

B312DH102
04/2022

Manufactured by **All Medicus Co., Ltd.**

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(8AM-8PM EST, Mon.-Fri.)
Outside hours, please contact your healthcare provider.

 www.metene.com

 cs@metene.com

metene

Blood Glucose Monitoring System

Model: AGM-513S

USER MANUAL

For Single Patient Use Only



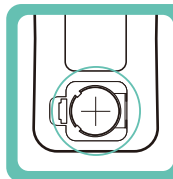
TEST SUMMARY

This summary is intended only as a quick reference and is not a substitute for **metene** Blood Glucose Monitoring System User Manual. Please read the entire User Manual before you begin the test.

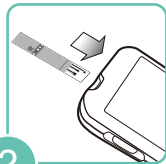


1

Check the expiration date printed on the strip vial label.

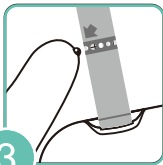


Remove the battery cover and put the battery with "+" sign facing up.



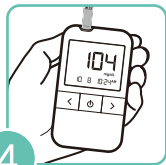
2

Insert a test strip. The meter will automatically turn on.



3

Apply the blood drop to the side edge of the yellow window of the test strip. Wait for the blood drop to completely fill the yellow window of the test strip and then the meter will begin the countdown.



4

The blood glucose result will be displayed on the meter in just 5 seconds.

“Thank you for using **metene**
Blood Glucose Monitoring System”

This User Manual will tell you all you need to know
about the system and how it works.

Please read this carefully before using the meter.

PRECAUTIONS



Intended Use

metene Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip. **metene** Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

metene Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. **metene** Blood Glucose Monitoring System is not for use in neonates.

metene Blood Glucose Test Strips are for use with **metene** Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

metene Control Solution is for use with **metene** Blood Glucose Meter and Test Strips to check that the meter and test strips are working together properly.



Test Principle

The **metene** Blood Glucose Monitoring System is based on measurement of electric currents caused by the reaction of glucose with the reagents on the gold electrode of the test strip. The blood sample is drawn into the test strip's reaction chamber through capillary action. Glucose in the sample reacts with glucose dehydrogenase and mediator on the test strip. This reaction creates electric currents. The consequent electric currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the **metene** Meter.



LIMITATION

- The **metene** Blood Glucose Monitoring System is only for use with capillary whole blood.
- Inaccurate results may occur when in shock, hypotensive, hyperglycemic, or hyperosmolar state and with or without ketosis.
- The **metene** Blood Glucose Monitoring System should not be used in critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- The **metene** Blood Glucose Monitoring System should not be for diagnosis of or screening for diabetes mellitus.

- A hematocrit that is either very high (above 65%) or very low (below 20%) can cause false test results.
- Not for neonatal use.
- Dehydration may cause higher test results.
- The system has not been tested above 10,000ft.



Precautions for Use

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 transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Carefully read and follow the instructions in the User Manual and package inserts for the test strips and control solution and practice the testing procedures before using the **metene** Blood Glucose Monitoring System. It is very important to follow the instructions in order to avoid an incorrect test result that leads to improper therapy.

Take note of information and cautions throughout this User Manual.

- The **metene** Meter is designed for use only with **metene** Test Strips. (manufactured by All Medicus Co., Ltd.)
- The **metene** Blood Glucose Monitoring System is calibrated to produce values equivalent to the results on plasma specimens on a laboratory analyzer (YSI 2300 STAT Plus).
- The **metene** Blood Glucose Monitoring System should be used for 50~104°F (10~40°C).
- The **metene** Blood Glucose Monitoring System is for *in vitro* diagnostic use.
- Do not drop the meter.
- Do not disassemble, repair or remodel without consultation. The sensitive parts could be damaged and the warranty will then become invalid.
- Handle all the reagents with care knowing that they are capable of transmitting infection.
- Used test strips, lancets and meter may be considered bio-hazardous waste in your area. Please contact your health provider for instructions on how to discard them.
- The **metene** Blood Glucose Monitoring System are for single patient use only and for over the counter use.



Precautions for Test Strip

- Store test strip vials in the place with temperature between 36~86°F (2~30°C) and humidity of 15-85% RH.
- Avoid direct sunlight, heat and excessive humidity.
- Always close the vial cap immediately after removing a test strip from the vial. If the test strip vial is left open for a long time, the test strips will become unusable.
- Use the test strip immediately after removing it from the vial.
- Use all the test strips within 4 months after the first opening.
- Store test strips only in their original vial and do not transfer them to a new bottle or any other container.
- Do not touch the test strip with wet hands.
- Do not use the test strip beyond the expiration date printed on the vial.
- Do not bend, cut, or damage the test strips.



Safekeeping

- Store the **metene** Meter in a room temperature between 32~104°F (0~40°C).
- Store the **metene** Meter where relative humidity is between 15~85%.
- Keep the **metene** Meter in sanitary environment.
- Keep the meter away from direct sunlight for a long time.
- Keep the test port away from dirt, blood or water.
- Do not store your meter and test strips in the car, the bathroom, or the refrigerator. (sensitive to temperature and humidity)
- Keep the meter, test strip vials and lancing materials away from children.
- The meter should be strictly kept away from contact with liquids, except for cleaning and disinfecting the meter. Please refer to the section entitled "Caring for your **metene** Blood Glucose Monitoring System" for additional information.



INFORMATION

If the meter does not work properly and you have followed the storage and handling instructions in this User Manual, contact your healthcare provider.

IMPORTANT SAFETY INSTRUCTIONS

For single patient - home use

Reports of Hepatitis B virus infection outbreaks linked to multiple people sharing glucose meters have been increasing. This notice serves as a reminder that 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 bloodborne pathogens.

“FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial communication Update 11/29/2010”

<http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm>

“CDC Clinical Remider: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens”(2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>



WARNING

1. Do not share the system with anyone.
2. All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfecting.
3. Always use a new, sterile lancet. Lancets are for single use only.
4. Please refer to page 25-30 of this manual for cleaning and disinfecting your **metene** Blood Glucose Monitoring System.

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- ① metene Meter
- ② Battery
- ③ Carrying case

- ④ User Manual
- ⑤ metene Test Strips
- ⑥ Lancing Device

- ⑦ Lancets
- ⑧ Control Solution 1
- ⑨ Control Solution 2

The following components are included in the package:

Meter, Battery, Carrying case, User Manual
Test Strips (100), Lancing Device, Lancets (100)

Control Solutions are not included in the package, they must be purchased separately.

1 LCD Display

- Test results, icons, symbols and simple messages appear here.

2 </> Button

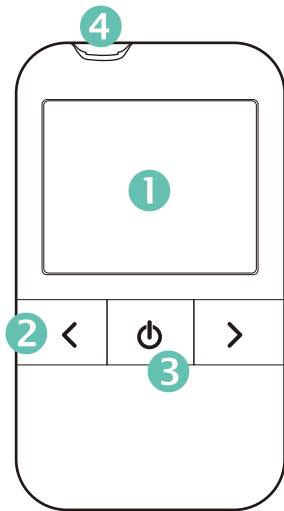
- Recall the stored test result in the MEMORY MODE.
- Select an event in the EVENT RECORD MODE.
- Change the date, time and options in the SET MODE.

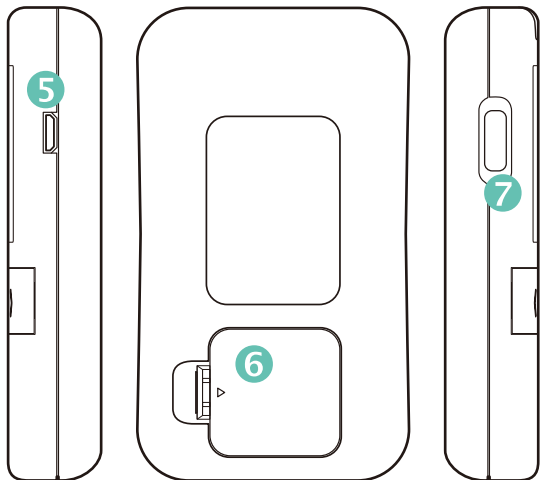
3 Power Button

- Turn the meter on/off.
- Enter into SET MODE while pressing the power button for more than 3 seconds.
- Delete all the stored test results in the AVERAGE MODE.
- Delete each test results in the MEMORY MODE.

4 Test Port

- Insert the **metene** Test Strip for testing. Then the meter turns on and BLOOD DROP ICON will blink.





5 Micro USB Port

- Transfer your test results from the meter to a computer.

6 Battery Cover

7 Test Strip Eject Button

metene Meter LCD Display

① BATTERY LIFE.

② SET MODE.

③ AVERAGE MODE.

④ MEMORY MODE.

⑤ MEMORY NUMBER.

The meter displays the current memory order number in the MEMORY MODE.

⑥ STRIP ICON.

When the STRIP ICON blinks, insert a test strip to the meter.

⑦ BLOOD DROP ICON.

When the BLOOD DROP ICON blinks, apply blood sample.

⑧ TEMPERATURE ICON.

When the meter is not used at a recommended temperature range, "Er1" and TEMPERATURE ICON appear.

⑨ CURRENT TIME and TEST TIME in the MEMORY MODE.

⑩ CURRENT DATE and TEST DATE in the MEMORY MODE.

⑪ UNIT OF MEASUREMENT.

⑫ EVENT ICON.

If you choose an event icon which correlates to test results, it helps to manage glucose level more effectively.

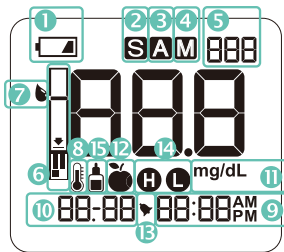
⑬ ALARM.

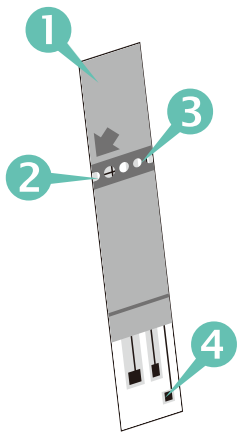
You can set up to four different alarms. Each alarm rings for 10 seconds.

⑭ HYPERGLYCEMIC, HYPOGLYCEMIC WARNING ICON.

⑮ CONTROL SOLUTION ICON.

The meter automatically recognizes the difference between the control solution and blood.



**1 Grip**

- Hold this part to insert a test strip.

2 Yellow Side-edge

- Apply blood sample here; blood is absorbed automatically.

3 Confirmation window (Reaction chamber)

- Confirm if enough blood entered the confirmation window.

4 Gold electrodes

- Insert this part into the meter's test port.

Control solution test is to check the performance of your meter and test strips. **metene** Control Solution contains a measured amount of glucose that reacts with the **metene** Test Strips.

The control solution test confirms that your meter and test strips are working correctly. Compare your control solution test results with the range printed on the test strip vial label. It is very important that you do this simple test routinely to make sure you get accurate test results.



INFORMATION

Check your system with the **metene** Control Solution under the following situations.

