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Document:1018U+-PMTL-002
Revision:V03
Issued:2024-08-26

GoChek2 Connect

BLOOD GLUCOSE METER

Instruction Manual

IVD

当前页/全部页码 _

微泰医疗®
WT MICROTECH MEDICAL

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本图纸应与说明，产品状况，产品结构设计图及有关图纸协调使用，发现任何差异请立即通知设计师.

图档中所有尺寸比例为1:1.

项目信息	
名称	迅易II型血糖仪说明书（美国电商版）
图纸号	
物料号	1018U+-PMTL-002
版本号	V03
版本变更描述	修改日期格式，控制液测试范围等详见附件

切刀
压线
开槽
半穿
粘合

备注
无印刷

尺寸：105*155mm	设计审核	日期
印刷颜色：四色印刷	设计	
材质：封面:200g铜版纸,表面覆哑膜 内页:70g轻涂纸	审核	
特种工艺:		
备注：	批准	

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BLOOD GLUCOSE METER

Instruction Manual

IVD

Dear User:

Thank you for choosing the GoChek 2 Connect Blood Glucose Monitoring System. Monitoring your blood glucose level is an integral part of treating diabetes. Microtech Medical is committed to help you control your condition so you can live a healthy and active life.

Please read this user manual to help master the simple functions of the GoChek 2 Connect Blood Glucose Monitoring System. If used properly, the blood glucose system will give you accurate results.

The GoChek 2 Connect blood glucose monitoring system will give you accurate readings from fresh whole capillary blood. This product is for self-testing by diabetics. Test results serve only as helpful information, not for the screening for or diagnosis of diabetes.

Limitation and Warnings:

- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to the transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after cleaning and disinfection.
- Do not drop the meter or get it wet.
- Only use the meter as directed by this instruction manual.
- **Only use GoChek 2 blood glucose testing strips** (hereafter referred to as “test strips”).
- Do not use the meter if it is not working properly or has been damaged.
- Do not place anything on top of the meter.
- This meter can only be used to determine blood glucose levels using whole blood samples from fingertips.
- Do not use an alternative site; only draw blood samples from fingertips.

- Remove the battery if the device will not be used for an extended period.
- Do not use test strips or control solution past the expiration date.
- Over the counter.
- For in vitro diagnostic use.
- For single-patient use only.
- This system should not be used for the diagnosis of, or screening for diabetes.
- This system is not for use on patients with abnormally low blood pressure or those who are in shock.
- Test results may be lower than the actual values or inaccurate if the individual is hypotensive, in a hyperglycemic-hyperosmolar state (with or without ketosis).
- This system is not for use with neonates.
- This system should not be used on critically ill patients.
- This system should not be used on patients with impaired peripheral circulation or severe dehydration.
- Altitudes above 10,000 feet may cause inaccurate results.
- If you are taking Vitamin C (ascorbic acid, blood concentrations >3 mg/dL) at doses higher than recommended, it may interfere with your glucose meter and cause you to get inaccurate results with this system.
- Do not use this system during or shortly after receiving xylose absorption therapy; xylose may case inaccurate blood glucose results.
- If the package is broken or any component is missing, please call the customer line +1-888-288-0017.

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Specification

Product Name: Blood Glucose Meter
Size: 83.5 mm (L) × 54 mm (W) × 19 mm (Thickness)
Glucose Test Range: 10-580 mg/dL
Results Display: Plasma equivalent
Minimum Sample Volume: 0.5 μL
Test Time: 5 seconds
Battery:CR 2032 3.0V coin cell battery
Battery Life: >1,000 readings
Glucose Concentration Units: mg/dL
Memory Storage: 500 test results with date and time
Auto Shutdown: Automatic shutdown after 2 minutes
Display Size: 40 mm × 42 mm
Weight: approximately 50 grams (including battery)
Operating Temperature: 41-113°F (5-45°C)
Operating Humidity: 10-90% (non-condensing)
Hematocrit Range: 10-70%
Altitude Range: up to 10,000 ft
Wireless Communication: Bluetooth

Indications for Use

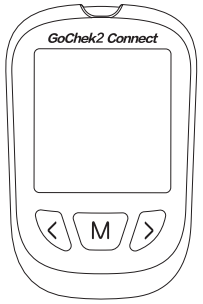
The GoChek 2 Connect Blood Glucose Monitoring System consists of the GoChek 2 Connect Blood Glucose Meter and GoChek 2 Blood Glucose Test Strips. The GoChek 2 Connect Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The GoChek 2 Connect Blood Glucose Monitoring System is intended for self-testing by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. The GoChek 2 Connect Blood Glucose Monitoring System is intended for single-patient use only and should not be shared.

The GoChek 2 Connect Blood Glucose Monitoring System is for *in vitro* diagnostic use.

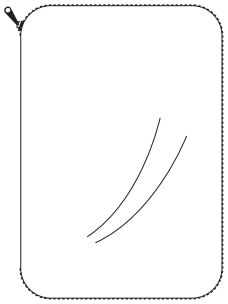
The GoChek 2 Connect Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes.

Product Components

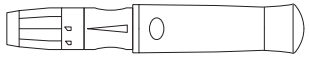
Included components: Glucose meter, lancing device, batteries, carrying case, blood glucose test strips



