

# ACCUGENCE<sup>®</sup> PLUS

## Multi-Monitoring System

Thank you for choosing ACCUGENCE<sup>®</sup>PLUS Multi-Monitoring System (Model: PM800). You now have a very simple and accurate way to test your Blood Glucose,  $\beta$ -Ketone, Uric Acid and Hemoglobin from fresh whole blood samples in just a few simple steps anytime, anywhere.

**Attention:** ACCUGENCE<sup>®</sup> Blood Glucose Test Strips, ACCUGENCE<sup>®</sup> Blood Ketone Test Strips, ACCUGENCE<sup>®</sup> Uric Acid Test Strips and ACCUGENCE<sup>®</sup> Hemoglobin Test Strips with ACCUGENCE<sup>®</sup>PLUS Multi-Monitoring System are intended for *in-vitro* diagnostic healthcare professionals in clinical settings.

To ensure accurate results from your ACCUGENCE<sup>®</sup>PLUS Multi-Monitoring System, please follow these guidelines carefully:

- Read instructions before use.
- ACCUGENCE<sup>®</sup> PLUS Multi-Monitoring System is intended for *in-vitro* diagnostic use only. It is intended to be used with ACCUGENCE<sup>®</sup> Blood Glucose Test Strips, ACCUGENCE<sup>®</sup> Blood  $\beta$ -Ketone Test Strips, ACCUGENCE<sup>®</sup> Uric Acid Test Strips and ACCUGENCE<sup>®</sup> Hemoglobin Test Strips to quantitatively measure glucose,  $\beta$ -hydroxybutyrate ( $\beta$ -ketone), uric acid and hemoglobin from whole blood sample.

**Note:** There are two types of ACCUGENCE<sup>®</sup> Blood Glucose Test Strips available, ACCUGENCE<sup>®</sup> Blood Glucose Test Strips using Glucose Oxidase (GLU GOD) and ACCUGENCE<sup>®</sup> Blood Glucose Test Strips using Glucose Dehydrogenase FAD-dependent (GLU GDH).

- ACCUGENCE<sup>®</sup>PLUS Multi-Monitoring Meter with ACCUGENCE<sup>®</sup> Blood Glucose Test Strips are intended for use by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus.

**Note:** When ACCUGENCE<sup>®</sup> Blood Glucose Test Strips (Glucose Oxidase) are used, only fresh capillary whole blood is allowable to be used for testing. When ACCUGENCE<sup>®</sup> Blood Glucose Test Strips (Glucose Dehydrogenase FAD-dependent) are used, fresh capillary whole blood or venous whole blood is allowable to be used for testing, but venous whole blood testing is limited for professional use only.

- ACCUGENCE<sup>®</sup>PLUS Multi-Monitoring Meter with ACCUGENCE<sup>®</sup> Blood Ketone Test Strips are intended for use for the quantitative measurement of  $\beta$ -hydroxybutyrate ( $\beta$ -ketone) in fresh capillary whole blood or venous whole blood. It should NOT be used to diagnose DKA, and it is limited for professional use only.

- ACCUGENCE®PLUS Multi-Monitoring Meter with ACCUGENCE® Uric Acid Test Strips are intended for use for the quantitative measurement of uric acid in fresh capillary whole blood or venous whole blood, and ACCUGENCE®PLUS Multi-Monitoring Meter with ACCUGENCE® Uric Acid Test Strips is limited for professional use only.
- ACCUGENCE®PLUS Multi-Monitoring Meter with ACCUGENCE® Hemoglobin Test Strips are intended for use for the quantitative measurement of hemoglobin in fresh capillary whole blood or venous whole blood, and ACCUGENCE®PLUS Multi-Monitoring Meter with ACCUGENCE® Hemoglobin Test Strips is limited for professional use only.
- The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.
- Use the assorted calibration chip that accompanies each type of test strip when tests are applied. Used with single-use, auto-disabling lancing device.
- Test only whole blood samples with the assorted ACCUGENCE® brand Blood Glucose Test Strips, Blood  $\beta$ -Ketone Test Strips, Uric Acid Test Strips and Hemoglobin Test Strips along with ACCUGENCE®PLUS Multi-Monitoring Meter.
- Keep out of reach of children.

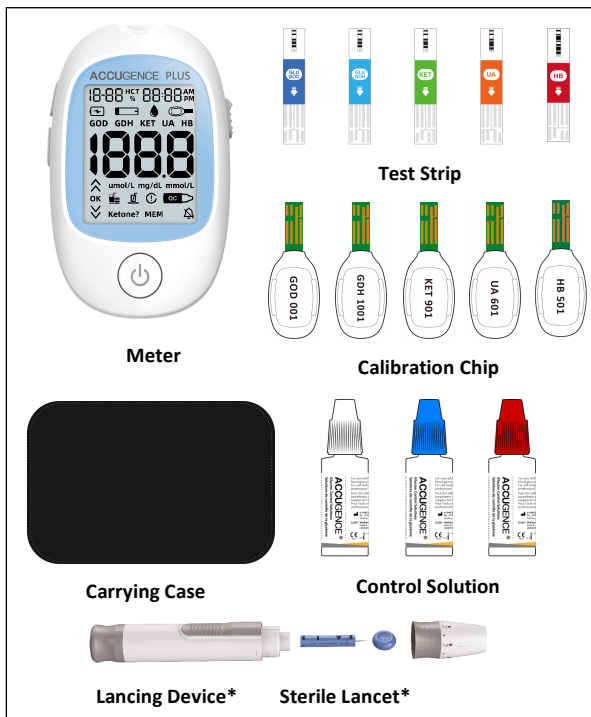
By following the instructions outlined in this User's Manual, you will be able to use your ACCUGENCE®PLUS Multi-Monitoring System to monitor blood glucose,  $\beta$ -Ketone, uric acid and hemoglobin and better manage your healthcare.

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# Getting Started

Before testing, read the instructions carefully and learn about all the components of your ACCUGENCE®PLUS Multi-Monitoring System. Please note that some of the components may need to be purchased separately from your local distributor. Please check the list of contents on the outer box for details on which components are included with your purchase.



**Note:** "\*" means the pictures are for reference only, subject to our available products.

## Components Descriptions

1. ACCUGENCE®PLUS Multi-Monitoring Meter: Reads the test strips for blood glucose,  $\beta$ -ketone, uric acid, hemoglobin and displays each concentration.
2. Test Strips: Strips with a chemical reagent system used with the meter to measure glucose,  $\beta$ -ketone, uric acid or hemoglobin concentration in blood.
3. Calibration Chip: Automatically calibrates the meter with the type of test strips a patient wants to perform once inserted into the meter.
4. Lancing Device: Used with sterile lancets to prick the fingertip for blood sample collection. The packaged lancing device has multiple depth settings, allowing users to adjust the depth of the puncture and minimize discomfort. It can also eject the used lancets.
5. Sterile Lancet: Single-use, sterile lancet is used with the lancing device to obtain blood samples. Discard it after a single use.
6. Control Solution: Verifies the proper operation of the ACCUGENCE®PLUS Multi-Monitoring System by checking the test strips and meter against a pre-calibrated control solution, which are available in the ACCUGENCE® Control Solution package which is sold separately.

**Note:** For Glucose and  $\beta$ -Ketone control solution, there are three levels with Level 1, Level 2 and Level 3. For Uric Acid and Hemoglobin control solution, there are two levels with Level 1 and Level 2.

7. Carrying Case: Provides portability for testing wherever you go.
8. User's Manual: Provides detailed instructions on using the ACCUGENCE®PLUS Multi-Monitoring System.

## ACCUGENCE® PLUS Multi-Monitoring Meter

The meter reads the test strips of blood glucose,  $\beta$ -ketone, uric acid and hemoglobin and displays each concentration. Please read diagrams below to become familiar with all the parts of your meter.



**Strip Port:** Test strips are inserted into this area to perform a test / Coding the meter by inserting the calibration Chip.

**Strip Ejector:** Slide the ejector forward to discard the used test strip.

**Liquid Crystal Display (LCD):** Shows your test results, and helps you through the testing process.

**Start/Power:** Enter setting model and confirm the setting, when the meter is in PC and Memory mode. Hold Start/Power button, the meter will turn on/off.

**Up Button:** Selects meter settings and performs other menu selection functions.

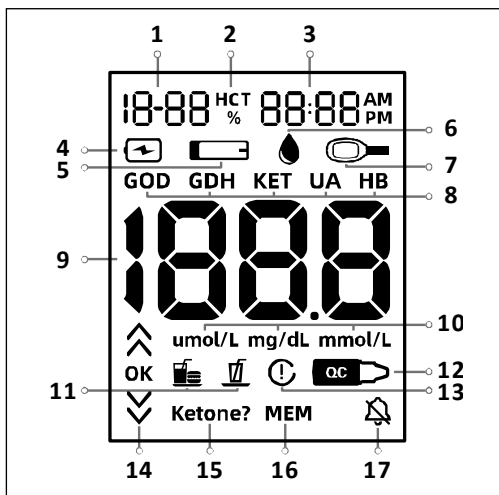
**Down Button:** Recalls previous test results from the meter memory and performs other menu selection functions.





**Battery Cover:** Remove the battery cover to install two CR2032 coin cell batteries.

**Data Transfer Port:** Sends information to a computer via an optional data transfer cable to view, analyze and print stored data in the meter. The data transfer cable is available for order as an optional add-on.