- When you want to check the performance of the meter and test strip.
- When you leave your test strip vial cap open for a long time.
- When you open a new vial of test strips.
- When you think that the test results are not accurate.
- When you drop the meter.
- When you suspect your meter or test strips are not working properly.
- When your blood glucose test results are not consistent.



CAUTION

- Use only the **metene** Control Solution for the test.
- Check the expiration date printed on the control solution vial. Do not use when the expiration date is expired. Discard the control solution on the expiration date printed on the vial or three months after first opening whichever comes first. When you first open a new vial of the control solution, count three months forward and write the expected discarding date on the label of the control solution vial for your convenience.
- When using the Control Solution to examine the system, the measurements should be tested within a temperature range of 10°C ~ 40°C (50°F ~ 104°F)

! CAUTION

- Do not drink the control solution.
- Tightly close the cap of control solution vial and store at 1°C ~ 32°C (34°F ~ 90°F) after the test.



1

Check the expiration date printed on the test strip vial.

Do not use the test strip beyond the expiration date.



2

Insert a Test Strip

Insert a test strip, with the printed side facing up, into the test port of the meter. Gently push it all the way in until it goes no further. The meter will turn on automatically and beep. Then the BLOOD DROP ICON will appear.

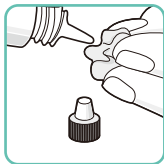
! CAUTION

- If the BLOOD DROP ICON does not appear, remove the test strip and insert it again.
- If the BLOOD DROP ICON still does not appear, contact the manufacturer.

! CAUTION

Do not force the test strip into your meter. This may cause malfunction.

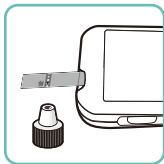
Checking Your System with metene Control Solution



3

Prepare the control solution

Remove the vial cap and place it on a flat surface with the top of the cap pointing up. Squeeze the vial to discard the first drop. Squeeze a drop into the small well on the top of the cap or onto another clean, non-absorbent surface.



4

Apply the Control Solution

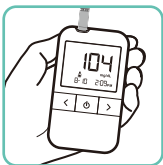
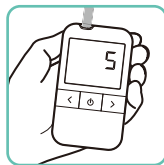
Slowly let the side edge of the yellow window of the test strip touch the drop of the control solution. Once the confirmation window fills completely, your meter will begin the countdown.



TIP

To ensure accurate test results

- Gently shake the control solution (vial) to ensure the control solution is mixed well before each test.

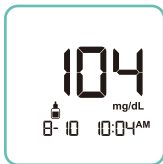


5

Test Result Appears in 5 seconds


Your meter will display countdown from "5" to "1", then the test result will appear.

! CAUTION



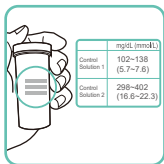
CONTROL SOLUTION ICON

Check the CONTROL SOLUTION ICON '  ' to appear. If CONTROL SOLUTION ICON '  ' is not displayed, repeat the test with a new test strip.

If the ICON '  ' still does not appear, contact your healthcare provider.

! CAUTION

The Control Solution range printed on the test strip vial is for the **metene** Control Solution only. It is used to check the performance of your meter and test strips. It is NOT a recommended range for your blood glucose level.



*The image is only an example of the control solution range.

6

Compare Control Solution Test Results

Compare the control solution test result to the control solution range printed on the test strip vial. The test result should fall within this range. Each vial of test strips may have a different control solution range. If the test result you get is not within this range, the meter and test strips may not be working properly. Repeat the control solution test. Refer to the **metene** Test Strip Instruction for the use.

7

Cleaning

Clean the top of the control solution cap with a clean, damp tissue or cloth.



INFORMATION

Out-of-range test results may be caused by one or more of the followings:

- Expired or contaminated control solution,
- Expired or damaged test strip,
- Use of control solution or test strip past its discarding date,
- Error in performing the test,
- Failure to shake the control solution vial well,
- Meter, test strips or control solution are kept too warm or too cold,
- or Meter malfunction




CAUTION

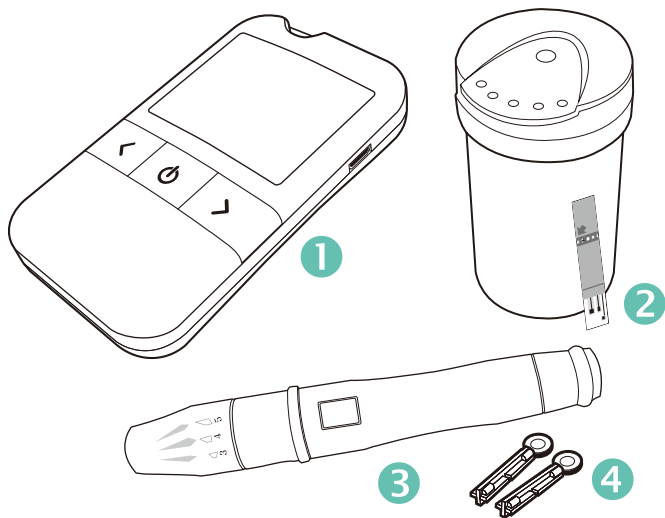
If your control solution test results continue to fall outside the range printed on the test strip vial, the **metene** Blood Glucose Monitoring System may not be working properly.

- If this is the case, do not use the system to test your blood glucose levels.
- Contact your healthcare provider and the manufacturer.



INFORMATION

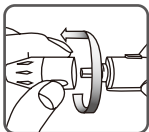
All the control solution test results are recorded with CONTROL SOLUTION ICON '  ' to distinguish them from those of actual blood glucose tests in the meter memory. Recorded control solution test results will not be calculated in your result averages.



