REF GHP-101ProSK

Acuteck™

BLOOD GLUCOSE MONITORING SYSTEM

USER' S MANUAL

IVD CE 0197

Blood Glucose Monitoring System

System: GHP-101ProSK

Meter: GOH-101

Test Strips: C902005

Control solution:C902095

Product introduction

Intended Use:Blood Glucose Monitoring System is an automatic *in vitro* monitoring system for quantitative detection of glucose concentration in fresh capillary whole blood or venous whole blood.

The system is intended for self-testing by people with diabetes or people suspected of having diabetes at home, and for near-patient testing by healthcare professionals in clinical settings.

The system is only used for the monitoring of blood glucose levels and the preliminary screening of blood glucose abnormalities, and is not suitable for the diagnosis of diabetes.

Test Principle: The Blood Glucose Test Strips are thin strips. They work with Blood Glucose Test Meter to quantitatively measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the Blood Glucose Test Meter. The amount of glucose is then calculated based on this current. The result is shown on the screen of the meter.

Please follow these guidelines:

- Read instructions before use.
- The Blood Glucose Test meter should only be used with *Acuteck* Blood Glucose Test Strips.

- For *in vitro* diagnostic use only. Blood Glucose Monitoring System is to be used only outside the body for testing purposes.
- For self-testing and near-patient testing.
- Do not change treatment plan based on the test results without advice of doctor or profession.
- For users, contact your doctor when the blood glucose reading is abnormal against your experiencing symptoms.
- Keep out of reach of children.

Main Features of Blood Glucose Monitoring System

- Pre-suction siphon designed test strip, easy and convenient to use.
- Tiny blood sample(0.6μL) for glucose testing.
- Fast measuring time: Blood glucose in 5 seconds.
- Large LCD for easy reading.
- Automatic 7,14&28 day averages for glucose testing.
- Can store 500 results of blood glucose testing.
- No Coding technology.

For more ordering information, please contact 400-853-5577 or email 'contact@diareagent.com'.

Incident Reporting

The summary of safety and performance Intended users and patients can log in to the European database on medical devices (Eudamed) to request the summary of safety and performance(SSP) of the device or contact the manufacturer to obtain it.

In the event of any serious incident that has occurred in relation to this product, please inform Assure of the incident, and the competent authority

of the Member State in which the user and/or the patient is established.

- the death of a patient, user or other person;
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health:
- a serious public health threat

Index of Symbols

REF	Catalog number		Temperature limitation
	Date of manufacture	UDI	UDI information
IVD	*In vitro* diagnostic medical device		Used by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	SN	Serial Number
	For near patient testing		For self-testing
	Consult instructions for use or consult electronic instructions for use		Electrical and electronic items should not be disposed of in your dustbin or wheelie bin, but should be recycled.
LOT	Batch code	CE	CE Marking
EU REP	Authorized representative in the European Community		

REV 0.0

Revision date: 2025-06-06

Table of Contents

Section 1 Introduction of Monitoring System

1.1 Packaging composition

Before testing, read the instructions carefully and learn about allthe components of your Blood Glucose Monitoring System. Depending on the product you purchased separately, please check the list of contents on the outer box for details of components.

Component Descriptions

① **Meter:** Reads the test strips and displays the blood glucose concentration.

② **Test Strips:** Blood Glucose Test Strips

③ **Sterile Lancets:** Used with the lancing device to collect blood specimens for individual test. Sterile lancets are inserted into the lancing device with each blood collection and discarded after use. (be packaged individually)

④ **Lancing Device:** Used with lancets to prick the fingertip for blood sample collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort.

⑤ **Carrying Case:** Makes this Blood Glucose Monitoring System easy to carry anywhere.

⑥ **User's Manual:** Provides detailed instructions on using the Blood Glucose Monitoring System.

⑦ **Quick Reference Guide:** Guide users to quickly start testing.

⑧ **Warranty Card:** Card included in the package, which should be completed and returned to the distributor to qualify for the 2-year meter warranty.

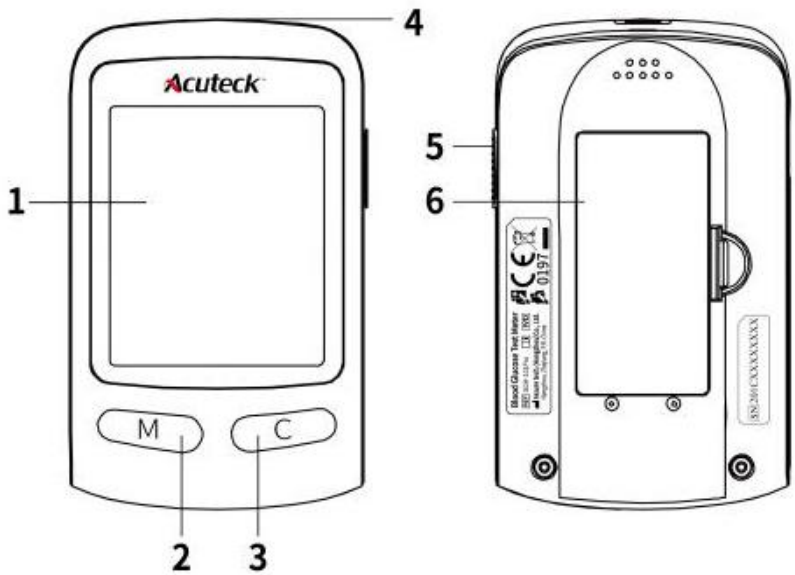
⑨ **Control Solution:** Control solution is used to check if the meter and test strips are correctly working together as a system. To ensure the accuracy of test results.

Note: Test strips and sterile lancets are disposable materials. Please use them before the expiration date.

1.2 Meter composition and display

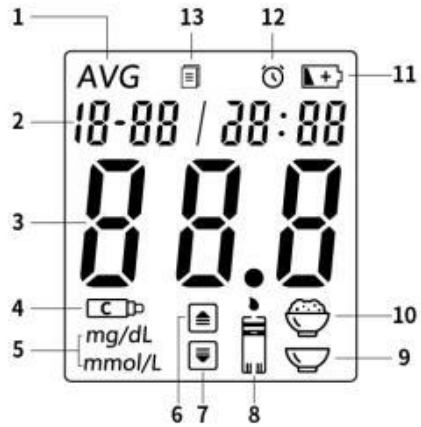
Blood Glucose Test Meter reads the test strips and displays the blood glucose concentration. Use the below diagram to become familiar with all the parts of your meter.

Main Body



1	LCD	Show your test results, and help you through the testing process.
2	Mode Button (M)	Press to recall memory and scroll through test results.
3	Set Button (C)	Press to adjust meter setting.
4	Strip Channel	Test strips are inserted into this area to perform a test.
5	Strip Ejector	Slip off the test strip.
6	Battery Cover	The battery cover is located on the back of the meter.