**Attention:** *Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.*

## Meter Display



Number	Symbol	Indicator	Means
1	18-88	Date	Indicates the testing date in month/day format.
2	HCT%	HCT value	Hematocrit value.
3	88:88 <sup>AM</sup> <sub>PM</sub>	Time	Indicates the time of 24H format or 12H format.
4		Low Power Icon	Warns you when you should replace the battery.
5		Strip Icon	Blood Drop / Strip Icon will appear before applying the sample and during the time of meter reminding. These two symbols appear at the same time.
6		Blood Drop Icon	Blood Drop / Strip Icon will appear before applying the sample and during the time of meter reminding. These two symbols appear at the same time.
7		Code Icon	Indicates the test strip calibration code number.



8	<b>GLU GOD / GLU GDH or KET or UA or HB</b>	Strip type or Test Parameter	Indicates different strip type or test parameter. GLU GOD / GLU GDH means the meter is currently performing the glucose test with strip of either GOD or GDH enzyme. KET means blood $\beta$ -ketone test, UA stands for uric acid test, and HB stands for hemoglobin test.
9	<b>1888</b>	Test Result Area	Indicates the test result and calibration code number.
10	<b>mg/dL mmol/L umol/L</b>	Measurement Unit	Measurement units differ from different test parameter, mg/dL and mmol/L are for Glucose, mmol/L are for $\beta$ -Ketone, mg/dL and $\mu$ mol/L are for Uric Acid, g/dL and mmol/L are for hemoglobin. <b>Note:</b> When glucose testing is performed, only one unit of measure will be displayed on your meter and it cannot be adjusted.
11		Before Meal Icon	Appears when before-meal test results are displayed.
		After Meal Icon	Appears when after-meal test results are displayed.
12		QC Icon	Indicates a test result when running quality control.
13		Invalid Value Icon	Appears if mark the value is invalid, and also will be displayed together with control solution value.
14		Glucose Target Range	Up Arrow Symbol appears when the blood glucose concentration is above the "Hyperglycemia" (high blood sugar level) target level that you have set. Down Arrow Symbol: Appears when the blood glucose concentration is below the "Hypoglycemia" (low blood sugar) target level that you have set.
15	<b>Ketone?</b>	Blood Ketone Reminder Symbol	Appears when the blood glucose concentration is above 16.7 mmol/L (300 mg/dl). This simply suggests that a $\beta$ -Ketone test is recommended. Consult your healthcare professional about testing for $\beta$ -Ketones. <b>Note:</b> This symbol does not mean that the system has detected $\beta$ -Ketones. It recommends that a $\beta$ -Ketone test should be taken.
16	<b>MEM</b>	MEM	Shows a test result stored in memory.
17		Sound Icon	This icon appears when the sound is turned off.

## Meter Use and Precautions

- Wait for the Blood Drop / Strip Symbol to appear before applying the sample.
- The meter is pre-set to display depending on which unit of measure is standard in your country. Blood glucose concentration in either millimole per liter (mmol/L) or milligrams per deciliter (mg/dL), uric acid concentration in either milligrams per deciliter (mg/dL) or micromole per liter ( $\mu\text{mol/L}$ ), hemoglobin concentration in either millimole per liter (mmol/L) or grams per deciliter (g/dL). This unit of measure cannot be adjusted.
- The meter will shut off automatically 2 minutes after inactivity.
- Do not get water or other liquids inside the meter.
- Keep the strip port area clean.
- Keep your meter dry and avoid exposing it to extreme temperatures or humidity. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test.
- Do not take the meter apart. Taking the meter apart will void the warranty.
- Keep the meter and all associated parts out of the reach of children.

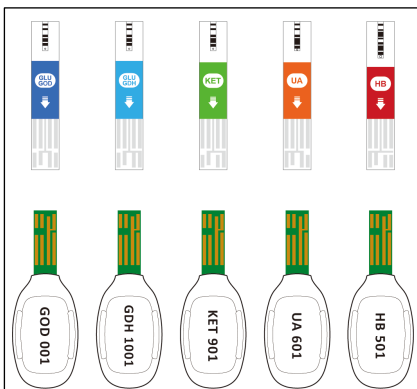
**Note:** Follow proper precautions and all local regulations when disposing of the meter and used battery.

## All Systems Preventive Warnings with Regard to EMC:

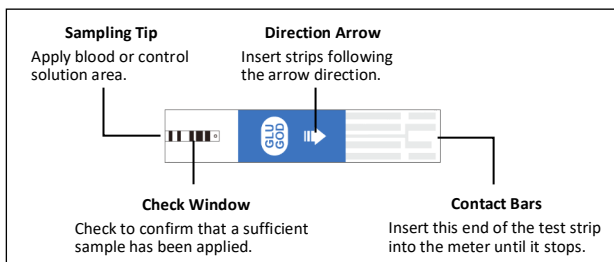
- This instrument is tested for immunity to electrostatic discharge as specified in IEC 61000-4-2. However, use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results.
- This instrument complies with the emission and immunity requirements described in EN61326-1 and EN61326-2-6. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with proper operation of the meter.
- For professional use, the electromagnetic environment should be evaluated prior to operation of this device.

## ACCUGENCE® GLU GOD/GLU GDH/KET/UA/HB Test Strips

The ACCUGENCE® GLU GOD/GLU GDH/KET/UA/HB Test Strips are thin strips with a chemical reagent which works with the ACCUGENCE®PLUS Multi-Monitoring Meter to measure the glucose,  $\beta$ -ketone, uric acid or hemoglobin concentration in whole blood respectively. After the strip is inserted into the meter, blood is applied to the sample tip of the test strip. The blood is then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood glucose,  $\beta$ -Ketone/uric acid/hemoglobin concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meter is calibrated to display plasma equivalent results.

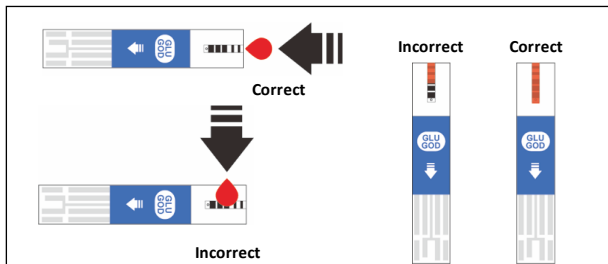


Example of a blood glucose test strip using glucose oxidase (GOD):



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

Hold the blood drop to the sample tip of the test strip until the check window is completely full and until the meter begins to count down. If you applied blood but do not see the starting of the count down, you may reapply a second drop of blood within 3 seconds. If the check window does not fill and the meter starts to countdown, then do not add more blood to the test strip. If you do, then you may get an E-5 message or an inaccurate test result. In this case, if the meter begins to countdown and the check window does not fill, discard the strip and begin the test again with a new test strip.



### Code Number

Each package of test strips is printed with a code number (CODE), lot number (LOT), unopened expiration date (☞) and control range. Please make sure that the calibration code number printed on the package of each test strip matches with the code inside of the package.

### Storage and Handling

Please review the following storage and handling instructions:

- Store test strips in a cool, dry place, 2 - 35°C (36 - 95°F) for glucose and  $\beta$ -ketone strips, 2 - 30°C (36 - 86°F) for uric acid and hemoglobin strips. Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Do not store or use test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- The test strip should be used immediately after removing it from the container.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Do not use your test strips past the unopened expiration date printed on the label. Using test strips past the unopened expiration date may produce incorrect test results.

**Note:** The expiration date is printed in Year-Month format. 2019-01 means January, 2019.

### **Special Instructions for Test strip in the Vial**

- Test strips must be stored in the original vial with the cap tightly closed. This keeps them in good working condition.
- Do not transfer test strips to a new vial or any other container.
- Close tightly the cap on the test strip vial immediately after removing a test strip.
- A new vial of test strips may be used for 6 months after being first opened. Write the opened expiration date on the vial label after opening. Discard the vial 6 months after you first open it. Usage after this period may result in inaccurate readings.

***Note:** Uric Acid and Hemoglobin test strips may only be used for 3 months after being first opened.*

### **Special Instructions for Test Strip in the Foil Pouch**

- Tear the pouch carefully from the tear gap. Avoid damaging or bending the test strip.
- Use the test strip immediately after removing it from the pouch.

### **Test Strip Precautions**

- For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Keep the test strips vial or the foil pouch away from children and animals.

See the **Test Strip Insert** for more details.

## ACCUGENCE® GLU/KET/UA/HB Control Solution

The ACCUGENCE® GLU/KET/UA/HB Control Solution contains a known concentration of glucose,  $\beta$ -ketone, uric acid and hemoglobin respectively. It is used to confirm that your ACCUGENCE®PLUS Multi-Monitoring Meter and test strips are working together properly and you are performing the test correctly. It is important to run a quality control test regularly to make sure you are getting correct results.

You should run a quality control test:

- Before you first use your meter, to familiarize yourself with its operation.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

Refer to the Section **Quality Control Test** for instructions on running a quality control test.

### Storage and Handling

Please review the following storage and handling instructions:

- Store the glucose and  $\beta$ -ketone control solution at 2 - 35°C (36 - 95°F), store uric acid control solution at 2 - 30°C (36 - 86°F), and store hemoglobin control solution at 2-8°C(36-46°F). Store them away from heat and direct sunlight.
- Do not refrigerate or freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.  
**Note:** *The expiration date is printed in Year-Month format. 2019-01 means January, 2019.*
- Each bottle of control solution can be used for 6 months after you first open it. Record the opened and the resulting expiration dates on the bottle label.  
**Note:** *Uric acid and hemoglobin control solution may only be used for 3 months after being first opened.*

### Control Solution Precautions

- For *in vitro* diagnostic use. The control solution is for testing only outside the body. Do not swallow or inject.
- Shake well before using.

