Blood Glucose Meter

User Manual

Please read this manual carefully before using this product. The pictures are for reference only. Please refer to the real objects.

Cofoe Medical Technology Co., Ltd.
Address:No. 87, Section 1 of Huanbao East Road, Yuhua District, 410000 Changsha, Hunan, PEOPLE’S REPUBLIC OF CHINA

Issue date: 2024.08.08 Version: A1

Preface

Thank you for choosing our KF-B06 Blood Glucose Meter (hereinafter referred to as blood glucose meter), KF-B06 Blood Glucose Meter and KF-B06 Blood Glucose Test Strips (hereinafter referred to as test strips) are combined to form a blood glucose monitoring system, which is used to monitor the concentration of glucose in the human body's capillary blood in vitro (usually collected from the fingertip blood), with simple operation, easy to use, and less blood collection, which can help you to control the glucose level better.

In order to measure the blood glucose concentration correctly, please read the instruction manual carefully before using this product.

For further details about this product, please call the after-sales service department

Contents

I. Product Overview 1
1.1 Main product composition structure 1
1.2 Intended use 1
1.3 Detection principle 1
1.4 Specifications 1
1.5 Attentions 2
II. Interface Display and Button Operation 4
2. 1 Display interface 4
2.2 User interface 5
2.3 Standby interface 8
III. Installation and Use Instructions 8
3.1 Use operation 8
3.2 Warning reminders 12
3.3 Special instructions for personal use by consumers 13
IV. List of Accessories 14
V. Inspection System 14
5.1 When to check the system 15
5.2 Glucose control solution check procedure 15
VI. Product Preservation and Maintenance Methods 17
6.1 Daily maintenance of the product 17
6.2 Common faults and troubleshooting methods 17
VII. Explanation of Symbols 18
VIII. Blood Glucose Reference Interval 19
IX. References 19
Warranty Card 20

I. Product Overview

1.1 Main product composition structure

Products include mainframe and accessories.The main unit is a blood glucose meter, which consists of a circuit board, shell, button, display, battery, Bluetooth chip, and embedded software.

1.2 Intended use

This product is used with matching Blood Glucose Test Strip for in vitro monitoring of glucose concentration in human capillary whole blood (generally collected fingertip blood), which can be used by professionals, non-professionals with diabetes and their families, who are skilled in this operation, for blood glucose monitoring at home or in medical units. The product is only used to monitor the effect of blood glucose control in diabetic patients, and cannot be used for the diagnosis and screening of diabetes or as a basis for adjustment of therapeutic drugs.

1.3 Detection principle

The reaction area of the blood glucose test strip is fixed with special chemicals, the glucose in the blood sample comes into contact with it and a chemical reaction occurs to produce a micro-current, which is detected by the blood glucose meter and converted into a blood glucose concentration result that is displayed.

1.4 Specifications

Model	KF-B06
Power supply	2 x 1.5V AAA batteries
Dimension	61.0mm×90.3mm×24.0mm
Maximum volume at work	70 dB
Memory capacity	600 sets of test values
Environmental conditions for meter use	Temperature 5℃～40℃, relative humidity 10%～80%RH
Environmental conditions of meter storage	Temperature -20℃ ～ +55℃, relative humidity 10% ～ 90%RH
Environmental	Temperature 10℃～37℃, relative humidity10%～90%RH

conditions for test strip use	
Measurement range	1.1mmol/L～33.3mmol/L(20mg/dL～600mg/dL)
Blood glucose measurement time	5 seconds
Accuracy	Allowable deviation does not exceed ± 0.83 mmol/L (±15 mg/dL) at glucose concentrations < 5.55 mmol/L (<100 mg/dL),or; Allowable deviation does not exceed ± 15 % at glucose concentrations ≥ 5.55 mmol/L(≥100 mg/dL).
Precision	Standard deviation SD< 0.42 mmol/L (7.7 mg/dL) for glucose concentration <5.55 mmol/L (<100 mg/dL). Coefficient of variation CV< 7.5% for glucose concentration ≥ 5.55 mmol/L (≥ 100 mg/dL).
Date of production	See body nameplate or outer packing
Service life	5 years

1.5 Attentions

1.5.1This blood glucose meter can not be used for diabetes diagnosis or blood glucose monitoring of newborns.

