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Blood Glucose Monitoring System
(Safe AQ pro Series) User manual

CE 0123

IVD For in vitro diagnostic use only

Sinocare

Dear Safe AQ pro series Blood Glucose Monitoring System users:

Sinocare thanks you for choosing the Safe AQ pro series (Safe AQ pro Ⅰ, Safe AQ pro Ⅱ, Safe AQ pro Ⅲ) Blood Glucose Monitoring System. This User Manual contains important information about the System and how it operates. Please read it carefully before using your new System.

The Safe AQ pro series Blood Glucose Monitoring System is designed for easy, user-friendly and convenient operation. The Safe AQ pro series blood glucose test strip does not require coding. This feature saves time and avoids errors due to incorrect coding. The Safe AQ pro Ⅰ memory allows you to save up to 500 blood glucose and 70 control solution test results, Safe AQ pro Ⅱ memory allows you to save up to 500 blood glucose and 60 control solution test results, Safe AQ pro Ⅲ memory allows you to save up to 500 blood glucose and 50 control solution test results. All these advantages make the Safe AQ

pro series Blood Glucose Monitoring system an excellent blood glucose monitoring tool.

The Safe AQ pro series Blood Glucose Monitoring system is designed to help you and your healthcare professional monitor your blood glucose levels. This user manual provides the instructions for the correct use of your system. Please read this manual carefully before use.

If you need to contact us, please call Customer Service at +86-731-89935987 or sent our email at support@sinocare.com or visit our website at https://en.sinocare.com .

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Safe AQ pro series
Blood Glucose Monitoring System User Manual

Introduction to the Blood Glucose Monitoring System

Intended Use

The Safe AQ pro series blood glucose monitoring system is intended for use in the quantitative measurement of glucose in human whole blood taken from the fingertip (capillary) or from the vein (venous). It is intended to be used by people with diabetes at home or clinical site as an aid in monitoring the effectiveness of their diabetes control programs.

The blood glucose monitoring system is for in vitro diagnostic use only. It is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.

The Safe AQ pro I blood glucose test strip is used with the Safe AQ pro I blood glucose meter in the quantitative measurement of glucose in human whole blood taken from the fingertip (capillary) or from the vein (venous).

The Safe AQ pro **II** blood glucose test strip is used with the Safe AQ pro **II** blood glucose meter in the quantitative measurement of glucose in human whole blood taken from the fingertip (capillary) or from the vein (venous).

The Safe AQ pro **III** blood glucose test strip is used with the Safe AQ pro **III** blood glucose meter in the quantitative measurement of glucose in human whole blood taken from the fingertip (capillary) or from the vein (venous).

The Sinocare blood glucose control solution is used with the Safe AQ pro series blood glucose meter and blood glucose test strip to check that the meter and test strip are working together properly. A control test also helps you practice proper testing technique.

Description

The blood glucose monitoring system includes:

Models of blood glucose meter	Models of blood glucose test strip	Control Solution
Safe AQ pro I	Safe AQ pro I	Sinocare blood glucose control solution
Safe AQ pro II	Safe AQ pro II	
Safe AQ pro III	Safe AQ pro III	

The blood glucose meters should be used with their respective model of blood glucose test strips, and Sinocare blood glucose control solution. They work together to accurately test blood glucose. Using other test strip and control solution with your blood glucose meter may produce inaccurate results.

You can purchase the applicable test strip and control solution by calling the customer service at +86-731-89935987 or sent our email at support@sino-care.com or contact your local dealers.

The lancing device and lancets are manufactured for Changsha Sinocare Inc, by certified suppliers.

They are used in combination with the Blood Glucose Monitoring system. Please refer to package of lancing device and lancet for detail information.

Test Principle

A glucose test is based on the measurement of electrical current caused by the reaction of glucose with the FAD glucose dehydrogenase on the electrode of the strip. The blood or control solution sample is drawn into the tip of the test

strip through capillary action. Glucose in the sample reacts with the FAD glucose dehydrogenase and generates electrons, which produce an electrical current. The blood glucose meter measures the electrical current and calculates the glucose result. The glucose result is displayed by the meter in the unit of mg/dL or mmol/L.

Important Safety Instructions

Read this section before using your blood glucose monitoring system. Always take the following basic safety precautions.

▶ Before use your blood glucose monitoring system for the first time, inspect the system to make sure
the package contents are complete and not damaged.

▶ For self-testing customer, your blood glucose meter and lancing device are for single person use only. Do not share them with anyone else, even family members.

▶ For professional use, if the meter is being used on the second person, the meter should be disinfected first.

▶ Close supervision is necessary when the device is used by, on, or near

children or people with physical limitations that may impair correct use of the system.

▶ Use the blood glucose monitoring system only for the intended use as described in this manual.

▶ Do not use other blood glucose test strip and control solution with the blood glucose meter.

▶ Do not use the blood glucose monitoring system if it is not working properly, or if it has suffered any damage.

▶ Before using any product to test your blood glucose level, read all instructions and practice a test.

▶ Keep the blood glucose test strip vial away from children. The strip vial, test strip, and control solution bottles can be choking hazards. Do not drink the control solution.

▶ All parts of this kit are considered biohazardous once they have been used for a blood test. They can potentially transmit infectious diseases, even after cleaning and disinfection.

▶If the system is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

DO NOT CHANGE YOUR TREATMENT BASED ON A SINGLE RESULT THAT DOES NOT MATCH HOW YOU FEEL OR A BELIEF THAT YOUR TEST RESULT COULD BE FALSE.

Patient Cautions

▶ Not for neonatal (newborn or infant) use.
▶ Not for screening or diagnosis of diabetes mellitus.
▶ For self–testing.
▶ Not for use on the critically ill patients.
▶ Not for alternative site testing (AST) use.
▶ For in vitro diagnostic use only.
▶ Please read the blood glucose meter user manual before test.
▶ Using other test strip and control solution with your blood glucose meter may produce inaccurate results.
▶ Keep the test strip vial away from children. The vial and the test strip can be a choking hazard. Never chew or swallow a test strip.