- Glucose and  $\beta$ -Ketone control solution tests are designed to be accurate only when tested between 5 - 45°C (41 - 113°F), while uric acid and hemoglobin control solution tests are safe to perform between 10 - 40°C (50 - 104°F).
- The control ranges shown on the test strip vial (or on the foil pouch) are not recommended ranges for your blood glucose/  $\beta$ -ketone /uric acid/hemoglobin level.
- Do not touch the test strip with the tip of the control solution bottle directly.
- Use only the same brand of control solution that was provided with your kit.

See the **Control Solution Insert** for more details.

## Installing Batteries

The batteries may not be preinstalled in the meter. Two CR2032 3.0V coin cell batteries are required. Please find the batteries in your carrying case and install them according to the following steps:

1. Turn over the meter and slide the battery cover in the direction of the arrow to open it.



2. Place two fresh CR 2032 3.0V coin cell batteries. Make sure they are aligned with the plus (+) side facing up in the battery carrier.



3. Close the battery cover and make sure that it snaps shut.



## Meter Setup Before Testing

Before using your meter for the first time, you will need to adjust the settings that are listed in detail below:

1. **Meter Setup Mode:** Press the Power button for 2 seconds. The meter will automatically enter the setup mode for the first time by any method. Please double check the battery level. Replacing with new batteries may also enable this mode.



2. **Clock:** Set the clock to 12 or 24-hour mode. Press the Up or Down button to switch between the two settings, then press the Power button to save your choice and then start setting the year, month and date.

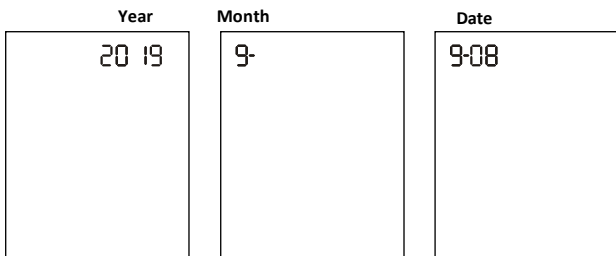
**Note:** The clock needs to be reset after replacing the batteries.



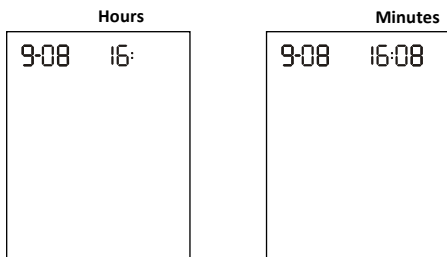
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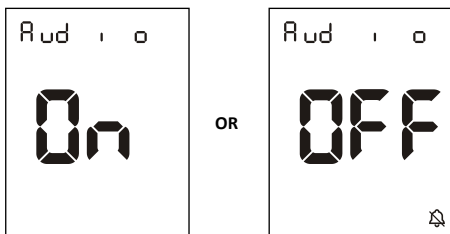
3. **Date:** The year will appear at the top of the display. Press the Up or Down button to select the proper year. Once you have selected the correct year, press the Power button to save your choice and start setting the month. Press the Up or Down button to select the proper month. Then press the Power button to save your choice and start setting the date. Press the Up or Down button to select the proper date. Then press the Power button to save your choice and start setting the time.



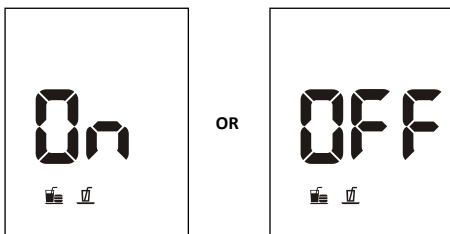
4. **Time:** The hour will appear at the top of the display. Adjust the hour with the Up or Down button until the correct hour is displayed. Press the Power button to save your choice and set the minutes. Press the Up or Down button to change to the correct minute. Pressing and holding can help with faster time adjustment. Press the Power button to save your choice and move to set the audio.



5. **Audio Feature:** The meter comes with the meter audio feature enabled. Press Up or Down button to switch between ON and OFF. The meter will give one short beep when it is turned on, after sample detection and when the result is ready. The meter will sound three short beeps to indicate a warning when an error has occurred. Please check the error number on the display to confirm what kind of error has occurred.

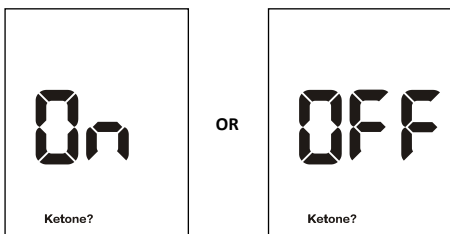


6. **Meal Marker:** The meter comes with the meal marker feature disabled. The meter allows the user to enable or disable the meal marker option. The words "On" or "Off" will be displayed on the large center segments of the display and the before meal icon together with the after-meal icon will be displayed as shown below.



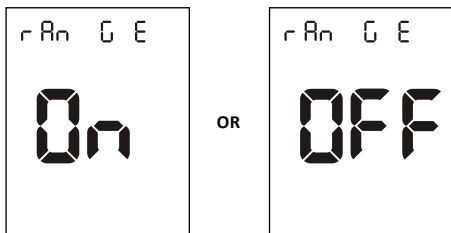
Press the Up or Down button to switch between turning the meal marker "On" and "Off". Press the Power button to confirm your selection.

7. **Ketone Indicator:** The meter comes with the ketone indicator feature disabled. Press the Up or Down button to switch between turning the ketone indicator "On" and "Off". Press the Power button to confirm your selection.

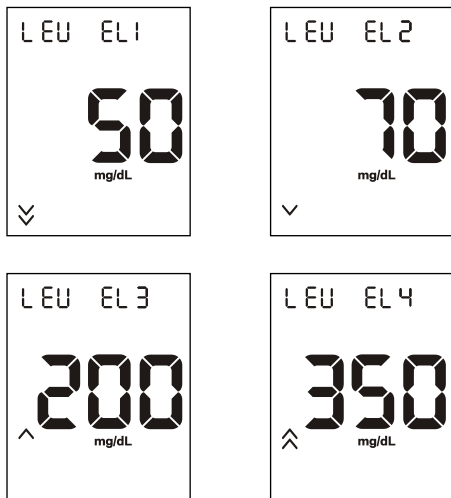


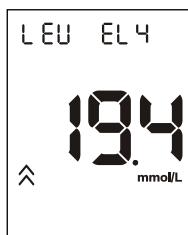
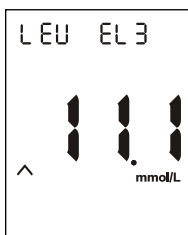
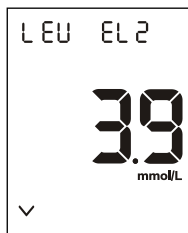
When the ketone indicator is enabled, if the test result is higher than 16.7 mmol/L (300 mg/dl) the symbol of "ketone?" will appear on the display.

8. **Range Indicator:** The meter comes with the Range indicator feature disabled. Press the Up or Down button to turn the Range indicator "On" or "Off". Press the Power button to confirm your selection. When the Range indicator is "Off", pressing the Power button (to select) will lead you to the Alarm set up.



When the Range indicator is "On", pressing the Power button will lead you to level set up. There are 4 levels of ranges you can set up, it is strongly recommended to consult with your healthcare specialist to select the ranges. After finishing the Range Indicator set up, it will then end the setup mode and the meter will power off.





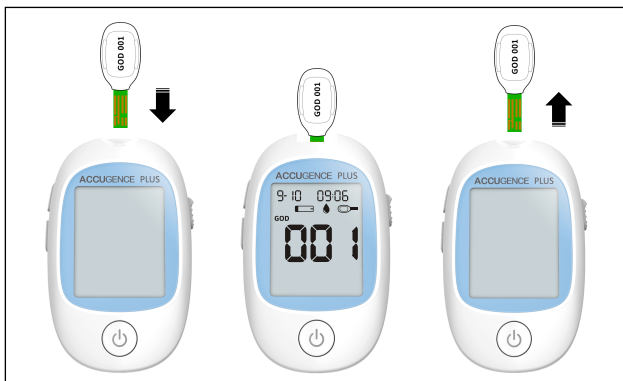
**Note:** The meter default setup level is Level 1 50 mg/dL (2.8 mmol/L), Level 2 70 mg/dL (3.9 mmol/L), Level 3 200 mg/dL (11.1 mmol/L), Level 4 350 mg/dL (19.4 mmol/L) for diabetes.

## Coding the Meter

It is necessary and important to calibrate the system every time you open a new kit box. To do that, simply insert the calibration chip to the strip port of the meter for corresponding tests every time you change to a new box of test strips. You can easily find a calibration chip in your strip box.

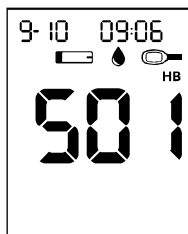
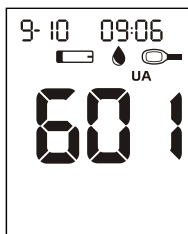
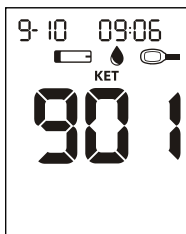
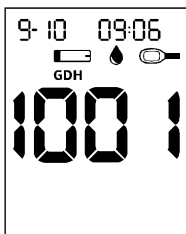
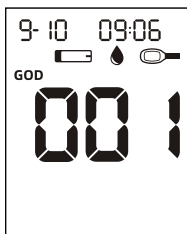
With your meter turned off, insert the corresponding calibration chip into the strip port of the meter. It should easily snap into place. Once you have coded the meter, you can take out the calibration chip and start testing blood glucose, blood  $\beta$ -ketone, uric acid and hemoglobin accordingly.

