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**yuwell**

Blood Glucose Meter  
Specification model: 710

User's Manual

Please read the operating instructions carefully!  
See certification of quality or packaging for production date



In vitro diagnostic products



## Welcome to use Yuwell series blood glucose meter

The scope of application: This blood glucose meter is matched with Yuyue blood glucose test strip (Y330) produced by Jiangsu Yuyue Medical Equipment & Supply CO., LTD.. It is used to measure the glucose concentration in capillary whole blood in hospitals and homes.

## Important information, please read first

Before using this product, please read this instructions in detail to ensure safe use and accurate detection. Note:

- This product is only used for blood glucose testing and can only be used to test blood glucose levels in fingertip fresh capillary whole blood. It cannot be used for the determination of plasma and serum.
- No contraindications.
- This product cannot be used for the diagnosis of diabetes or rapid blood glucose testing in newborns.
- This product cannot be used for any other test than blood glucose testing.
- The intended users of this product include professional medical staff and lay person.
- The treatment plan cannot be changed based on the test results without consulting the doctor or the diabetes expert.

- Please use the meter in a manner specified by Yuwell, or the protection provided by the meter may be impaired.
- To use this glucose meter properly for daily care of diabetic patients, consult your doctor or diabetes care specialist.
- Please check whether the packaging of the meter is complete and whether it is damaged due to transportation.
- Please use the instrument in accordance with the manufacturer instructions, otherwise, the user should be responsible for the risk.

Chapter 1: System Overview	
Description.....	01
Intended use.....	02
Blood glucose test strip.....	05
Chapter 2: Preparation for Use of Blood Glucose Meter	
Battery installation.....	06
Mode setting.....	07
Chapter 3: Testing Blood Glucose	
Use of blood sampling pen.....	10
Blood glucose test strip and meter preparation.....	14
Test of blood glucose.....	16

Chapter 4: Memory Function	
Display records.....	18
Check records.....	18
Clear records.....	20
Chapter 5: Quality Control Detection and Icon Settings	
Quality control detection.....	23
Control solution icon settings.....	24
Chapter 6: Storage and Maintenance	
Storage and maintenance.....	25
Chapter 7: Technical Parameters and Reference Standards	
Technical parameters.....	27
Reference standards.....	30

Chapter 8: Self-monitoring Time, Monitoring Frequency and Control Objectives of Blood Glucose	
Self-monitoring time of blood glucose.....	32
Self-monitoring frequency of blood glucose.....	33
Control objectives of blood glucose.....	34
Chapter 9: Other Information	
Precautions.....	35
The symbols and meanings of the safety requirements in this unit.....	36
Common troubles and elimination methods.....	38
Other common problems.....	41
Index.....	44

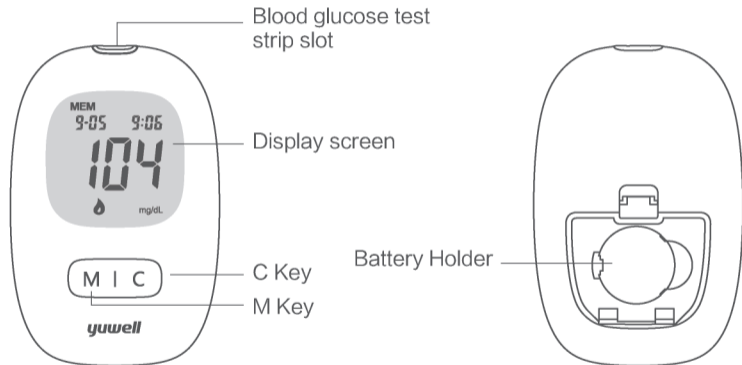
## Description

This product may contain the following contents: Blood Glucose Meter (Model: 710), user manual, a blood sampling pen, a 3V CR2032 lithium–manganese battery, certification of quality.