Important Health–Related Information

▶The blood glucose monitoring system was tested for interfering substances.

No significant interference was observed with these substances at therapeutic or naturally occurring levels.
◆ Insufficient sample may cause inaccurate test results.
◆ Hematocrit should between 10% –70%. Ask your healthcare professional if you do not know your hematocrit.
◆ Normal therapeutic concentrations of uric acid, ascorbic acid, acetamino–phen and other reducing substance do not significantly affect results. However, abnormally high concentrations of these substances in blood may cause inaccurately high results.
◆ Lipemic samples: blood concentrations of cholesterol in excess 600 mg/dL or triglyceride concentrations in excess of 750 mg/dL may affect blood glucose results.
◆ Bilirubin in excess 20 mg/dL may affect blood glucose results.
◆ Xylose: Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.
◆ Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare

professional immediately.

◆ Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may also occur in individuals experiencing a hyper-osmolar-hyperglycemic- state (HHS)

▶ If you have symptoms that do not reflect your blood glucose test results, and you have followed all instructions described in this owner’s manual, call your doctor or healthcare professional.

▶ 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.

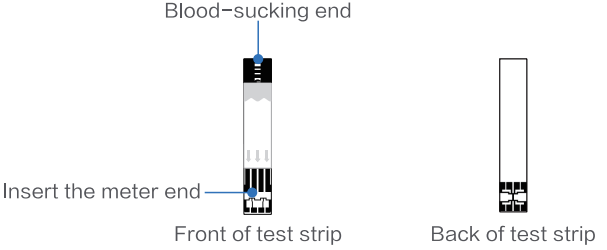
▶ Do not use this instrument in proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

▶ 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.

About the Blood Glucose Test Strips

The Safe AQ pro series blood glucose test strips used with the applicable blood glucose meters provides a complete test system that is intended for in vitro diagnostic use by people with diabetes at home or clinical site as an aid in monitoring the effectiveness of their diabetes control programs. The Safe AQ pro series blood glucose test strips do not require coding. Please refer to the “Performing a Blood Glucose Test” section for complete instructions.

The blood glucose test strip consists of the following parts:



Important Safe AQ pro series Blood Glucose Test Strips Information

▶ Store test strip vial in a cool dry place at a temperature between 5℃~30℃, DO NOT FREEZE. No more than 95% RH. Keep away from direct sunlight and heat.

▶ Keep your blood glucose test strips in the original vial. NEVER transfer test strips from one vial to another.

▶ Before handling the blood glucose test strip, clean your hands with soap and water and dry your hands. You may hold the sides of the blood glucose test strip when removing it from the vial or inserting it into the blood glucose meter.

▶ Only remove the blood glucose test strip from the vial when you are ready to perform a test. Firmly recap the vial immediately after use.

▶ Only apply blood to the tip of the strip. Ensure that the reaction zone is completely filled. Do not place blood on any other part of the test strip. This may cause an inaccurate result.

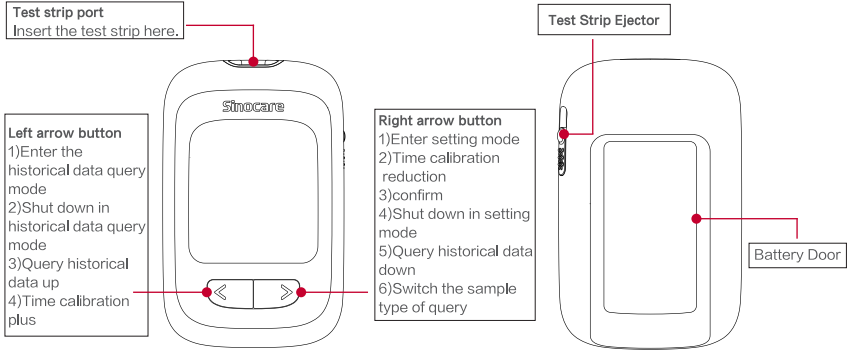
▶Write opening date on test strip vial label when removing the first test strip. Discard any remaining blood glucose test strip after 6 months from the date.

▶ Do not use the blood glucose test strip beyond the expiration date printed on the vial.

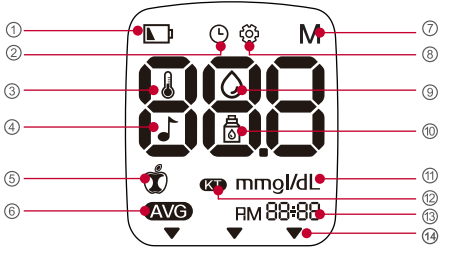
WARNING: Keep the blood glucose test strip vial away from children. The vial and the test strip can be a choking hazard. Never chew or swallow a blood glucose test strip.

Knowing Your Safe AQ pro series Blood Glucose Meters

Key Functions of the Blood Glucose Meter



Blood Glucose Meter Display



1. Battery symbol
2. Time setting symbol
3. Temperature symbol
4. Sound symbol
5. Random / Before / After meal symbol
6. Average value symbol
7. Memory symbol
8. Set symbol
9. Drop Symbol–Apply blood or control solution
10. Control Symbol–Result is from control solution
11. Unit of measurement
12. Blood ketone test reminder symbol
13. Date or time
14. Indicating value symbol

Note: The meter presets the unit of measure as mg/dL or mmol/L before leave factory. Users can not change the unit of measure.

Blood Glucose Meter Color Indication

There are three colors of red, green and yellow on the housing under the LCD screen of the instrument. When the test result is displayed, the LCD displays the icon indicating the color area, and the color area corresponding to the test result is as follows:

1. If test result is >70mg/dL(3.9mmol/L) and <126mg/dL(7.0mmol/L) the meter will display and Indicates the green area.
2. If test result is ⩾126mg/dL(7.0mmol/L) and ⩽250mg/dL(13.9mmol/L) the meter will display and Indicates the yellow area.
3. If test result is ⩽70mg/dL(3.9mmol/L) or >250mg/dL(13.9mmol/L) the meter will display and Indicates the red area.

