Blood Glucose Monitoring System

Blood Glucose Meter User Manual

Safe-Accu 2

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Dear Safe-Accu 2 Meter Owner

Dear Owner:

Sinocare thanks you for choosing the Safe–Accu 2 blood glucose monitoring system. This user manual contains important information about the meter and how it works.

Please read this user manual carefully before using your new meter, or the

protection provided by the meter may be impaired.

If you have any questions, please feel free to contact our Customer Service

If you have any questions, please feel free to contact our Customer Service at +86-731-89935581/+86-731-89935582 or your local dealers.

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Introduction to the Your Blood Glucose Monitoring System

Intended Use

The Safe–Accu 2 Blood Glucose Monitoring System is designed for the quantitative measurement of glucose in fresh capillary whole blood samples taken from the fingertip and in venous whole blood samples. The Blood Glucose Monitoring System is for use outside the body only (in vitro diagnostic use) for self–testing and professional use as an aid in the management of diabetes.

The Safe–Accu 2 Blood Glucose Monitoring System is intended for in vitro diagnostic use and should not be used for the diagnosis of or screening of diabetes.

The Safe-Accu 2 Blood Glucose Monitoring System includes: Safe Safe-Accu 2 blood glucose meter, Safe-Accu 2 blood glucose test strip, blood glucose control solution

NOTE: The blood glucose control solution is optional.

The Safe-Accu 2 meter display blood glucose results in mmol/L or mg/dL. Each meter only displays one unit of measurement. The unit is preset and you can't change the setting. Please confirm the unit before testing.

Test Principle

A blood glucose test is based on measurement of electrical current caused by the reaction of glucose with the reagents (special chemicals) 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 special chemicals and generates electrons, which produce electrical current. The blood glucose meter measures the electrical current and calculates the glucose result. The glucose result is displayed by your meter as mg/dL or mmol/L.

Important Safety Information

- ► For self-testing customer, your Safe-Accu 2 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 and lancing device should be disinfected first.
- ▶ Safe-Accu 2 test strip and lancet are for single use only. DO NOT REUSE.
- ▶ Do not use other test strips and control solutions with the Safe-Accu 2 meter.
- ▶ Do not use the meter if it is not working properly, or there is any damage.
- ▶ Keep the Safe-Accu 2 test strip vial away from children. The strip vial, test strips, and control solution bottles can be choking hazards. DO NOT drink the control solution.
- ▶ Remove the batteries if the meter is not likely to be used for some time.

DO NOT CHANGE YOUR TREATMENT BASED ON A SINGLE RESULT THAT DOES NO MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE FAIRSE

Patient Cautions

- Not for neonatal (newborn or infant) use
- Not for screening or diagnosis of diabetes mellitus.
- Not for use on the critical patients.
- For in vitro diagnostic use only.

Important Health-Related Information

The American Diabetes Association (ADA) suggests the following targets for normal blood glucose range. More or less stringent goals may be appropriate for each person. If your test result is out of the range or your test result is not in accordance with your feeling, retest your blood glucose. If still out of the range, please contact healthcare professional.

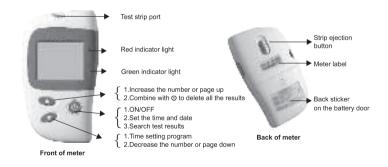
| Expected Results for people without diabetes: | |
|--|--|
| Plasma Blood Glucose Resul | |
| Fasting Plasma Glucose <100 mg/dl (<5.55 mmol/L) | |

FOR Safe-Accu 2 meter:

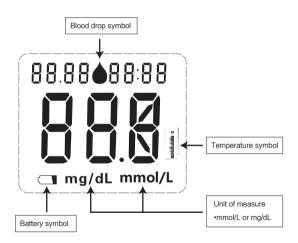
- 1. If test results greater than 600 mg/dL (33.3mmol/L) , the meter will display "HI" , retest your blood glucose immediately with a new test strip. If your reading is still "HI" , contact healthcare professional immediately.
- 2. If test results is lower than 20 mg/dL (1.1mmol/L) , the meter will display "LO" . Retest your blood glucose immediately with a new test strip. If your reading is still "LO" , contact healthcare professional immediately.
- 3. If test result is >70mg/dL (3.9 mmol/L) and $\leq 126 \text{ mg/dL}$ (7.0 mmol/L) , the meter will display the test result with green light on.
- 4. If test result is >126 mg/dL (>7.0 mmol/L) and \leq 250 mg/dL (13.9 mmol/L) , the meter will display the test result.
- 5. If test result is \leqslant 70mg/dL (\leqslant 3.9 mmol/L) or >250mg/dL (> 13.9 mmol/L) , the meter will display the test result with red light on.

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

About Your Safe-Accu 2 Meter



Full Screen Display



Button Functions

| Button | Function | Action | |
|--|---|---|--|
| | To turn the meter on and enter the blood glucose test result review mode. | Press and hold Φ for 3 seconds. | |
| O | To turn the meter off. | Press and hold Φ for 3 seconds. | |
| | To delete the blood glucose test results | In test results review mode, press 𝒪 and 🛦 together to delete all blood glucose test results. | |
| | To confirm date/time settings. | Press and hold ${\tt O}$. | |
| ▲ and ▼ To adjust settings for date-time/ scroll through test results. | | Press and release ▼ or ▲. | |
| ▼ To enter date-time setting mode. | | Press and hold ▼ for 3 seconds. | |

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Setting Up Your Safe-Accu 2 blood glucose meter

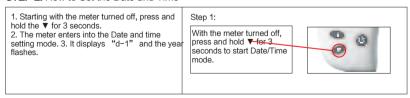
Setup steps for date/time

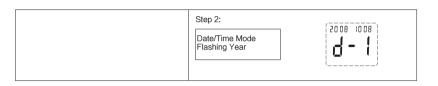
The Safe–Accu 2 blood glucose meter is preset with the date and time. You may need to adjust it to your local time zone. Check the date and time each time the batteries are replaced. Reset the date and time if they are not correct.

STEP 1: Insert the Batteries

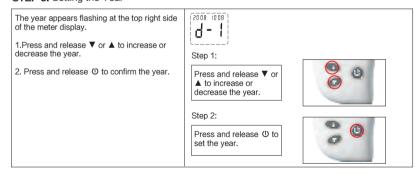
Open the Battery Cover on the back side of the Safe-Accu 2 blood glucose meter. Insert two AAA alkaline batteries as indicated by the "+" and "-" symbols.

STEP 2: How to Set the Date and Time

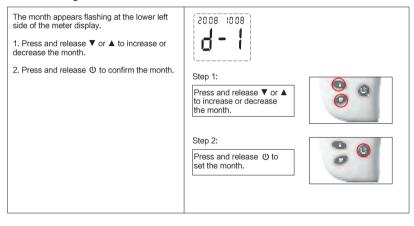




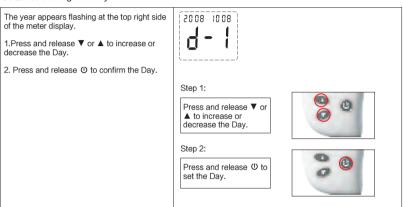
STEP 3: Setting the Year



STEP 4: Setting the Month



STEP 5: Setting the Day



STEP 6: Setting the Hour

The month appears flashing at the lower left side of the meter display.

- 1. Press and release ▼ or ▲ to increase or decrease the hour.
- 2 Press and release (I) to confirm the hour



Step 1:

Press and release ▼ or ▲ to increase or decrease the hour.



Step 2:

Press and release \circlearrowleft to set the hour.



STEP 7: Setting the Minutes

The year appears flashing at the top right side of the meter display.