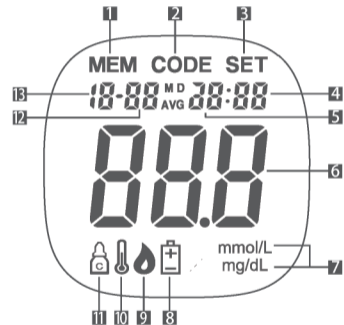
In order to use this product, users may also need to purchase the following products that complied with European Union regulations and standards: Blood glucose Strip (Model: Y330), yuwell blood glucose control solution, lancets.

## Intended use

- The yuwell 710 blood glucose meter is intended for use in quantitative measurement of glucose in human whole blood taken from the fingertip (capillary). It is intended to be used by lay person or clinical site by medical staff.
- This system is in vitor diagnostic medical device for self–testing.
- The yuwell 710 blood glucose meter can only used with the yuwell Y330 blood glucose test strip.
- The yuwell blood glucose control solution is used with the yuwell 710 blood glucose meter and Y330 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.



Full-screen display: the blood glucose meter will display the following content after booting



1. Display the storage result
2. Display the calibration code
3. In the setting state
4. Display minutes
5. Display hours
6. Display the test value
7. Unit of measurement
8. Low battery icon
9. Blood icon – add blood into the strip
10. Temperature icon
11. Control solution icon
12. Display the date
13. Display the month

Note: The unit of measurement is preset as mg/dL or mmol/L before leave factory, user can not change.

### Blood glucose test strips

This product uses electrochemical principle. The blood glucose test strip is inserted into the blood glucose meter. When the blood droplets come into contact with the blood inlet port of the blood glucose test strip, blood will automatically siphon into the reaction zone. The Glucose oxidase catalyzes the redox reaction of glucose in the blood, resulting in a micro current, and the glucose concentration value (mg/dL or mmol/L) is calculated and displayed by the blood glucose meter, and then stored.



### Battery installation

1. Open the battery back cover.
2. Insert the battery with the positive pole facing upward.
3. Close the battery back cover and installation is complete.



Note: The Meter is powered by a 3V CR2032 lithium–manganese battery, which can be purchased and replaced by the user.

## Mode setting

## Entering into the mode setting

1. Enter when the battery is newly installed or replaced.
2. Press the C key for 3 seconds to enter mode setting in power off state.



## Date and time settings

1. The year flashes, press M key to set the year (this unit only displays the last two digits of the year, i.e., 20=2020), press C key to confirm the year and switch to the month setting.
2. The month flashes, press M key to set the month, press C key to confirm the month and switch to date setting.
3. The date flashes, press M key to set the date, press C key to confirm the date and switch to the hour setting.



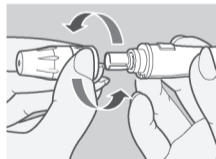


4. The hour flashes, press M key to set the hour (this unit uses the 24-hour clock), and press C key to confirm the hour and switch to the minute setting.
5. The minute flashes, press M key to set the minute, and press C key to confirm the minute.
6. There is no operation in the setting state. After 30 seconds, the blood glucose meter turns off.

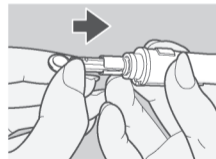


### Use of blood sampling pen

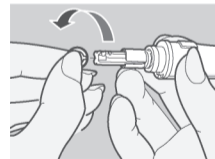
1. Unscrewing the cap of the blood sampling pen.  
(or Transparent protective cover)
2. Put the lancet and push the lancet to the bottom of the blood sampling pen holder.
3. Twist the protection cap from the lancet. Never throw away the protection cap (see procedure 9: Processing instructions after sampling blood).



1

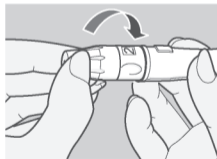


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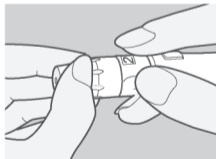


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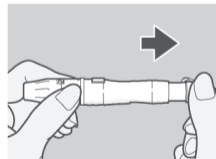
4. Install the blood sampling pen cap.
5. Adjust blood sampling depth. Recommended depth 2, users with thicker skin can adjust deeper appropriately.
6. Pull the handle of the blood sampling pen backward and let it open after hearing the clicking sound. At this point, the blood sampling pen is ready. (Please take blood immediately when the meter is ready and prompts blood collection.)



