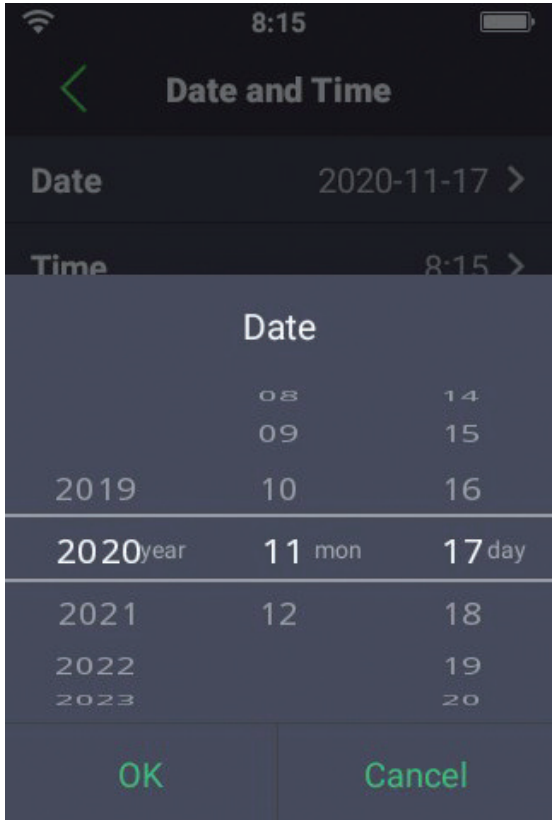
- Before setting the target glucose range, please make sure that the transmitter is connected to the sensor base, and that the PDA and transmitter have a good wireless connection.
- Press “Settings” on the PDA’s home screen to enter the Settings Menu.
- Press“Hi BG Threshold”to enter the desired sensor blood glucose threshold. The threshold range is 8-25mmol/L (144-450mg/dL) (default value is 12mmol/L).
- Press “Lo BG Threshold” to enter the desired low sensor glucose threshold. The threshold range is 2.2-5mmol/L (default value is 3.5mmol/L).

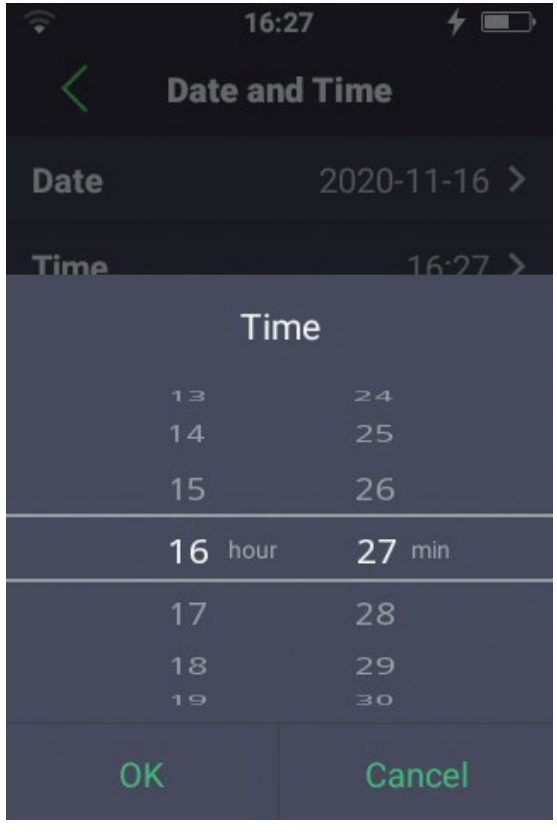


- After you finish this setting, press “OK” and the PDA will attempt to update the system settings. The PDA will display “settings change successful” when the setup is complete.
- If the PDA and transmitter are not within communication range, the PDA will display “Settings change failed, please verify that the PDA and transmitter are within communication range.”

Time and Date 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 and time and click OK.