Note: Do not change your treatment only based on test result and colors indications. Please consult healthcare professional for your treatment.

Setting Up Your Blood Glucose Meter

Setup steps for date/time and Sound switch

The blood glucose meter is preset with the date and time. You may need to adjust it to your local time zone. Check the date and time each time the batteries are replaced. Reset the date and time if they are not correct.

STEP 1: Insert the Batteries

Open the Battery Cover on the back side of the blood glucose meter. Insert two AAA alkaline batteries as indicated by the “+” and “–” symbols inside the battery compartment.

STEP 2: How to Enter the time and date setting mode

Meter enters time and date setting mode after installing the battery or When meter off, press and hold the " " button for 1.5 seconds to start setting mode and Displays “No”, short press the “ ” button to display “yes”, Then short press " " to enter the time and date setting mode;



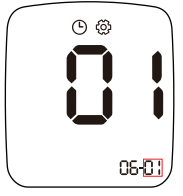
STEP 3: How to Set the year
The year (number) flashes. Press “ ” button to select the year. Press “ ” button to set.
note:
You can only set the last two digits of the year, from 19–99 (representing 2019–2099).



STEP 4: How to Set the Month
The month (number) flashes. Press “ ” button to select the year. Press “ ” button to set.



STEP 5: Repeat step 3 to set up date, hour and minutes.







STEP 6: How to enter the Sound (beep) On and Off settings
There are two ways to enter the Sound On and Off settings. One is when the time enters the setting mode and the time is adjusted, it will automatically enter the Sound On and Off setting mode.
The other is in setting mode, short press the " " button to select the "no" interface (as shown in the figure), short press the " " button to enter the Sound On and Off setting mode.



STEP 7: Sound On and Off settings

In the Sound On and Off setting mode, short press the " " button to select the sound on (as shown in Figure 1) or off (as shown in Figure 2), after selection, short press the " " button to confirm the save status and automatically exit Sound On and Off setting mode.

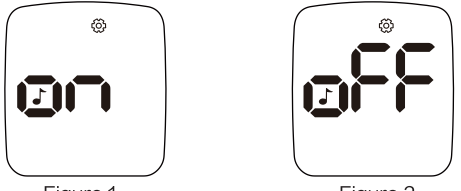


Figure 1

Figure 2

STEP 8: Exit setting mode.

After finish setting sound, meter turns off automatically.

Note:

If the batteries are replaced, the meter may lose its current date and time. Re-adjusting date and time setting will not change the time stamps of previously stored test results.

Power Saving

▶ Meter automatically turns off in 3 minutes if no sample is applied while in test mode.

▶ After testing sample, the result is displayed for 1 minute if the test strip remains in the meter. If the test strip is removed, the meter immediately turns off.

▶ Meter automatically turns off if there is no activity within 1 minute while in date and time setting mode, test results review mode, and control solution test review mode.

Control Solution Testing

Product Levels

Sinocare supplies two levels of blood glucose control solution with different concentrations of glucose: Level 1 and Level 2. Each blood glucose test strip lot has its own ranges for blood glucose control solution Levels 1 and 2.

Important Information

▶ Use only Sinocare blood glucose control solution with your blood glucose monitoring system.
▶ The Sinocare blood glucose control solution ranges are printed on the blood glucose test strip vial. They are not recommended ranges for your blood glucose.
▶ Write opening date on the control solution bottle label. Discard bottle if either expiration date printed on the bottle label or 3 months after first opening has passed, whichever comes first. Discard any bottle that appears to be cracked or leaking.
▶ Control solution is for in vitro diagnostic use only.

Why Perform a Blood Glucose Control Solution Test?

▶ Ensure that your blood glucose meter and blood glucose test strip are working properly.
▶ Allow you to practice testing without using blood.

When Should You Perform a Blood Glucose Control Solution Test?

▶ When you begin using a new vial of blood glucose test strip.
▶ When the blood glucose test strip has been exposed to extreme environmental conditions.
▶ If you drop the blood glucose meter.

Storage and Handling

▶ Ensure the Sinocare blood glucose control solution bottle cap is tightly closed after each use.
▶ Store the Sinocare blood glucose control solution at temperatures between 1℃~30℃.
▶ Do not freeze.

Performing a Blood Glucose Control Solution Test

Check the expiration and vial open date or open month on your Sinocare blood glucose control solution bottle and blood glucose test strip vial. Discard any expired test strip or control solution bottles.
Start with the blood glucose meter off state.
If the meter or the test strips have been stored under different temperature, allow at least 30 minutes for them to equilibrate to the same temperature condition.
STEP 1: Wash your Hands
Wash your hands with soap and water. Be sure to dry your hands before performing a test.
STEP 2: Insert a blood glucose test strip
Insert a blood glucose test strip with the printed side facing up and contact end toward the meter. Push the test strip into the meter Test Strip Port until it stops. Meter will turn on and beep (if sound is on). Then press and release the "" button, Meter will enter into control solution testing mode and display control symbol.

STEP 3: Apply the Sinocare blood glucose control solution
1. Gently shake the Sinocare blood glucose control solution bottle and remove the cap.
2. Squeeze the bottle and discard the first drop. Wipe the bottle tip with a clean tissue.
3. With the strip still in the meter, touch the tip of the blood glucose test strip to the control solution droplet until the blood glucose meter beeps (if sound is on). Make sure the reaction zone is completely filled.
4. The meter counts down for 5 seconds, then meter will display the control solution test result with the control symbol . If the meter does not display the control symbol, re-do the test.





