



# kinetik

## WELLBEING

Blood Glucose Monitoring System

Model Number: AG-607



OWNER'S MANUAL

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## **INTRODUCTION**

Thank you for purchasing the Kinetik (Model Number:AG-607) Blood Glucose Monitoring System. This manual provides important information to help you use the system properly. Before using this product, please read the Owner's Manual thoroughly. If you have questions regarding this product, please contact your place of purchase, or call the Customer Service . If you have questions or need assistance outside the operational days and times, please contact your the care provider.

## **INTENDED USE**

The Kinetik (Model Number:AG-607) Blood Glucose Monitoring System is intended to be used for:

- Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh
- Single person measurement only (it should not be shared)
- 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

The Kinetik (Model Number:AG-607) Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

- Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.
- The Blood Glucose Test Strips(EGS-2003) are intended for use with the blood Glucose meter (Kinetik (Model Number:AG-607)) to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the blood Glucose meter (Kinetik (Model Number: AG-607)).
- The control solutions(Level II ) are intended for use with the Kinetik (Model Number: AG-607) Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

## **IMPORTANT SAFETY INSTRUCTIONS**

Please read the following information carefully before using the blood glucose monitoring system. Always keep these instructions in a safe place for reference.

- Misuse of the blood glucose monitoring system can cause electrocution, burns, fire, and other hazards.
- The glucose meter and lancing device are for single patient use. Do not use either item on multiple patients.
- Do not share the meter or lancing device with anyone, including other family members.
- Do not place the blood glucose monitoring system in or near liquid.
- Use the blood glucose monitoring system only for the purpose described in the Owner's Manual.
- Use only accessories that are supplied by the manufacturer.

- Do not use the Blood Glucose Monitoring System if it has sustained any damage or is not working properly.
- Do not block test ports or place the Blood Glucose Monitoring System on soft surfaces that may block them. Keep test ports free from lint, hair, debris, etc.
- Do not place anything on top of the Blood Glucose Monitoring System.
- Do not place foreign objects into any opening in the Blood Glucose Monitoring System.
- Do not use the meter in a manner not specified by the manufacturer.
- All parts of the system are considered biohazards and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Please refer to the resources identified below for detailed information:
  - “FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010)  
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
  - “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010)  
<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

### **LIMITATIONS OF USE**

- The Blood Glucose Monitoring System is not intended for use on neonates.
- The meter is not intended for use on artery blood, serum, plasma and venous blood samples.
- The Blood Glucose Monitoring System should be only used with the Kinetik Wellbeing EGS-2003 test strips.
- The Blood Glucose Monitoring System cannot be used above an altitude of 10744 feet (3275 meters)
- If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >5 mg/dL) or Vitamin C (ascorbic acid, blood concentrations >4 mg/dL) at doses higher than recommended, these may interfere with your glucose meter and cause you to get inaccurate results with this system
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use on critically ill patients.
- Not to be used for patients who are dehydrated, hypertensive, hypotensive, or in shock.
- Do not use during or soon after xylose absorption testing.

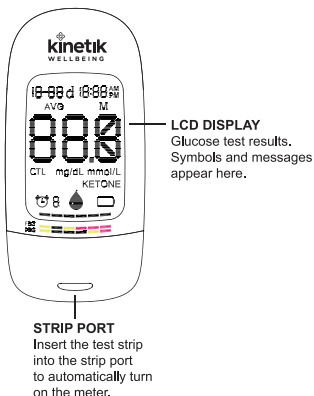
### **CONTENTS OF THE BLOOD GLUCOSE MONITORING SYSTEM**

Please refer to the package contents listed on the package you purchased.

1. Blood Glucose Meter
2. Battery (AAA\*2)
3. 25 x Test Strips
4. Lancing Device
5. 25 x Lancets
6. Logbook
7. Instruction Manual
8. Carry case

## Parts and Displays

### ●Blood Glucose Monitoring System

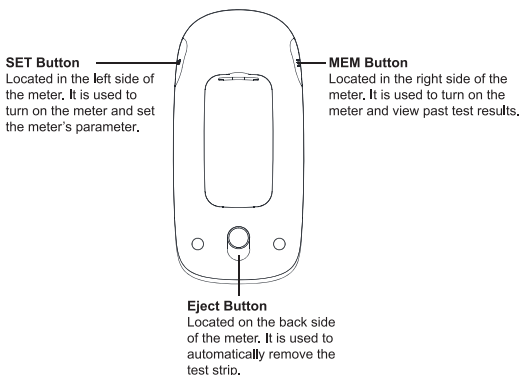


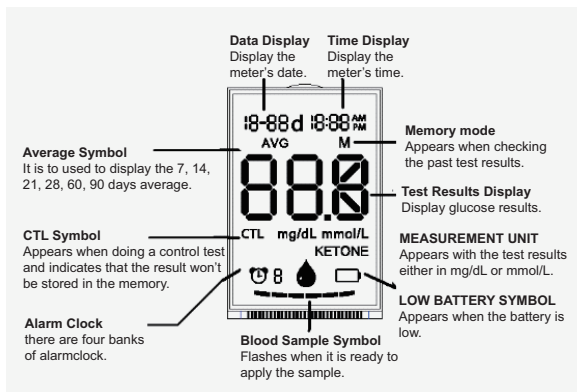
#### LCD Display

Glucose test results symbols and messages appear here.