Meter display



1	Show an average test result stored in memory
2	Month-Day and Hour -Minutes
3	Show test result
4	Control Solution reminder
5	Measurement unit
6	Appears when the blood glucose concentration is above the “Hyperglycemia' (high blood glucose) target level that you have set.
7	Appears when the blood glucose concentration is below the “Hypoglycemia' (low blood glucose) target level that you have set
8	Test strip reminder
9	After-meal indicator
10	Before-meal indicator
11	Battery symbol (Warms when you should replace the battery)
12	Test Reminder Symbol
13	Show test result stored in memory

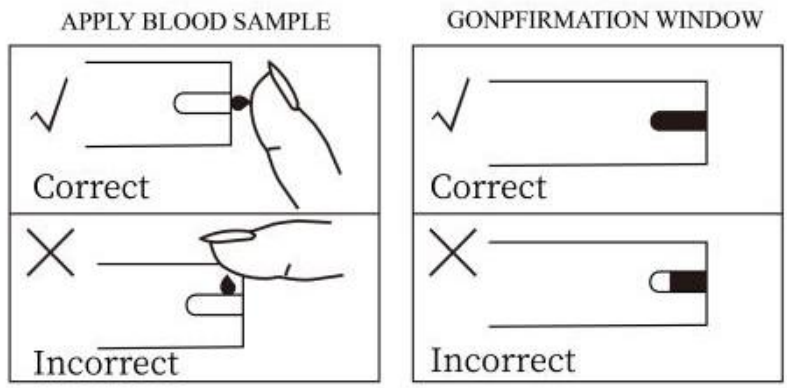
1.3 Test Strips

The *Acuteck* Blood Glucose Test Strips work with *Acuteck* Blood Glucose Test Meter to quantitatively measure glucose in fresh capillary whole blood or venous whole blood. Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell.The test strips rely on glucose dehydrogenase (GDH) to generate the glucose-specific electrochemical signal. After the glucose is oxidized,a mediator is commonly used to transfer the signal from enzyme to the working electrode. The resulting current can be detected by meter. Then the concentration of blood glucose is calculated based on this current, and the result is shown on the screen of the meter. The test procedure is automated.

Contact Bars: Insert this end of the test strip into the strip channel until it stops.

Top Edge: Apply blood here.

Confirmation Window: Check to confirm that sufficient sample has been applied.



Test Strip Package: Test strips are packed either in vial or single-bag. It depends on your purchase.

IMPORTANT: *Apply sample only to the sample tip of the test strips. Do not apply blood on the top of the test strip as this may result in an inaccurate reading.*

The meter will display inaccurate test results if blood is applied in a wrong way, such as insufficient blood sample or applying second drop of blood. Retest a fresh test strip when first drop is not enough on the test strip top edge.

Each package of test strips is printed with Lot number (LOT)and unopened expiration date.

1.4 Storage and Handling

Please review the following storage and handling instructions:

Store the test strip at temperatures between 2-30°C and keep out of direct sunlight.

Store the test strip≤90 % relative humidity.

- Do not freeze.
- Do not store or use test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips near bleach or cleaners that contain bleach.
- Immediately use the test strip after it removed out from vial or foil pouch.
- Use test strips before expired date.
- Do not reuse test strips.

1.5 Special Instructions for Test Strips in the Vial

- Test strips must be stored in the original vial with the cap tightly closed. This keeps them in good working condition.
- Do not transfer test strips to a new vial or any other container.
- Replace the cap on the test strip vial immediately after removing a test strip.
- A new vial of test strips may be used for 3 months after being first opened. Write the opened expiration date on the vial label after opening. Discard the vial 3 months after you first open it. Usage after this period may result in inaccurate readings.

1.6 Special Instructions for Test Strips in the Foil Pouch

- Tear the pouch carefully starting from the tear gap. Avoid damaging or bending the test strip.

- Use test strip immediately after removing it from the pouch.

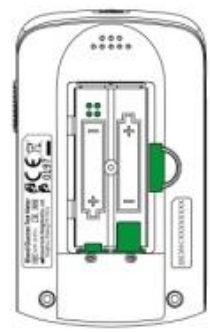
Section 2 Meter Setup Before Testing

2.1 Install the Battery

The batteries may not be preinstalled in the meter. The meter requires two 1.5V AAA batteries. Please find the batteries in your carrying case and install them according to the following steps:

1. Open the battery cover at the bottom of the meter.

2. Insert two 1.5V AAA batteries on top of the plastic tape.



3. Close the battery cover until it snaps shut.

Note: The meter has no external circuit.

2.2 Adjusting the Meter Settings

You need to adjust the meter settings before you first use your meter.
Press button ***"C"*** to enter into setup mode.

2.2.1 Set the year

The year will appear in the middle of the display.The year shown in 023 above is 2023.Press and release the button ***"M"*** to advance one year until the correct year appears. Press button "***C***" to save your choice and the "Date'figure is flashing automatically to start setting the month.

2.2.2 Set the date

Press and release the button ***"M"*** to advance one month until the correct month appears.

Press button “***C***' to save your choice, and the “Day' figure is flashing automatically to start setting the date. Press and release the button ***“M'*** to advance one day until the correct day appears.

Press button “***C***' to save your choice, and the “Time' figure is flashing automatically to start setting the time.

2.2.3 Set the time

Press and release the button "***M***"to advance one hour until the correct hour

appears.

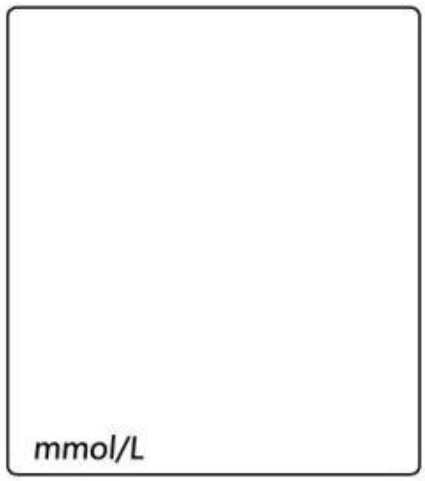
Press button "***C***" to save your choice, and the “Minute'figure is flashing automatically to start setting the minute.Press and release the button ***“M'***to advance one minute until the correct minute appear.

Press button “***C'*** to save your choice and start setting the unit.

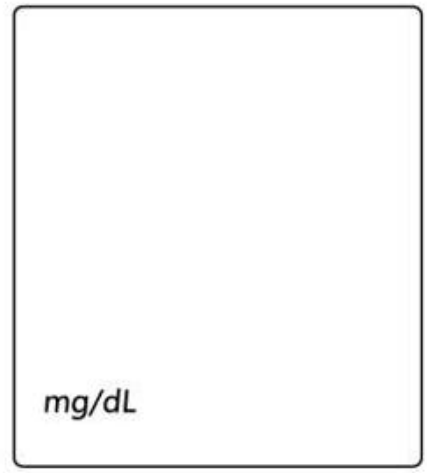
2.2.4 Set the Unit

In the state of the Time setting mode, press button "*C*" to enter the Unit

setting mode. Then press button "*M*", turn "mmol/L" to "mg/dL" to switch the unit function, As shown in the following picture.



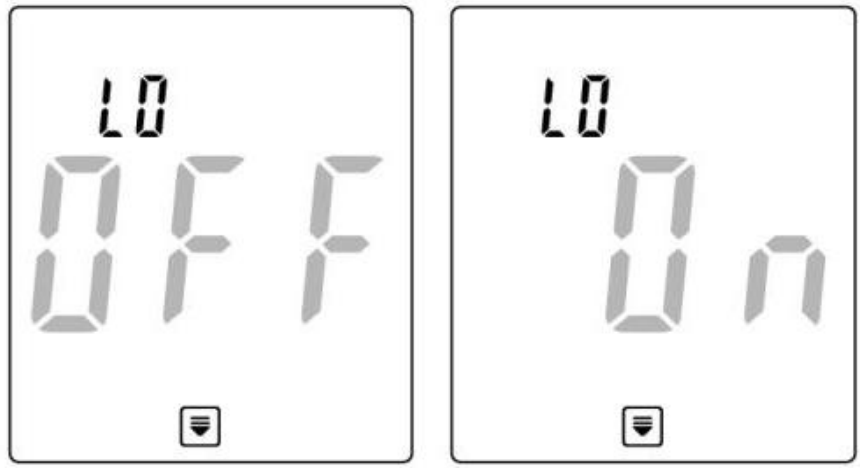
OR



Press the **"*C*"** key to save your choice and start setting Hypo Indicator

2.2.5 Hypo Indicator

In the state of the unit setting mode, press button "***C***" to enter the LO setting mode. Then press button "***M***", turn "OFF" to "ON" or "ON" to "OFF". As shown in the following picture.