Example of a blood glucose test strip using glucose oxidase (GOD):

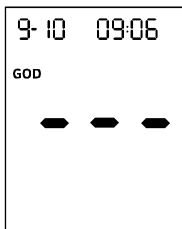


**Note:** Each calibration chip is printed with letters representing the strip type and code number. “GOD” indicates the calibration chip is for the blood glucose test strip using glucose oxidase, “GDH” indicates the calibration chip is for the blood glucose test strip using glucose dehydrogenase FAD-dependent, “KET” indicates the calibration chip is for the blood  $\beta$ -ketone test strip, “UA” indicates the calibration chip is for the uric acid test strip, and “HB” indicates the calibration chip is for the hemoglobin test strip. For example, “GOD 001” indicates that the calibration chip is for the blood glucose test strip using glucose oxidase, code number is “001”.

The code number for each type of test strip is different. The blood glucose test strip using glucose oxidase (GLU GOD) is with a 3-digit code number, the blood glucose test strip using glucose dehydrogenase FAD-dependent (GLU GDH) starts from “1000” with a 4-digit code number, the blood  $\beta$ -ketone test strip is with a 3-digit code number, the uric acid test strip is with a 3-digit code number, and the hemoglobin test strip is with a 3-digit code number.



The meter will automatically log in the last coding information for each parameter, if you forget to code the meter in this parameter, the meter will display “----” when you insert the strip into the strip port of the meter.



If the calibration chip is damaged or incorrect, the meter will report E10 or E11 directly.

**Note:** Once the meter is coded, it's not required to code again when switching among blood glucose &  $\beta$ -ketone & uric acid & hemoglobin. The meter will automatically detect the type of test when strip is inserted.

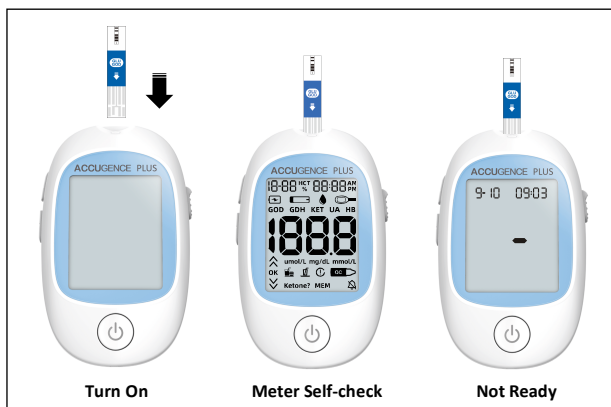
## Performing a Quality Control Test

The quality control test confirms that the test strips and meter are working together properly, and that you are performing the test correctly. It is important to perform this test:

- At the first time of use.
- Before using a new lot of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.
- After cleaning your meter.
- At least once a week.

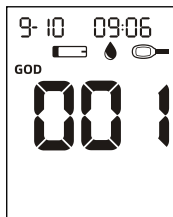
Example of a blood glucose test strip using glucose oxidase (GOD) :

1. Insert a test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.
2. Check the display to confirm that all of the display segments are turned on. Next, a dash will move across the display.



3. The display will show the date and time. The strip icon with the blood sample icon will blink to indicate that the test strip is inserted correctly.





**Note:** If the test strip has been inserted incorrectly, the meter will not turn on.

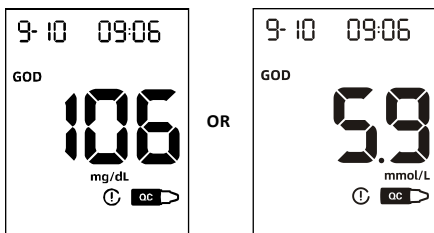
4. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the calibration chip that came with the box of test strips into the meter.
5. Shake the control solution bottle well, then squeeze it gently and discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Then shake again and use. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. If the audio option is turned on, the meter will beep to indicate a sufficient sample has been applied.



**Notes:**

- ACCUGENCE® Glucose Control Solution is a blue colored liquid with three levels (Level 1, Level 2, Level 3), and it's used both for Glucose GOD and GDH-FAD test strips.
- ACCUGENCE® Ketone Control Solution is a red colored liquid with three levels (Level 1, Level 2, Level 3), ACCUGENCE® Uric Acid Control Solution is red colored liquid with two levels (Level 1 & Level 2), and ACCUGENCE® hemoglobin Control Solution is red colored liquid with two levels (Level 1 & Level 2).

- Do not apply control solution to the test strip directly from the bottle.
  - If you applied the control solution sample but do not see the starting of the count down, you may reapply a second drop within 3 seconds.
6. Once a sufficient sample has been applied, the meter display will count down (4 for glucose, 4 for Ketone, 14 for UA, and 14 for HB) to 1 and then the result and a control solution symbol will be displayed on the screen. The control solution test results should be within the control range printed on the test strip vial (or on the foil pouch). This means that your multi-monitoring system is working properly and that you are performing the procedure correctly.



**Note:** Blood glucose test results are displayed either in mmol/L or mg/dL depending on the unit of measure that is commonly used in your country, while blood  $\beta$ -ketone test results are displayed as mmol/L, uric acid test results are displayed as  $\mu\text{mol/L}$  or mg/dL, and hemoglobin test results are displayed as mmol/L or g/dL depending on the unit of measure that is commonly used in your country.

The control solution range is the expected range for the control solution results. It is not a recommended range for a blood glucose level.

The display should also show a pound sign ( $\text{Ⓐ}$ ) indicating the test is a control solution test.

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



If the result falls outside the indicated control range:

- Confirm you are matching the correct range. Control Solution 1 results should be matched to the Level 1 range printed on the test strip vial (or on the foil pouch).
- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and control solution bottle have not been opened for more than 6 months (3 months for uric acid test strip, uric acid control solution, hemoglobin test strips and hemoglobin control solution). Discard any test strips or control solution that has expired.
- Confirm the temperature in which you are testing is between 5 and 45°C (41 - 113°F). Note that uric acid and hemoglobin control solution test only can be performed between 10 and 40 °C (50 - 104°F).
- Make sure that the test strip vial and control solution bottle have been tightly capped.
- Confirm that you are using the same brand of control solution that was provided with your kit.
- Make sure that you follow the test procedure correctly.

After checking all of the conditions listed above, repeat the quality control test with a new test strip. If your results still fall outside of the control range shown on the test strip vial (or on the foil pouch), your meter may be defective. Contact your local distributor for help.

Three levels of Control Solution are available labeled Control Solution 1, Control Solution 2 and Control Solution 3 for glucose and ketone, and two levels for uric acid and hemoglobin. Glucose Control Solution 2 can be sufficient for most of glucose testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 1 or level 3 test. The ranges for Level 1, Level 2 and Level 3 are displayed on the test strip vial (or on the foil pouch). Simply repeat step 4 through 6, using Control Solution 1 or Control Solution 3.

To confirm your results, Control Solution 1 tests should fall within the Level 1 range, Control Solution 2 tests should fall within the Level 2 range and Control Solution 3 tests should fall within the Level 3 range. If the control solution test results do not fall within their respective ranges, DO NOT use the system to test blood, as the system may not be working properly. If you cannot fix the problem, please contact your local distributor for help.

Please contact your local distributor for information on ordering the ACCUGENCE® Control Solution kit. The kit contains Control Solution 1, Control Solution 2 and Control Solution 3 for glucose and ketone, and Control Solution 1 and Control Solution 2 for uric acid and hemoglobin.

# Testing Your Blood

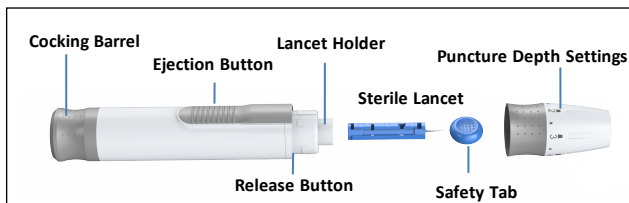
The following steps will show how to use the meter, test strips, lancing device and sterile lancets together to measure your blood Glucose/Ketone/Uric Acid/Hemoglobin concentration.

**Note:** *The pictures of Sterile Lancet and Lancet Device are for reference only, subject to our available products.*

## Step 1 – Getting a Drop of Blood

The ACCUGENCE®PLUS Multi-Monitoring System requires a very small drop of blood which may be obtained from the fingertip for glucose, or ketone, or uric acid, or hemoglobin test only. Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

**IMPORTANT:** Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.



**Note:** *the above picture is for reference only, subject to our available products.*

**Note:**

- *The information of sterile lancets suitable for ACCUGENCE®PLUS multi-monitoring meter is listed below.*

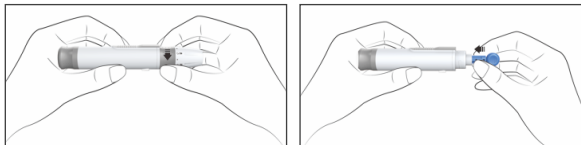
	Company	Authorized Representative	Notified Body
Sterile Lancet	SteriLance Medical (SuZhou) Inc. No.68 Litanghe Road, Xiangcheng, Suzhou, 215133, China	Emergo Europe Prinsessegracht 20, 2514 AP, The Hague, The Netherlands	CE 0197

- *Please contact your local distributor for supplies of sterile lancets.*

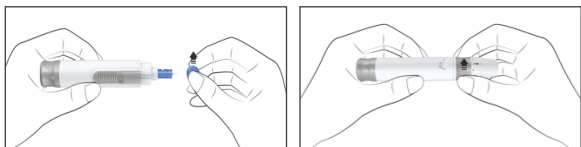
## Fingertip Testing

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

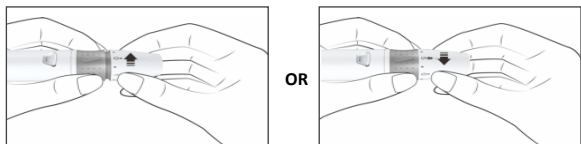
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancing device.