Blood Glucose Meter



Carrying Case

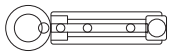


Lancing Device

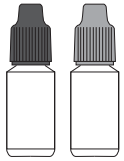
Battery

GoChek 2 Blood Glucose Test Strip

Components required but not included: Control solution, lancets



Disposable Lancet

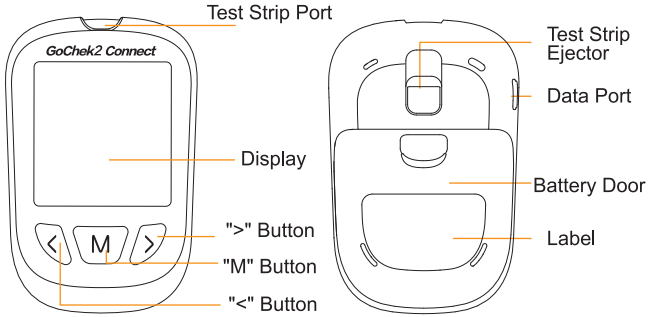


GoChek 2 Glucose Control Solution

Component Descriptions

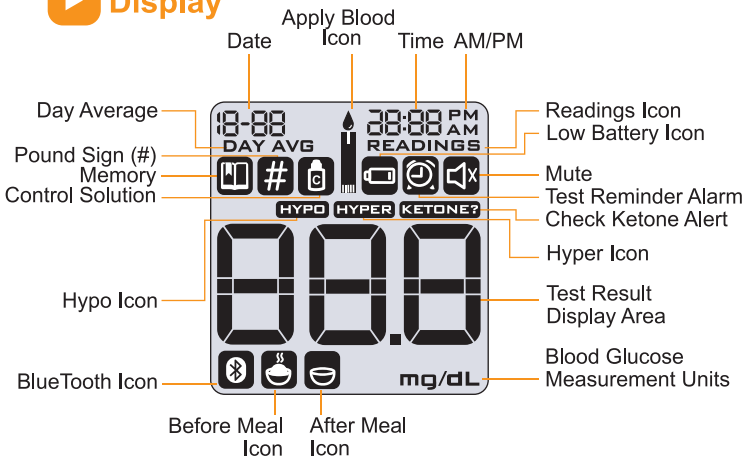
Blood Glucose Meter

The meter reads the test strips and displays the blood glucose concentration. Use this diagram to become familiar with all the parts of your meter. (The components of both the glucose meter models are the same)



Parts name	Function
Test Strip Port	Test strips are inserted into this area to perform a test.
Display	Displays test results, settings, and other information.
“<” Button	When the meter is off, holding the “<” button will turn it on and enter the system settings menu.
“M” Button	When the meter is off, holding the “M” button will enter memory mode. This button is also used to select/confirm.
“>” Button	When the meter is off, holding the “>" button will enter the test reminder alarm mode.
Test Strip Ejector	Slide the ejector forward to discard a used test strip.
Data Port	When used with a data cable, you can transfer the data stored in the meter to your personal computer, analyze it, and print it. (Requires data cable, please contact 7/24 customer service +1-888-288-0017)
Battery Door	Remove the battery door to install the CR 2032 coin cell battery.
Label	Contains product information.

Display



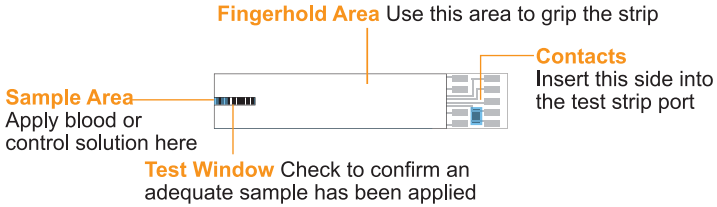
Icon description

Icon	Name	Functionality
18-88	Date	Display the current date.
	Apply blood Icon	Display when user need to apply blood into the test strip.
88:88	Time	Display the time.
PM AM	AM/PM	Show users whether the time is referring to AM or PM.
READINGS	Readings Icon	Display when users check their amount of readings.
	Low battery icon	Display when battery is low.
	Mute	Display when the device is mute.
	Test reminder alarm	Remind user to test their blood glucose level.

Icon	Name	Functionality
KETONE?	Check ketone alert	When your blood glucose reaches certain high level, this icon will be displayed to alert user to check their ketone level with other devices.
HYPER	Hyper Icon	Display when the test result is higher than preset hyper value.
HYPO	Hypo Icon	Display when the test result is lower than preset hypo value.
88.8	Test result display area	Display blood glucose test result.
mg/dL	Blood glucose measurement units	Display blood glucose unit. (for US customer, mg/dL only).
	After meal Icon	Mark the test result that taken after meal.
	Before Meal Icon	Mark the test result that taken before meal.
	Bluetooth Icon (only display on GoChek 2 Connect meter)	Display when the Bluetooth is connected with device.
	Control solution	Display when performing the control test.
	Memory	Display when you review your historical data.
#	Pound sign	Mark the test result.
DAY AVG	Day average	Display day average test result.

Test Strips

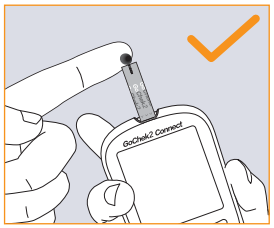
Components and function



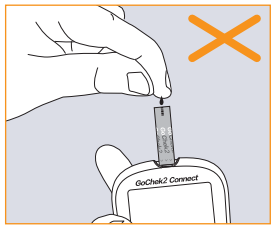
Sample Application

GoChek 2 blood glucose test strips contain chemical reagents. After the test strip is placed into the test strip port and a blood sample is applied, the blood automatically wicks into the test window. A transient electrical current is generated, and this current is measured to determine the correct blood glucose level reading.

IMPORTANT:
Make sure that the blood sample is applied at the edge of the test strip, never on the top surface. Applying blood to the top surface of the strip will lead to inaccurate results.

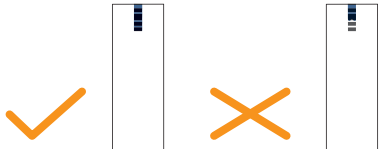


Correct



Incorrect

Apply blood drop into the sample area of the test strip until the test window is completely filled completely to trigger the meter for count down. and the meter begins to count down. If the test window does not get filled at once, do not reapply more blood into the sample area. Please discard this strip and use a new strip for retesting. In cases, where the test window is not filled, and the meter enters countdown. Discard the test strip immediately. Always use new test strips prior to each measurement.



Each test strip package is marked with a batch number (LOT) and expiration date (⌛) and a control solution range (CTRL1 and CTRL2). Please use the correct strips recommended for your meter. The use of third- party strips will result in the meter failing to start, or in an error message. Use of unauthorized accessories may damage the device.

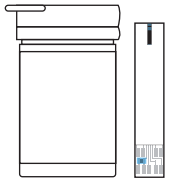
Storage and Handling

Please read and follow the storage and handling conditions below:

- Store test strips in a clean environment at 35.6-95°F (2-35°C) and 10%-90% relative humidity.
- Do not expose test strips to heat or direct sunlight.
- Do not refrigerate or freeze test strips.
- Do not store or use strips in a humid environment, such as a bathroom.
- Do not store the meter, test strips, or the control solutions near bleach or cleaning agents that contain bleach.
- Close the cap on the vial immediately after removing a test strip.
- Use the test strip immediately after removing it from the package. Close the vial immediately after use.
- Do not use expired test strips. Doing so may lead to inaccurate results. Check test strips package insert.