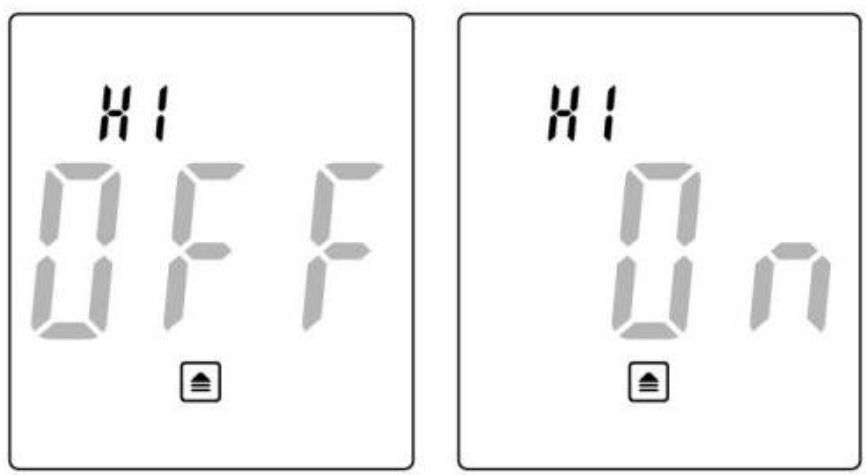


When the LO indicator is in the "off" state, pressing button ***"C"*** will enter the HI indicator setting. When the LO indicator is in the "on" state, pressing button ***"C"*** will take you to the LO indicator value settings. In the settings, press the button ***"M"*** to adjust the LO indicator value. After the adjustment is complete, press button ***"C"*** to enter the Hi indicator setting. As shown in the following picture.

Note: The meter allows the hypo blood glucose levels between 3.3mmol/L (60mg/dL) and 4.4mmol/L (80mg/dL). Consult your doctor before determining what your hypo blood glucose level is.

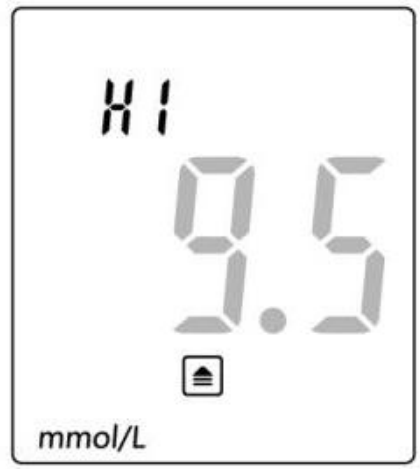
2.2.6 Hyper Indicator:

In the state of the LO indicator value settings mode, press button ***"C"*** to enter the HI setting mode. Then press button ***"M"***, turn "OFF" to "ON" or "ON" to "OFF". As shown in the following picture.



When the HI indicator is in the "off" state, pressing button ***"C"*** will enter the Test Reminder setting. When the HI indicator is in the "on" state, pressing button ***"C"*** will take you to the HI indicator value settings. In the settings, press the button ***"M"*** to adjust the HI indicator value. After the

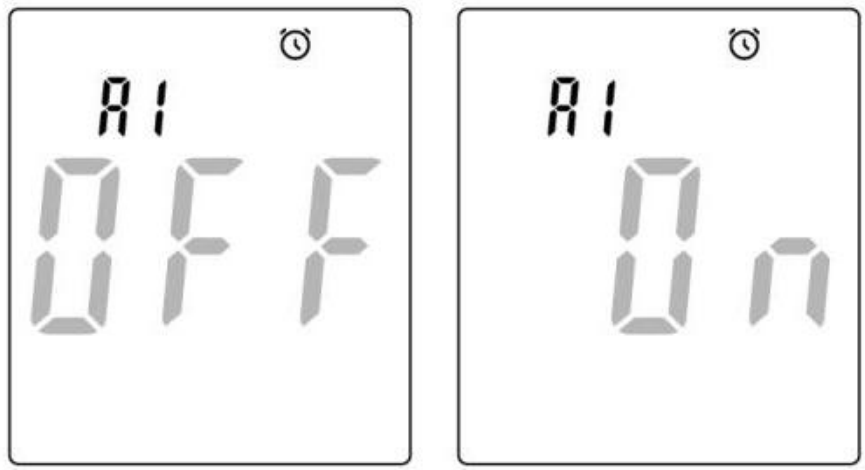
adjustment is complete, press button ***"C"*** to enter the Test Reminder setting. As shown in the following picture.



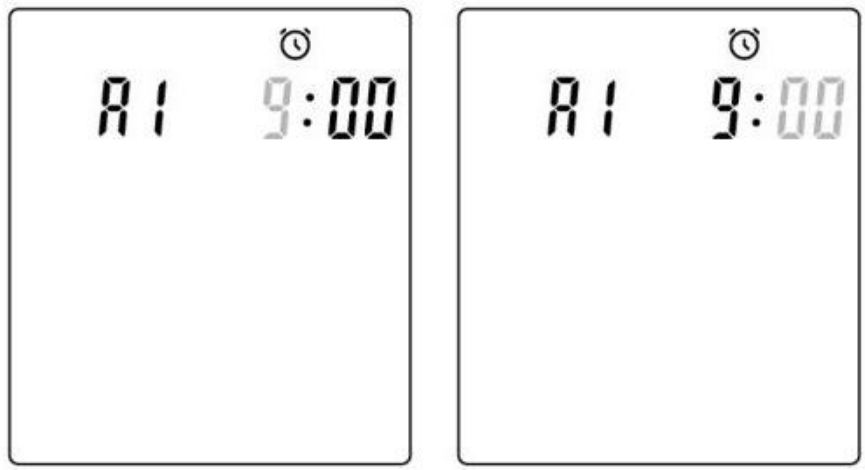
Note: The meter allows the hyper blood glucose levels between 7.8mmol/L (140mg/dL) and 11.1mmol/L (200mg/dL). Consult your doctor before determining what your hyper blood glucose level is.

2.2.7 Set the Test Reminder

In the state of the HI indicator value settings mode, press button ***"C"*** to enter the Test Reminder 1 setting mode. Then press button ***"M"***, turn "OFF" to "ON" or "ON" to "OFF". As shown in the following picture.



When the Test Reminder 1 is in the "off" state, pressing button ***"C"*** will enter the Test Reminder 2 setting. When the Test Reminder 1 is in the "on" state, pressing button ***"C"*** will take you to the Test Reminder 1 time settings. In the time settings, Press the 'M' button to adjust the hour. After adjusting the hour, press the button ***"C"*** to switch to the minute, and press the ***"M"*** button to adjust the minute. After the adjustment is complete, press button ***"C"*** to enter the Test Reminder 2 setting. As shown in the following picture.



