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CE 0197

Instructions for Use

Blood Glucose Meter

Model: A601, A608, A602, A606

➢ **Before you start a test, please read the instructions for use carefully!**

➢ **Take note of warnings and cautions throughout this User Guide!**

Table of Content

1. Intended Use

Blood Glucose Meter is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips of adults. The device is intended for self-testing use by people with diabetes at home or their family member to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or for testing newborns. It is only intended for testing outside the body (in vitro diagnostic use).

2. Test principle [1]

Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the result, and stores it in its memory.

3. Content of Package

One kit contains:

- 1 x Test Meter
- 1 x Instruction for use

Up button: To increase beep volume; to view history record.
Down button: To decrease beep volume; to view history record.
Home button: To turn on or off the meter.

Test Meter Display:

No.	Symbol Description
1	**System setting:** appears when in set mode of Date, Beep Volume, Alarm or Blood Glucose Unit
2	**Identification code: Identify blood glucose testing status**
3	**Average (AVG):** averages of 7 days, 14 days or 30 days
4	**Battery energy:** indicates meter battery is running low and needs to be replaced
5	**Date:** On the left side, the second and third number displays months, forth and fifth number displays day; On the right side, it displays time.
6	**Smiling face:** appears when the blood glucose level is in the range of normal values.
7	**Crying face:** appears when the blood glucose level is greater than the maximum normal value.
8	**Environment Temperature**
9	**Quality Control Solution Mode:** Appears when the control solution test results are saved or displayed
10	**Post meal:** used for tests done after eating
11	**Alarm Setting:** Appears when setting alarm
12	**Pre-meal:** used for tests done before eating
13	**Beep Volume Setting:** Appears when setting beep volume
14	**Date Setting:** Appears when setting date
15	**Blood Insertion:** indicates meter is ready for the application of blood or control solution
16	**Blood Glucose Unit**
17	**Blood Glucose Test Value**

4. What Else You Need

- Blood Glucose Test Strips (Glucose oxidase method)
- Lancing device
- Sterile lancet
- Clear Cap

5. Precautions

- For in vitro diagnostic use only.
- For self-testing only.
- Before using the meter, please consult your healthcare professional.
- Not to make any decision of medical relevance without first consulting his or her healthcare provider.
- Please review instructions for use of the meter, Blood Glucose Test Strips (Glucose oxidase method), lancing device and sterile lacet. For reliable results and to maintain the manufacturer's complete service, support, and warranty.
- The Meter should be used only with SA-102 Blood Glucose Test Strips (Glucose oxidase method) manufactured by AICARE.
- When the meter and test strips are not used, please store them in the package bag for safekeeping or carrying about.
- Do not let any liquid enter into the meter, and do not blow the meter with hair dryer.
- If your test result is below the normal values, consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Inaccurate results may occur in patients undergoing oxygen therapy.
- The procedures should be followed precisely for accurate results.
- Damage due to vandalism will not be covered by the warranty,

please do not tray to disassembly, impact, throw away, fix, or alter the meter in any way.

- Use the meter carefully, heavy pressure or huge vibration may damage its internal electronic performance.
- The device will calibrate automatically, do not calibrate it manually.
- Blood glucose results can be displayed in either mg/dL or mmol/L. If you do not know which unit of measurement is correct for you, contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.
- If your blood glucose result is displayed as LO or HI, contact your healthcare professional immediately.
- Protection impairment if used in a manner not specified by the manufacturer.

6. Warning

- The Meter should be used only with fresh capillary whole blood samples drawn from fingertips.
- Do not reuse test strips.
- Do not use test strips and meter past the expiration date.
- Do not swallow.
- Choking hazard. Small parts. Keep the meter and testing supplies out of the reach of children.
- Keep your hand dry and clean before and during test.
- Do not use the equipment out of doors.
- Do not use the same device with other user. [2,3]
- Please take out the battery and keep properly if the meter is not used for a long time.
- Handle test strips and test meter, as well as install the battery only with clean and dray hands.
- For detailed storage and usage information of test strips, refer to the instructions for use of test strips.
- **Warnings regarding EMC:**

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

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

c) This equipment is designed for use in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

7. Disposing of Meter and Battery, Testing Supplies

If you need to throw your meter, battery and testing supplies away, you should follow existing policies and procedures of your own country or region. For information about correct disposal, please contact your local council or authority.

During blood glucose testing, the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Before disposing the meter, remove the battery or batteries.