- ① metene Meter
- ② metene Test Strip
- ③ Lancing Device
- ④ Lancets

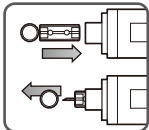
Preparing the Lancing Device (For single patient – home use)

Getting a blood sample from the fingertip

**1**

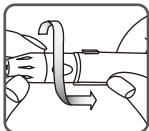
Remove the cap

Turn the cap of the lancing device counter-clockwise to remove the cap.

**2**

Insert a Lancet into the Lancet Holder.

Insert the lancet firmly into the holder until it comes to a full stop. When the lancet is placed in the lancing device, twist off the protective disk of the lancet. Do not discard the protective disk of the lancet; it will be used to dispose the lancet safely after its use.

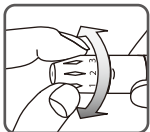
**3**

Replace the cap

Turn the cap of lancing device clockwise until it fits.

! CAUTION

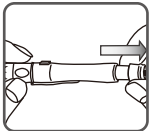
- Before using the lancing device, wash your hands in warm water with soap. Make sure to rinse and dry them thoroughly. Perspiration, dirt or water remaining on your hands may cause incorrect test results.
- Avoid using hand lotion or any other oily products before using the lancing device.



4

Adjust the Puncture Depth Setting

The dial for setting the puncture depth is at the tip of the lancing device. Higher number indicates deeper puncture. Thus, dial to the lower number for thin skin.



5

Charge the Lancing Device.

Draw back the end part of lancing device until it clicks, and then release it.



6

Check the expiration date printed on the test strip vial.

Do not use the test strip beyond the expiration date.



7

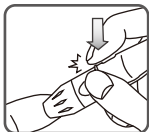
Insert a Test Strip

Insert a test strip, with the printed side facing up, into the test port of the meter. Push it all the way in until it goes no further. The meter will turn on automatically and beep.



CAUTION

Do not force the test strip into the meter. This may cause malfunction of the meter.



8

Lance your Finger

Place the lancing device carefully on the tip of your finger and press the release button.



9

Obtain a Blood Drop

Gently squeeze and/or massage your fingertip until a round drop of blood forms on your fingertip.



TIP

- Before puncturing, gently massage the fingertip to obtain a round drop of blood.
- Do not squeeze the finger to obtain a drop of blood.
- Do not smear the blood sample.



WARNING

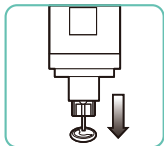
Blood glucose meters and reusable lancing devices are at the high risk of becoming contaminated with bloodborne pathogens such as Hepatitis B Virus (HBV). Transmission of this virus has been documented due to contaminated blood glucose meter.

Please refer to pages 25-30 for cleaning and disinfecting your **metene** Blood Glucose Monitoring System.

This lancing device is intended only for a single user and should not be shared.

Always wash your hands thoroughly with soap and water after handling the meter, lancing device, and test strips.

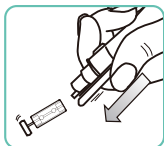
Removing the used lancet



1

Remove the Used Lancet

Place the protective disk on a flat surface. With the used lancet still in the lancing device, push the lancet needle completely into the protective disk. Push the lancet ejector forward with your thumb to dispose the used lancet in a proper bio-hazardous container.



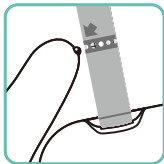
RECOMMENDED AVAILABLE LANCETS

metene Sterile Lancets

! CAUTION

- To reduce the risk of infection, never share a lancet with another person.
- Lancets are for single use only. Always use a new sterile lancet.
- Used strips, lancets and meter may be considered bio-hazardous waste in your area. Make sure to follow your healthcare professional's recommendations or local regulations for proper disposal.

Applying blood and reading results

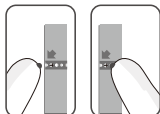


1

Apply the Blood Sample

Apply the round drop of blood to the side edge of the yellow window of the test strip and then blood drop will be absorbed into the narrow channel. Touch and hold the blood drop to the side edge of the yellow window of test strip until blood completely fills the confirmation window and the meter beeps. Then, your meter will start the countdown.

! CAUTION

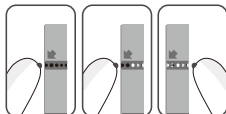


Correct **Incorrect**

You should apply blood to the left side edge of the test strip as directed.

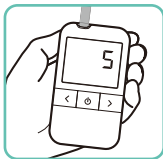
- Do not put blood on the top of the test strip.

! CAUTION



Correct **Er8** **Er9**

- If insufficient blood is inserted, error message (Er8) will be displayed. As you can see in the left illustration, you have to insert a sufficient amount blood in the blood checking area.
- Even if the meter begins the countdown despite the fact that the confirmation window is not completely filled, do not apply more blood to the test strip. Discard the test strip and repeat the test with a new test strip.
- If blood is inserted in the opposite direction, error message (Er9) will be displayed.



2

Test Results Appear in 5 seconds

Once the meter completes the countdown from “5” to “1”, your test result will appear on the meter display.

Without recording the event: If you remove the test strip immediately, only the test result will be automatically saved in the meter memory. (Only Test Results)

With recording the event: To enter the EVENT RECORD MODE, you may press \langle / \rangle button of the meter before removing the test strip from the meter. (See pages 18-19 for more details)

Recording the event with each test result may help with effective diabetes management. (Recording the Pre-Meal / Post Meal)



INFORMATION

If you do not apply a blood drop within 5 minutes, your meter will turn off automatically. Once the meter turns off, remove the test strip and then insert a new test strip into your meter to restart the test.