After Test Reminder 1 setting in the "OFF" or time adjustment is complete , press the "C" enter the Test Reminder 2 setting, following the same process as above until Test Reminder 5.

If Test Reminder 5 is in the "OFF" or time adjustment is complete, press the "C" button to turn off the instrument.

2.2.7.1 Test Reminder:

Test reminder is a useful way to remind you when to test. You can set 1 to 5 reminders per day. Your meter is preset with the test reminder disabled. Wait for the meter to say “Test Reminder' to set it. The words “On' or “Off' will be voiced. You must turn it on to use this feature.

- Enter the Test Reminder settings page, Press the button "***M***" to turn the first Test Reminder “On' and “Off'. Press the button "***C***" to confirm your selection. When the Test Reminder is “Off', pressing the button "***C***" will go to the setup of the second Test Reminder. When the Test Reminder is “On', pressing the button "***C***" will go to the setup of the time for the first Test Reminder. Press the button "***M***" to adjust the first Test Reminder time. Press the button "***C***" to confirm the first Test Reminder time and then go to the second Test Reminder set up.
- When the Test Reminder is “Off' during the second Test Reminder set up, pressing the button "***C***" will go to the setup of the third Test Reminder. When the Test Reminder is “On', pressing the button "***C***"

will go to the setup of the time for the second Test Reminder. Press the button "***M***" to adjust the second Test Reminder time. Press the button "***C***" to confirm the second Test Reminder time and then go to the third Test Reminder set up.

- Repeat the same set up procedure for Test Reminder 3, 4 and 5.
- After finishing the fifth Test Reminder set up, it will then end the setup mode and power off the meter.

If one or more test reminders have been set, the reminder symbol will always appear on the LCD screen when the meter is turned on. The display sample is shown below.

After setting the Test Reminder, the instrument panel will sound a beep sound at the corresponding time point, which will last for one minute, unless you insert a test strip or press any button to turn off the alarm. When the instrument emits a beep sound at the time set for testing the reminder function, it will display the date, time, and alarm symbol. The test reminder symbol will also flash. The display example is shown below.


12-03 /
8:08

Section 3 Using the Meter Memory

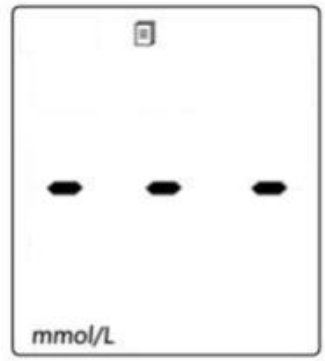
The Blood Glucose Test Meter stored glucose records and calculates overall average and before meal average and after meal average values of records from the last 7, 14 or 28 days for glucose.

3.1 Viewing Stored Records

To view stored records:

With power off, press ***"M'*** button to enter memory mode. The meter screen will display Glucose records firstly as below. Use ***"M'*** button to scroll up the memory.

If there is no glucose test results stored, the meter will display"---'as below. At this time, pressing the C key directly shuts down the instrument without entering the average result interface:

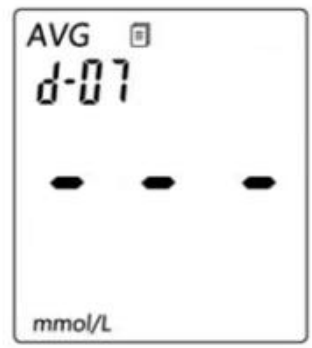


If there are glucose test results in the memory mode. Press the "C" key to enter the 7-day overall average interface. Then press the consecutive "M" key to switch to the 7-day before meal average and 7-day after meal average result interface.

Press the "M" key on the 7-day after meal result interface to switch to the 14-day overall average, 14-day before meal average, and 14-day after meal average results interface.

Press the "M" key on the 14-day after meal result interface to switch to the 28-day overall average, 28-day before meal average, and 28-day after meal average results interface. If you continue to press the "M" key, the interface will repeat the 7-day overall average interface.

If there is no result, it will be as shown in the following figure.



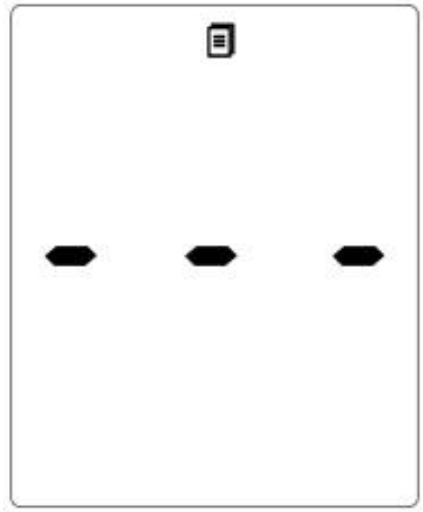
Press ***"C'*** button the meter will display **"**OFF***'*** and shut down.

3.2 Clearing the Memory

Take extreme caution when clearing the memory. This is not a reversible operation.

In the average result interface state, hold ***"C'*** for 2 seconds to enter the record deletion mode, and "dEL' is displayed.

Hold ***"M'*** button for 2 seconds to clear memory. Then screen will show as below:



Note: Please delete these stored results with caution, due to these data cannot be recovered once deleted.

To quit memory deletion interface if you do not want to clear memory, press ***"C'*** button to turn off the meter.