2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens. Then pull the safety tab off the lancet. Save the safety tab for lancet disposal.
3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.



4. Adjust the puncture depth by rotating the lancing device cover. There is a total of 11 puncture depth settings. To reduce the discomfort, use the lowest setting that still produces an adequate drop of blood.

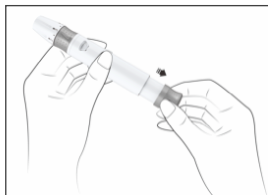


Adjustments:

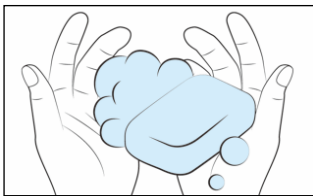
- 0 – 1.5 for soft or delicate skin
- 2 – 3.5 for normal skin
- 4 - 5 for thick or callused skin

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

5. Pull the cocking barrel back to set the lancing device. You may hear a click, while the release button changes to orange to indicate the lancing device is now loaded and ready for obtaining a drop of blood.

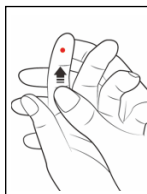
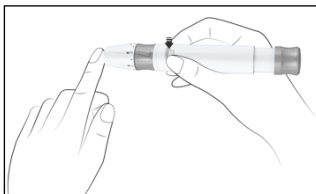


6. Prior to testing, clean your hands with an alcohol wipe or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.



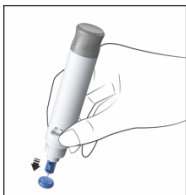
7. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You may hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.



### Disposal of the Lancet

1. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface. Then carefully insert the lancet needle into the safety tab.



2. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.



### Lancet Precautions

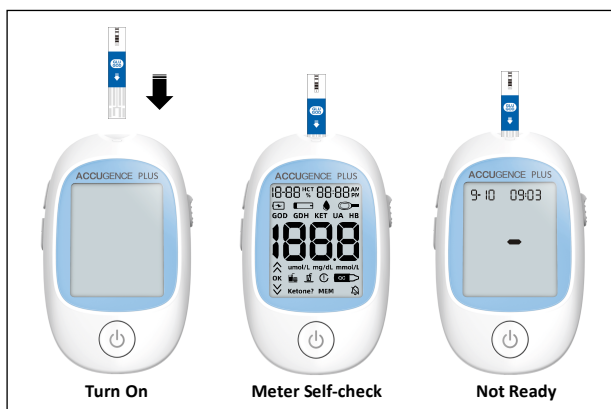
- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use caution whenever the lancet needle is exposed.
- Never share lancets or the lancing device with other people.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt or debris.

## Step 2– Testing Your Blood

**Note:** Insertion of a new test strip at any time, except while in the data transfer mode will cause the meter to automatically enter the test mode.

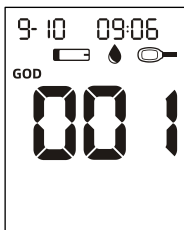
### Testing Your Blood Glucose

1. Insert a test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.
2. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display.

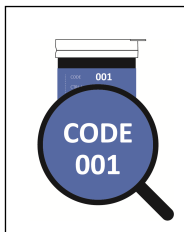
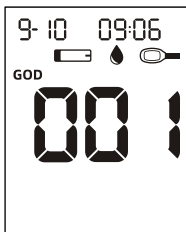


3. Following this display check, the system will enter the test mode. The display will show the date and time as well as the strip icon, and the blood sample icon starts blinking to indicate that the test strip is inserted correctly, and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time, a blood drop can be added.

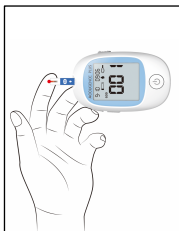




4. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the calibration chip that came with the box of test strips into the meters.

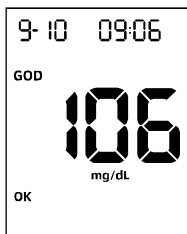
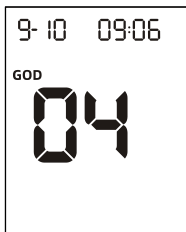


5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the measurement has started. If you applied a drop of blood, but do not see the starting of the countdown, you may reapply a second drop of blood within 3 seconds.

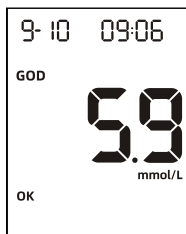


**DO NOT:**

- Apply the sample to the front or back of the test strip.
  - Smear the blood drop onto the test strip.
  - Press your finger against the test strip.
6. The meter will count down from 4 to 1 and then display the measurement's results. The meter will also beep to indicate that measurement is completed. Then your blood glucose level will display on the screen. The measurement's unit, date, and time of the test will also be displayed.

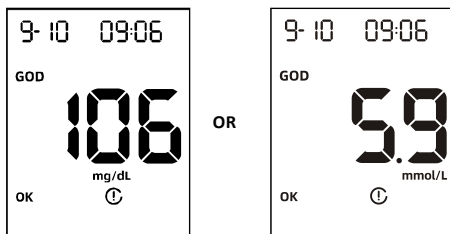


OR



**Note:** Blood glucose test results are automatically stored in the memory.

7. If a result is marked by accident, press the POWER button to unmark the result. Press the POWER button to mark the invalid result, A pound sign (Ⓒ) will appear on the display to show that the result will not be included. The pound sign (Ⓒ) will also be displayed when reviewing the results stored in memory. After marking the invalid result, run the test again with a new test strip.



When the above display is shown on screen, press the POWER button again to disable all markers for the result. If an invalid result is marked, run the test again with a new test strip.

8. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set. Refer to Suggested Test Times and Target Goals for more details on your target blood glucose concentration goals.
9. Slide the strip ejector forward to discard the used test strip.

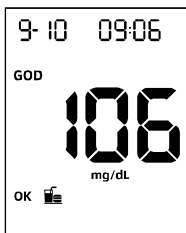
**Note:** Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.



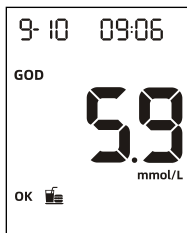
#### Before Meal or After Meal Remark:

When the meal marker feature is turned on and a test result is displayed, mark the result as “before meal”, or “after meal”.

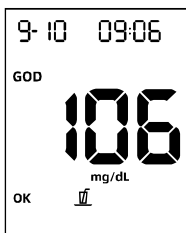
1. Press the POWER buttons one time to display the “before meal marker” Icon, indicating the result was taken before a meal.



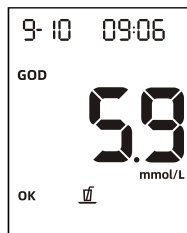
OR



2. Press the POWER button again to display the “after meal marker” symbol, indicating the result was taken after a meal.



OR



### Glucose Range Indicator Message

The meter comes with the Range indicator feature disabled. Please refer to **Meter Setup Before Testing** section to find out how to turn the range indicator function on.

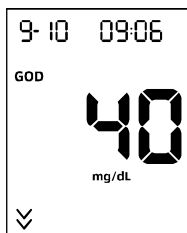
When the Glucose Range Indicator is “On”, pressing the Power button will lead you to level set up. There are 4 levels of ranges you can set up. We strongly recommend users to consult your diabetes professional to select your glucose ranges.

**Note:** The blood glucose range indicator feature is only available when glucose testing is applied.

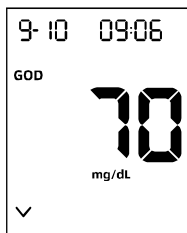
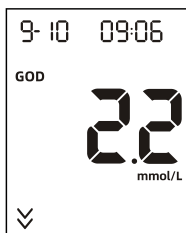
With the blood glucose range indicator feature turned on, when the blood glucose result is displayed, an arrow message may also appear depending on system configuration, notifying you if the result exceeds the specified limit values. Additionally an arrow “^” or “v” may appear next to the result to indicate that a result is out of range.

Double Down arrow means your blood glucose value is below the critical lower concentration. (Configurable range from 30 mg/dL to 60 mg/dL or equivalent to 1.7 mmol/L to 3.3 mmol/L).

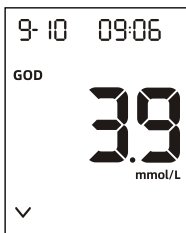
One Down arrow means your blood glucose value is below your target blood glucose concentration. (Configurable range should be above critical lower range and up to 120 mg/dL or equivalent to 6.6 mmol/L).