1.5.2 Diabetes treatment and blood glucose monitoring through this product must be conducted under the guidance and assistance of professional medical personnel. Do not interrupt or change your diabetes regimen solely on the basis of measurements made with this product.

1.5.3 Please keep the blood glucose meter and measuring instruments away from children. To prevent small objects such as battery cap, battery, test strip, and blood lancet, and lancet cap from being swallowed by mistake.

1.5.4 Users can only use the blood glucose meter in accordance with the purpose described in the instruction manual.

1.5.5 Only use matching blood glucose test strips provided or recommended by the manufacturer, otherwise incorrect measurement results will result.

1.5.6 If the blood glucose meter does not work properly or has been damaged due to collision, drop, water, etc., do not use the blood glucose meter until the fault is

removed; if the blood glucose meter has a fault that cannot be removed even by the method provided in the instruction manual, please contact the sales or manufacturer to solve the problem, and do not disassemble it by yourself.

1.5.7 The matching test strip adopts the reaction system of the glucose dehydrogenase method, and there are no interfering substances to affect the measurement results under normal diet and normal treatment. The test may be interfered when blood samples contain abnormally high concentrations of acetaminophen, ascorbic acid (vitamin C), dopamine, uric acid, mannose ⩾ 250 mg/dL, xylose ⩾ 6.25 mg/dL, and hematocrit in excess of 30% to 55%. Test strips have limitations such as expiration date, storage temperature and humidity, etc. Please use and store the test strips in accordance with the instructions for use.

1.5.8 In order to avoid unexpected factors affecting the test results, please do not use the blood glucose meter in moving transportation or noisy environment, and use it in an environment with stable temperature and humidity.

1.5.9 In order to reduce infection, wash your hands with soap or warm water before blood lancing, disinfect the blood lancing site with 75% medical alcohol, and wait for the alcohol to evaporate and dry before tying the lancet for blood lancing, and cannot be disinfected with iodine.

1.5.10 The blood glucose meter uses disposable sterile blood lancets, do not share the lancets or blood lancing device with others, and check whether the lancets or blood lancing device are new and sterilized every time you measure blood glucose.

1.5.11 Please properly dispose of used test strips, blood lancets and medical alcohol wool, etc., and dispose of them properly according to the relevant local laws and regulations to avoid cross infection and disease transmission.Please dispose of replaced batteries properly in accordance with local laws and regulations to avoid harm to the environment.

1.5.12 Keep the meter as far as possible from sources of interference, such as: cell phones, computers, induction cookers, etc.

1.5.13 Remove the battery when the meter is not used for a long time.

1.5.14 Do not put the meter into any liquid.

1.5.15 Do not use the expired test strips.

1.5.16 The meter mainly detects fingertip blood and is not suitable for other types.

1.5.17 Avoid bumping as much as possible when using the meter to avoid affecting

1.5.18 During testing, the meter may come into contact with blood. Therefore there is a risk that used meter may carry infectious materials. When this meter is used in a medical setting, health care workers should follow your facility's appropriate infection control procedures for sanitation equipment, such as wearing gloves or other personal protection.

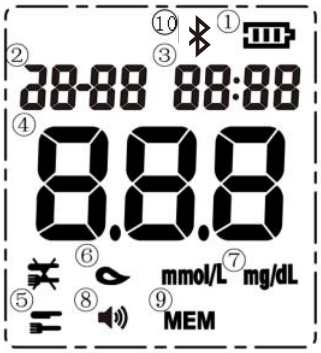
1.5.19 Before unpack,please confirm if the package is damage.

1.5.20 After unpacking,please check if accessory is complete according to packing list of specification.

II. Interface Display and Button Operation

2. 1 Display interface

After installing the batteries, the meter automatically turns on and displays the full-screen interface:



Full-screen interface description:

1.Battery symbol

2.Date

3.Time

4.Measurement result

5. Pre- and post-meal signs

6. Cue test strip blood-sucking symbol

7.Measurement unit of blood glucose, there are mmol/L and mg/dL (1mmol/L=18mg/dL)

8.Sound

9.Historical record

10. Blue-tooth

After you install the battery or replace the battery, the full display interface will be displayed for about 2 seconds, and then the version number will be displayed, such as 1.0. Press the "M" button in standby mode to power on, and then long press the "C" button to enter the setting mode.After entering the setting mode, the following interface will appear, when the number starts flashing, it means you can reset the value.