5. Check if the test result is in range. Compare the test result with the corresponding control range printed on the test strip vial you are using.
6. Eject the strip. Discard the used blood glucose test strip carefully as medical waste.

Questionable Results:

If the test falls outside the range printed on the blood glucose test strip vial, check the Troubleshooting Guide located in the System Troubleshooting section of this manual and repeat the test. Results that fall outside the control range may indicate:

▶ Error in performing the test
▶ Sinocare blood glucose control solution bottle has not been shaken well before use
▶ Expired or contaminated Sinocare blood glucose control solution
▶ Sinocare blood glucose control solution that is too warm or too cold
▶ Expired or deteriorated blood glucose test strip
▶ blood glucose meter malfunction

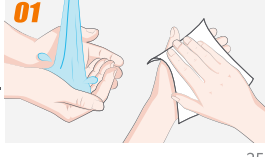
Caution: Do not use blood glucose test strip or Sinocare blood glucose control solution that is past the discard date, expired, or damaged. Otherwise your results could be inaccurate.

Contact Customer Service

If your blood glucose test strip has been damaged or if you continue to get out-of-range results, it means that the blood glucose monitoring system or the Sinocare blood glucose control solution may not be working as they should. DO NOT use the blood glucose meter to test your blood glucose level. If you are unable to resolve the problem, contact Customer Service at +86-731-89935987.

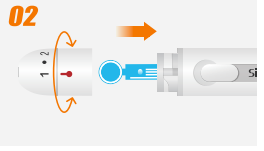
Performing a Blood Glucose Test

NOTE:
If the meter or the test strips have been stored under different temperature, allow at least 30 minutes for them to equilibrate to the same temperature condition.



STEP 1: Please wash your hands and dry them

STEP 2: Twist the adjusting shell thread of the lancet, and insert the lancet into the core rod



STEP 3: Twist off the lancet cap, but do not discard it.



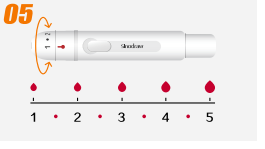
▶ The lancets are for single use only. Always use a new lancet.
▶ Avoid getting hand lotion, oils, dirt, food, liquids, or debris in or on the blood glucose meter, blood glucose test strip, lancets, or lancing device.
▶ Once they have been used to test blood, all parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
▶ The lancing device is prepared and ready to lance your finger for a blood sample. The lancet is for single patient use only.

To prevent the risk of blood-borne pathogens trans-mission, it shall not be shared with other people.

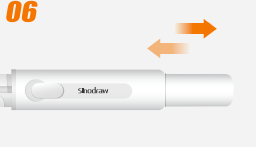
STEP 4: Close the cap



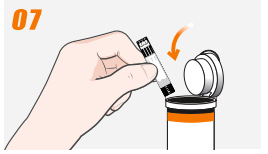
STEP 5: Adjust the digital ring based on the skin condition of the patient's fingers. The larger the number, the deeper it is.



STEP 6: Pull the adjusting device back to the end and the adjusting device automatically springs back



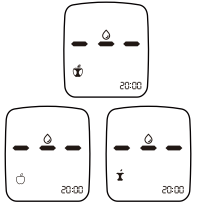
STEP 7: Take out the test strip and immediately cover the bottle cap to protect the test strip from moisture.



STEP 8: Insert the blood glucose test strip into the test strip port at the top of the meter. (Pull out the battery insulation film from the battery compartment if first time use the meter)
When the blood glucose meter screen displays a flashing blood drop symbol, Press the “ ” button to choose the meal marker of pre-meal or post-meal.



STEP 9: Press the lancing device firmly against the finger puncture site and press its release button. If need, thumb press near the puncture site to help form a drop of blood.
Attention: If you did not produce a large enough blood drop, gently massage your finger toward the puncture site. DO NOT SQUEEZE YOUR FINGER. Refer to step 5 to adjust the puncture depth and lance again.





STEP 10: Fill blood sample by touching the tip of the test strip to the drop of blood. The blood is drawn into the test strip automatically through the tip opening. (Apply blood only to the middle part of the strip tip end. Do not apply blood to the left or right corner of the tip, or on top of the test strip. Do not press your finger against the tip end of the test strip. Improper blood application could lead to inaccurate results.)



NOTE: Hold the tip of the test strip to the blood drop until the meter Beeps (if sound is on) and Visually confirm that the blood sample fills the entire Sample Tip at the end of the test strip.
If blood is not applied within 3 minutes of inserting a strip, the meter turns off. Reinsert the strip and start test as in Step 8.

Caution:
DO NOT smear or scrape the blood onto the blood glucose test strip
DO NOT apply blood to the blood glucose test strip when the strip is not in the meter.
DO NOT move blood glucose meter or blood glucose test strip when testing.

STEP 11: After a 5-second count down, the meter displays the test result.
Tips: If you do not choose the status of pre-meal or post-meal in add sample waiting, you can set it after the meter displays the test result.



STEP 12: Push the strip ejection slide to eject the used test strip from the meter. Dispose the test strip as medical waste.



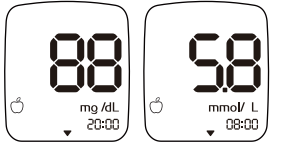
STEP 13: Jab the lancet needle into its cap and dispose it as medical waste.
Used lancets and strips may be biohazardous. Please discard them carefully according to your local regulations.



Note: Wash hands thoroughly with soap and water after handling the blood glucose meter, lancing device, or the blood glucose test strip.

Understanding Your Result

After the blood glucose meter counts down from 5, your blood glucose result appears along with the unit of measurement, and time. This blood glucose result is stored in the blood glucose meter memory.



Caution: If you cannot test due to a problem with your testing supplies, contact Customer Service at +86-731-89935987. Failure to test could delay treatment and/or lead to serious medical conditions.