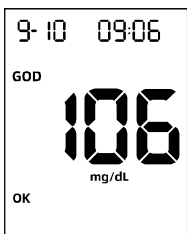
OR



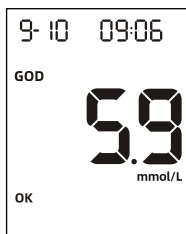
OR



OK means your blood glucose value is within safe range.

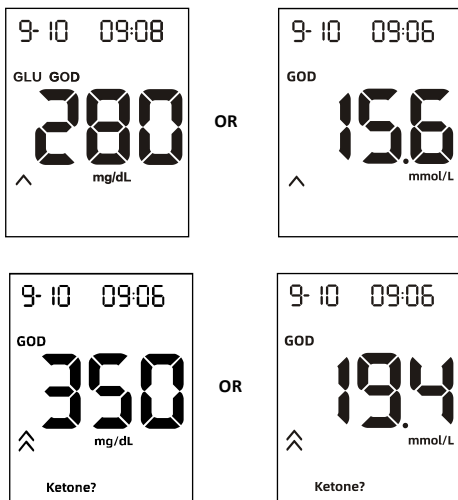


OR



One Up arrow means your blood glucose value is above your target blood glucose concentration. (Configurable range from 121 mg/dL to 230 mg/dL or equivalent to 6.7 mmol/L to 12.8 mmol/L).

Two Up arrows mean your blood glucose value is above the critical hyperglycemic concentration. (Configurable range should be above normal hyperglycemic range and up to 380 mg/dL or equivalent to 21.1 mmol/L).



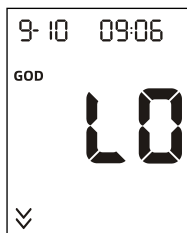
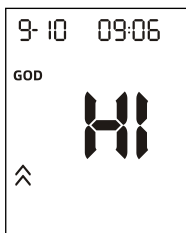
**Note:** These limit values define ranges that can either be configured individually by the system administrator in line with facility guidelines or are the (technical) limits of the system. Please consult your diabetes healthcare professional before determining what your hyper or hypo blood glucose levels are.

### “HI” and “LO” Messages

The meter can accurately measure blood glucose concentrations between 0.6 to 33.3 mmol/L (10 to 600 mg/dl). “HI” and “LO” messages indicate if results are outside of this range.

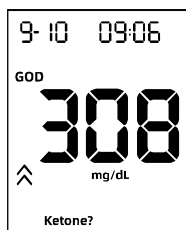
If “HI” appears on the display, the measured concentration value is above 33.3 mmol/L (600 mg/dl). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and the blood glucose is still consistently measured as “HI”, it indicates severe hyperglycemia (high blood glucose).

If “LO” appears on the display, the measured concentration value is below 0.6 mmol/L (10 mg/dl). The test should be retaken to ensure that no mistake was made in the procedure. If you are certain the meter is functioning properly and no mistakes were made in the procedure, and the blood glucose is still consistently measured as “LO”, it may indicate severe hypoglycemia (low blood glucose).

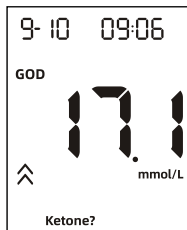


### “Ketone?” Message

If “Ketone?” appears on the display, the measured concentration value is above 16.7 mmol/L (300 mg/dL). This simply suggests that a  $\beta$ -Ketone test is recommended. Consult your healthcare professional about testing for  $\beta$ -Ketones.

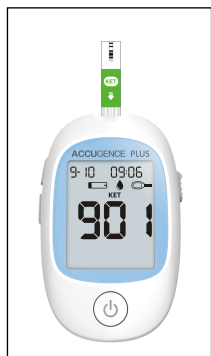


OR



## Testing Your Blood $\beta$ -Ketone

With your meter turned off, insert the blood ketone calibration chip into the strip port of the meter. It should easily snap into place. Once the calibration chip is inserted into the meter, the meter will automatically turn on, and you should see “KET” on the screen with the code number. Please make sure that the number displayed on the screen should match with the number on the vial or foil pouch of strips with which it was packaged. If the code number displayed on the meter does not match the code number on the test strip vial label or foil pouch, an erroneous result will be obtained. Contact the local distributor to correct the problem.

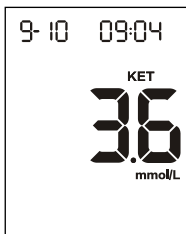
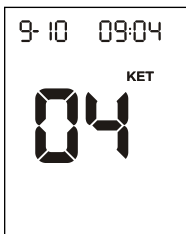


1. Now you are ready for the blood  $\beta$ -ketone test. Insert a blood  $\beta$ -ketone test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.
2. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.
3. Following this display check, the system will enter the test mode. The display will show the date and time and the strip icon with the blood sample icon blinking to indicate that the test strip is inserted correctly, and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time a blood drop can be added.
4. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on



the test strip vial (or strip foil pouch), code the meter again by inserting the calibration chip that came with the box of test strips into the meter.

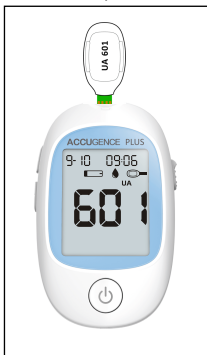
5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the meter starts to count down from 4 to 1. If you applied a drop of blood, but do not see the starting of the count down, you may reapply a second drop of blood within 3 seconds.



6. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set. Refer to **Suggested Testing Times and Target Goals** for more details on your target blood  $\beta$ -ketone concentration goals.
7. Slide the strip ejector forward to discard the used test strip.

## Testing Your Uric Acid

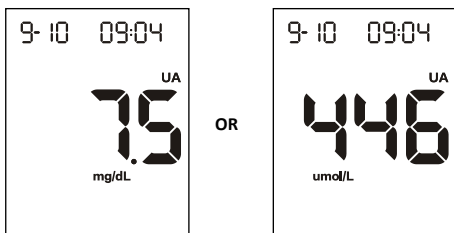
With your meter turned off, insert the uric acid calibration chip into the strip port of the meter. It should easily snap into place. Once the calibration chip is inserted into the meter, the meter will automatically turn on, and you should see “UA” on the screen with the code number. Please make sure that the number displayed on the screen matches with the number on the vial or foil pouch of strips with which it was packaged. If the code number on the meter does not match the code number on the test strip vial label or foil pouch, an erroneous result will be obtained. Contact the local distributor to correct the problem.



1. Now you are ready for uric acid test. Insert a uric acid test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.



2. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.
3. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the calibration chip that came with the box of test strips into the meter.
4. Following this display check, the system will enter the test mode. The display will show the date and time and the strip icon with the blood sample icon blinking to indicate that the test strip is inserted correctly and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time, a blood drop can be added.
5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the measurement has started. If you applied a drop of blood, but do not see the starting of the count down from 14, you may reapply a second drop of blood within 3 seconds.



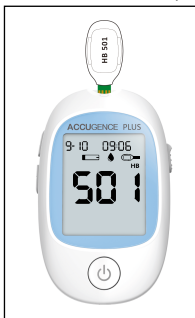
**Note:** The meter is preset to either micromoles per liter ( $\mu\text{mol/L}$ ) or milligrams per deciliter ( $\text{mg/dL}$ ) depending on the standard of your country, which you are unable to adjust by yourself.

6. After inspection, record valid results in your logbook with the date and time, and compare them to the target goals set. Refer to **Suggested Testing Times and Target Goals** for more details on the target uric acid concentration goals.
7. Slide the strip ejector forward to discard the used test strip.



## Testing Your Hemoglobin

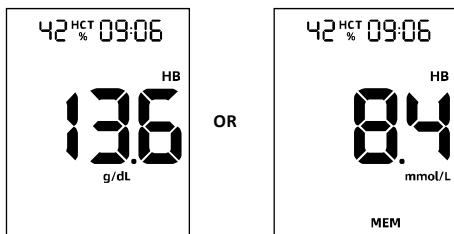
With your meter turned off, insert the hemoglobin calibration chip into the strip port of the meter. It should easily snap into place. Once the calibration chip is inserted into the meter, the meter will automatically turn on, and you should see “HB” on the screen with the code number. Please make sure that the number displayed on the screen matches with the number on the vial or foil pouch of strips with which it was packaged. If the code number on the meter does not match the code number on the test strip vial label or foil pouch, an erroneous result will be obtained. Contact the local distributor to correct the problem.



1. Now you are ready for hemoglobin test. Insert a hemoglobin test strip into the strip port, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.



2. Check the display to confirm that all the display segments turn on with no missing components. The display will then show only the date and time, with a dash moving across the display. Check the display to ensure no inappropriate segments or icons are permanently turned on.
3. Compare the strip type and code number on the meter display with the strip vial label (or strip foil pouch) which is being tested, and make sure that they match. If the code number on the display does not match the code number on the test strip vial (or strip foil pouch), code the meter again by inserting the calibration chip that came with the box of test strips into the meter.
4. Following this display check, the system will enter the test mode. The display will show the date and time and the strip icon with the blood sample icon blinking to indicate that the test strip is inserted correctly, and a drop of blood can be added. If the test strip has been inserted incorrectly, the meter will not turn on. The meter is ready for testing when the blinking blood drop and strip symbol appears. At this time, a blood drop can be added.
5. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will beep to indicate the sample is sufficient and the measurement has started. If you applied a drop of blood, but do not see the starting of the count down from 14, you may reapply a second drop of blood within 3 seconds.



**Note:** The meter is preset to either millimole per liter (mmol/L) or grams per deciliter (g/dL) depending on the standard of your country, which you are unable to adjust by yourself.