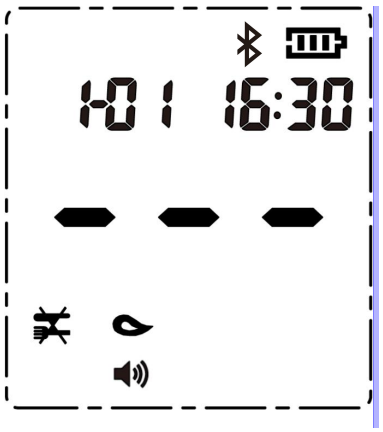
Detailed setup steps are as follows:

Press the "M" button to power on, then long-press the "C" button to enter the setting mode.The setting sequence is: year, month, day, hour, minute, unit, voice function switch setting and history clearing interface.When the four digits indicating the year 2020 begin to flash, press the "M" button to increase the number of years. Press the "M" button once, the year will be increased by 1, and when it is increased to 2050, it will automatically return to 2020.After setting the year, press the "C" button to enter the month setting. Press the "M" button to add 1 to the month and return to 1 when reaching 12.After setting the month, press the "C" button to enter the setting of the day.And so on set the day, hour and minute.After setting, press "C" to enter the unit setting. The system units are mmol/L and mg/dL.Press the"M" button for unit selection.After setting, press "C" to enter the voice function switch setting interface, and press "M" to select "ON" or "OFF ".Then press the "C" button to enter the delete memory mode. Long-press the "C" button to delete all historical data. After deleting, the display will show "---" and shut down after 5 seconds; if you don't want to delete the history data, press "C" to skip the settings and it will automatically save all settings and shut down.

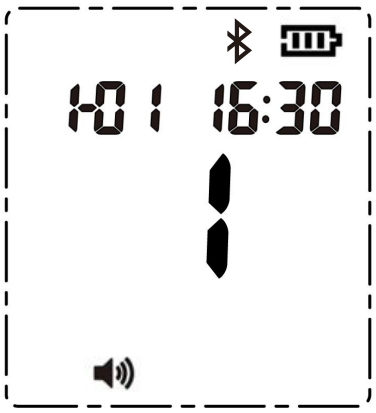
2.2 User interface

In standby mode or after pressing the "M" button to turn on the device, insert the test strip and the device will display a blood drip reminder interface. As shown in the figure below, the top row of values indicates the date and time, the bottom left

indicates the postprandial measurement (pre-meal and post-meal can be selected by pressing the "M" button), and the bottom middle blood drip symbol flashes to indicate the need to immediately drop blood into the blood suction port of the test strip.



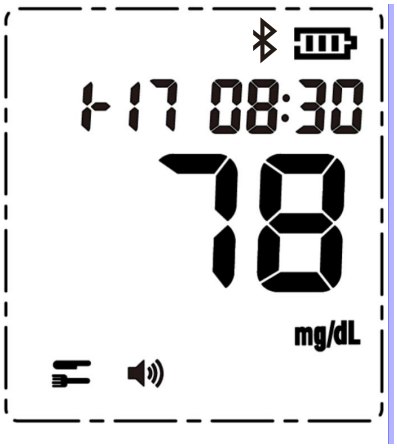
After dropping the blood, the meter displays the countdown interface and the test result is displayed after the number changes to 1.



The result display screen is as follows:

indicates that on January 1, the test result was 4.2 mmol/L at 16:30 before the meal.

indicates that on January 17, the test result was 78 mg/dL at 8:30 after the meal.

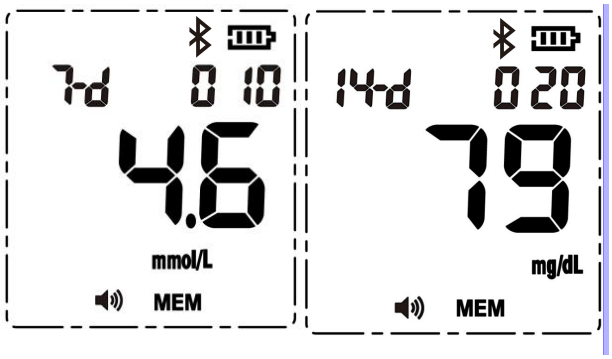


The test results are automatically stored in the meter after displayed.The test results will also be communicated to you by voice broadcast when the sound is not shut down.