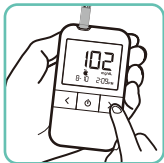


TIP

After the test, press any of \langle / \rangle button in the EVENT RECORD MODE before removing the test strip from your meter. Recording your condition will lead you to more effective diabetes management.

Entering the EVENT RECORD MODE

For effective diabetes management, stored test results with your condition (Pre-Meal, Post Meal) will help you and your healthcare professional to track changes in your blood glucose level.



1

Press \langle / \rangle Button after the Test

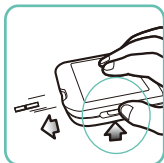
Press \langle / \rangle button after the test. Once the test result appears on the meter display, press any of \langle / \rangle button to enter the EVENT RECORD MODE.



2

Select the EVENT ICON

There are 2 different EVENT ICONs: Post Meal and Pre Meal. Press \langle / \rangle button to select an icon which correlates with the test result.



3

Remove the Test Strip

After the selection of an EVENT ICON, remove the used test strip. The used test strip will be discharged automatically by pushing the Ejector Button on the left side of the meter. After discharging the used test strip, the test result with the EVENT ICON will be saved in the meter memory automatically.



CAUTION

Once you remove the test strip from the meter, you cannot go back to the EVENT RECORD MODE. Do not remove the test strip from the meter until selecting an EVENT ICON is completed.



POST MEAL ICON

Select this icon when you have a test after meal (food intake).



PRE MEAL ICON

Select this icon when you have a test before meal.

Understanding Your Test Results

The **metene** Meter will display test result between 20 and 600 mg/dL. If your test result is lower than 20 mg/dL, "Lo" will appear on the meter display. If your test result is higher than 600 mg/dL, "HI" will appear on the meter display.

! CAUTION

The image shows a digital display of the word "HI" in large, black, sans-serif font, indicating a high blood glucose reading.

8-10 2:09 PM

The image shows a digital display of the word "Lo" in large, black, sans-serif font, indicating a low blood glucose reading.

8-10 2:09 PM

- If "HI" or "Lo" appears instead of a test result, retest your blood glucose level immediately with a new test strip. If the same message appears, check the system with the **metene** Control Solution. If your meter and test strip are working correctly, you must contact your healthcare professional immediately.

Expected Values¹

The fasting adult blood glucose range for a person without diabetes:

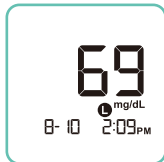
- Before meals < 100 mg/dL
- After meals < 140 mg/dL

*Reference: American Diabetes Association: Diabetes Care, 2017;
Volume 40, Supplement 1 : S11-S24*

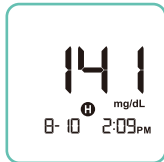


INFORMATION

Your meter uses the low and high range limits set in your meter to tell you when a test result is within, below or above the range limits.



If your test result is Low range limit set, “**L**” will appear on the meter display.



If your result is High range limit set, “**H**” will appear on the meter display.

If you need to change the pre-set limits, please go the SET MODE (page 34).

* The image is only an example of the low and high range limits set.

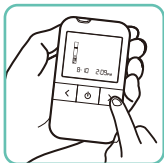


CAUTION

Be sure to talk to your healthcare professional about the low and high limits that are right for you. When selecting or changing your limits, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your healthcare professional.

Recalling the Previous Test Results

The **metene** Meter has a memory capacity to store up to 500 most recent test results with date, time and event. It also provides you averages of your blood glucose test results over a period of time (Options: 7d, 14d, 30d, 60d, or 90d average). You can review the test results stored in the memory by the following steps.

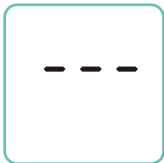
**1**

Press </> Button

To enter the MEMORY MODE, press </> button with the meter turned on.



INFORMATION



If there is no test result, the meter will not display anything and </> button will not operate.



A
7d
96
mg/dL

2

Indicate the Average Value

You can select the number of days for the average (7d, 14d, 30d, 60d, or 90d) in the SET MODE. "7d" shown in the right side indicates that the value 96 is a calculated average for the past 7 days. The meter is pre-set with the average day of 7d.



INFORMATION

When the whole test results' average is calculated, individual event records are not considered and "Lo" and "HI" are not included.



TIP



CLR

You can delete all the stored test results in the meter memory after the average value is displayed. Press and hold the power button for 5 seconds until "CLR" flashes and "---" appears.



3

Recall your Test Results

Press and release \leftarrow/\rightarrow button once to make the most recent test result appear on the meter display. Every time you press and release \leftarrow/\rightarrow button, the meter will display the next result up to 500 test results.



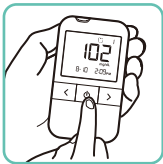
TIP

Press and hold \leftarrow/\rightarrow button in the MEMORY MODE in order to view the test results faster.



TIP

To delete individual test result in the MEMORY MODE, press and hold the power button for 5 seconds until "dEL" flashes and "----" appears.



4

Exit the MEMORY MODE

Press and release the power button once to exit from the MEMORY MODE.

Cleaning and disinfecting your metene Blood Glucose Monitoring System

For Single patient - home use

Why should cleaning and disinfecting the meter and the reusable lancing device be performed?

The cleaning is to remove gross soil and dirt on the all surfaces of the devices before the disinfecting is to kill the bloodborne pathogen stated below. Cleaning is part of your normal care and maintenance and should be performed prior to disinfection.

Blood glucose meters and reusable lancing devices are at the high risk of becoming contaminated with bloodborne pathogens such as Hepatitis B Virus(HBV). Transmission of this virus has been documented due to contaminated test meter. Cleaning and disinfecting test meters and lancing devices can prevent the transmission of HBV and other bloodborne pathogens through indirect contact.