- 1.Press and release ▼ or ▲ to increase or decrease the minutes.
- 2. Press and release 0 to confirm the minutes.



Step 1:

Press and release ▼ or ▲ to increase or decrease the minutes.



Step 2:

Press and release Φ to set the minutes.



STEP 8

Press and release Θ , the date and time is set and the meter turns off.



Note: Time is displayed in 24 hours format only. If the battery is replaced, it may cause the date and time to reset.

Resetting the date and time does not change the time stamps of previous test results.

Note: Unit of Measure is factory preset to mg/dL or mmol/L. It cannot be changed by the user.

Control Solution Testing

Why Perform a Control Solution Test

- Ensures that your meter and test strips are working properly.
- · Allows you to practice testing without using blood.

When Should You Perform a Control Solution Test

- · When you begin using a new vial of Test Strips.
- · When the vial cap is opened for a long time.
- When Test Strips have been exposed to extreme environmental conditions.
- When you want to check whether meter or test strips are work properly.
- When you drop or broken the meter.
- When you want to check whether the test steps are correct.

Important Information

- Use only Sinocare blood glucose control solution with your Meter.
- Check the expiration date on the control solution bottle. Do not use if expired.
- Use the test strips within a period of 6 months from the date that you first open the vial.
- Record the opened date on the control solution bottle, which is 3 months from when you first open it. Discard the bottle after 3 months.
- Discard any bottle that appears to be cracked or leaking.
- For in vitro diagnostic use only.

Performing a control solution test

Start with the blood glucose meter off. Prepare the following items before control solution test:

- a. blood glucose meter;
- b. blood glucose test strip;
- c. blood glucose control solution

STEP 1: Wash your Hands

Wash your hands with mild soap and water. Be sure to dry your hands before performing a test.

STEP 2: Insert a Safe-Accu 2 Test Strip

Insert a Safe-Accu 2 Test Strip with printing face up and the contact end into the test strip port until it cannot go any further. The blood glucose meter will turn on.

Attention: Only when meter display flashing blood drop symbol "•", can you apply control solution. If there is no blood drop symbol, restart the meter again.

STEP 3: Apply the Control Solution

- 1. Check the expiration date and discard dates on your control solution and Safe-Accu 2 test strip vials. Do not use control solution or test strip which expired.
- 2. Shake the control solution bottle well, then remove cap. Squeeze the bottle and discard the first drop. Squeeze the bottle again to get a second drop and bring the tip of the Safe–Accu 2 test strip to touch the drop of solution until the blood glucose meter beeps. After 10 seconds' count–down, meter will display control solution test result.
- 3. Control test results must be within range of the control solution level printed on test

strip vial label. If the result is out of range, test again. If still so, do not use test strips or meter for blood glucose testing. Call customer service at

- +86-731-89935581/+86-731-89935582 or contact local dealers for help.
- 4. Eject the test strip

Attention: Discard used test strip and control solution according to local regulations.

Keep control solution away from children and pets.

Questionable Results:

| Probable Cause | Action |
|--|---|
| Operation mistake | Retest according to correct steps |
| Control solution not being shaken well | Shake control solution well and retest with a new test strip. |
| Use the first drop of control solution | Retest with a new test strip |
| Expired or contaminated control solution | Change a new vial control solution and retest. |
| Expired or contaminated test strip | Change a new vial test strip and retest. |
| Temperature is too high or too low | Equilibrate meter, test strip and control solution in room temperature for 30 minutes and retest. |
| Meter malfunction | Contact customer service or local dealers |

Blood Glucose Testing

Prepare meter, strip, lancing device and lancet before test.

STEP 1: Wash your hands or use an alcohol swab to clean the fingertip. MAKE SURE YOUR HAND IS DRY BEFORE TESTING.



STEP 2: Unscrew the lancing device cover.



STEP 3: Insert a lancet into the lancing device until it comes to a full stop.