Press the "M" button in standby mode to enter the historical measurement data query mode. Press the "M" button, the latest test result will appear, then press the "M" button, the average value of 7 days will appear, then press the "M" button, the average value of 14 days will appear, the fourth press the "M", the average of 28 days will appear. (If the blood glucose meter is used for the first time, "---" indicates that no measurements have been made in memory.) These mean values were calculated from blood glucose measurements for the first 7,14, and 28 days.

After the 28-day blood glucose value is displayed, press the "M" button again, and the latest measurement result with date and time will be displayed. And so on, until you achieve the results you want to view. This meter can automatically store 600 test data. If the blood glucose meter is used for the first time, "---" indicates that no measurements have been made in memory. During viewing, you can press the "M" button for a long time to exit the query.

The following figures show that the average value of 10 measurements in the last 7 days is 4.6 mmol/L, and the average value of 20 measurements in the last 14 days is 79 mg/dL.



2.3 Standby interface

The standby interface is the interface when the meter is powered on, but there is no display on the meter screen. In standby state, you can enter the measurement mode by directly inserting test strip, or you can enter the data query mode by directly pressing the "M" button.

III. Installation and Use Instructions

3.1 Use operation

3.1.1 Installing the battery

The blood glucose meter requires two AAA batteries, and the two batteries can support 1000 times of testing. The device has a power-saving function design, when the blood drop state, about 3 minutes without operation then the meter automatically shut down. During the period, every minute there is a voice announcement: "please apply blood into the test strip", At the third minute,the voice prompt "Insufficient blood, please try again.See you" and then automatically shut down. When other interface state, about 1 minute without operation then the meter automatically shut down.

Install the battery as follows:

a) Push open the battery cover on the back of the meter;

b) Put in two AAA batteries according to the correct positive and negative direction；

c) Install the battery cover.

Attentions:

a）When the battery symbol “E-b” appears on the meter,warning and reminder of low power, please replace the battery as soon as possible；

b）If the meter is not used for a long time, please remove the battery;

c）Do not use inferior or expired batteries to avoid measurement errors;

d）Disused batteries should be disposed of in accordance with local environmental regulations.

3.1.2 Settings

After a new battery installation or battery replacement, if the user needs to set the time and test unit of the meter, see 2.1 for detailed setting procedures.

3.1.3 Testing

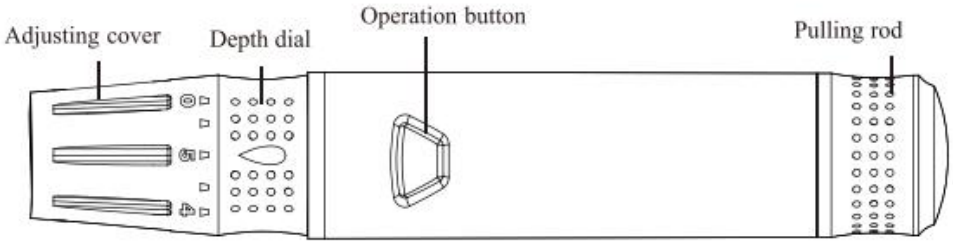
a) After taking a test strip out of the test strip jar, please cover the jar tightly immediately. (Note: Test strip is used quickly after removal.)

b) Insert the electrode end of the test strip (face up) into the test port of the meter and the meter will turn on automatically;If it is already on, please insert the test strip into the meter until the test is finished.

Note: If the test strip is removed from the jar for too long, an error message will be displayed after inserting this test strip into the meter, please remove and properly discard this test strip and use a new test strip for testing.

c) Wait for the blood drop symbol to be displayed on the meter screen.

d) At the fingertip, take a blood sample with a lancing device (structure diagram below.) and collect blood as follows:



Lancing device

(The pictures are for reference only. Please subject to the real objects.)

--- You wash your hands and wipe the blood lancing site with 75% alcohol before collecting blood with your fingertips and then allow it to dry completely.

--- Rotate to remove the tip of the lancing device, install the lancet inside the device and remove the lancet safety cap, then rotate to tighten the tip of the lancing device.

--- Adjust the depth dial to set the corresponding blood lancing depth according to the roughness of the epidermis of the lancing site.

--- Put the tip of the lancing device at your fingertips for blood sampling, hold the pen body and the lever with both hands and pull it back to make a "click", indicating that the setting is complete, aim the lancing device tip at the sterilized blood sampling site, and press the button , ready for blood lancing.