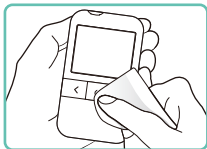
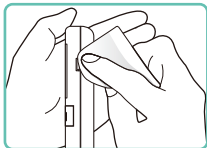
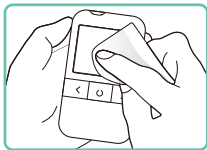
How to clean and disinfect the meter

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. Do NOT use organic solvents to clean the meter.

**NOTE**

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

Cleaning and disinfecting procedures for the meter



- 1 Wash your hands before performing cleaning and disinfecting procedures.
- 2 Remove a wipe from container.
- 3 Check if the meter is turned off.
- 4 For cleaning the meter, wipe the outside of the meter (Back and forth two times, a total of four passes).
- 5 For disinfecting the meter, wipe the outside of the meter (Back and forth two times, a total of four passes). The surface should remain visibly wet for 2 minutes right after the treatment.
- 6 Dispose of used wipes.
- 7 Wash your hands thoroughly with soap and water after handling the meter.



NOTE

1. The meter and the reusable lancing device should be cleaned and disinfected once per week at a minimum.
2. To achieve disinfection of the stated efficacy kill claim, the meter should remain visibly wet for 2 minutes right after the completion of disinfecting procedures.

Always keep the meter free from dirt, blood and liquid. The meter should be periodically cleaned and disinfected.



CAUTION

If the meter is operated by a second person providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

Cleaning and disinfecting procedures for the Reusable lancing device

1. Wash your hands before performing cleaning and disinfecting procedures.
2. Remove a wipe from container.
3. Check if the used lancet is removed.
4. For cleaning the lancing device, wipe the outside of the lancing device (Back and forth two times, a total of four passes).
5. For disinfecting the lancing device, wipe the outside of the lancing device (Back and orth two times, a total of four passes). The surface should remain visibly wet for 2 minutes right after the treatment.
6. Dispose of used wipes.
7. Wash your hands thoroughly with soap and clean water after handling the lancing device.



CAUTION

To achieve disinfection of the stated efficacy kill claim, the lancing device should remain visibly wet for 2 minutes right after the completion of disinfecting procedures.

Always keep the reusable lancing device free from dirt, blood and liquid.
The reusable lancing device should be periodically cleaned and disinfected.



NOTE

1. The **metene** Blood Glucose Monitoring System has an expected life of 3 years and should withstand the cleaning and disinfecting recommended in this User Manual. We tested the meter and lancing device with disposable medical disinfectant wipes representing daily cleaning and disinfecting

cycle (two separate steps) for three(3) years (Once per day(365 days) x 3 years x 2 cleaning and disinfecting cycles for a total of 1,095 times / meter and reusable lancing device) and any change in performance, accuracy, and appearance were not observed.

2. After cleaning and disinfection procedures, check if the reusable lancing device works properly or not.

If any of the following physical and functional signs of deterioration appear after cleaning and disinfecting the meter, stop using the meter and contact the manufacturer

- Meter screen is blurry.
- Meter displays broken characters or icons
- Meter will not power on
- Meter buttons or test strip eject button does not function.
- Control solution test falls out of range.
- Lancing device does not function.



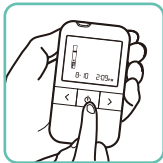
WARNING

Do not share reusable lancing device with anyone.

The **metene** Meter comes with date (1-1), date format(dd.mm) time (12:00AM), time format (12h), alarm(0), average day(7d), hypoglycemic limit, hyperglycemic limit and unit of measurement (mg/dL), beep (On) preset. However, if you need to change the setting of the meter, or if you replace the battery, you need to enter the SET MODE and reset them. It is important to set the correct time and date. Having the correct time and date of each blood glucose test result will help you and your healthcare professional to track changes in your blood glucose level.

**INFORMATION**

After replacing the battery, you should update the time and date setting.

**1****Press and Hold the Power Button for 3 seconds**

With the meter turned on, press and hold the power button until "SET" appears on the meter. Release the power button to enter the SET MODE. The Year flashes.

**INFORMATION**

To exit the SET MODE at any time, press and hold the power button for 3 seconds. The settings you have already made will be saved.

2**Set the Year**

Press and release </> button to adjust the year until the correct year appears on the meter display. If you press and release the power button, the meter advances next to the Month Setting.

S

20 15



TIP

Press and release the power button in order to advance to the next setting steps in the SET MODE. Press and release \leftarrow/\rightarrow button to adjust the number in the SET MODE. To move faster, press and hold \leftarrow/\rightarrow button.

S



3

Set the Month

The Month flashes. Press and release \leftarrow/\rightarrow button until you get the correct month. If you press and release the power button, the meter advances next to the Day Setting.

S



4

Set the Day

The Day flashes. Press and release \leftarrow/\rightarrow button until you get the correct day. If you press and release the power button, the meter advances next to the Date Format Setting.

S



5

Set the Date Format

The Date flashes. Press and release \leftarrow/\rightarrow button until you get the date format that you want. If you press and release the power button, the meter advances next to the Hour Setting.



6

Set the Hour

The Hour flashes. Press and release </> button until you get the correct hour. If you press and release the power button, the meter advances next to the Minutes Setting.



7

Set the Minutes

The Minutes flash. Press and release </> button until you get correct minute. If you press and release power button, the meter advances next to the Time Format Setting.



8

Set the Time Format

The "12h" or "24h" flashes. Press and release </> button to adjust until you get the correct time format. If you press and release the power button, the meter advances next to the Average Period Setting.