STEP 4: Twist and pull to remove the lancet protector. Retain the lancet protector for safe lancet disposal.



STEP 5: Screw the lancing device cover back on.



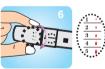
STEP 6: Twist the adjustable comfort tip to adjust the puncture depth.

Tips:

1-2 (least depth) for soft or thin skin,

3-4 (average depth) for average skin,

5 (deepest depth) for thick or calloused skin.



STEP 7: Pull the spring cover back to arm the lancing



The Sinocare lancing device is prepared and ready to lance your finger for a blood sample.

The lancet is for single use only. To prevent the risk of blood borne pathogen transmission, it shall not be shared with other people.

STEP 8: Take a strip out of the strip vial. Immediately close the vial lid.

Attention: Finish test within 3 minutes after take out strip. Otherwise test result may

be inaccurate.



STEP 9: Ilnsert strip into the test strip port. For Safe–Accu 2, meter will turn on. Tips: Insert the strip with the printed side facing up and contact end into strip port. Attention: If blood is not applied within 3 minutes, the meter will automatically turn off. Reinsert the strip and begin test.



If the meter display "E-2", it means the environment temperature is beyond 40° C or below 5° C, Please put the meter, strip, control solution at appropriate place (10° C~ 35° C), wait at least 30 minutes and test again.

STEP 10: Make sure the lancing device is pressed firmly to your finger. Press the button to lance. Attention: If you didn't get enough blood sample, please gently massage your finger. DO NOT SQUEEZE YOUR FINGER. Refer to step 6 to adjust puncture depth and lance again.



STEP 11: When the meter screen displays a flashing blood symbol, apply the blood sample to the reaction chamber.



Attention: Hold the tip of the test strip to the blood drop until the meter beeps. Visually confirm that the blood sample fills the entire reaction chamber at the end of the test strip. Do not move meter or strip and press main button when testing.

If you didn't apply enough blood sample to test strip, use a new test strip to test again.

Caution:

DO NOT smear or scrape the blood onto the Test Strip

DO NOT apply blood to the Test Strip when the Test Strip is not in the test strip port.

Do not use test strip press finger firmly, otherwise it may cause inaccurate test result.

DO NOT put blood or foreign objects into the test strip port.

STEP 12: After a 10-second count down, the meter displays the test result in mg/dL or mmol/L.



If the meter displays "E-3", please read the blood glucose testing section carefully and use a new test strip test again.

STEP 13: Eject the strip.



STEP 14: Remove the lancing device cover. With the lancet protector on the table, stick the needle of the lancet into the protector. Eject the lancet and screw the lancet cover back on.



Used test strip and lancet may be biohazardous. Please discard them carefully according to local regulation requirements.

If the meter is used by multiple people, use 75% alcohol to clean meter surface after testing to avoid pathogen infection.

Viewing test result

After the blood alucose meter counts down from 10, your blood glucose results appears along with the unit of measure. This blood glucose result is stored in the meter memory. Turn the meter off by removing the Safe-Accu 2 test strip. Discard the used test strip carefully to avoid contamination

If test result is above 600mg/dL (33.3mmol/L), the screen displays HI. Use a new test strip to test again. If still display HI, please contact healthcare professional immediately.







If test result is below 20 mg/dL (1.1mmol/L), the screen displays LO. Use a new test strip to test again. If still display LO, please contact healthcare professional immediately.



Attention: The test result of "HI" or "LO" will not store in memory.

Memory

The Safe-Accu 2 meter stores 200 blood glucose test results. You can review the individual results by entering the memory mode. Once 200 results are in memory, adding a new result causes the oldest one to be deleted. It also provides you with 7-, 14- and 28-day averages of your blood glucose test results. Recall the test results in memory with these easy steps.