--- For better access to the blood sample, lower your hand to waist height, gently massage your fingers from palm to fingertips, please let the blood sample form on your fingertips first, wipe off the first drop of blood, gently press out the second drop of blood (do not squeeze too hard), and then add the drop to the aspirating end of the test strip.

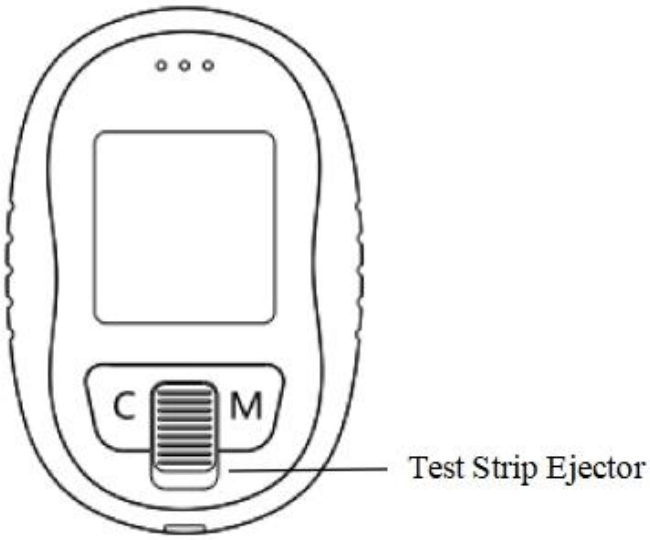
Note: The aspiration process should be completed at once. If there is not enough blood and the blood does not fill the reaction chamber at once, the test should be repeated with a new test strip.

--- When the test is complete, remove the blood collection lancet and discard it in an appropriate container.

e) Bring the edge of the collection end of the test strip that has been inserted into the meter into contact with the blood, the blood will be automatically drawn into the test strip and the meter will automatically start counting down after the blood aspiration is completed.

f) After the test is completed, the test result will be displayed on the meter screen.

g) Push the test strip ejector(The pictures are for reference only. Please subject to the real objects) to exit the test strip and discard it properly. The meter is turned off, and the test result information is automatically saved in the meter. (Note: If the test strip is removed during the countdown, the test will be canceled and the test result will not be saved.)



3.1.4 Querying the results

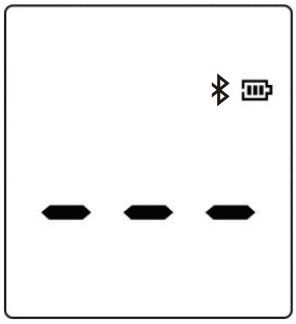
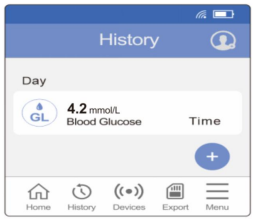
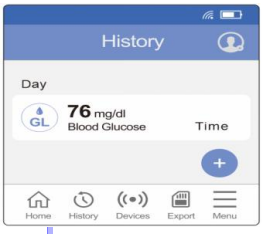
You can enter the query mode after the blood glucose meter is turned off or after finishing the measurement. See 2.2 for details of the query procedure.

3.1.5 Bluetooth data transmission function

The product has the ability to transmit your various test results to your mobile device via Bluetooth (your mobile device will need to have the Blood Glucose Management app installed.)

3.1.5.1 Steps

Steps and Descriptions	Illustrations

1. pair your mobile device with the blood glucose meter (The first time you use the Bluetooth function) a) When the meter is turned on, the Bluetooth function is turned on and the Bluetooth symbol of the meter blinks to remind the user to pair or connect with the meter. b) the Bluetooth symbol is always on if the connection is successful. Note: The glucose meter would automatically turn off the Bluetooth function and the Bluetooth symbol would go out when the mobile device fails to connected with the meter in one minute.	
2. upload the results When the glucose meter and the mobile device are successfully connected, the glucose meter will actively upload the results of each test to the mobile device Note: the meter will also automatically upload historical results that have not been uploaded before to the currently paired mobile device, as well as the historical query results.	 

3.1.5.2 Attentions

The glucose meter can only be paired with one mobile device at a time; when you pair a new device, new data will only be transferred to the new device, and old data can only be viewed on the old device.