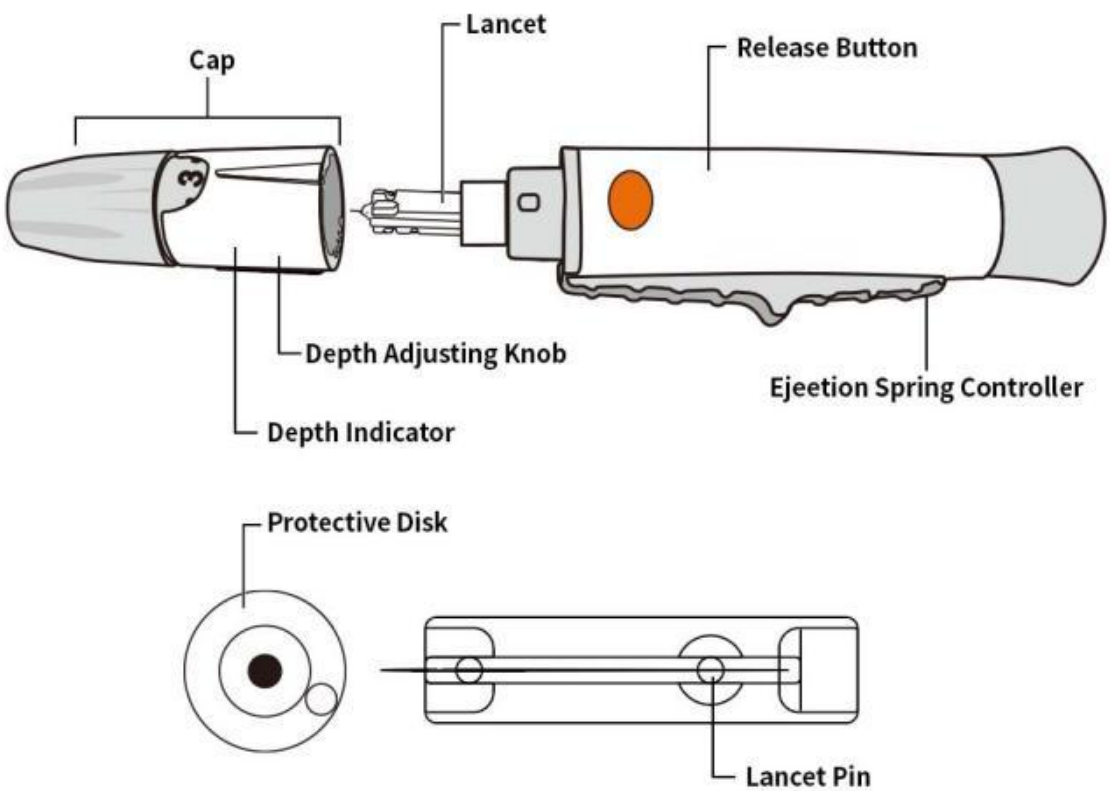
Section 4 Test Operation

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

4.1 Lancing Device and Lancets

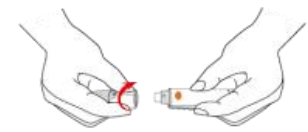
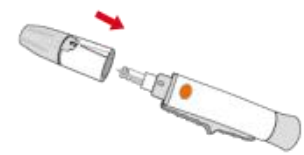
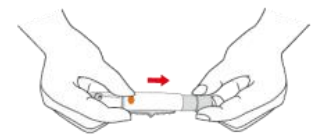
Lancing Device and Lancets are used as a whole unit to obtain blood sample.

Structure of Lancing Device



4.2 Getting a Drop of Blood

Prior to testing, wipe the test site with alcohol (75%) or lsopropyl alcohol (75%) or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

1. Turn the cap anti-clockwise to remove it. Insert a new sterilized lancet into the lancet holder and push it down firmly until it stops.	
2. Twist off the protective disk until it separates from the lancet. (Do not discard the protective disk.)	
3. Slide the cap on until it stops. (Avoid contact the lancet pin)	
4. Adjust puncture depth by turning the depth adjusting knob. The depth indicator shows the current depth selection. There are 5 optional depths. The higher of the number, the deeper of penetration.	
5. After slide the ejection spring controller back until it clicks. The lancing device is ready to use.	

6. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.	
7. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.	

Lancing Depth Guide:

number 1 for soft / thin skin

number 3 for average skin

number 5 for thick / calloused skin

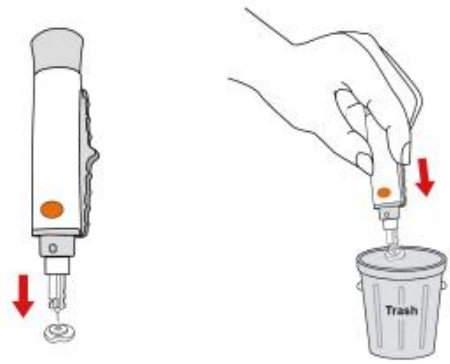
Increased pressure of the lancing device against the finger will also increase the puncture depth.

Note: To reduce infection risk, avoid contact with the lancet pin.

Disposal of the Lancet

1. Unscrew the lacing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.
2. Press the release button to make sure that the lancet is in the extended

position. Pull the lancet straight out of the lancet holder and discard it in an appropriate container. Place the lancing device cover back on the lancing device.



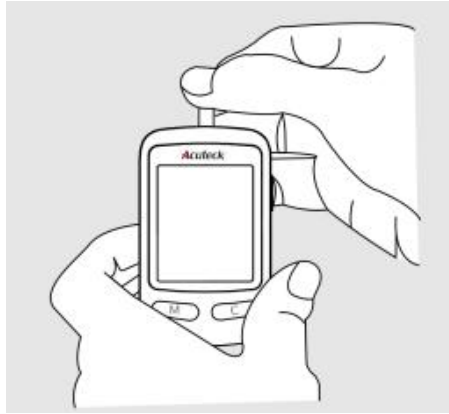
4.3 Testing Blood Glucose

Step1 Insert Test Strip

Ensure the meter is set up properly as described in previous sections. Insert contact strips into strip port, and push it in until stops. The meter will automatically turn on. The meter is not able to turn itself on when the test strip is not correctly installed.

Note: Gently and slowly insert the test strip to avoid damaging the meter.

The meter will run self-check. It will enter to testing mode if self-check passed.



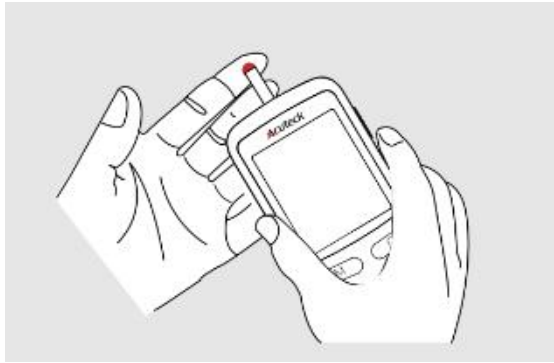
The LCD display E-t symbol to indicate over or below the operating temperature. Try operating the meter again half hour later after it positioned in operating temperature room.

When the battery is nearly exhausted, the meter will display“ ”. Replace the battery at this time.

Step 2 Apply Sample

The Blood Sample Reminder symbol flashes to remind applying blood.

Touch the blood drop to top edge of test strip. Hold until the confirmation window is full. Then, one beep sounds to remind you sample adding finished. The meter begins testing with display countdown.

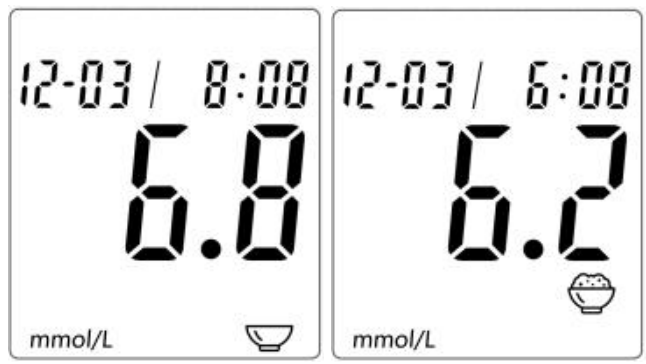


Step 3 Read Results

The screen will display test result and announced by voice.

Remove the used test strip. The meter will store the test results and automatically turn off.

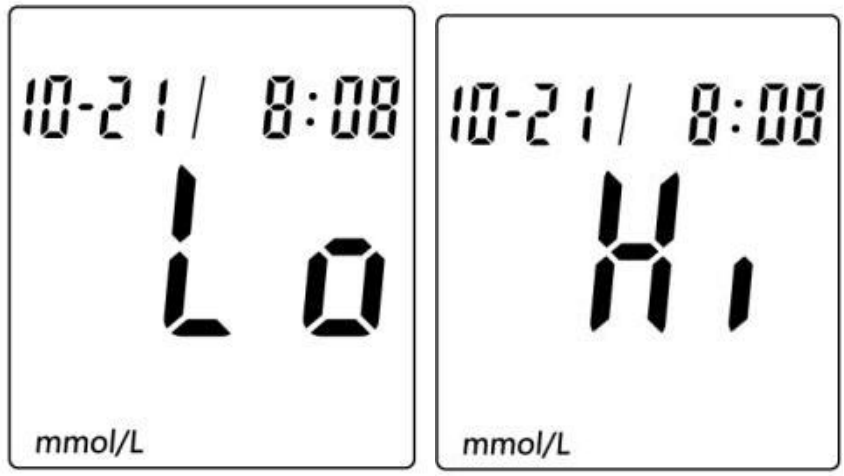
When the meal marker feature is turned on, the test result is displayed together with a suggested default meal marker based upon current time. After inserting the test strip, you can press the button "M" to switch the marking from "before meal" and "after meal" results. The selection of " before meal marking" or "after meal marking" for testing after the decision will be recorded.