Step1: Enter the memory mode and reviewing the averages

With the meter is off, press the O button for 3 seconds to turn the meter on. Meter will beep and display the 7-day average of your blood glucose test result.





mmol/L unit

ma/dL unit

Press ▲ once, the screen will display the 14-day average of your blood glucose test result.

Press **\(\Lambda \)** twice, the screen will display the 28-day average of your blood glucose test result.

Press ▲ three times, you will see the last test result displayed.

Press ▼ or ▲ to view all the blood glucose results in memory.

If no test results in memory, the meter will display 3 dashes with beep.

28 d - - - | 14 d

Step2: Delete Memory

How to delete blood alucose test results:

1. Press and hold @ for 3 seconds to turn the meter on. The meter will enter the test results review mode.

Step 1:

Press and hold ① for 3 seconds to turn the meter on and enter the test results

6.8

Test results review mode.

(1 d _ 2)

No test results saved.

2. Press and release ⊕ and ▲ at the same time.

The screen displays 3 dashes and the meter makes a short beep sound at the same time. All stored blood glucose test results are deleted.

Step 2:

Press and release ① and A at the same time.



All stored blood glucose test results are deleted.



Press © button 3 seconds to turn the meter off.

Note: You cannot review your test results when the test strip is in the test strip port.

Information for Healthcare Professional Use

- · Only trained healthcare professional be allowed to use Safe–Accu 2 blood 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.
- 1. Wear disposable gloves.
- 2. Healthcare professional use an alcohol swab to clean lance site. Then be sure dry stick site 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 and lancing device before use on next patient.

Comparing Meter with Laboratory Results

When comparing results between Safe-Accu 2 blood glucose monitoring system and a laboratory system, Safe-Accu 2 blood glucose monitoring system blood tests should be performed within 30 minutes of a laboratory test.

Cleaning and Disinfecting

- · Clean and disinfect meter immediately after getting any blood on the meter or if meter is dirty.
- · If the meter is being used on second person, the meter and lancing device should be clean and disinfected first. Do not clean the meter during the test.

To clean the meter

- 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 liquids enter the test strip port or other opening in the meter.
- 3. Let meter air dry thoroughly before using to test.
- 4. Wash hands thoroughly again after handing meter.
- 5. Verify the meter is working properly by performing control solution test. If your meter can't work properly, please contact customer service at +86-731-89935581/ +86-731-89935582 or contact local dealers

To disinfect the meter

Please according to clinic institution disinfect method to disinfect the meter.

Power Saving

- $\cdot\,$ If there is no blood applied to the test strip within 3 minutes, the meter will automatically turn off.
- After test, the test results will be displayed on the screen with test strip in strip port, If there no operation on the meter within 3 minutes, the meter will automatically turn off.
- · If there is no other operation on the meter within 1 minute, such as enter into test results review mode, the meter will automatically turn off.

Performance Characteristics

Accuracy: 95% test result of Safe-Accu 2 meet the requirement below:

| Concentration Range | | Bias% |
|---------------------|-------------------------|--------------------------------|
| | <5.5 mmol/L (100 mg/dL) | Within ± 0.83 mmol/L(15 mg/dL) |
| | ≥5.5 mmol/L (100 mg/dL) | Within ± 15% |

Precision: test result of Safe-Accu 2 meet the requirement below:

| Concentration Range | Requirement |
|-------------------------|-----------------------------|
| <5.5 mmol/L (100 mg/dL) | SD< 0.34 mmol/L (6.0 mg/dL) |
| ≥5.5 mmol/L (100 mg/dL) | CV<6.0% |

Details please read Safe-Accu 2 blood glucose test strip package insert.