3.2 Warning reminders

Display	Cause	Measure

	Test strips have been used or have become damp.	Do not insert used or damp test strips for reuse
	Blood glucose value above 33.3 mmol/L (600 mg/dL)	Please re-test, if the result is the same please contact the dealer or customer service center
	Blood glucose value below 1.1 mmol/L (20 mg/dL)	Please re-test, if the result is the same please contact the dealer or customer service center
	Voltage is too low	Please replace the batteries
	Abnormal room temperature	Move to room temperature 5℃ ~40℃ for operation.

3.3 Special instructions for personal use by consumers

3.3.1 Cover the test strip bottle cap immediately after taking out the test strip to avoid moisture and light affecting the unused test strip.

3.3.2 The test strip is a disposable product, please do not reuse it.

3.3.3 Electromagnetic compatibility

⚠ **Precautions：**

- Blood Glucose Meter meets the emission and immunity requirements specified by IEC61326-1 and IEC61326-2-6.
- It is recommended to evaluate the electromagnetic environment before using the equipment.

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

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

NOTE 3:The calculation formula to determine the separation distance between an

IVD MEDICAL EQUIPMENT and a mobile phone is given by d = 6/E ·√P, where d is the minimum separation distance in metres, P is the maximum power in watts, and E is the immunity test level in V/m.

⚠**Warning：**

- 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.

IV. List of Accessories

The sales unit of this product mainly includes the following items:

Item	Quantity
Blood glucose meter	1
Instruction manual	1
1.5V AAA battery(optional)	2
Storage bag	1
Lancing device(CE-marked, optional)	1
Lancet(CE-marked, optional)	/
Blood Glucose Test Strip(optional)	/
Glucose Control Solution(optional)	/

Test strips, blood lancet, blood lancing device, battery and control solution may not be included in the package. They can be purchased separately.

V. Inspection System

Glucose control solution is used as a test for control of the blood glucose testing system to ensure that the blood glucose meter and blood glucose test strips are working properly and that the user is testing the steps correctly. Regular system checks will ensure that the meter provides accurate test results.

You can contact customer service through your local distributor or by calling the hotline to obtain the quality control solution.

Note: Only blood glucose control solution manufactured by our company can be used.

5.1 When to check the system

When using a new bottle (box) of blood glucose test strips.

When the cap of a bottle of blood glucose test strips is open for a long time.

When you want to check whether the meter or blood glucose test strips are working properly.

When the temperature of the blood glucose test strip is outside the normal storage conditions.

When the meter is dropped or damaged.

When your blood glucose measurement result is not consistent with your self-perception.

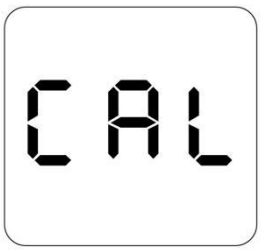
When you want to check whether your measurement procedure is correct.

5.2 Glucose control solution check procedure

5.2.1 Material preparation: Equilibrate the glucose control solution, blood glucose meter and blood glucose test strip at room temperature for at least 30 minutes.

Note: Please read the instruction manual of the control solution carefully and know the precautions for using the control solution.

5.2.2 Set the meter mode, long press the “M”button for more than 3s in standby state, “CAL” (as shown below) appears and the meter will announce the voice "Please wait.Enter calibration mode".



5.2.3 Take out the test strip and insert the blood glucose test strip into the insertion port of the meter, ready for use.

5.2.4 Inhale the control solution: Shake the control solution bottle moderately and

squeeze out the first drop of control solution and discard it. Squeeze out the droplet again and put the suction end of the test strip in contact with the droplet, the control solution will be automatically sucked into the reaction chamber of the test strip. When the meter emits a "Testing" tone, it indicates that the inhalation of the control solution is completed, and the meter automatically enters the countdown timer to start the test.

5.2.5 The blood glucose meter will automatically complete the test and display the test result on the meter display. When the test result is within the control range indicated by the test strip, it means that the meter and the test strip are working normally; if the test result is outside the range, please retest with a new test strip.

5.2.6 When the test is finished, push the test strip ejector to back the test strip.

Note: Please dispose of the used test strips and control solution according to the medical waste.