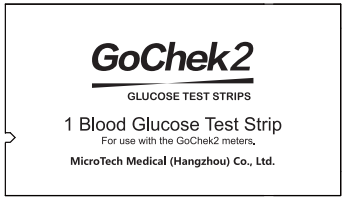
Note: The test strip label contains the expiration date in year-month-day format. For example, 2021-01-01 indicates that the test strips are valid until January 1st, 2021.

▷ Special Instructions for Test Strips Sold in a Vial



- Test strips should be stored in the tightly capped vial that is provided.
- Do not store tests trips outside of the provided vial. Test strips must be stored inside the original vial with the lid tightly sealed.
- Do not transfer test strips from the provided vial into another container.
- Close the vial immediately after use, the test strip should not be exposed to air for prolong period.
- A new vial of test strips may be used for 6 months after first being opened. Please take note of the date that the vial was first opened, and discard after 6 months.
- The close vial shelf-life for test strips is 2 years, please check the date before open the vial. Discard the vial if it's out of the shelf-life.
- Do not use expired test strips. Test strips are for single use. Do not reuse.

▷ Special instruction for Test Strip sold in single use package



- Tear the packet open carefully beginning from the tear gap. Do not damage or bend the test strip.
- Use the test strip immediately on opening.
- Use the test strip immediately after removing it from the packet.

◎ Test Strip Precautions

- For *in vitro* diagnostic use.
- Use the test strip immediately after removing it from the package, otherwise the test results may not be accurate.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test strip packaging away from children and pets.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.
- Please refer to the test strip instructions for more detailed information.

Control Solution

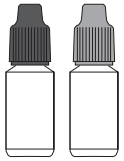
Control solution is a glucose solution of known concentration that is used to confirm that your meter and test strips are working properly. Two control solutions with different glucose concentration will be provided in order to test both high and low limits of the meter.

The CTRL1 control solution glucose range is 120±5mg/dL.

The CTRL2 control solution glucose range is 350±5mg/dL.

It is important to run a quality control test regularly to make sure that you are getting accurate results.

You should perform a quality control test in the following situations:



- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate or inconsistent with how you feel.
- When your meter has dropped or experienced physical shock.
- When you suspect that your meter has been damaged.
- After cleaning your meter.

Refer to page 18 for instructions on how to perform a quality control test.

▷ Storage and Handling

Please review the following storage and handling instructions:

- Store the control solution in the temperature range 35.6-95°F (2-35°C).
- Do not refrigerate or freeze the control solution.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Do not use expired control solution.

  Note: **The control solution label contains the expiration date in year-month-day format. For example, 2021-01-01 indicates that the control solution is valid until January 1st, 2021.**

- Control solution may be used for 6 months after the bottle is opened for the first time. Please take note of the date that the bottle was first opened, and discard after 6 months. Do not use beyond the expiration date.

◎Control Solution Precautions

- For in vitro diagnostic use. The control solution is for testing only outside of the body.
- Do not swallow or inject.
- Control solution should be shaken before use.
- Quality control tests should be carried out at 41-113°F (5-45°C).
- Do not let the control solution bottle touch the test strip.
- Use only the control solution that is recommended for your meter.
- The control ranges shown on the test strip package are not recommended ranges for your blood glucose level. Your target personal glucose range should be determined by your healthcare professional.

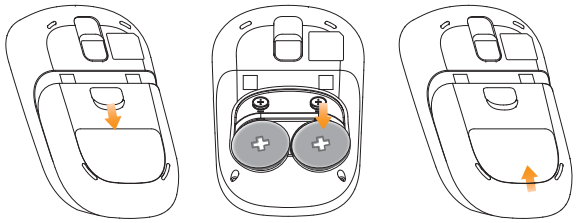
▼ Meter Setup Before Use

Meter Setup

▷ Step 1: Battery Installation

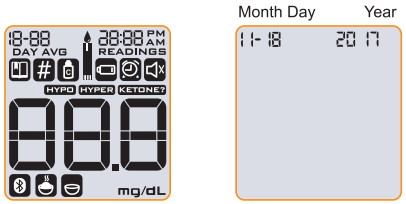
The GoChek 2 Connect Blood Glucose meter requires CR2032 3.0V coin cell battery. You can find two in the carrying case. Please follow the steps below for installation:

1. Turn the meter to the back side and press the button to open the battery door as shown in the picture.
2. Insert the battery. Make sure that the positive side (+) is facing up.
3. Replace the battery door, making sure that it is closed tightly.



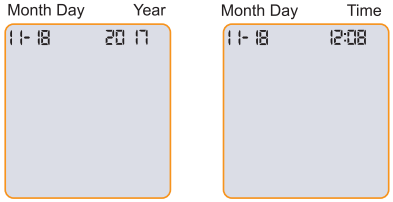
▷ Step 2: Turn ON the Meter

Long press the “<” button to hear “beep” sound, then all of icons on the display will show up at same time for a second and jump into the time setting right after.



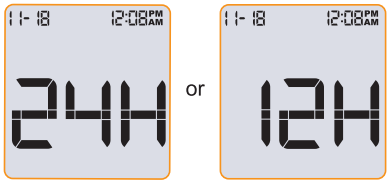
▷ Step 3: Time Settings

The display will show the month, day, and year. In the upper right portion of the screen, the year will flash. Press the “<” or “>” buttons to change the year, and then the “M” button to save your choice.



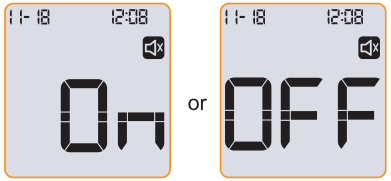
The display will now show the month and day in the top left corner. Follow the year setting procedure to set the month first and pressing” M” to save the number. Then repeat the steps for day setting.

Next, set the correct time. By default, the meter will show the time in 24-hour display mode. Press “M” to save the correct time. The meter will now allow you to change to either 24-hour or 12-hour display mode by pressing “<” or “>”. Press “M” to save and continue to the next step.



▷ Step 4: Audio Settings

You can turn your meter’s sound on and off in the audio settings menu. Press “<” or “>” to turn on or off the sound. Press the “M” button to save this setting.