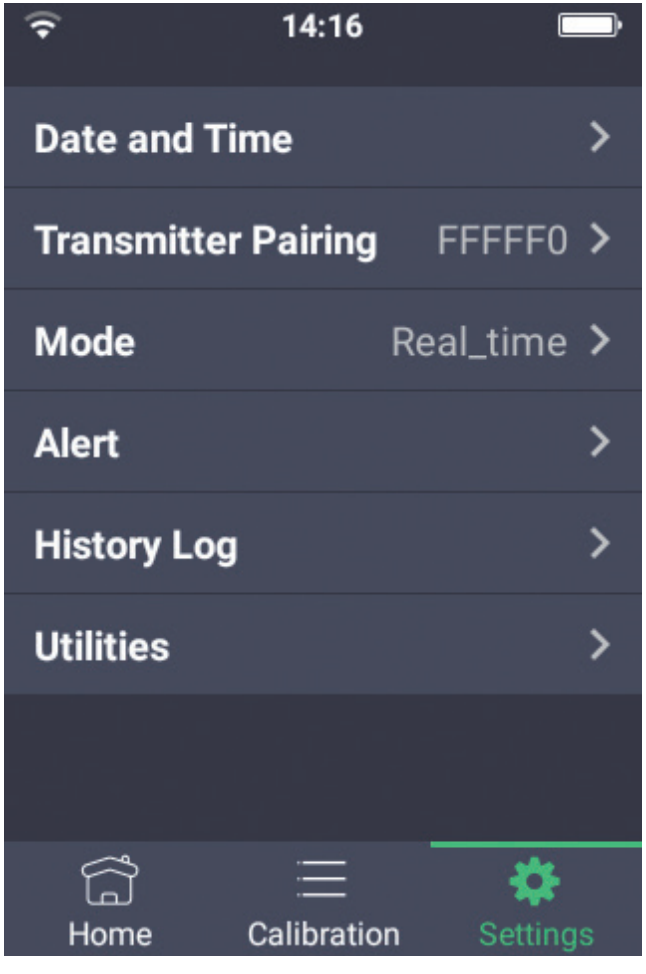


Pairing with a new transmitter

Note

For security reasons, PDA's are only allowed to be paired with one transmitter at a time.

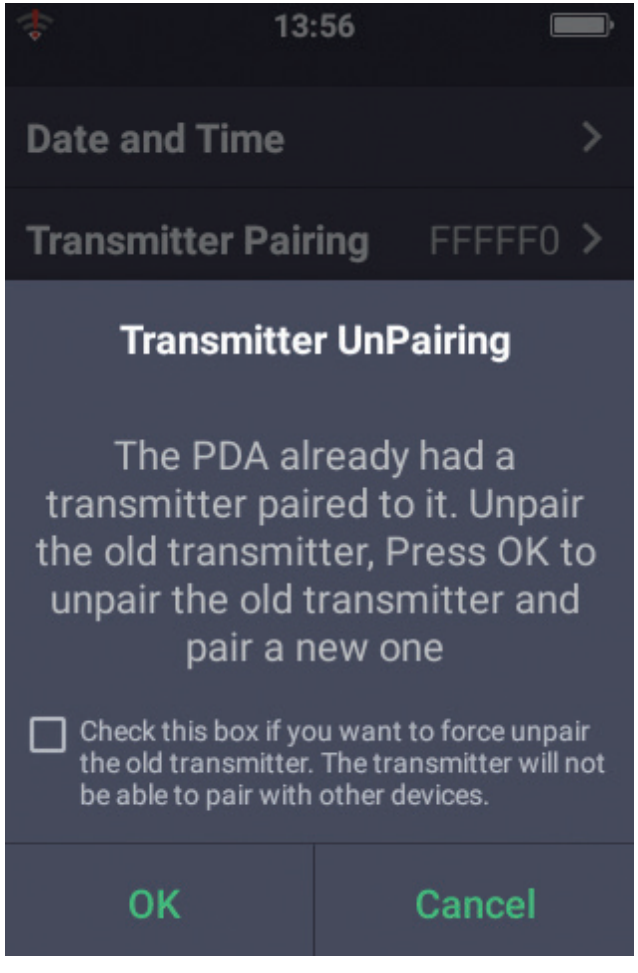
- Before pairing, please confirm that the serial number of the new transmitter is available, and the new transmitter has been successfully as sembled to the sensor base.
- Press "Settings" on the PDA's home screen to enter the Settings Menu.