Disposal the lancing devices and used strips properly in an appropriate container, to prevent any infection. Used test strips may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's recommendations or local regulations for proper disposal.

8. Limitations

- Blood glucose test strip (glucose oxidase method) can only use fresh fingertip whole blood drawn from fingertips, do not use venous whole blood, arterial whole blood, newborn whole blood, plasma or serum
- Extreme thirst or severe dehydration may result in coma or hypoglycemia during measurement. If you experience these symptoms, your blood glucose test value may be incorrect, please consult your specialist or medical professional immediately.
- Do not ignore the symptoms of hyperglycemia or

hypoglycemia.

- If you follow the steps in this manual but still have symptoms that do not seem to match your test results, or if you have questions, talk to your healthcare professional.
- Do not rely on the results of the meter for changing your treatment method.
- The amount of glucose in alternate sites differs from person to person.
- Compare test results between of blood glucose test meter and biochemical analyzer

The meter is corrected with plasma correction method, which helps you and your healthcare professional to compare the test results. Due to the environment, human operation and so on, there is a slight error of the test results between of blood glucose test meter and biochemical analyzer. The following condition may lead to error of test result:

(1) After just finishing meal, the test result of fingertip blood glucose is higher than that of venous blood glucose. [4]
(2) Hematokit of user is higher than 55% or lower than 30%
(3) User's body is dehydrated
(4) Temperature of testing environment is too high or too low, please run the meter at 5~40℃ room temperature.

- To obtain the accuracy close to that of biochemical analyzer, please follow the recommendations:

(1) Before going to the hospital:
Do not eat 8 hours before testing.
Take the meter to lab.
(2) In hospital:
Use the clean fingertip blood for testing.
Test with the meter according to instructions for use

9. How To Do the Test

9.1Prepare the Lancing Device

Step 1

Wash hands and sample site with soap and warm water. Rinse and dry thoroughly.

Prepare the lancing device carefully according to the instructions of lacing device.

9.2Prepare the Meter and Test Strip

Step 2

Insert a test strip with the contact bars facing upwards into the meter's test strip port. Push the strip gently until the meter beeps. The symbol will flash on the screen.

Pleas check first of all that the device is complete and is not damaged in any way. In case of doubt, do not use and contact your supplier or your service centre.

Do not allow any foreign substances, such as dirt, blood or water, enter into the meter. The meter may be damaged or occur mafunction.

Do not apply the blood sample directly to the test strip port.

Do not apply the blood sample to the test strip while holding the meter in a way that the tip of the test strip faces upwards. The blood sample may run down the surface of the test strip and flow into the test strip port.

Do not store your meter in unsanitary or contaminated sites.

Step 3

After inserting the test strip into test strip port, press Up Button and Down Button to select Pre-meal ( ), Post-meal ( ), or Quality Control testing.

9.3Apply Blood Sample

Step 4

Obtain a blood sample using the lancing device carefully according to the instructions of the lancing device. Take blood glucose measurement immediately after the sample is obtained. If the blood in the fingertip is clotted, the blood sample should be obtained using the lancing device again to ensure that the capillary whole blood samples drawn from fingertip is fresh. A minimum volume of 0.7μL is needed to fill the absorbent hole.

Step 5

After the symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the absorbent hole is not filled in time due to abnormal viscosity (thickness and stickiness) or insufficient volume, the E-4 message will appear.

It is recommended that the application of blood sample to the test strip be performed virtually vertical to the sample site as shown in the diagram below.

If there is too much sample at first time sampling, use alcohol cotton to wipe off the excess after the sample is obtained; if there is too little sample, gently press and rub to extract blood.

Note:

(1) The meter may power off if the blood sample is not applied within 120 seconds of appearing on the screen.
(2) If the meter powers off, remove the strip and reinsert it and apply blood sample after appears on the screen.

Step 6

When the blood sample reaches to the narrow end of the test strip and the meter beeps, the display segments will rotate clockwise while the blood is going in.

The test result will appear after the meter counts down from 5 to 1.

The result will be automatically stored in the meter's memory.

If the test strip is removed after the test result is displayed, the meter will automatically power off after 120 seconds.

Note:

(1) Results from alternate sites and fingertip samples may differ from each other as there is a time lag for the glucose levels to reach the same value. The Meter should be used only with fresh capillary whole blood samples drawn from fingertips.
(2) If the sample drop of blood runs or spreads due to contact with hair, do not use that sample. Try puncturing again in a smoother area.