4

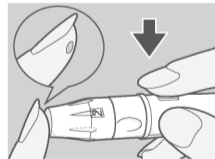


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6

7. Place the top of the prepared blood sampling pen on the part where the blood is to be collected and press the ejection button to collect the blood. Take away the blood sampling pen after the completion of blood collection.
8. When taking finger tip blood, it is recommended to wipe off the first drop of blood, and use the second drop.



7



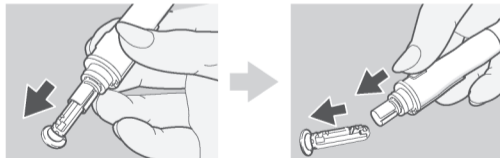
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Before blood collection, please wash your hands with soap and warm water and dry thoroughly.

## 9 Properly dispose of used blood sampling needles:

Unscrew the blood sampling pen adjustment cap, and cover the used lancet tip with a protection cap to prevent the lancet tip from being exposed. Push the unloading push rod forward and place the used lancet in a waste container.

Note: The blood sampling pen is limited to one person and cannot be used by multiple people. The lancet is only for single use, please do not re-use.




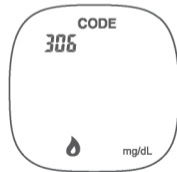
9

## Blood glucose test strip and meter preparation

1. Insert the test strip into the slot of the blood glucose meter and push the test strip to the end. (Trademarks facing upward, black stripes facing forward)
2. After hearing the beep, the blood glucose meter automatically turns on and displays the code. Check whether the code on the test strip bottle is consistent with the code displayed on the blood glucose meter. When the two codes are inconsistent, please test with another new test strip. If the codes are still inconsistent, please contact Yuwell customer service staff.



3. The blood droplet symbol  flashes on the screen to prompt blood collection. At this time, the date, time and code flash on the screen alternately.



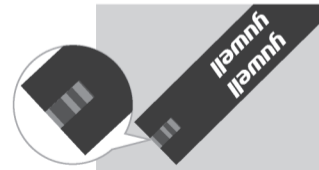
Note: the detection process should be completed within 3 minutes. The meter will automatically shut down without operation within 3 minutes.

### Test of blood glucose

1. Lightly touch the blood inlet port with blood sample, and blood droplets will be automatically sucked. Do not drip blood on the test strip.



2. Confirm that the blood volume is sufficient. We can observe that the color of the entire test strip reaction zone becomes darker.



Note: The test strip is only for single use, please do not reuse and split it.

3. The screen displays the blood glucose test results for 8 seconds. Do not shake the instrument and remove the strip while measuring and counting down.



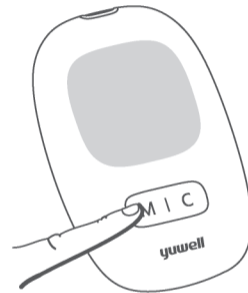
4. After obtaining the test results, pull out the test strip. The meter will automatically store the measurement results and shut down.

### Display records

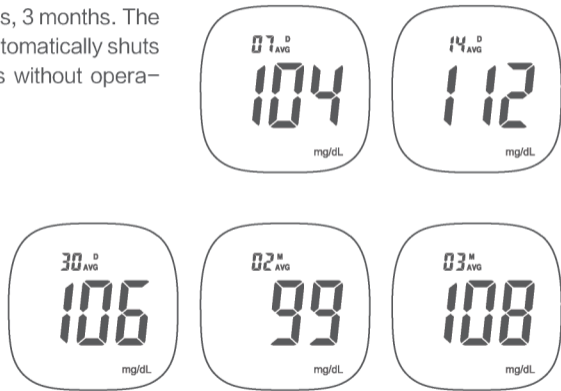
In the off state, press M key, the screen displays the latest test results. Press M key again to display all test results in sequence. The blood glucose meter automatically shuts down after 15 seconds without operation.