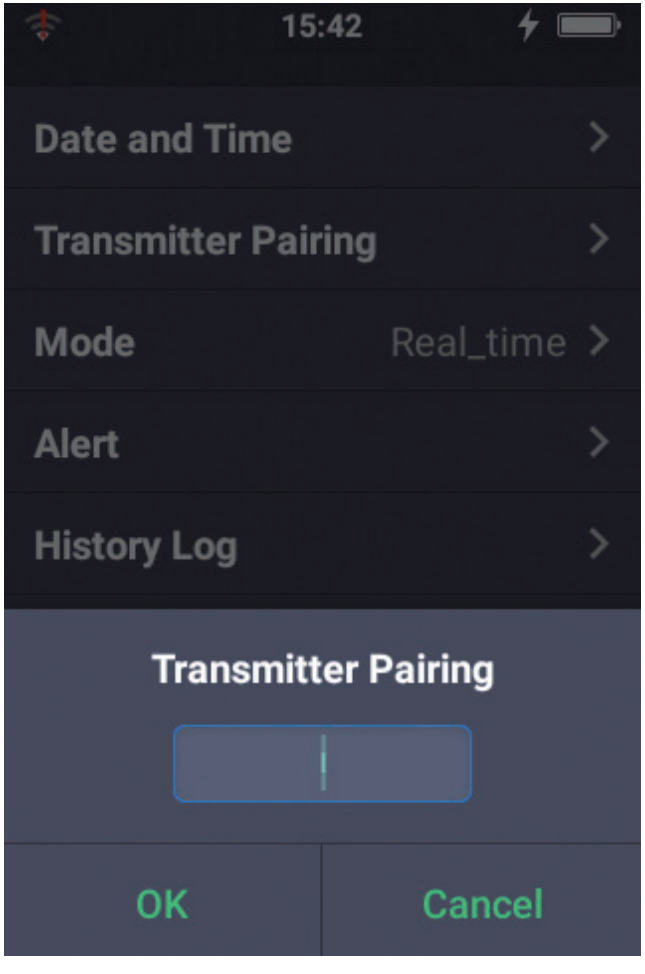
- Press “Pair Transmitter”.
- If the PDA is already paired with a transmitter, clicking “Pair Transmitter” will open a prompt “The PDA already had a transmitter paired to it. Unpair the old transmitter, Press OK to unpair the old transmitter and pair a new one.