#### STRIP PORT

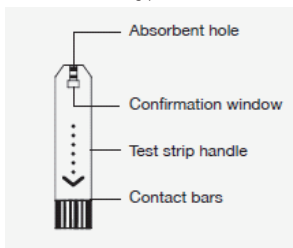
Insert the test strip into the strip port to automatically turn on the meter.



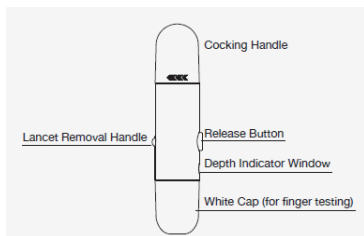


### ●Test Strips

Use only the test strips (EGS-2003) with the meter. Each test strip can be used only once, and consists of the following parts:



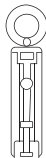
### ●Lancing Device



- Clear Cap for Alternative Site Testing



- Lancets



- Control Solution (Level II)



**Note:**

1. If any items printed on the package are missing from your package or the package appears to have been opened prior to your use, please call your local customer service.
2. Contents may vary according to geographic markets. Please check the contents with your package label.

**TEST PRINCIPLE**

Testing with the blood glucose monitoring system is based on the measurement of electrical currents generated by the reaction of glucose with the reagent of the strip. The blood glucose monitoring system measures the current and converts it to the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

**IMPORTANT TEST INFORMATION**

Please read the following:

- Severe dehydration and excessive water loss may cause inaccurate results.. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.

- Inaccurate results may occur in severely hypotensive individuals or patients who are in shock. Test results that are lower than actual values may occur in individuals who are in a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with Blood Glucose Meters.
- If you think your blood glucose results are inconsistent, repeat the test first. If you have symptoms or continue to get similar results, follow the treatment advice of your healthcare professional.
- If you are experiencing symptoms that are inconsistent with your blood glucose test, and you have followed all the instructions provided in this Manual, contact your healthcare professional immediately.
- Use only fresh whole blood samples to test your blood glucose.
- Do not use test strips that are expired or appear to be damaged as they may return inaccurate results.
- The lancing device is for self-use only. Do not share or re-use lancets. Please refer to the Lancing Device Manual for the detailed procedure.

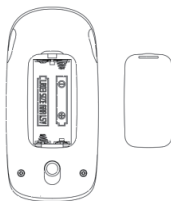
## INSTALL THE BATTERY

Your meter comes with two (AAA) batteries. Follow the instructions below to install the battery.

1. Open the back panel of the Meter.
2. Install the two new batteries, pay attention to the battery electrode.
3. Close the back panel of the Meter.



Disposal – Electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.



## SETTING THE METER

Before using your meter for the first time or if you have changed the meter battery, you should check and update these settings. Make sure you complete the steps below and have your desired settings saved.

### Entering the setting mode

Start with the meter off. Press **S** for about 2 seconds to turn on the meter

#### 1. Set the year

With the year flashing, Press **M** until the correct year appears. Press **S** to confirm and continue.

#### 2. Set the month

With the month flashing, Press **M** until the correct month appears. Press **S** to confirm and continue.



### 3. Set the day

With the day flashing, Press **M** until the correct day appears. Press **S** to confirm and continue.



### 4. Set the hour

With the hour flashing, Press **M** until the correct hour appears. Press **S** to confirm and continue.



### 5. Set the minute

With the minute flashing, Press **M** until the correct minute appears. Press **S** to confirm and continue.



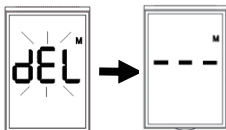
### 6. Select the unit of measurement

Press **M** to select the unit of measurement. Press **S** to confirm and continue.



### 7. Delete memory

When "dEL" and a flashing "**M**" symbol appears on the screen, press **S** to store results in the memory. To delete all the memory, press **M**, both "dEL" and "**M**" will flash, Press **S** to delete all the memory. The meter then displays "**M**" and "--", which means that the memory has been deleted.



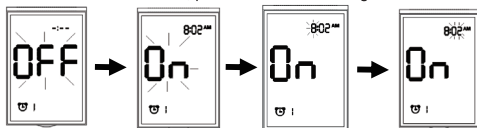
### 8. Set alarm

You may set up any or all of the alarms (1~4).