Specifications

| • | | |
|---|---|--|
| Blood volume | 0.6 μ L | |
| Sample type | Capillary whole blood, Venous whole blood | |
| Calibration | Plasma equivalent | |
| Measuring time | 10s | |
| Meter storage/transportation conditions | -20°C~55°C | |
| Dimension | 105*60*23 (mm) | |
| Weight | 77.2g,with battery | |
| Power source | 3V DC,10mA,2 AAA alkaline batteries | |
| Memory | 200 blood glucose test results | |
| Operating condition | 10°C~35°C ≤80% RH | |
| Construction | Hand-held | |
| Measurement units | mg/dL or mmol/L | |
| Measurement range | 20~600 mg/dL or 1.1~33.3 mmol/L | |
| Software Version(mmol/L) | 20160112(A.2.1) | |
| Software Version(mg/dL) | 20141014(A.1.1) | |
| | | |

| Additional features | | |
|------------------------------------|--|--|
| Auto electrode inserting detection | | |
| Auto sample loading detection | | |
| Auto reaction time count-down | | |
| Temperature Warning | | |
| Battery power Warning | | |
| Used test strips Warning | | |

Maintenance

- · 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.
- · Electromagnetic Compatibility (EMC): The meter complies with the electromagnetic requirements IEC 61326–2–6: 2012 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: 2012. The meter has been tested for radio frequency interference at the frequency range and test levels specified by IEC 61326–2–6: 2012.

- · Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation.
- · Avoid dirt, dust, blood, control solution or liquids into the meter test port.
- Do not keep meter in an area where it may be crushed.
- Store blood glucose monitoring system (meter, test strip, control solution) in a dry place.
- · Do not freeze.
- · Do not store in the kitchen or bathroom.

Changing the batteries

Make sure your meter is off when you change the batteries.

Caution: Keep batteries away from children. If the battery is swallowed call healthcare professional immediately.

Step 1: Slide the battery cover out of the meter.

Step 2: Remove the old batteries. Place the new ones in the drawer according to the inner compartment directs of "+" and "-" side.

Step 3: Slide the battery cover back into position until it locks into place.

Troubleshooting

| Display | What it means | What to do |
|---------|--|--|
| Lo | Your result is below the measurement limit, which is less than 20 mg/dL or less than 1.1 mmol/L. | Use a new test strip to test again, if meter still display "LO", call healthcare professional immediately. |
| HI | Your result is above the measurement limit, which is higher than 600 mg/dL or higher than 33.3 mmol/L. | Use a new test strip to test again, if meter still display "HI", call healthcare professional immediately. |
| E - 1 | Low battery power. | Replace the batteries immediately. |
| E - 5' | Meter is out of the required testing temperature range | Move meter, strip and control solution to appropriate place. Wait at least 30 minutes and test again. |

| Display | What it means | What to do |
|------------|---|--|
| | Test method error: insert strip into meter after apply sample to strip. | Insert test strip into meter before apply sample to strip. |
| - - | Used test strip | Use a new test strip to test again. |
| 6-3 | Expired test strip or damped test strip | Use a new test strip to test again. |
| | Test strip exposed to air more than 3 minutes. | Use a new test strip to test again. |
| E-5 | Parameter error. | Call Customer Service at +86-731-89935581/ +86-731-89935582 or contact your local dealers. |

| Display | What it means | What to do |
|---|--|--|
| | Battery is installed incorrectly; | Check that the battery is correctly installed with the right position of sign "+" and "-;" |
| | Low battery power; | Replace the battery; |
| | Test strip is inserted incorrectly or not completely in; | Insert the test strip correctly with the printing facing up and push it into strip port until it stops; |
| Meter does not turn on after inserting a test strip | No display. | Remove the battery, wait for 3 minutes, reinstall the battery. If still no display, call Sinocare customer service at +86-731-89935581/+86-731-89935582 or contact your local dealers. |
| | Test strip port malfunction | Call Sinocare customer service at +86-731-89935581/ +86-731-89935582 or contact your local dealers. |