When the sound is ON, the meter will provide a beep when:

a. The meter is powered ON
b. The blood sample is adequate
c. The test results are displayed
d. An error occurs
e. A test reminder alarm is activated

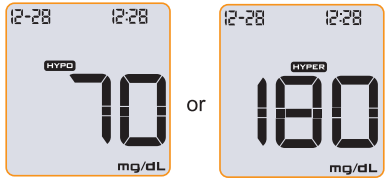
You will hear a one (1) beep when the meter is powered on, if the blood sample is adequately applied, and when the test results are displayed. You will hear two (2) short beep warning sounds if an error occurs. Please refer to the error code table included in this instruction manual.

After you have chosen the audio setting, the meter will enter the high and low blood glucose alert settings.

▷ Step 5: Presetting Hyper and Hypo Glucose Alert Settings

The meter can be preset for hypoglycemic (low blood sugar level) and hyperglycemic (high blood sugar level) values. You should set these values according to your health care professional’s advice. When your test result is lower than the Hypo alert value(the meter can be set to a maximum Hypo value of 100 mg/dL), the symbol “HYPO” will be displayed. When your test result is higher than the Hyper alert value (the meter can be set to a minimum Hyper value of 120 mg/dL), the symbol “HYPER” will be displayed.

The Hyper and Hypo settings are OFF by default.



To change the Hypo limit alert value (or turn off), press the “<” or “>” buttons and then the “M” button to save. Next, change the Hyper limit alert value (or turn off) by pressing the “<”or “>” buttons and then the “M” button to save. The meter will enter the ketone test warning setting.

◎ NOTE:
The Hypo and Hyper values differ for each individual and should always be set after consulting a physician.

▷ Step 6: Ketone Test Warning Settings

To turn on or off the blood ketone test warning, press the “<” or “>” buttons and then the “M” button to save. When the blood ketone test warning function is on, the “KETONE?” symbol will show in the upper right section of the display if your test result is higher than 300 mg/dL. After choosing the ketone test warning setting, the system will enter the meal marker setting.

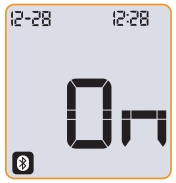
or

◎ NOTE:
This setting is not for the measurement of ketones. It’s only used to notify the user that they may check their ketone level.

▷ Step 7: Bluetooth Settings (for GoChek 2 Connect only)

The GoChek 2 Connect meter has the ability to transfer blood glucose history to a mobile phone. While the Bluetooth icon is flashing, press the “<” or “>” button to toggle the setting ON or OFF and then press the “M” button to save.

or

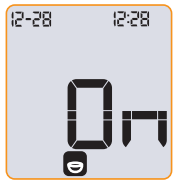


▷ Step 8: Meal Marker Settings

The meter has a meal marker function that allows you to mark your test result as before or after a meal. To turn on or off the meal marker function, press the “<” or “>” buttons and then the “M” button to save.

Since meal setting is the last setting option, therefore the meter will power off after this setting is chosen and the meter now is ready for testing.

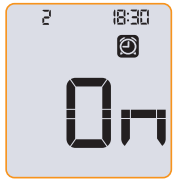
or



▷ Step 9: Test Reminder Alarm Settings

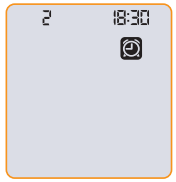
You can preset up to 10 different test reminder alarms that can remind you to regularly perform blood glucose tests. You can also turn on or off any of the reminder alarms.

When the meter is OFF, long press the “>” button until “beep” sound and the display show up, then enter the test reminder alarm settings. Press the “<” or “>” button to select the number alarm that you would like to edit, and then press the “M” button to confirm your choice. Now you can edit the time (hour/ minute) that you would like the alarm to sound by pressing the “<” or “>” button, and “M” to confirm/save. After saving the time, the meter will turn off.



or

The test reminder alarms sound for 1 minute, and then repeat at an interval of 5 minutes. The alarm is cancelled by inserting a test strip or by pressing any key. When a test reminder alarm is on, the alarm clock symbol will be displayed on the screen. An example is shown in the figure:



When the test reminder alarm sounds, the display shows:

◎ NOTE1:
If you hold the "<" or ">" button, the numbers will decrease or increase more quickly.

◎ NOTE2:
After you replace the battery, you will only need to reset the time. Other settings are stored in the meter memory.

Quality Control Tests

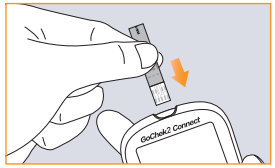
Quality control testing is done to verify that the blood glucose meter and test strips are working correctly, and to ensure the accuracy of the test results. There is no minimum test frequency to be enforced but we are recommending

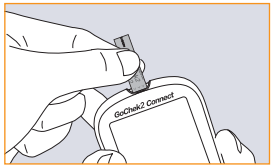
running control test at least once a week. However, the quality control test needs to be conducted in the following situations:

- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with the way you feel.
- When you suspect the meter is damaged.
- When you drop your meter.
- When your meter experienced physical shock.

▷ Quality Control Testing Procedure

Step1: Insert the test strip all the way into the test strip port, and the meter will turn on automatically. If the audio is ON, you will hear a "beep" sound, and all the icons on the display will turn on at the same time.





The screen will now display the date, time, and the flashing "apply blood" icon. The appearance of the "test strip" and flashing "blood drop" icons show that the test strip has been inserted correctly.

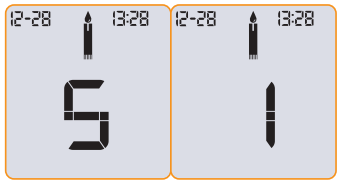
Tip: If the test strip is not inserted correctly, the meter will not power on.

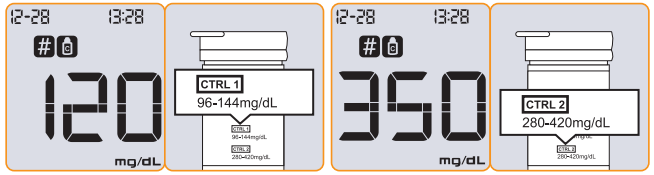
Step2: Shake the control solution bottle, gently squeeze out the control solution, discard the first drop, and drop the second drop onto a flat, clean and nonabsorbent surface such as glass surface, marble surface or benchtop. Now touch the second drop to the sample area of the test strip. Do not let the bottle come in contact with the test strip. If the audio is on, the meter will beep, telling you that enough control solution has been applied.