Cause	Measures
Wrong measurement operation	Re-measure strictly according to the operation procedure
Failure to shake the control solution well	Re-measure with a new test strip and shake well the control solution before testing
When testing, use the first drop of control solution after opening the bottle	Re-measure with a new test strip
Expired or spoiled control solution	Change a bottle of well-stored control solution within the expiration date and re-measure
Test strip expired or deteriorated	Replace the test strip with a new bottle (box) and measure again
Temperature of meter, test strip, control solution is too high or too low	Equilibrate the three at room temperature for 30 minutes, then re-measure
Meter malfunction	Please contact your distributor or customer service center

Note: If the test results are outside the control range, after doing the analysis of the reasons as above and taking the measures as above, the test results are still outside

the control range, the test system may not work properly, please do not test for the time being and contact your local distributor or customer service center.

VI. Product Preservation and Maintenance Methods

6.1 Daily maintenance of the product

The blood glucose meter may be contaminated by blood samples and other substances in the process of use, you can wipe it with a softer material such as cotton cloth dipped in water to keep it clean. Don't wipe the outer surface of the blood glucose meter with liquid other than water, don't let any liquid, dirt, dust, blood enter the blood glucose meter through the measurement port or data port, and don't try to make any disassembly, repair or modification to the blood glucose meter.

When moving (remotely carrying) the blood glucose meter, it should be placed in the box or in other protected state to avoid damage to the meter by collision, drop, moisture and water, strong shock, etc.

6.2 Common faults and troubleshooting methods

6.2.1 After inserting test strip, the blood glucose meter does not start:

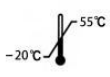
Possible causes	Measures
The test strip is not inserted correctly	Remove the test strip and reinsert it correctly
The test strip is not fully inserted	Remove the test strip so that the test strip is fully inserted again
The test strip is damaged	Use a new test strip for insertion
Meter power is low	Replace the batteries
The battery is placed in the wrong direction	Swap the positive terminal of the battery and load it again
The blood glucose meter or test strip is faulty	Please call customer service for assistance

6.2.2 The blood glucose meter did not start counting down after the blood sample was drawn:

Possible causes	Measures
Insufficient blood sample	Replace test strips with new ones and provide sufficient blood samples for retesting
Operation time exceeds 3 minutes and the meter has been turned off	Repeat the test with a new test strip. Inhale the blood sample only when the blood drop symbol is displayed on the screen
Problems with test strips	Test with a new test strip
Blood glucose meter is faulty	Call customer service for assistance

VII. Explanation of Symbols

The following symbols will appear in the blood glucose meter and its packaging, and the meanings of these symbols are as follows：

	In vitro diagnostic *medical device*
	Caution
	*Serial number*
	Keep away from sunlight
	Consult *instructions for use*
	Temperature limit
	Direct Current

	*Manufacturer*
	Fragile, handle with care
	Keep dry
	Symbol for the marking of electrical and electronics devices according to Directive 2012 /19 / EU . 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.

VIII. Blood Glucose Reference Interval

The normal fasting blood glucose levels of a non-diabetic adult are approximately 3.0 to 6.1 mmol/L. A criterion for judging whether adults have diabetes is to determine their fasting blood glucose level of 7.0 mmol/L (126mg/dL) or higher through two tests.

Please consult your physician about your ideal blood glucose range for details.

IX. References

1.American Diabetes Association. Glycemic Targets. Diabetes Care 2017 Jan; 40 (Supplement 1): S11-S24.

2. EN ISO 15197:2015 In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

Warranty Card

Customer Name		Contact Number	
Model Number		Date of Purchase	
Product Number		Dealer Seal	

Note: 1. This machine from the date of purchase, with the purchase invoice and warranty card to enjoy a two-year replacement, lifetime warranty.

2. Free warranty service will not be provided for failures caused by

a) unauthorized disassembly, modification of the product;

b) the lack of reasonable maintenance;

c) failure to operate in accordance with the correct instructions in the instruction manual, etc;

d) improper repair by non-authorized repair points, etc.

3. Reasonable charges will be made for repair services outside the scope of the warranty.

4. When requesting service, please contact the dealer.

5. When warranty service is performed, product circuit diagrams and information on repairable components may be provided to qualified technicians identified by us, if required.

Receipt Card（Kept by Dealer）

Product Model	
Product Number	
Date of purchase	
Customer Information（Dealer Seal）	
Customer Name	
Contact Number	

We reserve the right to make product improvements and changes are subject to change without notice.