### Check records

- Check the test averages for the last 7 days, 14 days, 30 days, 2 months, and 3 months.
- Hold down M key for 3 seconds in the off state to display the average blood glucose for 7 days. Press M key again to display the average blood glucose for 14



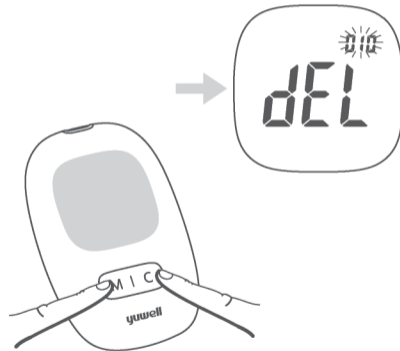
days, 30 days, 2 months, 3 months. The blood glucose meter automatically shuts down after 15 seconds without operation.

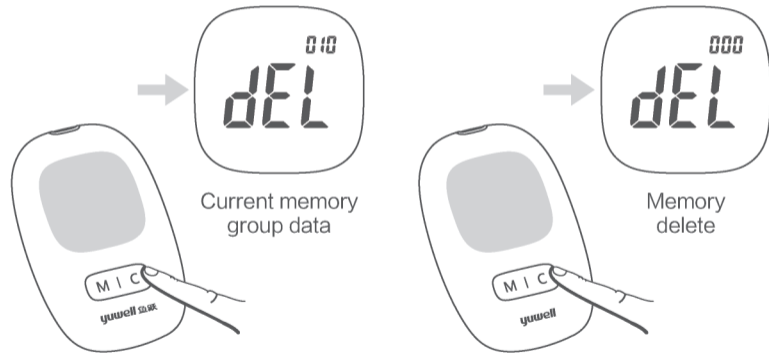


Clear records (Operate with Care)

#### Whole group deleting

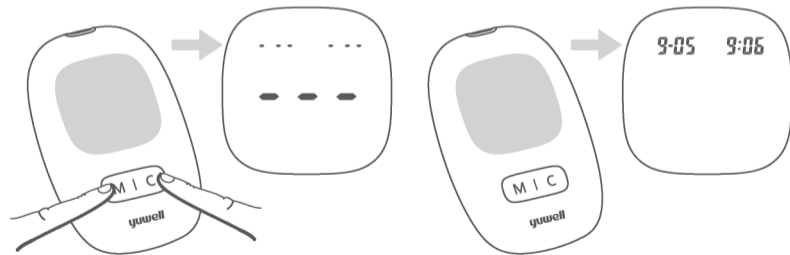
When two MC keys are pressed together for 3 seconds in the off state or in the memory review state, the “dEL” icon will appear, and the current memory group number will flash in the upper right corner. Press C key at this point and press again. The number of memory groups changes to 0, indicating that the entire memory has been cleared.





## Delete the current measurement results

After the test results are displayed, hold down M C key for 2 seconds before the test strip is pulled out, the current measurement results are deleted and the memory will not be stored. Release the two keys and return to the clock display mode.



## Quality control detection


If you want to know whether your blood glucose meter operating system is working properly, please perform quality control detection on your blood glucose meter.

Note: It is forbidden to use expired control solution.

The scrapping disposal of meters, blood glucose test strips, blood sampling needle, batteries and their accessories must comply with European Union laws and regulations.

## Control solution icon settings

The control solution value is only used for meter quality control, and checking whether the measurement result is within the control solution range.

1. Use the control solution detection. After the insertion, press C key to display the control solution  icon. The control solution test is performed at this moment.
2. Replace blood with quality control solution, and refer to “Testing Blood Glucose” .





### Storage and maintenance

- Use warm water to clean the blood sampling pen adjustment head and dry thoroughly after cleaning. It can also be disinfected with 75% alcohol.
- For the storage of blood glucose test strip, see the test strip instructions.
- Please remove the battery when the blood glucose meter is not used for a long period of time.
- The product should be stored in a dry, cool, non-corrosive atmosphere and in a well-ventilated place.
- Transportation and storage:  
Ambient temperature range:  $-10^{\circ}\text{C} \sim +50^{\circ}\text{C}$   
Relative humidity range:  $<90\%$ , no condensation  
Atmospheric pressure range:  $500\text{hPa} \sim 1060\text{hPa}$

- Please use a clean, soft, damp cloth to clean the meter, use 75% alcohol, bleaches or strong cleaners are forbidden. It is recommended to disinfect and clean the meter daily for use in hospitals, and weekly for personal use.
- Laboratory tests should be conducted regularly and the results of the blood glucose meter test should be compared with the laboratory results.
- The maintenance of this product is handled by the customer service center. Do not beat or disassemble the meter.
- If an accident occurs during the use of this product, call the emergency hotline immediately and seek the help of a professional medical staff.