“Hi' and “Lo' Messages

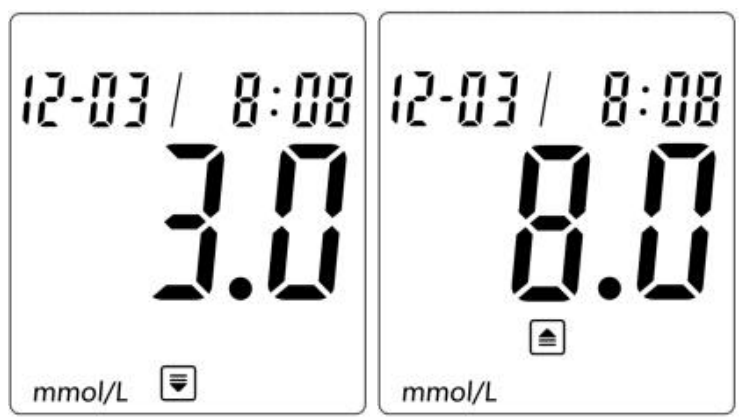
“Lo' symbol will appear on screen if blood glucose is below 0.6mmol/L (10mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as “Lo', it may indicate severe hypoglycemia (low blood glucose). You should contact your doctor immediately.

“Hi' symbol means that test result of blood glucose is higher than 33.3mmol/L(600mg/dL). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and your blood glucose is still consistently measured as “Hi', it indicates severe hyperglycemia (high blood glucose). You should contact your doctor immediately.



“Hypo' and “Hyper' Messages

If “ ' appears on the display, the measured concentration value is below the “Hypo' (low blood glucose) target level that you have set.If “ ' appears on the display, the measured concentration value is above the “Hyper' (high blood glucose) target level that you have set.



Note:

1. Gently and slowly insert the test strip to avoid damaging the meter.
2. Test results vary from the way to apply blood sample. The meter will be displayed inaccurate test results by the wrong way to apply blood,

insufficient blood sample or applying second drop of blood. Retest with a new strip when first drop is not enough on the test strip top edge.

Step 4 Discard Used Test Strip

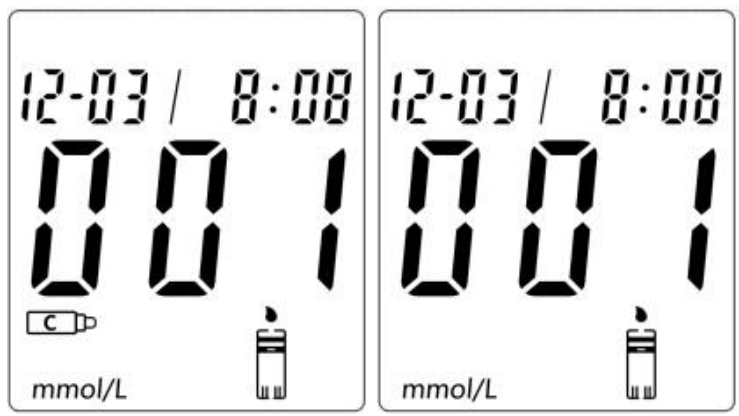
Slide forward the strip ejector to discard the used test strips.

Section 5 Performing a Quality Control Test

Quality Control Test is very important to make sure that the system is under correct operation and work properly.

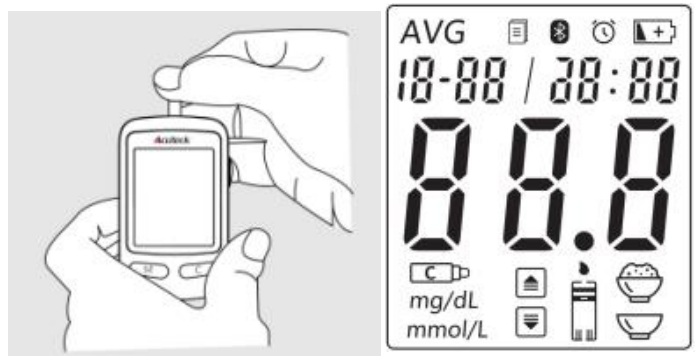
Before using the control solution test, please set up the meter.

1) In the state of inserting test strips into the instrument, press the "C" key to open the quality control mode and display the icon as shown in the following figure. Press the "C" button again to cancel the quality control mode, and the icon will disappear.



Note: After the control solution test is completed, follow Step (1) to turn off quality control mode as shown in the figure below. Press "C" button continuously and the meter will enter standby mode.

1) Insert a test strip into strip port and push it in until stops, contact strip end first and facing up. The meter will automatically turn on and shortly display symbols on screen. Make sure all the symbols are completely displayed.



2) After the meter running self-check, the screen will display date and time. When the control symbol appears along with the flashing blood sample reminds, it is ready to apply control solution.

3) Shake the control solution bottle well. Squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Then shake again and use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop.When the solution is fully applied, the meter begins measuring process. At the end of countdown, the screen will display solution test results.

4) Slide forward the strip ejector to discard the used test strip.

Note: Control solution results will not be counted in the 7, 14 and 28-day averages.

If the result falls outside the indicated control range:

- Check the expiration date of the test strip and control solution. Make sure that the test strip vial has not been opened for more than 3 months and the control solution bottle has not been opened for more than 3 months. discard any test strips or control solution that has expired.
- Confirm the temperature in which you are testing is between 20-25°C (68-77°F).
- Make sure that the test strip vial and control solution bottle have been tightly capped.
- Confirm that you are using the same brand of control solution that was provided by Assure Tech.

Two levels of control solution are available labeled Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most all 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 CTRL 1and CTRL 2 are displayed on the test strip vial (or on the foil pouch). Simply repeat step 2and 3, using Control Solution 2.

To confirm your results, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should fall within the CTRL 2range. If the control solution test results do not fall within their respective ranges, DO NOT use the system to test blood, as the system may not be working properly.

Section 6 Precautions and Warnings

6.1 Meter Use and Precautions

- Do not get water or other liquids on or inside the meter.
- Keep the Strip Channel clean.
- Keep the meter dry and avoid exposing it to extreme in temperatures and humidity.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Refer to Maintenance for details on cleaning the meter.
- Keep the system and all associated parts out of reach of children.
  Note: Follow proper precautions and all local regulations when disposing of the meter and used batteries.
- Only use fresh capillary whole blood or venous whole blood.Do not use serum or plasma.
- Test results displayed on the meter are concentration of blood glucose.
- Do not use the system in any manner not satisfied by the manufacturer. Otherwise, the protection provided by the system may be impaired.
- Blood glucose test results vary by the red cell count that is very high (above 70%).
- Severe diabetics are not recommended to use the Blood Glucose Monitoring System without doctor's instructions.
- Do not use the system in strong electromagnetic environment.
- The system can also be intended for neonatal heel blood.
- Strong electromagnetic fields may interfere with the proper

operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.

- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.
- If the outer packaging is seriously damaged during transportation, please contact your local dealer. Please check the completeness of the product. Check the use by date on the product. Do not use the product after that date.