Note

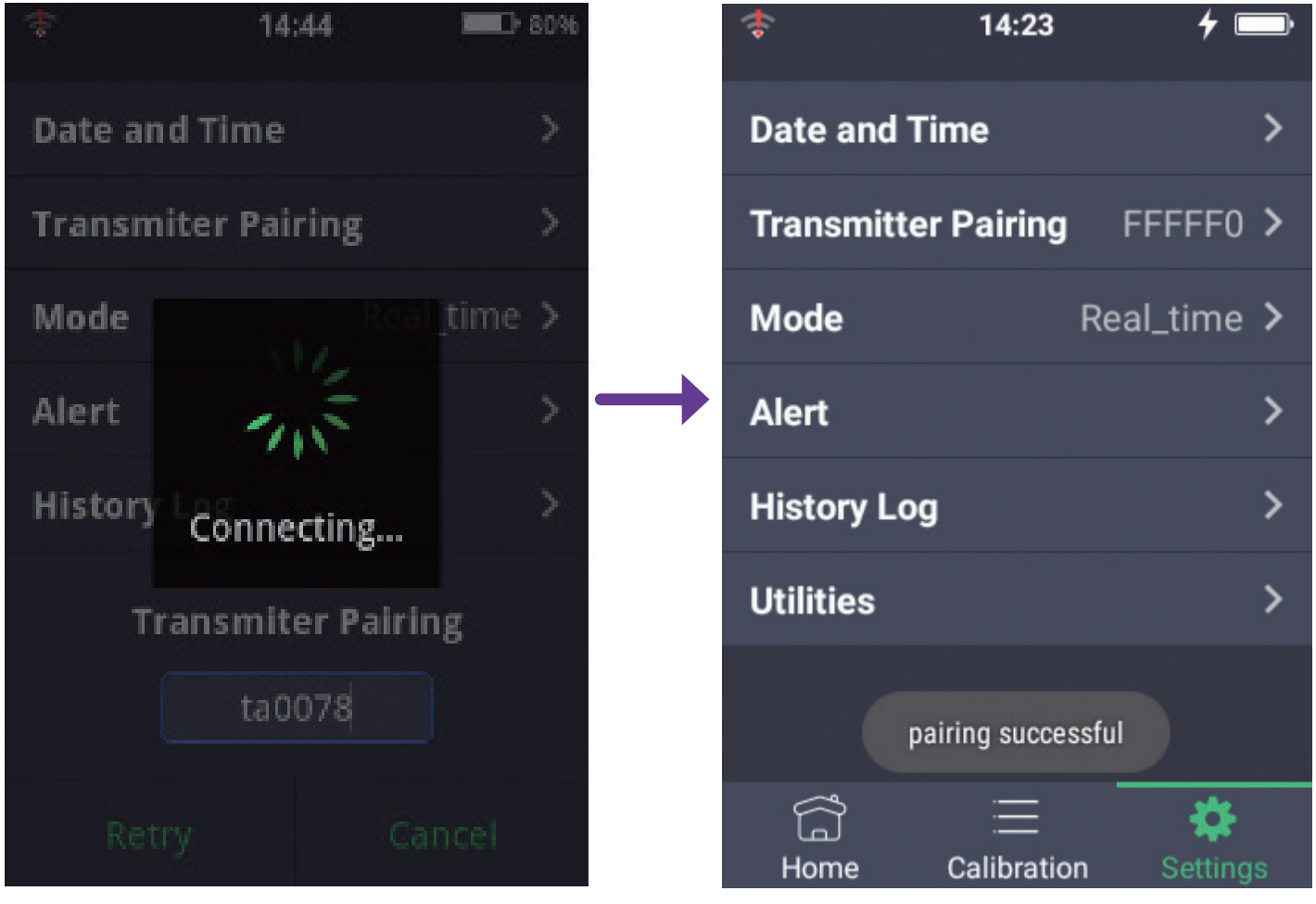
When unpairing an old transmitter, be sure that the PDA and transmitter are within communication distance and have a good connection. If the connection is lost during unpairing, the transmitter may encounter difficulties re-pairing to PDA in the future.



- Enter the transmitter’s serial number when prompted.



- Click “Confirm” on the PDA and it will attempt to establish a connection to the Transmitter. After the PDA connects to the Transmitter, the PDA will display “pairing successful”.



Alarm System Description

The AiDEX™ CGMS has a comprehensive safety system to check if abnormal situations require immediate attention. The system will send notification alarms using sound, LEDs, or vibrations as well as provide information on the PDA display.

The AiDEX™ CGMS only contains medium and low priority alarms – no high priority alarms (as defined by ISO standards).

The low priority prompt message may be a physiological status alarm message (hyperglycemia alert) or a technical alarm/message. When such an alarm is triggered, it will not have a negative impact on the user immediately, but the user needs to pay attention to such information and make decisions to restore the blood sugar to the normal range or ensure the real-time continuous glucose monitoring system continues to be reliable.