10.How To Read Results

(1) Symbol smiling face " " appears when the blood glucose level is in the range of normal values.

(2) Symbol crying face " " appears when the blood glucose level is greater than the maximum normal value and may indicate severe hyperglycemia (much higher than normal glucose levels); or when the blood glucose level is lower than minimum normal value and may indicate severe hypoglycemia (very low glucose levels).

Period	Normal values	
	mmol/L	mg/dL
Pre-meal	4.0~7.0	72~126
Post-meal	4.0~10.0	74~180

If crying face appears again upon retesting, please contact your healthcare professional immediately.

Please contact your authorised meter sales representative if crying symbol appears even though you do not have hyperglycemia or hypoglycemia.

11.Lo and HI Message

The meter displays results between 1.0-33.3 mmol/L (20-600 mg/dL).

Lo appears when the blood glucose level is lower than 1.0mmol/L (20 mg/dL); Hi appears when the blood glucose level is higher than 33.3 mmol/L (600 mg/dL).

12.Targe Blood Glucose Ranges

Reminders	Your target ranges From your healthcare professional
Time of day	
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hours after meals	
Between 2 a.m. and 4 a.m.	

Expected Values [5]: Normal blood glucose levels for an adult without diabetes are below 100 mg/dL (5.6 mmol/L) before meals and fasting and are less than 140 mg/dL (7.8 mmol/L) two hours after meals.
*Fasting is defined as no caloric intake for at least eight hours.

13.History Record

On Test Strip Insertion Page, press Up and Down button to view Post-meal or Pre-meal history or Quality Control test results (Including blood glucose testing and quality control testing). The meter can save up to 500 glucose test results.

14.Viewing Averages

The meter calculates and displays the averages of total test results, Pre-meal test results ( ), Post-meal test results ( ),

Viewing Averages Steps

On Test Strip Insertion Page, press Home button 1 time, to view Averages Page; Averages are recent 7-day, 14-day, and 30-day blood glucose average values (Not including quality control values), and 7-day average values display by default;

Press Up and Down button to switch time;
Press Home button again to return Test Strip Insertion interface;
If there is no testing of blood glucose in the set days, three cross bars will display.

15.Setting

During powering off, long press Home button to enter into Setting mode;
Symbol flashes when it is selected, press Home button to enter into set up mode, and press Up and Down button to switch the setting items;
The sequence of items switched by Up and Down button is: Date Beep, Alarm Clock and Blood Glucose Unit (mg/dL or mmol/L).
Long press Home button again to switch off the meter.

15.1 Date Setting

During powering off, long press Home button to enter into Setting mode;
Press Up and Down to select Date item, when Date symbol flashes, press Home button to enter Date setting mode;
The sequence of setting items is:
Year-Month-Day-Hour-Minute-12h/24h mode switch;
Press Up and Down button to set the date, press Home button to confirm and enter into next setting item;

12h/24h mode: 12h mode displays AP/PM, 24h mode times by 24 hours;

After Date setting if finished, return to Setting Home Page, the Beep Setting will be selected automatically.

15.2 Beep Setting

Beep Setting status: On 1 (50% volume), On 2 (100% volume), Off (Shut down the volume);
When Beep symbol flashes, On 1 is the current beep setting status, press Home button to set;

Press Up and Down button to switch, press Home button to confirm and enter into next setting item;

15.3 Alarm Clock Setting

Totally 4 alarm clocks can be set to alarm regularly every day;
In Alarm Clock Setting Mode,

press Up and Down button to switch clock, press Home button to edit the selected clock;

On end page press Home button to end Alarm Clock Setting, return to Setting Home Page and Blood Glucose Unit Setting is selected;

There are two setting ways for Alarm Clock Setting:

- Select alarm clock → Turn on alarm clock→ Set Hour-Minute → Finish setting
- Select alarm clock → Turn off alarm clock → Finish setting

15.4 Blood Glucose Unit Setting

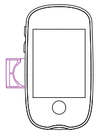
After Alarm Clock Setting ends, Blood Glucose Unit symbol is located to automatically and flashes;
Enter into Blood Glucose Unit Setting page, press Up and Dow to select the unit (mg/dL or mmol/L), press Home button to confirm, return to Setting Home Page, the Date Setting symbol is located to all over again.