| Display | What it means | What to do |
|--|---|--|
| | Not enough blood sample | Repeat the test with a new test strip with enough sample |
| Meter doesn't begin test after applying a blood sample | Sample is applied to wrong area of test strip | Repeat the test with a new test strip with blood sample drawn into right area Please refer to "Blood glucose testing" section. |
| | Used test strip | Repeat the test with a new test strip |
| | Test strip exposed in air too long after opening the vial or package | Finish the test immediately after taking out a test strip from a vial or package; |
| | The end of test strip may press too firmly to your finger, blood sample cannot be drawn into test strip reaction chamber; | Use the side of test strip reaction chamber gently touch against the fingertip to draw a drop of blood; |

| Display | What it means | What to do |
|---|--|--|
| Meter displays incorrect test result | The test strip package is damaged, and desiccant tablet becomes soft; the test strip vial open for too long; | |
| | Expired test strip; | Use test strip from a new vial within USE-BY date. |
| | Meter or test strip malfunction | Call Sinocare customer service at +86-731-89935581/ +86-731-89935582 or contact your local dealers. |
| Meter begins to | Test strip may be affected with damp | Use a new test strip to test. |
| countdown after inserting a test strip without sample | Test strip inserted incorrectly or incompletely | Insert the test strips with the arrow side facing up and in the direction of the arrows untio it will go no further. |

| Display | What it means | What to do |
|---|-----------------------|--|
| Test result is "HI" or "LO", but no red light on. | LED light malfunction | Call Sinocare customer service at +86-731-89935581/ +86-731-89935582 or contact your local dealers. |
| Test result is >70mg/dL (>3.9 mmol/L)and ≤ 126 mg/dL(≤ 7.0 mmol/L), but no green light on | | |
| Test result is ≤70mg/dL (≤ 3.9 mmol/L) or >250 mg/dL (>13.9 mmol/L), but no red light on. | | |

If you follow the actions recommended but the problem is not resolved, please contact Customer Service at +86-731-89935581/+86-731-89935582 or contact your local dealers for assistance.

Explanation of symbols

| (i | Consult instructions for use | * | Keep dry |
|-------------|---|--------|---|
| \triangle | Caution | * | Keep away from sunlight |
| -30°C | Storage and transportation Temperature limit | SN | Serial number |
| ••• | Manufacturer | EC REP | Authorized representative in the European Community |
| IVD | In vitro diagnostic medical device | € 0123 | CE marking and notify body No. |
| Ī | Fragile, handle with care | & | Biological risks |
| X | 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 at the end of the usage, please follow Local Ordinance or Regulatory for disposal. | | |

Warranty

Changsha Sinocare Inc. provides the following Warranty to the original purchaser of the Safe–Accu 2 blood glucose monitoring system:

- Changsha Sinocare Inc. warrants this meter to be free of defects in materials and workmanship from the date of purchase. If the meter does not work properly, Sinocare will replace it with a new 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 avoid the warranty and cause the meter to display false results.
- 4. If you meter does not work properly, please fill in warranty card carefully. Use 75% alcohol to clean your meter and send your meter with warranty card to your local dealer.

References

- 1. American Diabetes Association Standards of medical care in diabetes-2016.
- 2. Larsson-Cohn U: Difference between capillary and venous blood glucose during oral glucose tolerance tests. Scand J Clin Lab Invest 36:805–808, 1976

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Thank you for choosing Safe Accu 2 blood glucose meter, a free replacement under normal operation is provided. Please do complete the warranty card and send it back to our agent or our factory. we will inform you with information of the meter. Thank you for supporting our product and us!

Purchase date: ______

Meter No.: _____
(Please reserve this part, and show it when in need)

Appendix 2 Warranty card (returned to producer)

| Name: | Tel: | | | |
|---|------------|--|--|--|
| Age: | Gender: | | | |
| Purchase date: | Meter No.: | | | |
| Zip code: | _ | | | |
| Address: | | | | |
| Purchase place (full name of the agent): | | | | |
| | | | | |
| | | | | |
| Please complete the table correctly, we will provide you with | | | | |
| an excellent after-service. | | | | |