When the "OFF" or "On" and "1" with a bell icon symbols appear on the screen, press **M** to turn on or off the first alarm.

Press **M** to select on and press **S** to set the hour. With the hour flashing, press **M** to add an hour. When the correct hour is set, press **S** to confirm and go on to set the minutes. Press **M** to add one minute. Hold **M** longer to add minutes faster.

When the correct minute is set, press **S** to confirm and go to the next alarm setting.



If you do not wish to set an alarm, press S to skip this step.

If you wish to turn off an alarm, find the alarm number by pressing S in the setting mode, press M to change from "ON" to "OFF".

At the time of your alarm setting, the meter will beep and automatically turn on. You can insert a test strip to begin testing.

If you do not want to test at this time, press S to switch off the meter. If you do not press S, the meter will beep for 30 seconds then switch off.

NOTE:

The year, month, day, hour, minute, unit, memory deletion and alarm can only be changed in the setting mode. These parameters cannot be changed when performing a blood glucose testing.

If the meter is in the setting mode, the meter will turn off automatically if no button is pressed within 3 minutes.

### Test blood glucose level

CAUTION:

To reduce the chance of infection:

- Choose a clean, dry work surface.
- Never share a lancing device or lancet with other person.
- Always use a new and sterile lancet.
- Always use a new test strip. the test strip is for single use only.
- Avoid getting lotion, oils, dirt, or debris in or on the lancet and lancing device.

**A sample may be obtained from the finger by the following steps:**

1. Wash your hands all the time, before the following steps.

2. Insert the test strip into the meter's strip port. Insert the test strip into the strip port with the contact bars facing toward you. The meter will display as Picture (a) first, and then the Blood Sample Symbol will be flashing (displaying as Picture (b)).

3. Prepare the lancing device.

① Snap off the lancing device cap

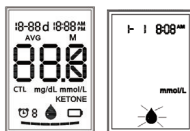
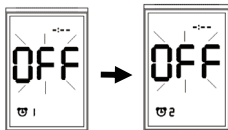
② Insert a new lancet firmly into the lancing holder cup

③ Twist the lancet cover off

④ Replace the lancing device cap

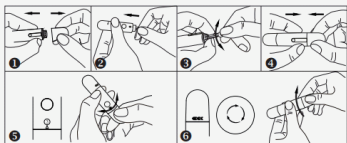
⑤ Set the lancing level

⑥ Twist the handle until it clicks



Picture (a)

Picture (b)



4. Obtain a blood sample.

Press the lancing device against the site to be lanced. Press the release button to puncture the site. Squeeze your finger until a drop of blood forms. Wipe away the first blood drop and squeeze until a second small blood drops forms.



5. Apply the blood sample to the test strip.

Quickly apply the blood sample to the absorbent hole of the test strip. Make sure the confirmation window of the test strip is completely filled with the blood sample.

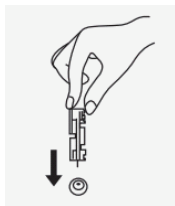
Quickly remove your finger from the test strip when the countdown (from 5 to 1) begins on the meter display.

6. The test result will appear on the meter after counting down from 5 to 1.



*Note: The results obtained from the glucose meter are plasma-calibrated. This helps you and your physician or other qualified healthcare providers to compare your meter results with laboratory tests. Refer to the instructions given by your physician or other qualified healthcare providers, do not deviate from these instructions on the basis of the result without first consulting your physician.*

7. Discard the used test strip and lancet. Remove the used test strip from the meter using a small amount of tissue paper. Discard the used test strip and lancet properly. (Tip: Prior to disposal, stick the lancet into the cover.)



## REFERENCE VALUE OF THE Kinetik (Model Number:AG-607) BLOOD GLUCOSE METER

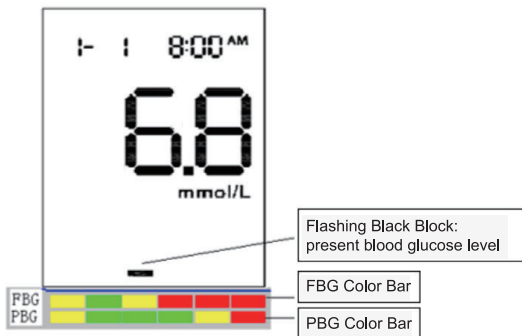
| Time of day              | People without diabetes |
|--------------------------|-------------------------|
| Fasting and before meals | <100 mg/dL              |
| 2 hours after meals      | <140 mg/dL              |

Source: American Diabetes Association: Classification and Diagnosis of Diabetes (Position Statement). Diabetes Care 39 (Supp. 1) S15, 2016.

Please consult a healthcare professional for interpretation of your blood glucose measurements and determine a target range that is best for you.