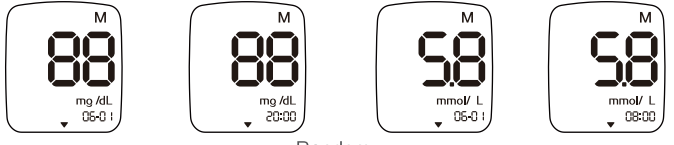
Using the Blood Glucose Meter Memory

The Safe AQ pro series blood glucose meter can store test results with the date and time in its memory. You can review the individual results by entering the memory mode. The storage quantity is as follows:

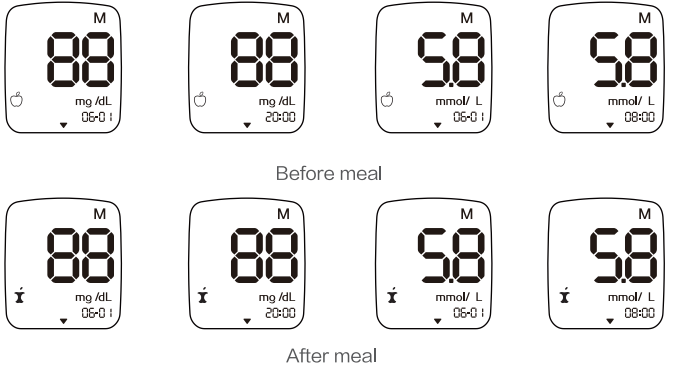
Models of blood glucose meter	blood glucose test results	control solution test results
Safe AQ pro I	500	70
Safe AQ pro II	500	60
Safe AQ pro III	500	50

STEP 1: Enter the Memory Mode

When the blood glucose meter is off, press and hold the " " button for 1.5 seconds to turn on the blood glucose meter. The latest blood glucose test result is displayed, and the date and time of the test result are displayed alternately.



Random



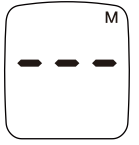
Before meal

After meal

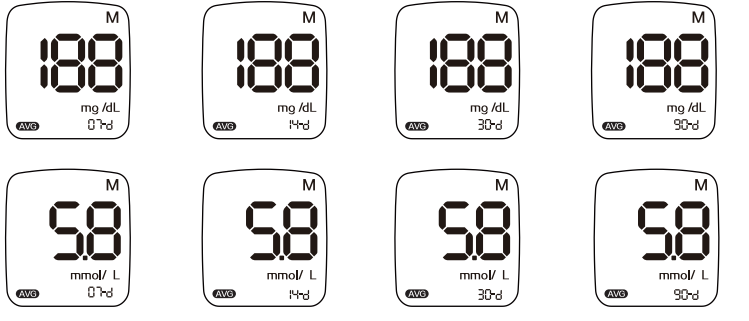
STEP 2: Reviewing the Blood Glucose Test Results

Press " " button to view all the blood glucose results in memory. Press " " button to view the average of test result of total blood glucose/before meal blood glucose /after meal blood glucose in 7/14/30/90 days. The Average of days that you are viewing is displayed in the lower right corner of the

screen. If no blood glucose test results been stored, meter display “- - -”.

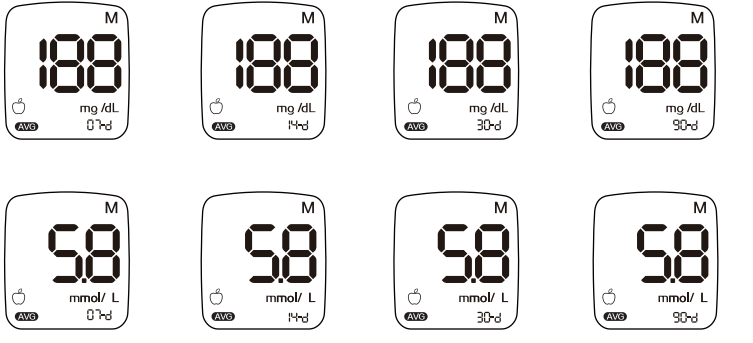


7-day, 14-day, 30-day, and 90-day average of total blood glucose:



7 days average | 14 days average | 30 days average | 90 days average

7-day, 14-day, 30-day, and 90-day average of before meal blood glucose:



7 days average | 14 days average | 30 days average | 90 days average

7–day, 14–day, 30–day, and 90–day average of after meal blood glucose:













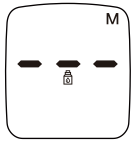




7 days average | 14 days average | 30 days average | 90 days average

STEP 3: Reviewing the Control Solution Test Results

In query blood glucose historical data mode, press and hold " " button, the meter will switch to control solution historical data query mode, the screen will display the latest control solution historical data, if no control solution historical data, it will display " - - ". Short press " " button to query the historical data of other quality control solutions.





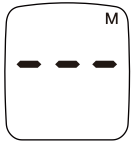




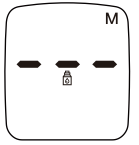


STEP 4: Deleting Test Results from Memory

Starting in either test results review mode or control solution test review mode, press and hold “ ” button and “ ” button at the same time until the screen displays 3 dashes and a short beep (if sound is on) , all blood glucose test results been deleted.



No stored blood test result



No stored control solution test result

The meter can store test results in memory. If these numbers are exceeded, any new results cause the oldest result in memory to be deleted. The storage quantity is as follows:

Models of blood glucose meter	blood glucose test results	control solution test results
Safe AQ pro I	500	70
Safe AQ pro II	500	60
Safe AQ pro III	500	50

STEP 5: Exit historical data query mode
In the historical data query mode, press and hold the " " button for 1.5 second, the instrument exits the query mode.

Information for Healthcare Professional Use

- Only trained healthcare professional be allowed to use glucose monitoring system on multiple patients.
- Only trained healthcare professional be allowed to collect venous blood samples.
- Any patient who has infectious diseases must use his/her own meter.
- If the same meter be used on multiple patients, there is risk of infection between both patients and healthcare professional.
- Water or other disinfection solution which remains on skin may dilute blood and cause inaccurate test results.
- Please dispose used lancet, test strips and expired control solution as medical waste.