Tips: Bubbles may be formed on the bottle neck when the bottle is getting squeezed, and it will reduce the liquid volume that obtained. Wipe the bubble with clean paper towel until full liquid drop comes out and follow the instruction for next steps. If one drop of control solution does not fill the test window, please discard the test strip and try again.

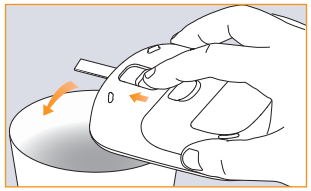
Step3: After applying enough control solution, the display will count down 5 seconds and the control solution test result will be displayed on the screen.

If the control solution test result falls within the control range that is printed on the package (CTRL 1 on test strip vial or foil pouch), this indicates that the meter is working normally, and the system is functioning properly.





Step4: After the test has been completed, slide the test strip ejector to pop out the test strip, and the glucose meter will automatically turn off.



◎ NOTE:

The device can differentiate the test result of control solution and blood sample. When a Control Solution test is performed, the test results marked with 'control solution sign' and the 'pound sign' will be automatically displayed by the meter. These test results will not be included into 'day average' calculation

When " 🔒 " and "#" are displayed simultaneously, the result is from a control solution test, and it will not be included in the 7, 14, 30, 60, or 90-day average. When you access your test history, the control solution results are not displayed.

If the control solution results are outside of the reference range marked on the bottle:

- 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 41-113 °F (5- 45 °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 call our 7/24 customer service+1-888-288-0017.

Two levels of control solution are available labeled Control Solution 1 and Control Solution 2. 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 Steps 4 through 6, 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. If the control solution test results do not fall within the respective ranges, DO NOT use the system to test blood, as the system may not be working properly. If you cannot fix the problem, contact your dealer for help.

Please contact your dealer to purchase control solution. Each box of control solution contains both Control Solution 1 and Control Solution 2.

Testing Your Blood

The following steps show how to use the meter, test strips, lancing device and sterile lancets together to measure your blood glucose concentration. The main steps are as follows:

Step 1: Insert the test strip face up into the test strip port. The meter will automatically turn on and display the flashing "Apply Blood" icon.

Step 2: You can choose any fingertip for the blood collection site. Usually a tiny amount of blood is enough. Touch the blood drop lightly to the edge of the sample area. Complete the test within two minutes, or the meter will automatically power off.

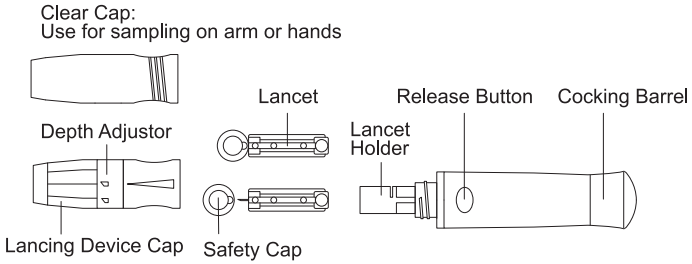
Step 3: After the meter detects that there is an adequate amount of blood, it will count down 5 seconds and display the glucose test results. The test result will be stored in the history automatically. Slide the test strip ejector to eject the test strip, and the meter will shut off automatically.

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:

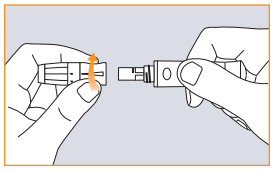
Prior to testing, wash your hands with soap thoroughly. Dry your hands and the sampling site, ensuring that there is no soap residue remaining. Then use 70% isopropyl alcohol wipes that are recommended for use on human skin to disinfect the sampling site. Use warm water to increase blood flow if necessary. Do not use the CaviWipes (EPA number: 46781-8) on your skin.

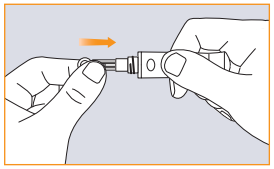


Fingertip Testing:

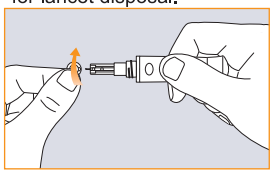
Adjust the depth penetration to reduce the discomfort.

1. Remove the lancing device cap. Insert the lancet into the lancet holder until it comes to a complete stop.

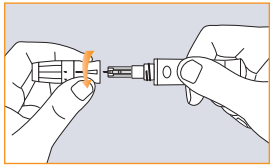




2. Twist off the safety cap from the lancet, save the safety cap for lancet disposal.



3. Carefully install the lancing device cap onto the lancing device and avoid touching the lancet needle tip.



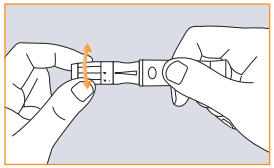
4. Adjust the puncture depth by rotating the depth adjustor (the lancing device has 5 puncture depth settings). To reduce discomfort, choose the lowest setting that still produces an adequate blood sample.

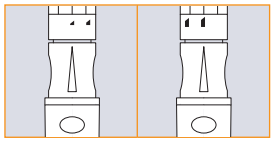
Depth Adjustment :

1 and 2: for delicate skin

3: for normal skin

4 and 5: for thick or calloused skin



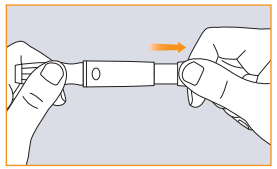


Shallow Puncture Deep Puncture

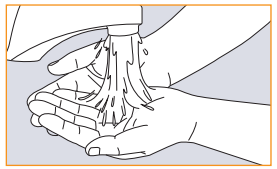
NOTE

Greater pressure of the lancing device against the finger will also increase the puncture depth.

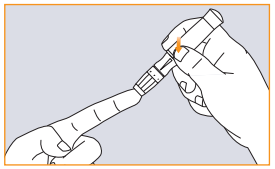
5. Pull back the cocking barrel until you hear a click. Now the lancing device is loaded and ready to draw blood.

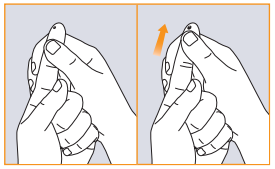


6. Before taking a blood sample, wash your hands or use an alcohol swab to clean the area. Washing your hands in hot water increases blood circulation.



7. Holding the lancing device against the side of the finger to be lanced, press the release button and then put down the lancing device. Wipe away the first drop of blood and use the second drop for the test strip.