## Technical parameters

Unit of measurement	mg/dL
Measuring range	20~600mg/dL (1.1 ~ 33.3 mmol/L)
Target bloods	Fingertip fresh capillary whole blood
Calibration standard	Plasma calibration
Blood volume	Refer to the test strip manual
Hematocrit	30% ~ 60%
Testing time	<10s
Number of memory groups	Measurement results of 250 groups
Automatic shut-down	15 second to 3 minutes
Display screen	LCD
Equipment operation mode	Continuous operation
Input power	DC 3.0V, 30mA
Battery life	One CR2032 battery can measure about 1,000 times

Size	18 mm(H)*85 mm(L)*55.5 mm(W)
Weight	About 40 g (Except for the battery)
Equipment type	Internal power supply equipment
Service life	5 years
Pollution degree of the intended environment	2
Electromagnetic interference	Electromagnetic interference with other devices has not been observed in this product, which complies with the current international electromagnetic emission standards. To avoid electromagnetic interference in the use environment and affect the measurement results, keep away from mobile phones, computers, and other household appliances while measuring.
Normal working conditions	Ambient temperature range: 10°C ~ 40°C; Indoor use Relative humidity range: <85%

Note: The battery provided with this machine is only used for testing when the device is turned on. It is recommended to replace a new battery to ensure that the blood glucose meter will not work due to battery undervoltage during the test when the testing organization needs to test the performance of the instrument.

### Reference standards

- The accuracy of Yuwell blood glucose monitoring system is required to meet one of the provisions of the international standard ISO15197: 2013 In vitro diagnostic test Systems – Requirements for blood–glucose monitoring systems for self–test–ing in managing diabetes mellitus:

A) The glucose recovery rate for blood glucose meters and blood glucose test strips is 80% to 120%.

B) 95% of the deviation of the test results of blood glucose meters and blood glucose test strips should meet the following table:

Test range	Accuracy
< 100mg/dL (< 5.55 mmol/L)	$\leq \pm 15$ mg/dL ( $\pm 0.83$ mmol/L)
$\geq 100$ mg/dL ( $\geq 5.55$ mmol/L)	$\leq \pm 15\%$

- The repeatability of Yuwell blood glucose monitoring system is required to meet the provisions of the national standard ISO15197:2013 In vitro diagnostic test Systems – Requirements for blood–glucose monitoring systems for self–testing in managing diabetes mellitus:

Test range	Precision
<100mg/dL (<5.5mmol/L)	SD<7.7mg/dL (<0.42mmol/L)
≥100mg/dL (≥5.5mmol/L)	CV<7.5%

### Self–monitoring time of blood glucose

Diabetics need to regularly monitor their blood glucose levels to keep abreast of changes in blood glucose levels. Your doctor will advise you on your blood glucose test time and control level according to your specific situation. The following is the blood glucose monitoring time recommended by experts, for reference only!

- Just waking up and having not eaten yet
- Breakfast blood glucose
- 1–2 hours after breakfast
- Before lunch
- 1–2 hours after lunch
- Before and after physical exercise
- Before dinner
- 1–2 hours after dinner
- Before going to bed at night
- After eating dessert
- 2–3 o'clock in the morning (if insulin is injected)

### Self-monitoring frequency of blood glucose

- The blood glucose of patients with poor blood glucose control or critically ill patients should be monitored for 5–7 times a day, 3 days a week until the condition is stable and blood glucose is controlled.
- When the condition is stable or has reached the goal of blood glucose control, it can be monitored for 2 times a day, 3 days a week.
- The blood glucose of patients under insulin therapy should be monitored for at least 5 times a day at the beginning of treatment, and should be self-monitored for 2–4 times a day after reaching the treatment goal.
- The blood glucose of patients taking oral medications and lifestyle interventions should be monitored for 2–4 times per week.