## ABOUT THE DOUBLE COLOR BARS

On the panel of the AG-607 Blood Glucose Meter, there are two color bars which have two acronyms with “FBG” and “PBG”. They are used as a reference to let you know whether the value of your blood glucose is normal or abnormal. The Double Color Bar’s image is showing in picture (c) as below.



Picture (c)

The flashing black block means the present blood glucose level of FBG or PBG.

The FBG means “Fasting Blood Glucose”.

The PBG means “Postprandial Blood Glucose”. This color bar can be used as reference only if you have just finished a blood glucose test at 2 hours after a meal.

According to the classification criteria of blood glucose which is announced by WHO and IDF in 1999, the meaning of the color bars are explained as below.

| the Value of Blood Glucose (mg/dL) | the color block in FBG Color bar | Meaning   | the color block in PBG Color bar | Meaning  |
|------------------------------------|----------------------------------|---|----------------------------------|--|
| <70                                | Yellow Block                     | Lower than normal value of fasting blood glucose  | Yellow Block                     | Lower than normal value of postprandial blood glucose  |
| 70≤N<110                           | Green Block                      | Normal  | Green Block                      | Normal   |
| 110≤N<126                          | Yellow Block                     | In the range of imprilglucosetolrnce              | Green Block                      | Normal   |
| 126≤N<140                          | Red Block                        | Higher than normal value of fasting blood glucose | Green Block                      | Normal   |
| 140≤N<200                          | Red Block                        | Higher than normal value of fasting blood glucose | Yellow Block                     | In the range of imprilglucosetolrnce                   |
| ≥200                               | Red Block                        | Higher than normal value of fasting blood glucose | Red Block                        | Higher than normal value of postprandial blood glucose |

## REVIEWING SAVED TEST RESULTS ON THE METER

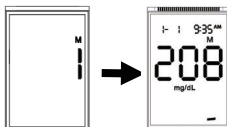
### Reviewing Blood Glucose Day Average Results

1. Press and hold the **M** button for 3 seconds to view the test results stored in the meter. The first reading shown will be the most recent 7-day average blood glucose result.
2. Press M button to review 7-, 14-, 21-, 28-, 60- and 90- day average results stored in the meter.



### Reviewing Test Results

1. After reviewing the 90-day average results, press M again. The first reading shown will be the most recent blood glucose result.



2. Continue to press M to recall the test results stored in the meter.

Note: When the memory is full, the oldest result is deleted and the newest result is added.

3. Exit the Memory Mode

When reaching the last test result. "End" will display, and the meter will turn off automatically.



### Cleaning and Disinfection

The cleaning and disinfection is necessary for the test procedure.

The meter and lancing device should be cleaned and disinfected following each use.

We suggest that you use CaviWipes™ (Metrex® Research Corporation, EPA Reg. No. 46781-8, EPA Est. No. 56952-WI-001). CaviWipes, with isopropanol and diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride as the active ingredient, have been shown to be safe for use with the meter and lancing device.

You can purchase this product from the suppliers listed below:

(1) Visit the website [www.metrex.com](http://www.metrex.com) or contact Metrex at 800-841-1428 for product or technical information.

(2) visit store like Walmart or Sears holdings

(3) Visit the following website

Amazon.com:

[http://www.amazon.com/s/ref=nb\\_sb\\_noss?url=search-alias%3Daps&field-keywords=CaviWipes,or](http://www.amazon.com/s/ref=nb_sb_noss?url=search-alias%3Daps&field-keywords=CaviWipes,or)

Endochoice.cm : <http://www.endochoice.com/Equipment?search=wipe>. or

Metrex corporate and distributor <http://www.metrex.com/how-to-buy>

The meter and the lancing device are for single - patient use, If user test 6 times every day, the meter and lancing device should be cleaned and disinfected 6 times per day which equals to 10950 number of cycles over the 5 year life of the devices. The meter and lancing device were validated for 11,000 cycles which could support up to 6 cleaning and disinfection cycles per day.

Below are the steps on how to clean and disinfect the meter and lancing device.

1. After a test, clean and wash your hands.
2. Use one CaviWipe to carefully to clean the entire external surface of the meter.
3. Then wipe the entire external surface of the meter with another wipe, and keep the surface wet for 2min.
4. Use the same method with the CaviWipes to clean and disinfect the lancing device.

Note:

- ① Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.
- ② Only the surface of the meter can be cleaned and disinfected with the disinfecting towelette. Do not insert the disinfecting towelette into the test strip port and the metal connector, or else the performance of the meter may be affected.
- ③ If you have any questions you can call your local customer service.
- ④ If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.



## **SIGNS OF POTENTIAL PHYSICAL AND PERFORMANCE DETERIORATION**

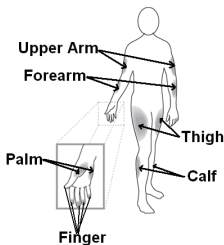
If you start experience one of the following, Stop using and contact local customer services or the place of purchase for assistance.