PDA Alarm Priority Levels

Alarm Level	Visual Signal	Audio Signal	Sound Pressure (dB)
Medium Priority	Flashing Yellow Light	Three consecutive beeps	60-90
Low Priority	Steady Yellow Light	Two consecutive beeps	60-90

PDA Alarms

Alarm Description	Priority	Solution/Action
Low Blood Glucose	Medium	Perform a finger-tip glucose measurement using an approved glucose meter to confirm the sensor glucose reading. If the measurement indicates low blood glucose, please take actions to raise blood glucose immediately and call for medical assistance
High Blood Glucose	Low	Perform a finger-tip glucose measurement using an approved glucose meter to confirm the sensor glucose reading. If the measurement indicates high blood glucose, please take medicine or inject appropriate amount of insulin according to doctor's prescription.
Sensor Expired	Low	Remove the current glucose sensor and replace it with a new sensor.
Sensor Error	Low	Check if the current sensor has peeled off or partially peeled off from the skin. If yes, please remove the current sensor and replace 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, lease remove the current sensor and replace it with a new sensor.
Other Unspecified Errors	Low	Please switch off the PDA and restart it. If the error message continue to appear, please contact our customer service.

Using the Built-in BGM

The built-in blood glucose meter uses an chemical reagent (glucose oxidase, GOD) reaction to detect blood glucose levels. After the test strip is placed into the test strip port and a blood sample is applied, the blood automatically wicks into test window. A transient electrical current is generated, and this current is measured to determine the correct blood glucose level reading.

Blood Sampling

Before testing, first become familiar with how to collect blood and then choose a clean and dry place to conduct the test.

Important

Prior to testing, use with either alcohol or soapy water to disinfect the sampling site. Use warm water to increase blood flow if necessary. Dry your hands and the sampling site, ensuring that there is no soap residue remaining.