The lancing device we provide with the system is for personal use only, do not SHARE with more than one person.

Perform test:

1. Wear disposable gloves and other protective equipment required by the work.
2. Healthcare professional use an alcohol swab to clean lancing site. Then be sure to let lancing site dry before testing.
3. Use qualified lancing device and choose suitable penetrate depth for patients.
4. Using lancing device to lance.
5. Hold the tip of the test strip to the blood sample until the test strip reaction zone is full and the meter begin countdown.
6. Wash hands thoroughly with soap and water after handling the meter, lancing device or test strips.
7. Cleaning and disinfecting meter before use on next patient.

Performance Characteristics

Accuracy:

95% test result of meet the requirement below:

Concentration Range	Bias%
20mg/dL≤ the test result <100mg/dL (1.1mmol/L≤the test result<5.55mmol/L)	within±15mg/ dL (0.83mmol/L)
100mg/dL≤ the test result ≤600mg/ dL (5.55mmol/L≤the test result≤33.3mmol/L)	Within ±15%

Precision: test result of meet the requirement below:

Concentration Range	Requirement
20mg/dL≤ the test result <100mg/dL (1.1mmol/L≤the test result<5.55mmol/L)	SD ≤6mg/dL(0.33mmol/L)
100mg/dL≤ the test result ≤600mg/ dL (5.55mmol/L≤the test result≤33.3mmol/L)	CV<6.0%

Details please read blood glucose test strip package insert.

Specifications

Sample volume	Refer to blood glucose test strip user manual
Sample type	Fresh capillary blood, venous blood
Results Value	Plasma equivalent values
Assay method	Electrochemical
Meter storage and transport conditions	-20℃~55℃ ≤95%RH
Dimensions	85mm(L) x53mm(W)x23.6mm(H)
Weight	53.8g without battery
Power source	2 AAA alkaline batteries (3V DC ,20mA)
Battery life	Approximately 1,000 tests
POLLUTION DEGREE of the intended environment	2
Display	LCD

Memory	Models of blood glucose meter	blood glucose test results	control solution test results
	Safe AQ pro I	500	70
	Safe AQ pro II	500	60
	Safe AQ pro III	500	50
Test condition	Temperature: 10℃~40℃ Relative Humidity: ≤ 90% RH (non-condensing) Hematocrit: 10%~70% MAX.altitude:3078 meters Note: Use within specified environmental conditions only.		
Construction	Hand-held		
Test strip chemical composition	FAD glucose dehydrogenase, potassium ferricyanide, non-reactive ingredients		
Control solution chemical composition	Water, glucose, preservative, dyes, phosphate buffer, viscosity enhancing agents		
Test strip storage condition	5℃~30℃ ≤95%RH		

Control solution storage condition	1℃~30℃
Measurement units	mg/dL or mmol/L
Measurement range	20~600 mg/dL, 1.1~33.3 mmol/L
The lifespan of the blood glucose meter	10 years.

Caring for Your Blood Glucose Meter

Maintenance

The blood glucose meter does not require professional maintenance services.

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

▶Electromagnetic Compatibility (EMC): The meter complies with the electro-magnetic requirements IEC 61326-2-6: 2020 specified in ISO 15197-2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment

likely to interfere with the meter. Immunity to electrostatic is charge meets the requirements of IEC 61326-2-6: 2020. The meter has been tested for radio frequency interference at the frequency range and test levels specified by IEC 61326-2-6: 2020.

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

▶ Avoid getting dirt, dust, blood, Sinocare blood glucose control solution, foods, or liquids inside the blood glucose meter.

▶ After each use, store the blood glucose meter, blood glucose test strip, and the Sinocare blood glucose control solution in the carrying case at room temperature in a dry place.

▶ Do not freeze the test kit.

▶ Do not store the test kit in bathroom or kitchen.

▶ Your blood glucose meter is a precision instrument. Handle with care.

▶ The blood glucose meter has been tested and proven robust to the recom-mended cleaning and disinfection procedures. If meter deterioration occurs (e.g., foggy LCD Display screen, failure to detect inserted test strip, faded or

missing LCD Display screen segments, false high or false low results), stop using the meter and contact Customer Service at +86-731-89935987.

Cleaning and Disinfection of your System

Clean the blood glucose meter and Sinocare lancing device to remove blood, skin oils, dirt, and dust after each use. Disinfect the blood glucose meter and Sinocare lancing device at least once a week to eliminate infectious agents.

Meter Cleaning Procedure

1. Wash hands thoroughly with soap and water.
2. Make sure meter is off and a test strip is not inserted. Use 75% alcohol to rub the entire outside of the meter. Make sure no liquid enters the test strip port or other openings in the meter.
3. Let meter air dry thoroughly before test.
4. Wash hands thoroughly again after handing meter.
5. Verify the meter is working properly by performing control solution test. If your meter cannot work properly, please contact customer service at+86-731-89935987 or contact local dealers.

Meter Disinfecting Procedure

The disinfection procedure is intended to eliminate infectious agents on the blood glucose meter. Meter disinfection should be performed at least once a week. Please follow your clinic institution disinfect method to disinfect the meter.

▶ Wash hands thoroughly with soap and water after handling the blood glucose meter, Sinocare lancing device, or blood glucose test strip.

▶ Make sure no cleaning and disinfection fluid enter the meter through buttons, speaker window, test strip port or open parts of the case.

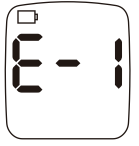
Battery

Your blood glucose meter is powered by 2 AAA alkaline batteries. You can find replacement batteries in most stores. The meter shows a battery symbol only when the batteries are low.

Low Battery

The meter shows a battery symbol and E-1 in the display to indicate the condition of the meter batteries. When these messages appear, there is

battery voltage is out of range. Replace the batteries as soon as possible.