1. The device does not work.
2. Discoloration of the meter casing or lancing device; for example, it is difficult to read the labeling information.
3. Corrosion, crazing (fine cracks), embrittlement, and/or cracking of the meter casing or lancing device.

## INFORMATION ABOUT ALTERNATIVE SITE TESTING (AST)

### What Is Alternate Site Testing?

Alternative site testing (AST) is the use of parts of the body, other than the fingertips, to check blood glucose levels. Kinetik (Model Number:AG-607) Glucose Monitoring System allows you to test on the palm, forearm, upper arm, calf, or thigh with equivalent results to fingertip testing when used at appropriate times.



There are limitations for doing AST. Please consult your healthcare professional before you conduct AST. The Kinetik (Model Number:AG-607) Glucose Monitoring System should only be used for AST under steady-state blood glucose conditions.

### What Is the Advantage of Alternative Site Testing?

Pain is felt more readily on the fingertips because they are full of nerve endings (receptors). At other body sites where nerve endings are not so condensed, pain is not felt as acutely.

### When Should You Use Alternative Site Testing?

Food, medication, illness, stress, and exercise can affect blood glucose levels. Capillary blood from the fingertips reflects these changes faster than capillary blood from other sites. Therefore, when testing blood glucose levels during or immediately after meals exercise, or when another of the above-noted conditions applies, take a blood sample from your fingertips only. AST should be used only during steady-state times when glucose levels are not changing rapidly.

Blood glucose results from the forearm, upper arm, hand, thigh and calf are not always the same as results from fingertips. Alternative Site Testing is suitable in the following instances:

- In a pre-meal or fasting state (two hours or more after the last meal)
- Two hours or more after taking insulin
- Two hours or more after exercising

**Caution:** Do not use sites other than fingertips for testing when blood glucose is rapidly rising or falling, within 2 hours of eating, after taking insulin, immediately after exercise, or when you are ill or under stress. Alternative Site Testing should not be used to calibrate continuous glucose monitoring systems (CGMs). Results from Alternative Site Testing should not be used in insulin dose calculations. Do not use AST if:

- You think your blood glucose is low
- You are unaware that you might have hypoglycemia
- You are testing for hyperglycemia
- Your AST results do not match the way you feel
- Your routine glucose results fluctuate often

## IMPORTANT INFORMATION ABOUT CONTROL SOLUTION TESTS

Control solution contains a known amount of glucose that reacts with test strips and is used to check that your meter and test strips are working together properly.

### Materials needed to perform a control solution test:

- Blood Glucose Meter
- Blood Glucose Test Strip (EGS-2003)
- Control Solution

### Perform a control solution test when:

- Checking the meter and test strips (which should be done at least once a week)
- Using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose test results are not consistent with your expectation, or you think the results are not accurate
- Practicing the testing process
- The meter has been dropped or damaged

## PERFORMING A CONTROL SOLUTION TEST

**Step 1:** Turn on the control solution test (CTL) mode.

Insert the test strip into the meter's strip port to turn on the meter. When the blood sample symbol appears on the meter display, press the S button to turn on the CTL mode.

When the CTL symbol appears, the meter is in control mode and will not save this test result in memory.

Note: Be sure to set the meter and/or app on the CTL mode before performing a control solution test. The control test result will not be saved in the meter.

**Step 2:** Press the S button again to turn off the CTL mode and switch back to the regular testing mode.

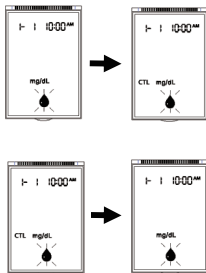
**Step 3:** Apply the control solution.

- Shake the control solution vial before each use.
- Squeeze a drop of control solution into the vial cap. For better results, it is recommended that you use the second drop of the control solution (discard the first drop).
- Hold the meter and move the absorbent hole of the test strip to catch the drop. Once the confirmation window fills completely, the meter will start counting down. Remove the control solution sample from the test strip when the countdown begins.

Note: To avoid contaminating the entire vial of control solution, do not directly apply control solution onto a strip.

**Step 4:** Read and compare the results.

After the meter counts down to "1," the control solution test result will appear on the meter display.



The result of the control solution test should be within the range printed on the test strip vial label. If the test result falls outside the specified range, repeat the test, carefully following the steps above.

### **Out-of-Range Results**

Results falling outside the specified range may be caused by:

- An error in the test
- Expired or contaminated control solution
- An expired or contaminated test strip
- Meter malfunction

If you continue to get control solution test results that fall outside of the range printed on the vial, the meter may not be working properly. Discontinue use and please call your local customer service.

To purchase additional control solution, please visit [kinetikwellbeing.com](http://kinetikwellbeing.com).

### **NOTE:**

Do not use expired control solution.