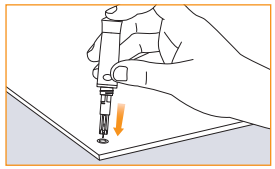


◎ NOTE

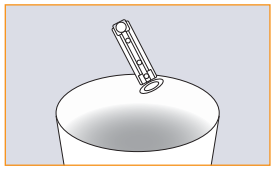
To reduce pain, prick on the sides of the fingertips, where there are fewer nerve endings. Rotate finger locations as much as possible to accelerate wound healing and decrease callouses.

Lancet Removal

1. Unscrew the lancing device cap. Firmly push the needle into the safety cap.



2. Pull out the lancet from the lancet holder. Please dispose of the used lancet properly.



◎ Lancet Precautions:

- **Do not use a lancet if the safety cap is loose or missing.**
- **Do not use a lancet if the needle is bent.**
- **Use caution whenever a lancet needle is exposed.**
- **Do not share lancets with other people.Do not reuse.**
- **To avoid cross contamination, always use a new sterilized lancet. Do not reuse lancets.**
- **Avoid contaminating lancets with hand lotion, detergents, oil, and other debris.**

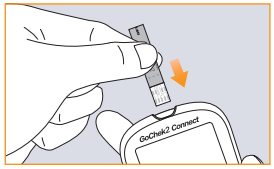
Reminder:

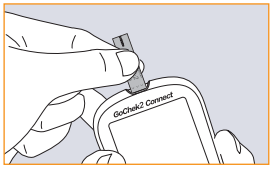
- Lancing devices and lancets is intended only for a single user and should not be shared. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.
- Clean your lancing device before and after use with 70% isopropyl alcohol or a disinfectant wipe. Be sure to clean the part of the device that touches the finger. Do not immerse the lancing device in water.
- Control excess bleeding and disinfect your wound after use.

Testing Blood Glucose

When you insert the test strip, the meter will automatically turn on (except in data transfer mode).

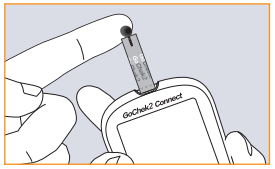
1. Insert the test strip all the way into the test strip port, and the meter will turn on automatically. If the audio is on, you will hear a “beep” sound, and all of the icons on the display will turn on at the same time. If the strip is inserted upside down, the meter will not turn on.





2. The test strip has been inserted correctly when you see the “Apply Blood” icon and drop icon flashing. If the test strip is not correctly inserted, the meter will not turn on – repeat the steps above.

3. Apply blood to the sample area of the test strip. If the audio is on, the meter will beep, telling you that enough blood has been applied and the meter will start to measure.



IMPORTANT:

- **Do Not apply blood to the front or back of the test strip.**
- **Do Not smear the blood drop onto the test strip.**
- **Do Not press your finger against the test strip.**

4. The display will count down 5 seconds during the measurement process. If the audio is on, the test will end with a beep. If you applied a blood sample but the meter does not begin account down, please discard this strip and use a new test strip.

   If you do not want to save the result for any reason, press the “>” button, the test results will be marked with the “#” icon. Test results marked with “#” icon will not be included in the 7, 14, 30, 60- and 90-days average.

   If you accidentally mark your result with the “#” icon, simply press the “>” button again to cancel the mark.

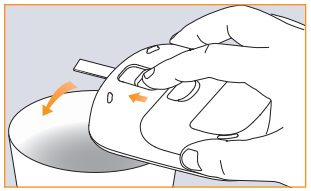
   After marking a result with “#”, please test again with a new strip. If the before/after meal marker setting is on, you can press the “<” button to tag the reading before or after meal, as shown in the figure:

   Press the “M” button to confirm.

   If an error code is displayed, please check the troubleshooting instructions. If “HI” or “LO” symbol is displayed, refer to the “HI” and “LO” Messages section.

5. Record valid results in your logbook with the date and time and compare them to the target goals set by your healthcare professional.

6. After the test has been completed, slide the test strip ejector to pop out the test strip, and the glucose meter will automatically turn off.



◎ NOTE:
Please wash your hand with soup and water thoroughly after handling the meter, lancing device or test strip.

Understanding Test Results

Suggested Test Times and Target Goals

Tracking your glucose concentrations with regular blood glucose testing is an important part of managing diabetes. Your healthcare professional will help you decide the normal target range for your glucose levels and how often you should test according to your situation.
Suggested times to test include:

- When you wake up (before eating)
- 1-2 hours after breakfast
- 1-2 hours after lunch
- Before dinner
- Before bedtime
- 2-3 o'clock in the morning (if taking insulin)
- Before breakfast
- Before lunch
- Before and after exercises
- 1-2 hours after dinner
- After a snack

More frequent tests may be required when:

- You adjust your medication dosage.
- You think your glucose levels may be too high or too low.
- You feel ill.

Reference: Normal blood glucose target ranges (from Standards of Medical Care in Diabetes - 2020, Diabetes Care 2020 Jan; 43(Supplement 1): S1-S2).

Target Blood Glucose Range at Different Time period

Time	Target Range (mg/dL)
Empty stomach	70-100
2 hours after a meal	<140

(Note: 1 mmol/L = 18 mg/dL)

How many times per day should I test?

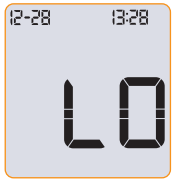
The testing frequency should be determined by your health care provider. Please discuss the number of tests and test times with your healthcare professional.

Record your blood sugar levels and other relevant information in your logbook. Bring your records when you visit your healthcare professional. It will help him understand your condition and help him modify your treatment plan.

“HI” and “LO” Messages

Your meter can accurately measure blood glucose concentrations between 10-580 mg/dL. “HI” and “LO” messages indicate that the test measurement was outside of this range.

If “HI” is displayed, it indicates the test result is above 580 mg/dL. You should test again to ensure that no mistake was made in the procedure. If you are sure your glucose meter is functioning properly, no mistakes were made, and the test results still show “HI”, then you may be in a state of severe hyperglycemia, please contact your healthcare professional immediately.



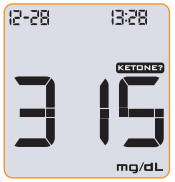
If “LO” is displayed, it indicates the test result is below 10 mg/dL. You should test again to ensure that no mistake was made in the procedure. If you are sure your glucose meter is functioning properly, no mistakes were made, and the test results still show “LO”, then you may be in a state of severe hypoglycemia, please contact your health care professional immediately.