16.Battery energy

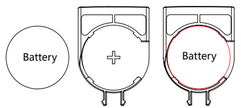
Symbol  displays when residual battery energy is 100%~85%, and symbol  displays when residual battery energy is 15%~0%.

- **How to install and change the batter**

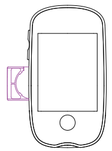
(1) Remove the battery from the device



(2) pull out the old battery from the slot and pull in new battery to the slot (the backup)



(3) Put the battery into the device



17.Error Messages

Error displays in the middle of interface when the meter occur error.

Code	Description	Method
E-1	Test strip is used	Change new test strip and retest
E-2	Temperature is lower	Use the strips at 10~40℃
E-3	Temperature is higher	
E-4	Blood volume is insufficient	Retest with sufficient blood volume
E-5	Testing failure	Use the strips at 10~40℃; Retest with sufficient blood volume; Change new test strip and retest
E-6	Power supply problem	Check if the battery is installed well; Replace the battery
Lo	Lower than 1.0 mmol/L	Change new test strip and retest
Hi	Higher than 33.3mmol/L	Change new test strip and retest

18.General Troubleshooting

Problem	Troubleshooting
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely into the test strip port. • Check if the appropriate test strip was used. • Check whether the battery is inserted with the + side facing up. • Replace the battery.
The test does not start even after applying the blood sample on the strip.	• Check if the absorbent hole is filled completely. • Repeat the test with a new test strip.
The test result does not match the way you feel.	• Repeat the test with a new test strip. • Check the expiration date of the test strip. • Perform control solution test.

19.Cleaning and Disinfecting

Use a soft cloth or tissue to wipe the meter exterior. If necessary, dip the soft cloth or tissue in a small amount of alcohol to disinfect the device.
Do not use organic solvents such as benzene, acetone, or any household and industrial cleaners that may cause irreparable damage to the meter.
Do not wash the meter sticked with foreign body, with highly corrosive alcohol, gasoline, etc.

20.Maintenance

- Store and transport the meter as required in this instruction.
- Do not use the meter at high altitude.
- No special maintenance, don't let dirt, dust, blood, or other liquid enter the meter through test strips port or gap.
- Operating environment and condition

Testing environment	Temperature: 5-40 ℃ (41-104 °F) Related Humidity: 20%-80%RH Atmospheric pressure: 80-106kPa Maximum Altitude: 2000m
Blood volume ratio	30~55%

21.Storage

(1) Store at -10 ℃ to 40 ℃ and ≤80% humidity in a well ventilated room without any corrosive gas up to the expiration date.
(2) Indoor use only.
(3) Keep away from direct sunlight, moisture, heat, dust, high temperature, high humidity, violent vibration, and shock.
(4) Strong electromagnetic radiation may interfere with the proper operation of the device. Keep the device away from sources of strong electromagnetic radiation, especially when measuring your blood glucose.

22.Transportation

(1) Transport at -10 ℃ to 40 ℃ and ≤80% humidity.
(2) Keep away from direct sunlight, moisture, heat, dust, high temperature, high humidity, violent vibration and shock during transportation.

23.Quality Control

23.1 When to test with control solution

- If you suspect the meter and test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you drop or damage the meter.

23.2 How to test with control solution

Please use the control solution manufactured by our company, because using other control solution may generate other inaccurate results. Three rangers Level 0, Level 1, Level 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 0 or level

2 test. Follow the test procedure below to run a quality control test:

Step 1
Take out one test strip out of the vial and put on the cap tightly.
Note: Make sure the test strip is complete and in the shelf life.
Step 2
Test according to the test method referenced from test meter.
Step 3
Shake the bottle gently to make the quality control fluid is mixed well before open the bottle of quality control solution.
Step 4
Squeeze a small drop of quality control solution onto a non-absorbent surface. Do not add quality control liquid directly from the bottle to the test paper. Put the cap on the quality control fluid bottle.
Step 5
After the test strip absorbs quality control solution, the meter counts down from 5 to 1, and the test result appears.
Note:

- For confirmation of results, Control Solution 0 tests should fall within the Level 0 range, Control Solution 1 tests should fall within the Level 1 range, Control Solution 2 tests should fall within the Level 2 range. When testing with Control Solution 1, make sure you are matching the results to the Level 1 range on the vial label.
- Quality control solution is not included in the content of package of test strips, and please contact with after-sale service to purchase the solution you need to perform quality control testing.