The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.

## **COMPARING GLUCOSE METER TEST RESULTS WITH LABORATORY RESULTS**

The meter provides you with results. The result you obtain from your glucose meter may differ somewhat from your laboratory results due to normal variation.

Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

### **Before the Lab Test**

- Perform a control solution test to make sure that the meter is working properly.
- If possible, fast at least eight hours before conducting a comparison test.
- Take your meter to the lab.

### **While at the Lab**

Make sure that samples for both tests are taken and tested within 15 minutes of each other.

- Wash your hands before obtaining a blood sample.
- Never use your glucose meter with blood samples collected in a test tube.
- Use fresh capillary blood only.

## **BLOOD GLUCOSE MONITORING SYSTEM SPECIFICATIONS**

1. Model: Kinetik Wellbeing
2. Machine size: 4.3"× 2.05"× 0.81" (110mm × 52mm ×20.5mm)
3. Measuring method: Amperometric technology using glucose dehydrogenase
4. Result range: 20 mg/dL ~600 mg/dL (1.1 mmol/L ~33.3mmol/L)
5. Power source: DC3V === (AAA×2)

- 6.Storage condition: Test Strips 39°F~86°F (4°C~30°C), Humidity 10%~80%RH  
 7.Storage condition:The meter-4°F~131° F (-20°C~55°C); Humidity 10%~80%RH  
 8.Operating conditions: 50°F~104°F (10°C~40°C) , 25%RH~80%RH  
 9.Blood source: Fresh capillary whole blood  
 10.Blood volume: Minimum 0.7 micro liter  
 11.Life span: Five years

The table of substances below shows the highest concentration without significant interference ( $\pm 10\%$  error).

| Compounds     | Limitation |
|---------------|------------|
| Ascorbic acid | 2mg/dL     |
| Uric acid     | 10mg/dL    |
| Acetaminophen | 5mg/dL     |
| Bilirubin     | 15mg/dL    |
| Dopamine      | 0.03mg/dL  |
| L-dopa        | 0.45mg/dL  |
| Methyl dopa   | 0.75mg/dL  |
| Tolbutamide   | 24mg/dL    |
| Triglycerides | 2000mg/dL  |
| Hemoglobin    | 250mg/dL   |

### Maintenance and Storage of Your Meter


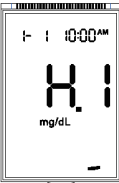
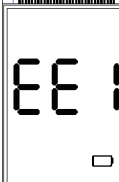

- Always use care when handling the Blood Glucose Meter. Dropping or throwing the meter may cause damage.
- Always wash your hands with soap and water, and rinse and dry them completely before handling the Kinetik (Model Number:AG-607) Blood Glucose Meter and test strips.
- Red blood cell count (hematocrit) extent 20%-60% can lead to incorrect test results. If you do not know your hematocrit level, please consult your healthcare provider. We recommend periodic comparison of the meter to another monitoring system known to be well maintained and monitored by a healthcare provider.
- When traveling across time zones, living on or near a time zone boundary, you need to be aware that the logged glucose measurement times may not be synchronized to your normal day-to-day regime.
- If you take insulin and will be traveling across time zones, talk to your health care professional before your trip.

We recommend periodic comparison of the System to another monitoring system known to be well maintained and monitored by a healthcare provider.

### SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to repair the meter by yourself and never try to disassemble the meter under any circumstances.

## Display Messages

| Message   | What It Means  | What To Do   |
|---|--|--|
|  <p>The image shows a digital display on a glucose meter. At the top, it shows a battery level indicator, a vertical bar, and the time '10:00 AM'. The main display shows 'Lo' in large characters, with 'mg/dL' written below it. A small horizontal bar is visible at the bottom left of the display area.</p>  | <p>Blood glucose level is lower than 20mg/dL (1.1mmol/L).</p>    | <p>The message indicates very low blood glucose. Consult with your healthcare professional.</p>            |
|  <p>The image shows a digital display on a glucose meter. At the top, it shows a battery level indicator, a vertical bar, and the time '10:00 AM'. The main display shows 'Hi' in large characters, with 'mg/dL' written below it. A small horizontal bar is visible at the bottom right of the display area.</p> | <p>Blood glucose level is higher than 600mg/dL (33.3mmol/L).</p> | <p>The message indicates severe hyperglycemia (high blood glucose). Seek immediate medical assistance.</p> |
|  <p>The image shows a digital display on a glucose meter. The main display shows 'EE' in large characters, followed by a vertical bar. At the bottom right, there is a small battery icon.</p>   | <p>The battery in your meter is low on power.</p>                | <p>Please change the battery.</p>  |
|  <p>The image shows a digital display on a glucose meter. The main display shows 'EE2' in large characters.</p>   | <p>Problem with the meter.</p>                                   | <p>Re-test with a new test strip.</p>  |