9

Set the Average Period

The Average Period flashes. Press and release \langle / \rangle button until you get the period of average setting that you want (7,14,30,60,or 90). If you press and release the power button, the meter advances next to the Hypoglycemic Warning Limits Setting.



10

Set Hypoglycemic Warning Limit

Press \langle / \rangle button to select the hypo (lower) blood glucose level. If you press and release power button, the meter advances next to the Hyperglycemic Warning Limits Setting.



11

Set Hyperglycemic Warning Limit

Press \langle / \rangle button to select the hyper (upper) blood glucose level. If you press and release power button, the meter advances next to the Beep Setting.



CAUTION

- Hypoglycemic warning limit cannot be higher than hyperglycemic warning limit.
- Hyperglycemic warning limit cannot be lower than hypoglycemic warning limit.



CAUTION

Be sure to talk to your healthcare professional about the low and high limits that are right for you. When selecting or changing your limits, you should consider factors such as your lifestyle and diabetes therapy. Never make significant changes to your diabetes care plan without consulting your healthcare professional.



12

Set the Beep

When "On" or "OFF" flashes, press \langle / \rangle button, then you can set the beeper "On" or "Off". If you set it "On", press and release the power button. And then the meter advances next to the Alarm Setting.

If you set it "Off", you don't need to set the alarm and the meter exits the SET MODE.



13

Set the Alarm (up to 4 different Alarms a day)

The Alarm times flash. Press and release \langle / \rangle button until you get the alarm times (0 to 4th) setting that you want. If you press and release the power button, the meter advances next to the Alarm Time Setting.

If you set it "0", the meter exits the SET MODE.



14

Set the Alarm Time

The Hour of the Alarm Time flashes. Press and release \langle / \rangle button to set the alarm time the same as the Time Setting (6-7).

15


Save the Setting Information

Press and release the power button, and then the meter will turn off. The setting information you entered will be saved.



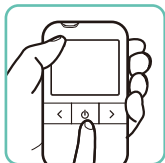
TIP

Totally four different alarms can be set. You can continually set alarm right after the first setting. Press and release the power button after you complete the first alarm time setting. Then "2" appears, you can repeat to set the next alarm time.

A battery (CR2032) will provide you enough power to perform about 1,000 tests. The meter will alert you when the energy level is getting low by displaying the message (). In this case you can test a few more times but the battery should be replaced to new one as soon as possible. If "bAt" appears on the meter display, the meter will not operate. The battery must be immediately replaced.

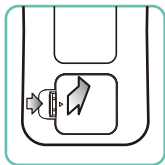
CAUTION

Always turn off the meter before replacing the battery. Replacing the battery with the meter power on may lead to malfunction of the meter.

**1**

Turn off the Meter.

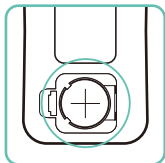
Press the power button to turn off the meter.



2

Remove the Battery Cover

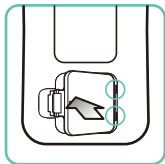
Remove the battery door from the back of the meter by pushing the tab in the direction of the arrow and pulling up the door.



3

Replace the Battery

Remove the old battery and put the new one with "+" sign facing up.



4

Close the Battery Cover

Put the battery door back in place and snap it closed.

How to Use LinkDr. 2.0

metene is designed to connect with PC using Micro USB cable and to transfer test results to PC. Through diabetes management software LinkDr. 2.0, you can review your test results and print the report.

To learn more about LinkDr. 2.0, please contact your distributor.

The image shows the letters "USB" in a stylized, blocky font, representing a USB connection.

- 1 Visit www.metene.com and download LinkDr. 2.0. And set up LinkDr. 2.0 in your PC.
- 2 Run LinkDr. 2.0.
- 3 Connect the meter with your PC using Micro USB cable.
If the meter is connected with PC, "USB" appears on meter display.
- 4 Select Date Range and click "Yes".
Meter data will be transferred to your PC.
- 5 After the download is completed, you can see the summary report and the meter turns off.



INFORMATION

LinkDr. 2.0 PC requirements

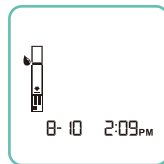
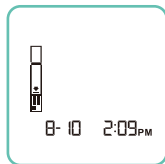
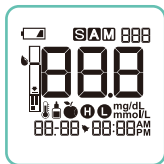
- CPU : Pentium4 2.4GHz or higher
- Memory : 256 MB or higher
- HDD : 500 MB or higher
- OS : Windows XP or higher



CAUTION

Until the download is completed, do not disconnect the meter with PC and do not turn off the meter.

Message



What it means.

System check. This display always appears when you press the power button to turn on the meter.

The system is ready for you to insert a test strip.

The meter is ready for a blood drop or control solution.

The meter displays countdown from 5 to 1, while calculating a blood glucose test result.

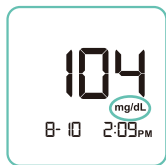
Action

You should check that your meter matches the example exactly every time your meter turns on. Do not use the meter if the display check screen does not exactly match the example. Please contact your healthcare provider.

Insert a test strip into the test port of your meter.

Apply a blood sample to the test strip. (See page 12-17 for how to test your blood glucose level)

No action is required.



A blood glucose test result in mg/dL

No action is required.



System is ready to record the EVENT ICON which correlates with your test result.

Select an EVENT ICONs using \langle / \rangle button before discarding the used test strip.