Battery Replacement

To replace the batteries, make sure the blood glucose meter is turned off.

Step 1: With the blood glucose meter turned off, press the latch on the Battery Cover and lift up to open.

Step 2: Remove the two used AAA alkaline batteries from the meter and replace them with 2 new AAA alkaline batteries. Install the batteries according to the "+" and "–" symbols in the battery compartment. Check that you have placed the batteries correctly and close the Battery Cover.

Step 3: Check the date and time.

Replacing the batteries does not affect the test results stored in the meter memory. However the date and time settings may need to be re-set.

Caution:

As with all small objects, keep batteries away from small children. If a battery is swallowed, seek medical help right away.

Remove the batteries when the blood glucose meter is not in use for extended period. This will prevent damage to the blood glucose meter from battery leakage during such time.

System Troubleshooting

Special Messages

Special messages and error messages help to identify certain problems. However, improper use may cause an inaccurate result without showing an error message.

In the event of a problem, refer to the Troubleshooting Guide below. If you follow the actions recommended but the problem is not resolved, please contact Customer Service at +86-731-89935987 for assistance.

Message	Description
	What it means: The blood glucose test result is less than 20 mg/dL(1.1mmol/L). Action: Use a new test strip and test again. If the meter still displays “LO”, please contact your doctor.

Message	Description
	What it means: The blood glucose test result is greater than 600 mg/dL (33.3mmol/L). Action: Use a new test strip and test again. If the meter still displays “HI”, please contact your doctor.

Message	Description
	What it means: The control solution test result is less than 20 mg/dL(1.1mmol/L). Action: Use a new test strip and test again. If the meter still displays “LO”, please Call Customer Service at +86-731-89935987 or contact your local dealer.

Message	Description
	What it means: The control solution test result is greater than 600 mg/dL (33.3mmol/L). Action: Use a new test strip and test again. If the meter still displays “HI”, please Call Customer Service at +86-731-89935987 or contact your local dealer.

Error Message	Description
	What it means: Low battery. A test cannot be performed. Action: Replace the batteries.

Error Message	Description
	What it means: Meter operation outside of temperature range. Action: Move the meter and test strip vial to an appropriate location. Wait at least 30 minutes and test again.

Error Message	Description
	What it means: Wrong operation. For example, re-used a strip. Action: Use a new test strip and test again.

Error Message	Description
	What it means: code exception Action: Use a new test strip and test again. If the meter still displays E-4, Call Customer Service at +86-731-89935987.

Error Message	Description
	What it means: Operation error. For example, the test strip was ejected during test process. Action: Use a new test strip and test again.

Error Message	Description
	What it means: Meter internal error. Action: Call Customer Service at +86-731-89935987.

Error Message	Description
	What it means: Insufficient sample size. Action: Use a new test strip and test again with enough sample.

Error Message	Description
	What it means: Test process error. Action: Use a new strip and test again.

Error Message	Description
	What it means: Meter recoverable errors. For example, the meter is disturbed by environment. Action: Reinstall the battery on the meter, If the meter still displays E-0, Call Customer Service at +86-731-89935987.

Troubleshooting Guide

1. After inserting test strip, meter does not turn on.

Reason	Action
Test strip inserted upside down or backwards	Remove test strip. Re-insert correctly.
Test strip not fully inserted	Remove test strip. Re-insert test strip fully into meter.
Test strip error	Repeat with new test strip
Dead or no battery	Replace battery.
Battery in backwards	Check that the batteries are correctly installed in the proper orientation of “+” and “-”.
Meter Error	Call Customer Service at +86-731-89935987.

2. After applying sample, test does not start (meter does not beep (if sound is on) nor begins count down).

Reason	Action
Sample drop too small	Repeat test with new test strip and larger sample drop.
Sample is applied to wrong area of test strip	Repeat test with new test strip and apply the sample to the tip of the Reaction Zone.
Test strip inserted incorrectly	Insert the contact end of the test strip into the meter until it stops Printed side of strip must be facing toward the front of the meter. Reapply the blood sample.
Sample applied after 3 minutes shut-off	Repeat test with new test strip. Apply sample within 3 minutes of inserting test strip into the meter.
Problems with test strip	Repeat with new test strip. If meter still does not begin testing, call Customer Service at +86-731-89935987.
Problems with meter	Call Customer Service at +86-731-89935987.

3. Without applying sample, test starts (meter beeps (if sound is on) or begins count down)

Reason	Action
Test strip may be wet	Use new test strip and test again.

4. Control test result is out of range

Reason	Action
Error when testing.	Read the instructions of use thoroughly and repeat test.
Control solution bottle is not shaken well before use.	Gently shake the control solution bottle and repeat test.
Use the first drop control solution to test.	Repeat the test with new test strip
Expired or contaminated control solution.	Check the expiration and vial open date of the control solution. Use control solution that is within the expiration and discard dates.

Reason	Action
Control solution temperature exceed 1~30℃, or is substantially higher or lower than the meter temperature	Place control solution at room temperature for 30 minutes and test again.
Test strip error	Repeat the test with new test strip. If meter still does not begin testing, call Customer Service at +86-731-89935987.
Meter error	Call Customer Service at +86-731-89935987.

Information about your Blood Glucose Meter

Comparing Blood Glucose Meter and Laboratory results

The test results obtained from your blood glucose meter may differ from laboratory results due to normal variation. Blood glucose meter results can be affected by factors and conditions that do not affect laboratory results in the same way. See blood glucose test strip package insert for important information on its limitations. To make an accurate comparison between blood

glucose meter and laboratory results, follow the guidelines below.