|  |  |                                       |
|--|--|---------------------------------------|
|  | <p>Problems have occurred that are related to test strip use, such as:</p> <ul style="list-style-type: none"> <li>- test strip may be wet or damaged</li> <li>- test strip may be removed too early</li> <li>- you applied more blood after testing began</li> </ul> | <p>Retest using a new test strip.</p> |
|  | <p>Problem with the meter.</p>   | <p>Re-test with a new test strip.</p> |

|  |   |  |
|--|---|--|
|  | <p>The environmental temperature is lower than 50°F (10°C).</p>   | <p>The operating temperature is 50°F ~ 104°F (10°C ~ 40°C)</p> |
|  | <p>The environmental temperature is higher than 104°F (40°C).</p> | <p>The operating temperature is 50°F ~ 104°F (10°C ~ 40°C)</p> |

## Troubleshooting


| Problem  | Possible Causes   | Solution(s)  |
|--|---|--|
| Display remains blank after the test strip has been inserted into the meter.                       | <ol style="list-style-type: none"> <li>1. Battery power is too low for use.</li> <li>2. Too much time has passed between inserting the test strip and performing the test.</li> <li>3. Test strip has not been fully inserted into the meter.</li> </ol>  | <ol style="list-style-type: none"> <li>1. Please change the battery.</li> <li>2. Reinsert the test strip into the meter.</li> <li>3. Reinsert the test strip into the meter, pressing firmly.</li> </ol>   |
| Test results are inconsistent or control solution test results are not within the specified range. | <ol style="list-style-type: none"> <li>1. Not enough sample in the test strip.</li> <li>2. Test strip or control solution has expired.</li> <li>3. Test strip has been damaged due to heat or humidity so that the sample cannot be applied, or the speed of application is too slow.</li> <li>4. System is not performing due to the environment being above or below room temperature.</li> </ol> | <ol style="list-style-type: none"> <li>1. Re-test with a new test strip and make sure that enough sample has been applied.</li> <li>2. Re-test with a new test strip or new control solution.</li> <li>3. Perform a control solution test using a new test strip. If the results are still out of range, replace with new vial of test strips.</li> <li>4. Bring the system to a room-temperature environment and wait approximately 30 minutes before performing a new test.</li> </ol> |
| The meter countdown did not start.   | Test strip has not been inserted correctly.   | Use a new test strip and redo the test.  |

## International Blood Glucose Units of Measure

| Country                    | Unit of Measure Used | Country            | Unit of Measure Used |
|----------------------------|----------------------|--------------------|----------------------|
| Algeria                    | mg/dL                | Australia          | mmol/L               |
| Argentina                  | mg/dL                | Canada             | mmol/L               |
| Austria                    | mg/dL                | China              | mmol/L               |
| Bahrain                    | mg/dL                | Czech Republic     | mmol/L               |
| Bangladesh                 | mg/dL                | Denmark            | mmol/L               |
| Belgium                    | mg/dL                | Finland            | mmol/L               |
| Brazil                     | mg/dL                | Germany            | mmol/L               |
| Caribbean Countries        | mg/dL                | Hong Kong          | mmol/L               |
| Chile                      | mg/dL                | Ireland            | mmol/L               |
| Colombia                   | mg/dL                | Kazakhstan         | mmol/L               |
| Ecuador                    | mg/dL                | Malaysia           | mmol/L               |
| Egypt                      | mg/dL                | Malta              | mmol/L               |
| France                     | mg/dL                | Netherlands        | mmol/L               |
| Georgia                    | mg/dL                | New Zealand        | mmol/L               |
| Greece                     | mg/dL                | Norway             | mmol/L               |
| India                      | mg/dL                | Qatar              | mmol/L               |
| Indonesia                  | mg/dL                | Russia             | mmol/L               |
| Israel                     | mg/dL                | Singapore          | mmol/L               |
| Italy                      | mg/dL                | Slovakia           | mmol/L               |
| Japan                      | mg/dL                | South Africa       | mmol/L               |
| Jordan                     | mg/dL                | Sub-Saharan Africa | mmol/L               |
| Korea                      | mg/dL                | Sweden             | mmol/L               |
| Kuwait                     | mg/dL                | Switzerland        | mmol/L               |
| Lebanon                    | mg/dL                | Ukraine            | mmol/L               |
| Luxembourg                 | mg/dL                | United Kingdom     | mmol/L               |
| Mexico                     | mg/dL                | Vietnam            | mmol/L               |
| Oman                       | mg/dL                |                    |                      |
| Peru                       | mg/dL                |                    |                      |
| Philippines                | mg/dL                |                    |                      |
| Poland                     | mg/dL                |                    |                      |
| Portugal                   | mg/dL                |                    |                      |
| Saudi Arabia               | mg/dL                |                    |                      |
| Spain                      | mg/dL                |                    |                      |
| Syria                      | mg/dL                |                    |                      |
| Taiwan                     | mg/dL                |                    |                      |
| Thailand                   | mg/dL                |                    |                      |
| Tunisia                    | mg/dL                |                    |                      |
| Turkey                     | mg/dL                |                    |                      |
| United Arab Emirates (UAE) | mg/dL                |                    |                      |
| United States              | mg/dL                |                    |                      |

Note: The default setting in US is mg/dL. Please contact customer support if your meter isn't set to mg/dL when purchased.