6. After inspection, record valid results in your logbook with the HCT value and time, and compare them to the target goals set. Refer to **Suggested Testing Times and Target Goals** for more details on your target hemoglobin concentration goals.
7. Slide the strip ejector forward to discard the used test strip.

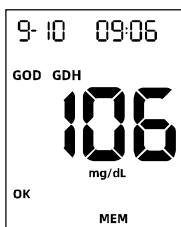
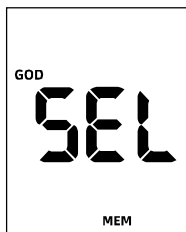
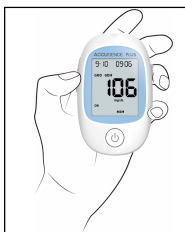
## Recall the Meter Memory

The meter automatically stores up to 300 test records for blood glucose, 100 for blood  $\beta$ -ketone and uric acid each, 200 test records for hemoglobin. Each record includes the test result, date and time. The oldest record will be erased to make room for a new one if memory reaches its limit.

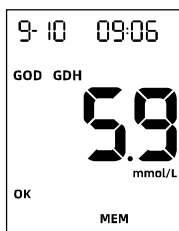
### Viewing Stored Records

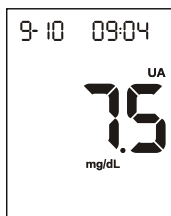
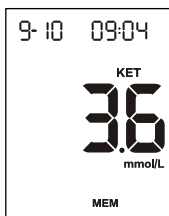
To view stored records:

1. Press the Down button to turn the meter on and enter memory mode. The word "SEL" together with "MEM" will appear on the display. You can simply access stored records for blood glucose, blood  $\beta$ -ketone, uric acid or hemoglobin by pressing the Down button. Once you have chosen the stored record, press the Up button to confirm.

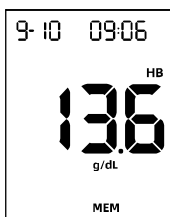
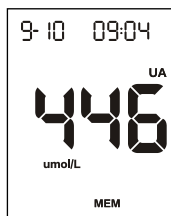


OR

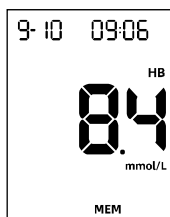




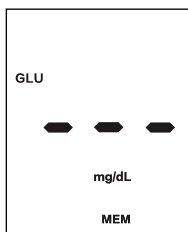
OR



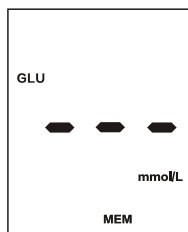
OR



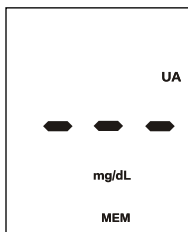
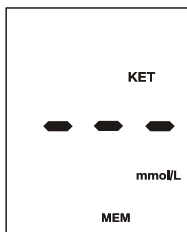
2. If you are using the meter for the first time, the meter display will show three dashed lines (---), the word "MEM" and the unit of measure. This shows that no data has been stored in memory.



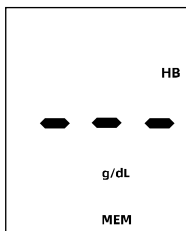
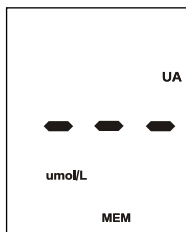
OR



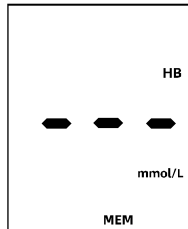




OR



OR



3. The date and time will be displayed together with the results stored in memory.
4. Press the Down button again to review the memory. The first result showed on the screen is the latest result that you have taken. Press the Down button to go through the stored records.

**Note:** If you do not wish to view your average measurements, you can press the Power button again to turn off the display.

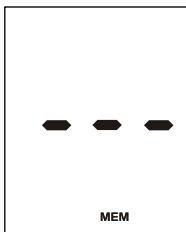
## Clearing the Memory

Extreme caution should be used when clearing the memory. This is not a reversible operation. To clear the memory:

1. With the meter off, press and hold the Down Button for 2 seconds. This will turn on the meter and enter the delete mode.



2. Then press and hold both the Up and Down buttons for 2 seconds again to clear the memory.
3. The display will show "MEM" and "---", then the meter will clear its memory and turn itself off after a moment.



4. If you entered the delete mode but want to exit without deleting the recorded data, press the Power button. This will turn the meter off without deleting any data.

## Transferring Records

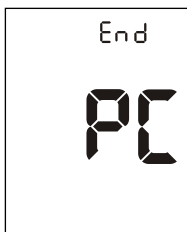
The meter can transfer stored information to a Windows-based personal computer (PC) using a data transfer cable and software package. To make use of this feature, you need the ACCUGENCE®PLUS Data Management Software and a USB data transfer cable from **e-LinkCare**.

1. Install the software to your personal computer (PC) according to the instructions from the ACCUGENCE®PLUS Data Management Software Kit.
2. Connect the USB cable to your PC and plug the audio jack of the cable into the meter data port.
3. With the meter off, press and hold the Up button for 2 seconds. This will turn on the meter and enter the “PC” mode.



**Note:** When the meter is in “PC” mode, it does not turn to waiting for sample application mode after strip is inserted into meter.

4. Run the ACCUGENCE®PLUS Data Management Software, and refer to the instructions from the software for how to transfer records.
5. During the data transfer, the meter will display “to” and “PC”. This indicates the data is being transferred from the meter to the PC.
6. Once the data transfer is complete, the meter will display “End” and “PC”.



7. After data transfer from meter to PC is completed, the meter will turn itself off. Press the POWER button to turn off the meter.


See the package insert included with your **ACCUGENCE®PLUS Data Management Software Kit** for detailed instructions.

# Maintenance

Proper maintenance is recommended for best results.

## Replacing the Batteries

Your ACCUGENCE®PLUS Multi-Monitoring Meter uses two 3.0 Volt CR 2032 lithium batteries.

When the battery icon () is showing, it means the Meter Battery is running dry. You should replace the Meter Battery as soon as possible. An “E-7” error message will appear if the Meter Battery is too low to perform any more tests. The meter will not function until the Meter Battery is replaced.

### **Instructions:**

1. Turn the meter off before removing the battery.
2. Turn the meter over, slide the battery cover in the direction of the arrow to open it.
3. Remove and discard the old battery. Insert two new CR 2032 3.0V coin cell batteries in the battery carrier. Make sure the plus (+) side is facing up.



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

## **Caring for Your ACCUGENCE®PLUS Multi-Monitoring System**

### **Meter**

Your ACCUGENCE®PLUS Multi-Monitoring Meter does not require special maintenance or cleaning. A cloth dampened with water and a mild detergent solution can be used to wipe the outside of the meter. Take care to avoid getting liquids, dirt, blood or control solution into the meter through the strip or data ports. It is recommended that you store the meter in the carrying case after each use.

The ACCUGENCE®PLUS Multi-Monitoring Meter is a precision electronic instrument. Please handle it with care.

### **Lancing Device**

Use mild soap and warm water to clean with a soft cloth as required. Carefully dry the device thoroughly. Do not immerse the lancing device.

Please refer to the lancing device insert for more details.

## Suggested Testing Times and Target Goals

### Blood Glucose

Tracking the blood glucose concentration through frequent tests is an important part of proper diabetes care. They will also help you to determine when and how often to test your blood glucose.

Some suggested times are:

- When you wake up (fasting level)
- Before breakfast
- 1 - 2 hours after breakfast
- Before lunch
- 1 - 2 hours after lunch
- Before or after exercise
- Before dinner
- 1 - 2 hours after dinner
- Before bedtime
- After a snack
- At 2 or 3 AM, if taking insulin

You may need to test more often whenever<sup>1</sup>:

- You add or adjust your diabetes medication.
- You think your blood glucose levels may be too low or too high.
- You are ill, or feeling uncomfortable over long periods of time.

Expected blood glucose levels for people without diabetes<sup>2</sup>:

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 - 100	3.9 - 5.6
2 Hours after Meals	Less than 140	Less than 7.8

Talk to your healthcare professional to set your own daily target ranges.

Time of Day	Your Target Range
Waking up (Fasting level)	
Before meals	
2 hours after meals	
Bedtime	
2 AM to 3 AM	
Other	

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

Use the logbook to record the blood glucose measurements and related information. This can help you and your healthcare professional make the best decisions about your glucose control plan.

## **β-Ketone**

Continuous high blood glucose means your body does not have enough insulin to burn glucose, instead it will start burning fat and this produces a chemical called β-Ketone. If left untreated, β-Ketones continues to rise and can result a condition called Diabetic Ketoacidosis, or DKA. This condition may lead to death therefore requires immediate medical attention. It is suggested that if your blood glucose level is above 300 mg/dL or 16.7 mmol/L for two tests in a row, a β-Ketone test needs to be applied immediately.

There are situations when you have positive β-Ketones without blood glucose being too high. Positive β-Ketones are not a problem when blood glucose levels are within range and you are trying to lose weight.

The normal adult blood β-Ketone range for person without diabetes is less than 0.6 mmol/L. Consult with your healthcare professional for the blood β-Ketone range that is appropriate for you. If your blood β-Ketone test result is between 0.6-1.5 mmol/L and glucose is higher than 300 mg/dL, this may indicate development of a medical concern. You need to contact with your healthcare professional for assistance. If your blood β-β-Ketone test result is more than 1.5 mmol/L and glucose is higher than 300 mg/dL, contact with your healthcare professional immediately. This indicates a risk of developing diabetic ketoacidosis (DKA).