Before you go to the laboratory:

Perform a Sinocare blood glucose control solution test to make sure that the blood glucose meter is working properly. It is strongly recommended to fast for at least eight (8) hours before doing comparison tests. Take your blood glucose meter with you to the laboratory. You may still have a variation in the results because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medications, or experienced stress.1 In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 70mg/dL (3.9mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test.[2] Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of bodily fluids (severe dehydration) may also cause the blood glucose meter result to be different from a laboratory result.

While at the laboratory:

▶ Make sure that the fingertip blood sample for the blood glucose meter and

the venous blood sample for the laboratory analyzer are drawn within 15 minutes of each other.

▶ Wash your hands before drawing a blood sample.

▶ Only use fresh capillary blood with the blood glucose monitoring system.

Expected Test Results

Please consult your physician for your ideal glucose ranges. The American Diabetes Association (ADA) suggests the following targets for most non-pregnant adults without diabetes. More or less strict goals may be appropriate for each person.

Time	Range
Fasting	< 100mg/ dL (5.55mmol/L)

American Diabetes Association

Diabetes Care. 2021; 44(Suppl.1): S15-S33

Your blood glucose meter is designed to help you and your healthcare professional manage your diabetes. You must always rely on your healthcare professional to interpret your test results and to decide how to treat your diabetes.

Unexpected Test Results

Unexpected test results can occur. If this happens, please refer to the cautions below.

Caution: Low Blood Glucose Test Results

False low results may occur if you are severely dehydrated. If you think that you are severely dehydrated, contact your healthcare professional right away. If your test result is lower than 70 mg/ dL (3.9mmol/L) or "LO" appears on your blood glucose meter screen, this could be a result of hypoglycemia.

Although this result could be due to a testing error, it is best to treat first and retest later. Contact your doctor or healthcare professional right away.



Caution: High Blood Glucose Test Results
If your test result is higher than 200 mg/dL (11.1mmol/L), this could be a result of hyperglycemia. Retest if you are uncertain about this test result. If the result continues to be higher than 200 mg/dL (11.1mmol/L), follow your healthcare professional's instructions or contact your healthcare professional right away.



If "HI" appears on your blood glucose meter screen, this could be a result of severe hyperglycemia (results higher than 600 mg/dL(33.3mmol/L)). Retest your blood glucose. If "HI" appears again, contact your doctor or healthcare profession right away.

If you continue to get unexpected test results, check the performance of your blood glucose monitoring system by performing a Sinocare blood glucose control solution test. Refer to the "Performing control solution test" section in this manual.

Unusual Red Blood Count

A blood sample with extremely high (above 70%) or low (below 10%) hematocrit level (percentage of red blood cells in the blood) can also cause incorrect readings.

Electromagnetic Compatibility

The meter complies with the electromagnetic requirements IEC 61326-2-6: 2020 specified in ISO 15197-2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the meter. Immunity to electrostatic is charge meets the requirements of IEC 61326-2-6: 2020. The meter has been tested for radio frequency interference at the frequency range and test levels specified by IEC 61326-2-6: 2020.

The meter is intended for use in an electromagnetic environment as specified below. And the user of the meter should ensure that it is used in such environment conditions.

Phenomenon	Test value	Compliance level
Radiation emission	Meet Group 1 Class B device limits	Complied
Electrostatic discharge	Air discharge: ±2kV, ±4kV, ±8kV Contact discharge: ±6kV	Air discharge: ±2kV, ±4kV, ±8kV Contact discharge: ±6kV
	Air discharge: ±15kV Contact discharge: ±8kV	Air discharge: ±15kV Contact discharge: ±8kV
electromagnetic fields	10V/m,80MHz~1.0GHz 3V/m, 1.0GHz ~6.0GHz	10V/m,80MHz~1.0GHz 3V/m, 1.0GHz ~6.0GHz
magnetic fields	30A/m,50/60Hz	30A/m,50/60Hz

Caution:

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

2. This equipment is designed for use in a HOME HEALTHCARE ENVIRONMENT (indoor) . 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.
3. A mobile phone should be used no closer than 30 cm to any part of the Blood Glucose Meter.

Explanation of symbols

	Consult instructions for use
	Caution: the user manual must be consulted in all cases where this symbol is marked.
	Storage and transportation Temperature limit
	Manufacturer
IVD	In vitro diagnostic medical device

	Fragile, handle with care
	Keep dry
	Serial number
	Biological Risk
	Authorized representative in the European Community
	CE marking and notify body No.
	Symbol for the marking of electrical and electronics devices according to Directive 2012 /19 / EC . The device, accessories and packaging have to be disposed of waste correctly of waste correctly at the end of the usage, please follow Local Ordinance or Regulatory for disposal.
	Direct current.

Warranty

Changsha Sinocare Inc. provides the following Warranty to the original purchaser of the blood glucose monitoring system:

1. Changsha Sinocare Inc. warrants this meter to be free of defects in materials and workmanship for 10 years from the date of purchase. If during this 10 years period, the meter does not work properly, Sinocare will replace it with a new blood glucose meter or equivalent product free of charge. Failure of the meter due to abuse or use not in accordance with the instructions for use is not covered by this Warranty.
2. This warranty does not include the battery supplied with the meter.
3. Do not take the meter apart. This action will void the warranty and cause the meter to display false results.
4. Changsha Sinocare Inc. disclaims liability for incidental, consequential, indirect, special, or punitive damages for breach of any expressed or implied Warranty, including any implied Warranty of merchantability or fitness for a particular use with respect to the meter. Some states do not allow the limitations of incidental or consequential damages, so the above limitations may not apply to you.

5. This warranty gives you specific legal rights which vary from country to country.

References

1. Guideline for the prevention and treatment of type 2 diabetes mellitus in China (2020 edition). Chin J Diabetes Mellitus, April2021,Vol.13,No.4
2 American Diabetes Association. Glycemic Targets. Diabetes Care 2021; 44 (Suppl.1): S15–S33
3. EN ISO 15197:2015 In vitro diagnostic test systems–Requirements for blood–glucose monitoring systems for self–testing in managing diabetes mellitus

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