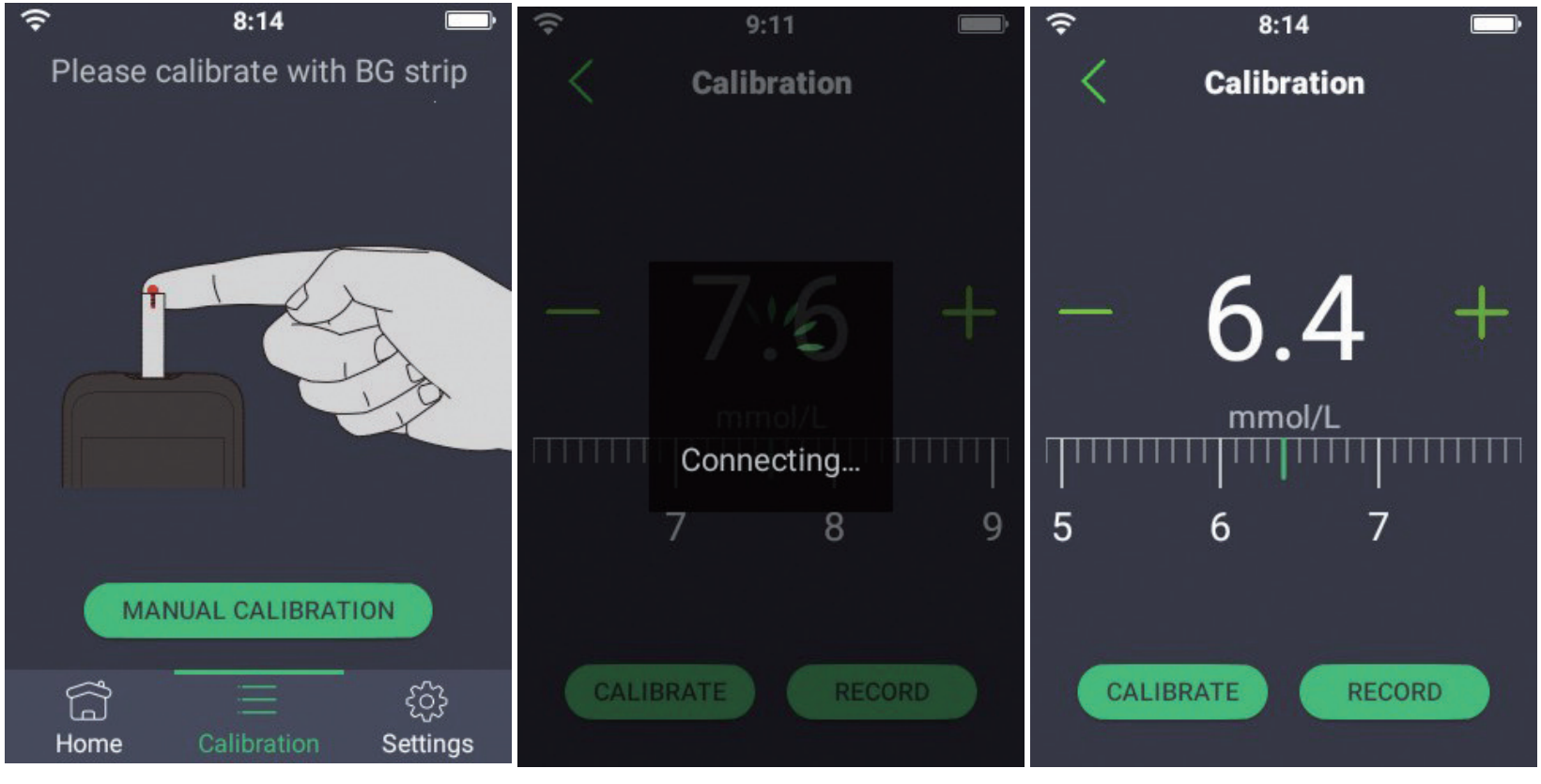
Fingertip Testing

Adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

Blood Glucose Test

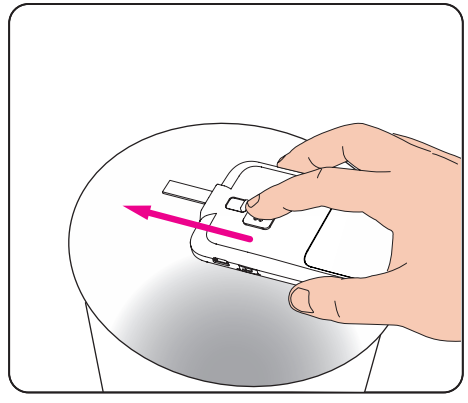
If the PDA's screen is on, the PDA will automatically go to the blood glucose test screen when insert a test strip into the test strip port. An animation will prompt you to apply blood to the test strip.

After applying a blood sample to the test strip, the PDA will count down 5 seconds and display the test result.



Eject the test strip

After the test has been completed, slide the test strip ejector to pop out the test strip, as shown in the picture.



Comparing Blood Glucose Meter and Laboratory Results

Your PDA's blood glucose meter and laboratory equipment both report glucose concentrations in the serum or plasma component of your blood. However variations between the two are normal, and your meter results and laboratory results may be slightly different.

To ensure a reasonable comparison between your meter and laboratory results, please follow these guidelines:

- Make sure your PDA is working properly.
- Comparisons will be more accurate if you do not eat for at least four hours (preferably eight hours) before testing.
- Bring your PDA, test strips, and control solution to the lab.