“HYPO” and “HYPER” Messages

If “HYPO” is displayed, it indicates the test result is below the hypoglycemia limit that you entered in the settings.

If “HYPER” is displayed, it indicates the test result is above the hyperglycemia limit that you entered in the settings.

Blood Ketone Test Reminder: if “KETONE?” is displayed, this indicates a blood ketone test is necessary because your blood glucose test results are higher than 300 mg/dL. Please contact your healthcare provider.



Notes:

- This meter system is only for in vitro diagnostic use, and only can be used with GoChek 2 test strips. The meter is not compatible with other test strips.
- This meter can only be used to determine blood glucose levels with fingerstick samples.
- This meter can be used within a hematocrit (HCT) range of 10% ~ 70%.

  Note: **Please do not use this product for testing if your hematocrit value is out of this range. Ask advice from your doctor if you are not sure about your hematocrit value.**
- Patients who are severely ill, suffer from severe dehydration, or diagnosed hyperosmolarity (with or without ketosis) should not use the GoChek 2 connect Blood Glucose Monitoring Systems. Please contact your physician if you are not sure about your health condition.
- This product is only suitable for self- monitoring.
- Carefully discard all consumables (i.e strips, lancets, etc.) from the use of your device according to instructions provided by your health care providers.

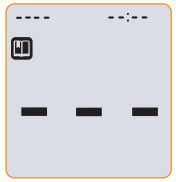
Meter Memory

The glucose meter can store up to 500 test results with the corresponding time and date. If 500 test results already exist, a new result will overwrite the oldest one. The glucose meter also is capable of calculating 7, 14, 30, 60- and 90-day averages from the stored results.

Memory Mode

1. Press the “M” button to enter memory mode. The “ ” icon and latest test result will be displayed.

If the blood glucose meter is used for the first time, “-–” and “ ” will be displayed. The date will not be shown for the first test.



2. The stored test result along with the associated time and date are displayed at the same time. Test results marked with “#” icon will not be included in the 7, 14, 30, 60 and 90day averages.
3. Press the “<” or “>” button to review all stored test results.
4. Press button “M” again to enter the data average screen. The number of days (“DAYAVG”) and number of readings (“READINGS”) used in the average calculation will be displayed. If no data has been recorded, then the meter will turn off.

5. Press the “M” button again, and then use the “<” or “>” buttons to scroll through the 7, 14, 30, 60, and 90-day averages. Press the “M” button to see the before meal and after meal marker averages. The meter will calculate the historical averages according to the parameters that you choose, and the meter will show how many records are used to calculate the average.

6. If the meter has not been used for 7 days which is the minimum amount of time indicated as the “day average”, the meter will not show an average.
7. Finally, press “M” one last time to turn off the meter.

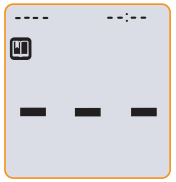
Note: The result marked by the pound sign “#” symbol will not be count into the average result

Clearing the Memory

Please be careful when using the clear memory function because the action is irreversible. Once the memory is deleted, it cannot be restored. The clear memory function will erase all test records.

1. While in the memory mode, press the “<” and “>” buttons at the same time enter the clear memory mode.

2. Press “M” to confirm that you would like all records to be erased. The “ ” and "---"icons will display at the same time, and the meter will turn off automatically after a few seconds.



3. If you want to abort the memory delete function, you can cancel by pressing the “<” and “>” button instead of the “M” button. The memory will not be erased.

Bluetooth Data Transfer (for GoChek 2 Connect only)

The GoChek 2 Connect meter has the ability to transfer blood glucose history to iOS and Android mobile phones that support Bluetooth. First download the App from your device's app store (Apple or Google Play).

Then, turn on the Bluetooth function on your meter (Step 7 of the "Meter Setup Before Use" section). Turn off the meter, and then enter the Memory mode by long pressing the "M" button. The meter will enter Memory mode and the Bluetooth icon will appear. While the icon is active, enter the pairing mode on your phone and enter the meter's serial number.

Now that your meter and phone are paired, the meter will automatically send blood glucose readings to your phone app. Refer to instruction for use of Pancares app directions for more information.

Comparing Meter and Laboratory Results

Your 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. Glucose concentration results can be affected by a number of factors and conditions, but these factors and conditions will not affect the test results of biochemical analyzers.

Under normal conditions, the difference between measurements with your meter and laboratory results are within the range allowed by national standards.

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

1. Make sure your meter is working properly.
2. Comparisons will be more accurate if you do not eat for at least four hours (preferably eight hours) before testing. (if you are insulin dependent, please do not skip meals for this testing)
3. Bring your blood glucose meter, test strips, and control solution to the lab.
4. Ensure that the time between tests with your meter and the laboratory is within 15 minutes.
5. Wash and dry your hands before obtaining a blood sample.
6. Make sure you closely follow the instructions in this manual.

Maintenance

Blood Glucose Meter Storage

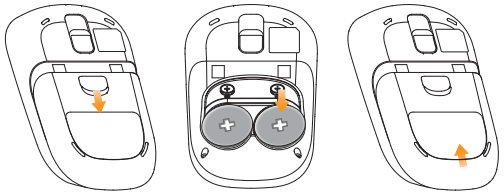
- Keep the test strip port area clean.
- Keep the meter surface dry. Do not allow liquids to enter the housings.
- Avoid extreme temperature and humidity. The storage condition for blood glucose meter is -40°C to 55°C and less then 90% relative humidity.
- Do not leave the meter in your car.
- Avoid dropping the meter. If you accidentally drop it, perform a quality control test to verify the system is working properly.
- Keep the meter, test strip, lancet and control solution away from children and pets.
- Do not disassemble the meter. Disassembly will void the warranty.
- Please follow the local regulations to dispose of the meter and battery properly.

Replacing the Battery

The meter uses CR 2032 3.0V coin cell battery. When the meter displays the battery symbol ( ), this indicates that the battery is low, and you should replace the battery as soon as possible. The "E-6" error code means that the battery is empty, and you cannot use the meter until the battery is replaced.

How to replace the battery:

1. Make sure the meter is off.
2. Open the battery door on the back of the meter.
3. Remove the old battery and replace with new CR 2032 3.0V coin cell battery, making sure that the positive (+) side is facing up.
4. Replace the battery door.
5. After replacing the battery, you may need to re-enter some settings in the settings menu.