Manufactured by **ANDON HEALTH CO., LTD.**
















 No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin 300190, China.

Europe:

 iHealthLabs Europe SAS [www.ihealthlabs.eu](http://www.ihealthlabs.eu)  
36 rue de Ponthieu, 75008, Paris, France

**If you have questions or need assistance outside the operational days and times, please contact your health care provider**

### EXPLANATION OF SYMBOLS

- |  |   |
|--|---|
|  Invitro diagnostic medical device   |  Authorised representative in the European Community     |
|  Serial number   |  Caution, consult accompanying documents                 |
|  Consult instructions for use  |  Manufacturer  |
|  Environmental Protection—Electrical products waste should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice. |   |
|  Keep away from rain   |  Symbol for “Manufacture Date”                           |
|  Use by date   |  Sterilized Using Irradiation                            |
|  Catalogue number   |  Storage Temperature Limitation                         |
|  Do not re-use   |  <b>CE 0197</b> Complies with IVD98/79/EC requirements |

### IMPORTANT INFORMATION REQUIRED BY THE FCC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

## ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 For all ME EQUIPMENT and ME SYSTEMS

| <b>Guidance and manufacture's declaration - electromagnetic emissions</b>   |            |  |
|---|------------|--|
| The Blood Glucose Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Glucose Monitor should assure that it is used in such an environment. |            |  |
| Emissions test  | Compliance | Electromagnetic environment - guidance   |
| RF emissions<br>CISPR 11  | Group 1    | The Blood Glucose Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.   |
| RF emissions<br>CISPR 11  | Class B    | The Blood Glucose Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2   | Class A    |  |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3   | Complies   |  |

Table 2 For all ME EQUIPMENT and ME SYSTEMS

| <b>Guidance and manufacturer's declaration - electromagnetic immunity</b>   |                              |                              |  |
|---|------------------------------|------------------------------|--|
| The Blood Glucose Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Glucose Monitor should assure that it is used in such an environment. |                              |                              |  |
| IMMUNITY test   | IEC 60601 test level         | Compliance level             | Electromagnetic environment - guidance   |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8  | 3 A/m                        | 3 A/m                        | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.      |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.   |                              |                              |  |

Table 3 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING


| <b>Guidance and manufacturer's declaration - electromagnetic immunity</b>   |                            |                         |   |
|---|----------------------------|-------------------------|---|
| The Blood Glucose Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Glucose Monitor should assure that it is used in such an environment.   |                            |                         |   |
| <b>IMMUNITY test</b>  | <b>IEC 60601test level</b> | <b>Compliance level</b> | <b>Electromagnetic environment - guidance</b>   |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m 80 MHz to 2,5 GHz    | 3 V/m                   | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Blood Glucose Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance :</b></p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.   |                            |                         |   |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |                            |                         |   |
| <p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Blood Glucose Monitor is used exceeds the applicable RF compliance level above, the Blood Glucose Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Blood Glucose Monitor.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p> |                            |                         |   |

Table 4 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

| <b>Recommended separation distances between portable and mobile RF communications equipment and the Kinetik (Model Number:AG-607)</b>   |   |  |   |
|---|---|--|---|
| The Kinetik (Model Number:AG-607) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Kinetik (Model Number:AG-607) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kinetik (Model Number:AG-607) as recommended below, according to the maximum output power of the communications equipment. |   |  |   |
| Rated maximum output power of transmitter<br><i>W</i>   | Separation distance according to frequency of transmitter<br><i>m</i> |  |   |
|   | 150 kHz to 80 MHz<br>$d = 1.2\sqrt{P}$                                | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2,5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0,01  | 0,12  | 0,12                                   | 0,23                                    |
| 0,1   | 0,38  | 0,38                                   | 0,73                                    |
| 1   | 1,2   | 1,2                                    | 2,3                                     |
| 10  | 3,8   | 3,8                                    | 7,3                                     |
| 100   | 12  | 12                                     | 23                                      |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.   |   |  |   |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.   |   |  |   |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |   |  |   |

**NOTE 1** It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

**NOTE 2** It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.

Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

## RETURN POLICY

Product may be returned if faulty, please contact the Retailer or Kinetik directly if you're experiencing issues with your product. This does not affect your statutory rights. Please note the retailer's own return policy may still be valid, contact the retailer for more information.

Authorised Distributor