Your blood glucose result is higher than 600 mg/dL

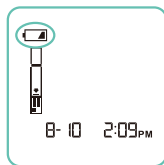
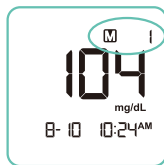
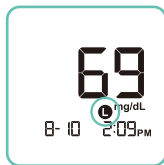
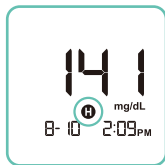
Repeat the test using a new test strip and/or check the system with the **metene** Control Solution. If the test result is "HI" again even though your system is working correctly, contact your healthcare professional immediately.



Your blood glucose result is lower than 20 mg/dL

Repeat the test using a new test strip and/or check the system with the **metene** Control Solution. If the test result is "Lo" again even though your system is working correctly, contact your healthcare professional immediately.

Message



What it means.

Your blood glucose result is higher than the hyperglycemic warning limit.

Your blood glucose result is lower than the hypoglycemic warning limit.

A blood glucose test result stored in the memory.

Battery is low but you can still perform a few more tests.

Action

No action is required.

No action is required.

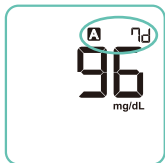
No action is required.

Turn off the meter and replace the battery as soon as possible.



The energy level of the battery is too low to provide accurate test results.

Turn off the meter and replace the battery immediately.



The average of blood glucose test results for the past 7 days.

No action is required.



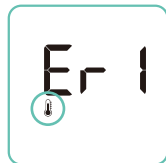
The meter is connected with PC using Micro USB cable.

Transfer meter data to PC. (page 39)



No test result in memory

No action is required.



The meter is used outside the proper range of temperature.

Leave the meter at a temperature between 50~104°F (10~40°C)

Message

Er2

Er3

Er4

Er5

What it means.

The used test strip was inserted in the test port.

The test strip was removed during testing.

There was an electrical noise during the test.

The meter has an internal electric circuit problem.

Action

Retest with a new test strip.

Retest with a new test strip. Do not remove the test strip until test result appears on the meter display.

Retest with a new test strip.

Contact your healthcare provider.

Er6

The meter has a problem with strip connection.

Contact your healthcare provider.

Er7

The meter has a problem with strip connection.

Contact healthcare provider.

Er8

Not enough blood or control solution was drawn into the test strip for a test.

Retest with a new test strip.

Er9

Blood is applied to wrong direction into the test strip.

Apply blood to right direction into a new test strip.

Troubleshooting

Cause

Action

1. The meter does not turn on after inserting a test strip.

Battery is dead.

Replace the battery.

The battery is installed incorrectly or there is no battery in the meter.

Check if battery is correctly installed with the positive "+" sign facing up. (See pages 36-37)

The test strip is inserted upside down or incompletely.

Insert the test strip correctly with the printed side facing up.

The meter may not be working properly.

Contact your healthcare provider.

Product Name	metene Blood Glucose Monitoring System
Model Name	AGM-513S
Assay Method	Electrochemical method
Sample Type	Fresh capillary whole blood
Sample Volume	0.5 μ l
Measurement Range	20~600 mg/dL
Measurement Time	5 seconds
Calibration	Plasma-equivalent
Battery Type	One 3-volt lithium battery (coin cell type CR2032)
Battery Life	Approximately 1,000 tests
Unit of Measurement	mg/dL
Operating Ranges	Temperature: 50~104°F (10~40°C) Relative Humidity: 15~85% Altitude: Up to 10,000 feet (3,048m) Hematocrit: 20~65%
Dimension	50 X 87.3 X 17.5 (mm), 2.0 X 3.4 X 0.69 (inches)
Weight	Approximately 47.2g or 1.7 oz. (with battery)
Display	44.0 X 38.0 (mm) LCD, 1.7 X 1.5 (inches) LCD
Memory Capacity	500 test results (with date, time & event)
Data Management	Micro USB
Automatic Shutoff	5 minutes after last action

The performance of the **metene** Test Strips has been evaluated in clinical tests.

Accuracy:

The user performance for the **metene** Blood Glucose Monitoring System was evaluated by using capillary blood samples from 405 patients with those obtained using a YSI Model 2300 STAT Plus Glucose Analyzer.

For glucose concentration < 75mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Site 1	0/1 (0%)	1/1 (100%)	1/1 (100%)
Site 2	7/7 (100%)	7/7 (100%)	7/7 (100%)
Site 3	5/7 (71.4%)	7/7 (100%)	7/7 (100%)
Total (3 Site)	12/15 (80%)	15/15 (100%)	15/15 (100%)

For glucose concentration ≥ 75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Site 1	103/142 (72.5%)	137/142 (96.5%)	142/142 (100%)	142/142 (100%)
Site 2	118/161 (73.3%)	156/161 (96.9%)	161/161 (100%)	161/161 (100%)
Site 3	71/87 (81.6%)	87/87 (100%)	87/87 (100%)	87/87 (100%)
Total (3 Site)	292/390 (74.9%)	380/390 (97.4%)	390/390 (100%)	390/390 (100%)

Measurement precision:

Measurement repeatability (using venous whole blood):			Intermediate measurement precision (using control solution):		
Level	STD	CV	Level	STD	CV
39.1 mg/dL	2.7 mg/dL	6.3%	37.2 mg/dL	1.4 mg/dL	3.7%
85.5 mg/dL	3.2 mg/dL	3.9%	80.4 mg/dL	1.8 mg/dL	2.2%
121 mg/dL	4.2 mg/dL	3.7%	118 mg/dL	2.6 mg/dL	2.2%
205 mg/dL	6.3 mg/dL	3.4%	200 mg/dL	3.5 mg/dL	1.7%
352 mg/dL	11.7 mg/dL	3.7%	353 mg/dL	7.4 mg/dL	2.1%