Cleaning and Disinfection

Clean and disinfect your device is very important for preventing bloodborne pathogen transmission. Without proper cleaning and disinfection instructions, users may face an increased risk of infection, which can lead to serious injury or death.

Disinfecting is killing the bacteria and viruses on a surfacewhile cleaning is removing foreign mater from a surface. Therefore, it is possible that your device to be clean but not disinfected, or disinfected but not clean. We are recommending CaviWipes (EPA number: 46781-8) for you to clean and disinfect your device at the same time. This wipe can be found in most retail stores such as Amazon, Walmart and Office Depot etc. The device has been validated for 7 times wipe per day for 3 years in total, however it is too much of a burden for you to clean the meter 7 times per day. Therefore, we recommend you clean and disinfect your device at least once a week.

Disinfection Materials Safety Composition/Ingredients

CaviWipes (EPA number: 46781-8), with following as the active ingredient:

Component	Amount
Isoproponal	17.2%
Ethylene Glycol Monobutyl Ether (2- Butoxyethanol)	1-5%
Diisobutylphenoxyethoxyethyldim ethylbenz ylammonium chloride	0.28%
Water	70-80%

The CaviWipes has shown to be safe for use with the GoChek 2 series meter and lancing device.

Glucose Meter instruction

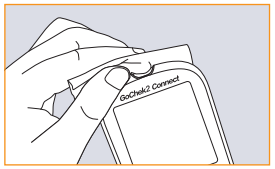
Step1: Clean the screen

Step2: Clean the button

Step3: Clean the test strip port

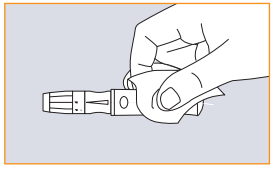
Carefully wipe the test strip port, button and housing with CaviWipes (EPA number: 46781-8) until they are wet and wait for the contact time which is 2 minutes. Allow meter to air dry for 2 minutes after the disinfectant wiping process. Discard the wipe after use.

Be careful not to immerse the device into any liquid. We recommend that you store the meter in the carrying case after use. Your blood glucose meter is a precision instrument. Please be careful.

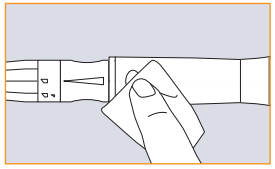


Lancing Device instruction

Step1: Clean the housing

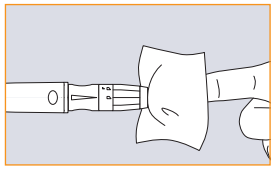


Step2: Clean the release button



Step3: Clean the lancet holder

Carefully wipe the lancet holder, release button and housing with CaviWipes (EPA number: 46781-8) until they are wet and wait for the contact time which is 2 minutes. Allowed meter to air dry for 2 minutes after the disinfectant wiping process. Discard the wipe after use. Do not immerse the lancing device into any liquid.



If the device color is fading or changing, the device shape is distorted or the device surface is rusty, if you think your device is experienced any unusual change after cleaning and disinfection, please stop cleaning and disinfection and call 7/24 customer service +1-888-288-0017. Do not use it to measure your blood glucose level meanwhile.

◎ NOTE:
Please wash your hand with soup and water thoroughly after handling the meter, lancing device or test strip.

Troubleshooting

The meter has built-in messages to alert you of problems. When error messages appear, note the error number, turn off the meter, and then follow these instructions.

Display	Causes	Solution
Meter does Not turn on	Battery may be damaged or not have enough charge	Replace the battery.
	Meter is too cold	Allow the meter to warm to room temperature for 30 minutes, then use.
	Insert wrong side or wrong tip of the test strip	Double check if you insert the contact part into the test strip port while the print side is facing you.
	Third party test strip (test strips manufactured by other companies) used	Please be sure to use Gochek 2 test strip.
E-1	Unqualified test strip detected	Please use a new Gochek 2 test strip. If the new test strip has no problem, discard the damaged or unsupported test strip
E-2	Test strip is wet, contaminated, or used;Meter self-test error;Sample applied to the test strip too soon	Make sure that the strip has not expired, is not damp, or used. If the test strip is ok, remove the battery for 30 seconds, and retest with a new strip. If the problem persists, Please call our 7/24 customer service number +1-888-288-0017.
E-3	Insufficient sample	Retest with a new strip. Make sure there is enough blood to fill the test window.
E-4	Test strip was removed during the test	Repeat the test and ensure test strip remains in place.
E-5	Temperature exceeds the normal operating range 41-113°F (5°C ~ 45°C)	Move to a place within the normal operating temperature range and repeat the test.
	The battery is low, but may be used for another 20 tests	The next 20 results will still be accurate but replace the battery as soon as possible.
E-6	The battery has been fully discharged – no more tests are possible	Replace the battery and repeat the test.

Display	Causes	Solution
E-7	Strip testing error	Repeat test. If problem persists, please contact 7/24 customer service number +1-888-288-0017.
HI	The meter has recorded a level that is higher than the range of the meter	Repeat test. If you see HI again, contact your doctor immediately.
LO	The meter has recorded a level that is lower than the meter test range	Repeat test. If you see LO again, contact your doctor immediately.

Warranty

The use life for this product is 5 years. The warranty for this product is 5 years and start with the date of your purchase. Please complete the warranty card that came with this product and mail it to your dealer to register your purchase. Please keep your sales receipt and other related purchase documents. If the meter fails for any reason other than obvious abuse within the warranty period, we will repair or replace it free of charge. Please note the date of purchase.

Date of Purchase: _____

Note: The warranty covers only the blood glucose meter and does not include the battery.

Reference

1. FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) https://www.fda.gov/medical-devices/vitro-diagnostics/letter-manufacturers-blood-glucose-monitoring-systems-listed-fda

2. CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

3. Standards of Medical Care in Diabetes - 2020, Diabetes Care 2020 Jan; 43(Supplement 1): S1-S2

Symbol Index

	Consult instructions for use	IVD	For *in vitro* diagnostic use
	Use by	LOT	Lot Number
	Manufacturer		DC Power
SN	Serial Number	CTRL	Control Range
	1 Time Use		Do not dispose with household waste
-40°C 55°C	Storage Temperature Range		Biohazard

FCC Statement

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.

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

NOTE: 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 accordance 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.

Important Note: Change or modifications not expressly approved by the manufacturerresponsible for compliance could void the user'sauthority to operate theequipment

RF Exposure Information

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.