## **Uric Acid**

It is important to monitor your Uric Acid level because high levels of uric acid in the blood can cause solid crystals to form within joints. This causes a painful condition called gout. If gout remains untreated, these uric acid crystals can build up in the joints and nearby tissues, forming hard lumpy deposits called tophi. High levels of uric acid may also cause kidney stones or kidney failure.

Most labs that carry out uric acid test will have slightly different definitions of low, Normal and high levels of uric acid in the blood. As such, the information here and all you come across online should be interpreted as a guide only. It will be the decision of your doctor as to whether or not your levels are in the safer regions.

Men	3.4 to 7.0 Milligrams per Deciliter	202 to 416 Micromoles per Liter
Women	2.4 to 6.0 Milligrams per Deciliter	142 to 347 Micromoles per Liter
Children	2.0 to 5.5 Milligrams per Deciliter	119 to 327 Micromoles per Liter

## **Hemoglobin**

Hemoglobin Test Strips are used to quantitatively measure the hemoglobin level in fresh capillary whole blood or venous whole blood.

Reference Values<sup>3</sup>

Male	13.0 – 17.0 g/dL (8.1 – 10.5 mmol/L)
Female	12.0 – 15.0 g/dL (7.4 – 9.3 mmol/L)

1. Jennifer Mayfield and Stephen Havas, "Self-Control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes – An American Family Physician Monograph"
2. ADA Standards of Medical Care in Diabetes, 2015. Diabetes Care, 2015, Vol.38, Supplement
3. Dacie and Lewis Practical Hematology, 10th ed., 2006



## Comparing Meter and Laboratory Results

Your ACCUGENCE®PLUS Multi-Monitoring System and laboratory results both report the glucose,  $\beta$ -Ketone, uric acid, hemoglobin concentration in the serum or plasma component of your blood. However, the results may differ somewhat due to normal variation. The meter results can be affected by factors and conditions that do not affect laboratory results in the same way. See ACCUGENCE® GLU GOD/GLU GDH /KET/UA/HB Test Strips' package insert for typical accuracy and precision data, and for important information on limitations.

To ensure a reasonable comparison, follow these guidelines.

### **Before you go to the lab:**


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

### **At the lab:**

- Wash your hands before obtaining a blood sample.
- Obtain blood samples for a laboratory test and for your meter within 10 minutes of each other. This will ensure an accurate comparison of results.
- Never use your meter with blood that has been placed in test tubes containing fluoride or other anticoagulants. This will cause falsely low results.

## Troubleshooting Guide

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

Display	Causes	Solution
Meter fails to turn on	Battery may be damaged or not be charged.	Replace battery.
	The operation environment is too cold.	If meter has been exposed to or stored in cold conditions, wait 30 minutes to allow the meter to reach room temperature then repeat the test.
<b>E-0</b>	Power On self-check error.	Remove the battery for 30 seconds and then put it back and turn meter on again. If the problem persists, please contact your local distributor.
<b>E-1</b>	Internal calibration check error.	Turn off the meter or take out the test strip. If the problem persists, please contact your local distributor.
<b>E-2</b>	Test strip is contaminated or used, or being exposed to moisture.	Repeat the test with a new test strip.
<b>E-3</b>	Sample was applied to the test strip too soon.	Repeat the test and apply sample after blood drop/test strip symbol appears.
<b>E-4</b>	Strip is removed during testing.	Repeat the test slowly and steady.
<b>E-5</b>	Insufficient sample.	Repeat the test and apply enough sample to fill the test strip check window.
	Sample application error due to late sample re-dosing.	Repeat the test and apply enough sample to fill the test strip check window within 3 seconds.
<b>E-6</b>	Sample application improperly or HCT value out of range.	Check the blood HCT value and Repeat the test.
	Battery is running out. Only allow maximum 5 tests.	Replace the battery as soon as possible.














Display	Causes	Solution
<sup>Ⓜ</sup> E-7	Battery is discharged and the meter does not allow more tests until replacement with a new battery.	Replace the battery and reset, then repeat the test.
E-8	The operation Temperature is anomalous changed.	Please double check the operation condition is steady, then repeat the test.
HIT	Temperature has exceeded the operating temperature of the system.	Move to a cooler environment and repeat the test.
LOt	Temperature is below the operating temperature of the system.	Move to a warmer environment and repeat the test.
E-9	Hardware damaged.	Please contact your local distributor for meter replacement.
E 10	Calibration chip failure or damaged.	Replace the calibration chip and perform the test again.
E 11	Calibration chip not matched.	Replace the calibration chip and perform the test again.
E 12	Communications failure; This Error may also appear when a test strip is inserted and start flashing “---” while connect to a cable OR when the meter is ready for blood dropping / counting down for a test while connect to a cable.	There is an error in transferring data to the PC. See the package insert included in the ACCUGENCE® Data Management Software for troubleshooting.

## Specifications

Feature	Specification
Parameter	Blood Glucose, Blood $\beta$ -Ketone, Uric Acid, Hemoglobin.
Measurement Range	Blood Glucose: 0.6 - 33.3 mmol/L (10 - 600 mg/dL) Blood $\beta$ -Ketone: 0.0 - 8.0 mmol/L Uric Acid: 3.0 - 20.0 mg/dL (179 - 1190 $\mu$ mol/L) Hemoglobin: 3.0 - 26.0 g/dL (1.9 - 16.1 mmol/L)
Hematocrit Range	Blood Glucose and $\beta$ -Ketone: 10% - 70% Uric Acid: 25% - 60% Hemoglobin: 9%-77%
Result Calibration	Plasma-equivalent
Sample	When testing $\beta$ -Ketone, Uric Acid, Blood glucose with Glucose Dehydrogenase FAD-Dependent or hemoglobin, use fresh capillary whole blood and venous Blood samples; When testing Blood glucose with Glucose Oxidase: use fresh capillary whole blood
Minimum Sample Size	Blood Glucose: 0.7 $\mu$ L Blood $\beta$ -Ketone: 0.9 $\mu$ L Uric Acid: 1.0 $\mu$ L Hemoglobin: 1.2 $\mu$ L
Test Time	Blood Glucose: 5 seconds Blood $\beta$ -Ketone: 5 seconds Uric Acid: 15 seconds Hemoglobin: 15 seconds
Units of Measure	Blood Glucose: The meter is preset to either millimole per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country.
	Blood $\beta$ -Ketone: The meter is preset to millimole per liter (mmol/L)

	<p>Uric Acid: The meter is preset to either micromoles per liter (<math>\mu\text{mol/L}</math>) or milligrams per deciliter (<math>\text{mg/dL}</math>) depending on the standard of your country.</p> <p>Hemoglobin: The meter is preset to either millimole per liter (<math>\text{mmol/L}</math>) or Grams per deciliter (<math>\text{g/dL}</math>) depending on the standard of your country.</p>
Memory	<p>Blood Glucose: 300 tests Blood <math>\beta</math>-Ketone: 100 tests Uric Acid: 100 tests Hemoglobin: 200 tests</p>
Automatic Shutoff	2 minutes
Meter Size	86 mm $\times$ 52 mm $\times$ 18 mm
On/Off Source	Two CR 2032 3.0V coin cell batteries
Battery Life	Around 1000 tests
Display Size	32 mm $\times$ 40 mm
Weight	53 g (with battery installed)
Operating Temperature	<p>Glucose and Ketone: 5 - 45 <math>^{\circ}\text{C}</math> (41 - 113<math>^{\circ}\text{F}</math>) Uric Acid and Hemoglobin: 10 - 40 <math>^{\circ}\text{C}</math> (50 - 104<math>^{\circ}\text{F}</math>)</p>
Operating Relative Humidity	10 - 90% (non-condensing)
Operating Altitude	0 - 10000 feet (0 - 3048 meters)
Data Port	19200 baud, 8 data bits, 1 stop bit, no parity

## Index of Symbols

	Consult instructions for use
<b>IVD</b>	For <i>in vitro</i> diagnostic use only
	Caution
	Store between -20 – 50 °C (-4 – 122 °F)
	Contains sufficient for <n> tests
	Use by
<b>LOT</b>	Lot Number
	Manufacturer
<b>EC REP</b>	Authorized Representative
<b>STERILE R</b>	Sterilized using irradiation
<b>REF</b>	Catalog #
<b>MODEL</b>	Model Number
<b>SN</b>	Serial Number
	Do not reuse
	6 months expiry date from the date of first open vial
	Do not dispose along with household waste
	Fragile, handle with care
	This Side Up
	Keep away from sunlight and heat
	Keep Dry

## Warranty Card

Please complete the warranty card that came with this product and mail it to your dealer to register your purchase and validate your warranty.

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge.

For your records, also write the purchase date of your product here.

Date of purchase: \_\_\_\_\_

Model Number: \_\_\_\_\_

Meter Serial Number: \_\_\_\_\_

The problem description: \_\_\_\_\_

You expect:

- Replace a new meter
- Return after maintenance

**Note:** *This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.*

Local Dealer Information:



**Contact Address:**

Contact Name: \_\_\_\_\_

Contact Cellphone Number: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_

State/Province/Region: \_\_\_\_\_

Postal Code: \_\_\_\_\_

**Thanks so much for your kind support!**

Effective Date: 2022-07-20