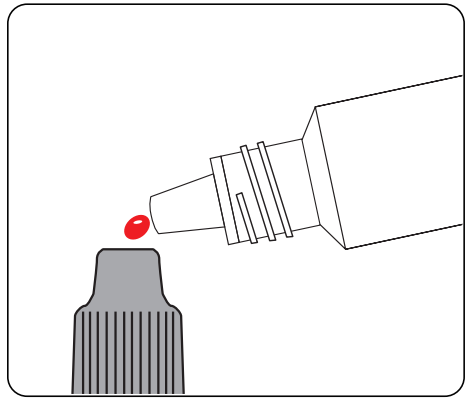
- Ensure that the time between tests with your PDA and the laboratory is within 15 minutes.
- Wash and dry your hands before obtaining a blood sample.
- Make sure you closely follow the instructions in this manual.

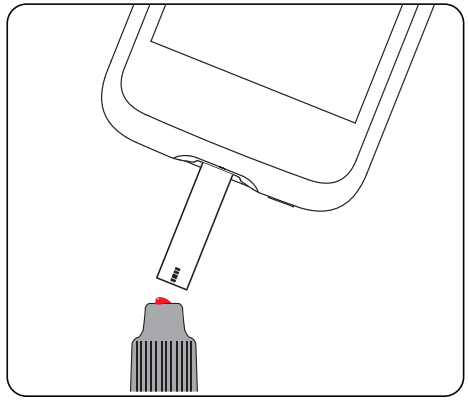
Test results may show small deviations, this may due to the following reasons: Blood oxygen and red blood cell count vary from person to person, and even with in the same person. The glucose meter tests blood glucose concentrations for the widest range of people possible. If the user's blood indexes fall within the middle of the range, the result will be ideal. Otherwise, there will be some small devia tions. (The deviations should be within the range allowed by local government.)

Quality Control Tests

Control solution is a glucose solution of known concentration that is used to confirm that your PDA blood glucose meter and test strips are working properly. Control solution 1 is usually used first and control solution 2 is used when a second level test is required. MicroTech offers a separately available control solution package that contains both Control Solution 1 and Control Solution 2. Always use a control solution for quality control testing to ensure you get accurate blood glucose levels.

You should perform the control solution test below if you suspect that the meter or test strips are not working properly or when you suspect that your test results are inaccurate, or inconsistent with how you feel:





- When the PDA display is on, just insert a test strip into the PDA's test strip portand the blood glucose test screen will appear. Check the "Control Solution Test" check box at the bottom. The animation will be replaced with an animation of a control solution drop. Shake the control solution bottle, gently squeeze out the control solution, discard the first drop, and drop the second drop onto a clean nonabsorbent surface. Now touch the second drop to the sample area of the test strip. Do not let the bottle come into contact with the strip itself.
- When enough control solution has been applied, the screen will count down 5 seconds and then display the test result. The result is displayed in the top half of the screen. If the result falls within the range printed on the test strip package (typically CTRL1) the device is working properly.
- After the test is finished, eject the test strip. If the control solution results are outside of the reference range:

. Confirm you are matching the correct range. Control Solution 1 results should be matched to the CTRL1 range printed on the test strip vial (or foil pouch).

. Check the expiration date of the test strip and control solution. Make sure that the packages have not been opened for more than 6 months. Discard any expired test strips and control solution.

. Confirm that you are testing within the correct temperature range (15-30 °C). Make sure that the test strip vial and control solution bottle have been tightly closed.

. Make sure that you are using the correct brand of control solution.

. Make sure you are following the user guide instructions properly.

After checking all of the conditions above, repeat the quality control test with a new test strip. If the quality control test results are still outside of the range printed on the test vial (or foil pouch), there may be a problem with your meter. Please seek help and contact your dealer.

Control Solution 1 is sufficient for most self testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. The ranges for both (CTRL 1 and CTRL 2) are displayed on the test strip vial (or on the foil pouch). Simply repeat the test procedure, using Control Solution 2. For confirmation of results, Control Solution 1 tests should fall within the CTRL1 range, and Control Solution 2 tests should fall within the CTRL2 range.