Caution:
If your quality control test result falls outside the control range shown on the test strip vial, do not use the meter and test strips to test your blood, as the system may not be working properly. If you cannot correct the problem, contact your distributor for help.

24.Performance Characteristics

24.1 Specifications

Measurement range	20-600 mg/dL (1.0-33.3 mmol/L)
Sample volume	Minimum 0.7 μL
Test time	5 seconds
Sample type	Fresh capillary whole blood samples drawn from the fingertips
Calibration	Plasma-equivalent
System reference	YSI 2300 Stat Plus
Measurement units	mg/dL or mmol/L
Day average	7, 14, and 30days
Auto-ejection of strip	For A601 and A608: No For A602 and A606: Yes
Hematocrit (HCT) range	30%–55%
Shelf life of test strips	24 months
In-use stability of test strips	90 days
Code type	No code
Assay method	Electrochemical
Overvoltage category	I
Pollution degree of the intended environment	PD 2
Battery life	1,000 tests for glucose testing
Power	A601 and A608: One 3.0 V lithium battery A602 and A606: Two 3.0 V lithium batteries (Disposable, type CR2032)

Memory	500 test results
Size	A601 and A606: 96.5*52.5*13.5mm A602 and A608: 90*61.5*12.8mm
Weight	A601 and A606: 44g A602 and A608: 45g
Operation Condition	Temperature: 5-40 ℃ Related Humidity: 20%-80% Atmospheric pressure: 80-106kPa Maximum Altitude: 2000m
Transport and Storage Condition	Temperature: -10℃ to 40℃; Relative humidity: ≤80%

24.2 Clinical Accuracy

The system accuracy of the meter was assessed by comparing blood glucose results with those obtained using Blood Glucose Test System (Accu-Chek Performa) from Roche. The test results were shown in the table below:

Clinical Study – AICARE Result vs. Roche Result		
System Accuracy Results for Glucose Concentration ≥ 100 mg/dL (5.55 mmol/L)		
Within ± 5%	Within ± 10 %	Within ± 15 %
252/396 (63.6%)	369/396 (93.2%)	396/396 (100%)
System Accuracy Results for Glucose Concentration < 100 mg/dL (5.55 mmol/L)		
Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
156/204 (76.5%)	196/204 (96.1%)	202/204 (99.0%)
System Accuracy Results for Glucose Concentration Between 46.8 mg/dL (2.6 mmol/L) and 478.8 mg/dL (26.6 mmol/L)		

Within ± 15 mg/dL (± 0.83 mmol/L) or ± 15 %	
598/600 (99.7%)	

24.3 Precision

The precision studies were performed in a laboratory using Blood Glucose Meter and Blood Glucose Test Strips (Glucose oxidase method).

Within Run Precision (mg/dL)				
Lot 1				
Sample concentration level (mg/dL)	YSI	AICARE		
		Average	SD	CV
30-50	36.3	39.9	1.4	3.6%
	35.9			
51-110	72.1	79.9	3.3	4.2%
	71.9			
111-150	117	130.5	5.8	4.4%
	116			
151-250	179	200.4	6.2	3.1%
	181			
251-400	293	325.3	9.5	2.9%
	295			
Lot 2				
Sample concentration level (mg/dL)	YSI	AICARE		
		Average	SD	CV
30-50	36.5	40.1	1.4	3.4%
	35.4			
51-110	72.6	80.1	3.2	4.0%
	72.1			
111-150	117	128.3	5.8	4.5%
	117			
151-250	180	199.5	6.3	3.2%
	181			
251-400	294	326.1	9.2	2.8%
	295			
Lot 3				
Sample concentration	YSI	AICARE		

level (mg/dL)		Average	SD	CV
30-50	36.2	40.0	1.4	3.4%
	35.4			
51-110	71.9	80.0	3.5	4.3%
	72.5			
111-150	117	130.5	5.8	4.4%
	118			
151-250	180	200.8	6.1	3.0%
	181			
251-400	293	325.4	9.2	2.8%
	292			

Between Run Precision (mg/dL)				
Sample concentration level (mg/dL)	Lot	Average	SD	CV
30-50	1	40.2	1.5	3.6%
	2	39.8	1.3	3.3%
	3	40.0	1.4	3.5%
96-144	1	125.0	4.1	3.3%
	2	124.6	4.6	3.7%
	3	125.6	4.4	3.5%
280-420	1	349.7	5.8	1.7%
	2	349.3	5.6	1.6%
	3	351.2	6.1	1.7%

24.4 Linearity

The linearity studies were performed in a laboratory using Blood Glucose Meter and Blood Glucose Test Strips (Glucose oxidase method).
For Lot 1: Y = 0.99860x + 1.62061, R2 = 0.99885
For Lot 2: Y = 1.00489x + 1.25294, R2 = 0.99834
For Lot 3: Y = 1.01388x – 0.99857, R2 = 0.99857
Studies have shown that this reagent has a good linear relationship between 10mg/dL and 650mg/dL, so the linear range

of this reagent is determined to be 10mg/dL to 600mg/dL.