6.2 Warnings

- During blood glucose testing, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Before discarding the meter, remove the battery or batteries. Discard used meters according to the regulations applicable in your country. Contact the local council and authority for information about correct disposal.
- The meter's category under the WEEE Directive 2012/19/EU is 5th category (Small equipment(no external dimension more than 50 cm))
- Discard used batteries according to local environmental regulations.

6.3 Strips

Test strips should be stored tightly capped in their protective package to keep them in good working condition.

- Do not store test strips outside their protective vial or pouch.
- Do not transfer test strips from original vial to any other container.
- Replace the cap on the test strip vial immediately after removing a test strip.
- Write the first date of opened vial on its label. All the test strips in this vial will be expired after 3 months.
- Do not use test strips in damaged package it will cause inaccurate results.
- Use test strip immediately after removing it from the pouch.
- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test stripaway from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.
- Not intended for the diagnosis of or screening for diabetes mellitus.
- When testing alternative sites, test when in steady state only (such as before eating, before taking medication, before exercising, or 2 hours after eating).

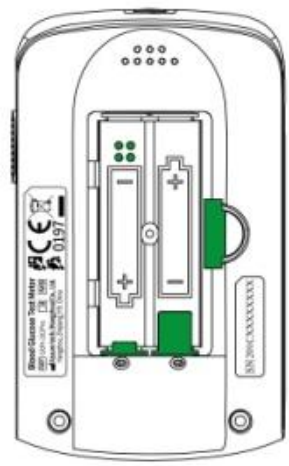
6.4 Blood Sampling

- Dispose of the blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Be sure to follow your local regulation for proper disposal.
- Thoroughly dry the puncture site. Remaining water or alcohol causes inaccurate results.
- Try different setting to find your best depth. The best depth setting is lowest depth that let you get enough blood for the test.
- Do not reuse lancet, properly dispose and discard used lancets to avoid injuries.
- Never share lancet device with anyone.
- Make sure lancing device work properly before use.
- Use carefully whenever the lancet needle is exposed.
- To reduce infection risk, do not use expired lancets.
- Do not use the lancets that the protective disk is loose or dropped-off.
- Do not use the lancet if the needle is bent.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.
- If anticoagulant blood collection tubes are required, the recommended anticoagulants are heparin or EDTA.

Section 7 Maintenance

7.1 Battery Replacement

1. Turn the meter off before removing the batteries.
2. Turn the meter over. And then slide the battery cover in the direction of the arrow to open it.
3. Remove and discard the old batteries. Insert two new AAA batteries in the battery carrier. Make sure to match up the minus (-) and plus (+) symbols.



4. Close the battery cover until it snaps shut.
5. Recheck and reset the clock setting after battery replacement if necessary. To set the meter clock, see **Section 2 Meter Setup Before Testing**.

7.2 Meter and Lancing Device Cleaning and Disinfecting

The Blood Glucose Test Meter does not require special cleaning. If the meter or lancing device is getting dirt, dust or blood, use disinfected with alcohol(75%)or isopropyl alcohol (75%), so the surface of the product needs to be disinfected before use to ensure the safety of the product and exposed parts.

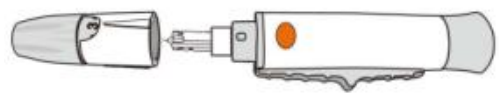
The following parts of the meter and lancing device should be cleaned and disinfected:

- The area around slots and openings (do not get any moisture in slots or openings)

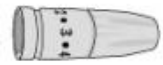
- The meter display

- The entire meter surface

- The entire lancing device surface



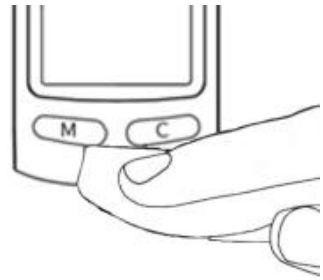
- The cap



Detailed steps for meter and lancing device cleaning and disinfection

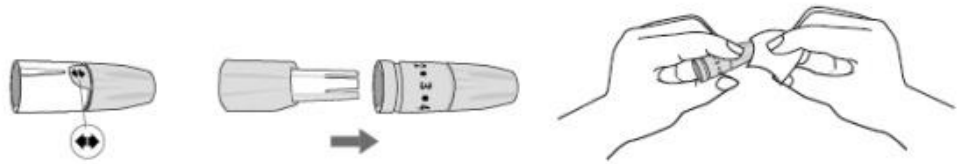
1. Wash hands thoroughly with soap and water.

2. Turn the meter off and wipe the entire meter surface with alcohol(75%)or isopropyl alcohol (75%) for 1 minute each time.Carefully wipe around the test strip slot and other openings. Make sure that no liquid enters any slot or opening.



3. Clean the surface of the lancing device with a soft cloth dipped with clean water. Please don’t immerse the body of lancing device into any liquid to avoid damage. The surface of the lancing device can be wiped and disinfected with alcohol (75%) or isopropyl alcohol (75%). If there is blood stain inside the cap of lancing device, turn the Depth Dial to arrow “ ◆◆ ' position and pull out the Depth Dial to wipe and clean the blood stain with alcohol (75%) or isopropyl alcohol (75%) (as shown in

the figure). After disinfection, align the arrow mark on the Depth Dial with the Depth Indicator arrow and install the Depth Dial back to the End Cap.



4. Wash hands thoroughly with soap and water after finishing.

The following points should be noted when cleaning and disinfecting the meter and lancing device.

- DO NOT clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.
- DO NOT throw away the cap after each lancing device use. Use the approved cleaning and disinfecting product on the cap.
- Always remove the lancet before cleaning or disinfecting the lancing device.

Note:

1. Clean and disinfect the meter and lancing device at least once per week

and when blood is present on the surface of the meter.

2. Clean and disinfect the meter and lancing device before allowing anyone else to handle the meter and lancing device.
3. The meter is a precision device. Handle it with care. Avoid water or dirt going inside the meter from the slots.

Section 8 Trouble Shooting

Message	Possible Cause	Solution
Failure to turn the meter on	Low battery or damaged battery	Replace the battery
E-U	Test strip has been used or contaminated	Repeat the test with a new test strip.
E-b	Low battery	Replace the battery and repeat the test.
E-t	Over operating temperature	Place the Blood Glucose Test Meter in an appropriate operating environment (10-40°C) for 30 minutes before testing.
	Below operating temperature	
E-C	The test strip is in poor contact with the meter	Replace the test strip
Lo	Blood Glucose is below0.6 mmol/L (10 mg/dL)	Retest with a new strip and contact your doctor if the same result display.
Hi	Blood glucose is higher than33.3mmol/L(600 mg/dL)	
- - -	Data is empty during historical query	Query after testing
	Low battery, but testing is still possible	Please replace with two AAA batteries battery

Section 9 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase within 30 days of purchase.

Note: This warranty applies only to the system in the original purchase. It does not apply to the other materials included with the system.

Assure Tech. (Hangzhou) Co., Ltd. warrants to the original purchaser that this system will be free from defects in materials and workmanship for a period of two years (24 months)since the latest date of original purchase or installation, except as noted below. During the stated two years period, Assure Tech. shall replace the system under warranty with a reconditioned system or, at its option, repair at no charge if a system that is found to be defective. Assure Tech. shall not be responsible for shipping charges incurred in the repair of a system.

This Warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost.