Prompt information

BG Alert Message	Message Type	Solution
BG Meter initialization error	Audio and Vibration Alert with Message Window	Restart your PDA. If the problem persists, contact your distributor.
Test strip was removed during the test	Audio and Vibration Alert with Message Window	Repeat the test and ensure test strip remains in place.
Test strip is contaminated, used, or the blood sample is added to the test strip prematurely	Audio and Vibration Alert with Message Window	Retest with a new strip.
Insufficient sample	Audio and Vibration Alert with Message Window	Retest with a new strip. Make sure there is enough blood to fill the test window.
Temperature exceeds operation range	Audio and Vibration Alert with Message Window	Move to a place within the normal operating temperature range and repeat the test.
Test result is below the measurement range	Audio and Vibration Alert with Message Window	Repeat test. If you see the same result, contact your healthcare professional immediately.
Test result is above the measurement range	Audio and Vibration Alert with Message Window	Repeat test. If you see the same result, contact your healthcare professional immediately.
Check Ketones	Audio and Vibration Alert with Message Window	Check Ketones and contact your healthcare professional immediately.

Charging the 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 220V 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.

Caring for Your CGMS

Cleaning the PDA and Transmitter

- Clean the outer surface of the PDA using a mild detergent and a soft damp cloth. Use another cloth to dry.
- Disinfect the PDA and Transmitter with an alcohol wipe.
- Do not use solvents, nail polish remover, or paint thinner to scrub the outer surface.
- Keep the PDA and Transmitter dry, avoid water.
- Do not use any lubricant.
- Keep the test strip port area clean.

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.

Disposal

Dispose of old PDA's, transmitters, and sensors in compliance with local regula-

tions for electronic devices, batteries, sharps, and biohazard materials. Please do not discard old products or accessories directly into trash. 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.

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 for repair. No third-party individuals or organizations are allowed to perform repairs. Circuit diagrams and component lists are not provided in the manual.

Specifications

Item	Subcomponent		
	Transmitter	Sensor	PDA
Model Number	G7-T01 G7-T01A G7-T01B	G7-S01 G7-S01A G7-S01B	G7-P02
Operating Temperature	5-40°C（41-104 °F）		
Operating Humidity	10-93%（non-condensing）		
Storage and Transportation Temperature	-20°C -60°C	4°C -30°C	-20°C -60°C
Storage and Transportation Humidity	5-95%（non-condensing）		
Storage and Transportation Pressure	700hpa~1060hpa		
Ingress Protection Level	IPX7		IPX0
Use Life	4 Years	G7-S01A: 14 days G7-S01B: 10 days G7-S01C: 7 days Shelf life: 1 year	4 Years
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 concentration ≤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 Modulation	GFSK		
Radiated Power	-2dBm		

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 fol lows:

#	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 ad-

jacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

The basic performance is described in the table below:

Performance	Description
Measurement Accuracy	When the glucose concentration is >75mg/dL, the sensor accuracy deviation does not exceed ±20%; When the glucose concentration is ≤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.

IEC 60601-1-2: 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	±1KVLine 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 10V/m 80MHz~2.5GHz	3V(Vrms) 10V (Engineering medical frequency band) 10V/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 $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$ 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.

Appendix

Symbols

1. PDA

Biohazard		Class 2 Equipment	
In Vitro Diagnostic Device	IVD	See Instructions for Use	
Non-Ionizing Radiation			

2. Transmitter

Water Resistance Level	IPX7	Non-Ionizing Radiation	
Type BF Applied Part		See Instructions for Use	

3. Glucose Sensor

Storage Temperature		Single Use Only	
Sterilized by Radiation	STERILE R	See Instructions for Use	

4. Other

Consult Instructions for Use	

MicroTech Medical (Hangzhou) Co., Ltd.
Address: No.9 Haishu Road,Yuhang District
Hangzhou, Zhejiang 311121 China
Website: http://www.microtechmd.com

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

1016-PMTL-203. V01