24.5 Packed Cell Volume (Hematocrit)

The test results show that accurate reading can be obtained when testing within the hematocrit range of 30%–55%.

24.6 Interferences

The effect of various interfering substances was evaluated in whole blood samples on glucose measurements.

Compound	Below the concentration does not affect the test value
Acetaminophen	≤ 20 mg/dL
Ascorbic acid	< 3 mg/dL
Cholesterol	≤ 500 mg/dL
Conjugated-Bilirubin	≤ 50 mg/dL
Creatinine	≤ 10 mg/dL
Dopamine	≤ 20 mg/dL
EDTA	≤ 200 mg/dL
Galactose	≤ 100 mg/dL
Gentisic acid	≤ 100 mg/dL
Glutathione (Reduced)	≤ 92 mg/dL
Hemoglobin	≤ 500 mg/dL
Heparin Sodium	≤ 8000 u/L
Ibuprofen	≤ 50 mg/dL
L-DOPA (Levo-Dopa)	≤ 3 mg/dL
Maltose	≤ 100 mg/dL
Methyl-DOPA	≤ 1.5 mg/dL
Pralidoxime Iodide (PAM)	≤ 80 mg/dL

Salicylic Acid	≤ 60 mg/dL
Tolazamide	≤ 40 mg/dL
Tolbutamide	≤ 100 mg/dL
Triglycerides	≤ 3000 mg/dL
Unconjugated-Bilirubin	≤ 40 mg/dL
Uric Acid	≤ 24 mg/dL

24.7 User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
99.0% within ±15 mg/dL (± 0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and 100% within ±15% of the medical laboratory values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).
100.0% within ±15 mg/dL (± 0.83 mmol/L) of the layer person values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and 100% within ±15% of the layer person values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).

25.Reference

(1) Electrochemical Glucose Sensors and Their Applications in Diabetes Management. Chemical Reviews. 2008, 108(7): 2482-2505.
(2) FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication (2010)
(3) CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (2010)
(4) Larsson-Cohn U: Difference between capillary and venous blood glucose during oral glucose tolerance tests. Scand J Clin Lab Invest. Vol. 36:805-808, 1976.
(5) American Diabetes Association Professional Practice Committee. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes [J]. Diabetes Care, 2022, 45 (Supplement_1): S17–S38.

26.Warranty Information

(1) From the date of purchasing the meter, you enjoy 1-year free warranty with purchasing invoice. But the warranty does not cover the failures due to the following human factors:

- Disassembly and altering the product without authorization
- Inadvertently dropping during use and transportation
- Lack of reasonable maintenance
- Not correctly using according to instructions for use
- Improper repairing

(2) To obtain warranty service, please send the product to the designated professional service shop for repair.

Warranty Card

Name	
Gender	
Age	
Tel.	
Purchasing Date	
Meter Serial No.	
Post Code	
Contact Address	
Purchasing Address	

27.Model Difference

Three models only differ in appearance, and their specifications, buttons, display and functions are totally same.

Difference	A601	A608	A602	A606
Appearance				

28.Meaning of Symbols

EC REP	Authorized Representative in the European Community		WEEE (Waste Electrical and Electronic Equipment)
	Keep away from Sunlight		Keep Dry
	Consult Instructions for Use		Temperature Limitation (Store at)
	Caution	SN	Serial Number
	Use-by Date		Biological Risks
	Manufacturer		Date of Manufacture
IVD	In Vitro Diagnostic Medical Device	REF	Catalogue number
CE 0197	CE mark		

Jiangxi AICARE Medical Technology Co., Ltd.
No. 6, South Side of Nanhuan Road, Qianping Industrial Park, Le'an County, Fuzhou City, Jiangxi Province, China

EC REP Caretechion GmbH
Niederrheinstr. 71,40474 Dusseldorf,Germany.