Assure Tech. Shall not be required to make any repairs or replace any parts

that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the meter in accordance with the user's manual, or maintenance by anyone other than Assure Tech. Furthermore, Assure Tech. assumes no liability from malfunction or damage to meters caused by the use of devices other than devices manufactured by Assure Tech. Assure Tech. reserves the right to make changes in the design of this meter without obligation to incorporate such changes into previously manufactured meters.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties expressed or implied(either in factor by operation of law),including the warranties of merchantability and fitness for use,which are expressly excluded, and is the only warranty given by Assure Tech.

Limitations of Liability

In no event shall Assure Tech. be liable for indirect, special or consequential damages, even if Assure Tech. has been advised of the possibility of such damages. For warranty service, please contact your local distributor.

Section 10 Recommended Reference Range

Blood Glucose Monitoring System is very important for diabetics to track the blood glucose level. The system test results will help doctor to monitor the effectiveness of treatment for a better control of diabetes.

Blood glucose varies throughout the course of a day.Expected Blood glucose ranges are shown below according to ADA Clinical Practice Recommendation:

Time	Range,mg/dL	Range,mmol/L
Fasting and Before Meals	70-110	3.9-6.1
2 Hours After Meal	Less than 140	Less than 7.8

Section 11 Specifications

11.1 Meter

Feature	Specification
Measurement range	Glucose:0.6-33.3mmol/L(10~600mg/dL)
Test result	Corresponding to blood glucose concentration
Sample	Fresh capillary whole blood or venous whole blood
Sample size	Blood Glucose: Approximate 0.6 microlitre
Measuring time	Blood Glucose:5 seconds
Battery	(⎓ 3V)Two1.5V AAA battery
Battery life	6 months or approximately 1,000 tests
Units	mmol/L or mg/dL for blood glucose test
Meter size	94.7*57.5*21.1mm(L*W*H)
Display size	41.0*46.5mm(L*W)
Weight	Approximately 80g (contain battery)
Meter storage conditions	-5~45°C(23~113°F); ≤90%RH

Meter operating conditions	10~40°C(50~104°F); ≤90%RH; ≤3048 meters
Hematocrit range	Glucose: 0~70%
Pollution Level	II

11.2 Strips

1) Repeatability Evaluation

Five heparinized venous blood samples at five concentration levels were measured by ten meters in the test, using three batches of test strips. Summary results are shown below:

Average	mmol/L	2.51	5.55	7.25	12.05	18.56
Standard deviation	mmol/L	0.14	0.17	0.23	0.28	0.47
Coefficient of variation (%)		/	3.06%	3.17%	2.32%	2.53%

2) Intermediate Precision Evaluation

Control solutions at three levels were measured by ten meters in the test, using three batches of test strips. Summary results are shown below:

Average	mmol/L	2.45	7.06	19.50
Standard deviation	mmol/L	0.11	0.23	0.43
Coefficient of variation (%)		/	3.23%	2.18%

3) Accuracy

For venous whole blood test

Blood glucose system accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL):

Within ± 0.28 mmol/L (within ± 5 mg/dL)	Within ± 0.56 mmol/L (within ± 10 mg/dL)	Within ± 0.83 mmol/L (within ± 15 mg/dL)
36/75 (48.0%)	67/75 (89.3%)	75/75 (100%)

Blood glucose system accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL):

Within ± 5%	Within ± 10%	Within ± 15%
77/133 (57.9%)	129/133 (97.0%)	133/133(100%)

For capillary whole blood test

Blood glucose system accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL):

Within ± 0.28 mmol/L (within ± 5 mg/dL)	Within ± 0.56 mmol/L (within ± 10 mg/dL)	Within ± 0.83 mmol/L (within ± 15 mg/dL)
28/55 (50.9%)	51/55 (92.7%)	55/55 (100%)

Blood glucose system accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL):

Within ± 5%	Within ± 10%	Within ± 15%
81/160 (50.6%)	142/160 (88.8%)	159/160 (99.4%)

See the strip package insert for more details.

4) User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 106 lay persons showed the following results: 100.00% within ±0.83 mmol/L (±15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL), and 100.00% within ± 15% of the medical laboratory values at glucose concentrations above 5.55 mmol/L (100 mg/dL).

Appendix1 Electromagnetic compatibility

The Meter meets the emission and immunity requirements of EMC standard EN 61326-1 and EN 61326-2-6.

Electromagnetic emission

The METER is used in the following provisions of the electromagnetic emission test environment		
Emission Test	**Conformity**	**Electromagnetic Environment**
Electromagnetic emission EN 61326-1	Meet the equipment limits of Group 1 Class B	The Meter only supplies its internal function by use of radio frequency energy. As a result, the analyzer radio frequency is low, and the probability of interference on nearby electronic equipment is very small.

Electromagnetic Immunity

The METER is used in the following provisions of the Electromagnetic Immunity test environment.			
Immunity Test	**Test**	**Conformity**	**Electromagnetic Environment**
ESD IEC 61000-4-2	Air discharge： ±2kV, ±4kV, ±8kV,±15kV Contact discharge: ±4kV, ±6kV, ±8kV	Air discharge: ±2kV, ±4kV, ±8kV,±15kV Contact discharge: ±4kV, ±6kV, ±8kV	The ground should be wood, concrete or ceramic tile, if the ground covered with synthetic material, relative humidity should be at least 30%.
The rated power frequency of the magnetic field IEC 61000-4-8	30A/m, 50Hz & 60Hz	30A/m, 50Hz & 60Hz	Power frequency magnetic field should accord to the typical commercial or hospital environment level.
Radiated electromagnetic field IEC 61000-4-3	10V/m, 80MHz～1.0GHz ; 3V/m, 1.0GHz～6.0GHz	10V/m, 80MHz～1.0GHz ; 3V/m, 1.0GHz～6.0GHz	Convenient and portable radio frequency communication equipment should not be nearer than the Recommended Separation distance to any part of the meter.The distance is obtained by the formula of transmitter frequency. The Recommended distance

			d=1.2√P 80MHz～800MHz d=2.3√P 800MHz～2.0GHz p-The maximum rated power output (W), d- The distance (m).interference: 

1: Frequency is 80MHz or 800MHz by high frequency format.
2: The guidelines may not be suitable for all situations, electromagnetic propagation influenced by buildings, objects, the breathing and reflection of the body.

a. Stationary transmitter, such as: wireless (cellular/cordless) phones and ground mobile wireless phone base stations, amateur radio, am and FM radio and television broadcasting, etc., the field intensity cannot be predicted accuracy. For the evaluation of fixed rf transmitter electromagnetic environment, electromagnetic site survey should be taken into account. If field intensity is higher than the place of the above applicable radio frequency (rf), the meter should be observed to works well. If performance abnormal, the supplementary measures such as to adjust the direction or position of the meter may be necessary.
b. Frequency is 150kHz～80MHz，the field intensity is lower than 3V/m.

The recommended separation distance of the Convenient & portable radio frequency communication equipment and the meter is as below.

The meter is expected to be used in the controlled radio-frequency radiation electromagnetic environment. Communications equipment based on maximum rated power output, The electromagnetic interference can be avoided in the following minimum distance.		
The maximum rated power output W	Distance /m	
	80MHz-800MHz d=1.2√*P*	80MHz-2.0MHz d=2.3√P

0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
1000	12	23
P-The transmitter maximum rated power output provided by the manufacturers(W) 1: The frequency is 80MHz or 800MHz by high frequency format. 2: The guidelines may not be suitable for all situations, electromagnetic propagation influenced by buildings, objects, the breathing and reflection of the body.		

The meter meet the requiremnt of standard IEC 61010-1

CE 0197

EC REP

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