### Reference value and diagnostic criteria for diabetes









WHO 1999		
	Fasting blood glucose (mg/dL)	OGTT diagnosis (mg/dL)
Normal glucose range	< 110	< 140
Impaired fasting glucose	110 ~ 126	< 140
Reduced glucose tolerance	< 110	140 ~ 200
Diabetes	≥ 126	≥ 200






This product is only used to measure blood glucose levels of diabetic patients, and can not be used for the diagnosis and screening of diabetes.

## Precautions


- This product is used for the monitoring of blood glucose levels in diabetics. It cannot be used for the diagnosis and screening of diabetes, nor can it be used for the glucose test related to glucose metabolism disorders.
- It is forbidden to use expired, damaged or contaminated blood glucose test strips. Blood glucose testing must be performed in accordance with standard procedures, otherwise false test results may be produced.
- The Blood-sampling needle is only for single use, please do not re-use.
- The test result is between 20~600mg/dL. when the test result is lower than 20mg/dL, “ **LO** ” is displayed. when the test result is higher than 600mg/dL, “ **HI** ” is displayed.





The symbols and meanings of the safety requirements in this unit

Symbol	Meaning	Symbol	Meaning
	Upward		Consult instructions for use
	Keep dry		In vitro diagnostic medical device
	Fragile, handle with care		CE marking and notify body number
	Serial Number		Manufacturer

Symbol	Meaning	Symbol	Meaning
	Authorized representative in the European Community		Storage and transportation temperature limit
	Caution, the accompanying document must be consulted in all cases where this symbol is marked		Biological RISKS, indicate that the used equipment may cause the user to be infected
	Symbol for the marking of 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		

## Common troubles and elimination methods

Code Error	Description	Solution
<b>E01</b>	Blood glucose test strips have been contaminated or used	Replace test strip with a new one to re-measure
<b>E02</b>	Calibration code error	Please re-insert the test strip and confirm that the test strip matches with the machine
<b>E04</b>	System error	Please detect with new glucose test strip; if the problem persists, please contact with dealer or manufacturer
<b>HI</b> 	Blood glucose test results are higher than the detection range	It indicates that you may have severe hyperglycemia. Please immediately follow the doctor's instructions for repeated detection or treatment

Code Error	Description	Solution
	Blood glucose test results are lower than the detection range	It indicates that you may have severe hypoglycemia. Please immediately follow the doctor's instructions for repeated detection or treatment
	Ambient temperature is above 40°C	Please place the meter under a 10°C~40°C environment for 30 minutes before detection
	Ambient temperature is below 10°C	Please place the meter under a 10°C~40°C environment for 30 minutes before detection
	The battery is not enough and the meter will turn off automatically	Please replace with new batteries immediately

Code Error	Description	Solution
	Battery power shortage	Please replace with new battery

During the warranty service, if it needs to provide circuit diagrams, necessary materials, and electrical wiring, please contact your manufacturer.

Note: if the above situation can not be ruled out during use, or unexpected failures occur, please contact Yuwell customer service center!



## Other common problems

Problems arisen	Solution
Blood glucose meter does not test after adding blood	<ol style="list-style-type: none"> <li>1. Confirm whether the test strip is fully inserted into the slot</li> <li>2. Check whether there is foreign matter on the test strip</li> <li>3. Blood should be sucked into the blood inlet port of the test strip correctly</li> <li>4. Please do not add blood sample before the blood droplet icon flickers</li> </ol>
Abnormal test results	<ol style="list-style-type: none"> <li>1. Check whether there is foreign matter on the test strip</li> <li>2. Check whether the test strip is within the validity period</li> <li>3. Check whether the test strip is exposed for a long time</li> <li>4. Confirm whether the calibration code of the blood glucose meter is consistent with that of the test strip.</li> <li>5. Check whether the temperature icon appears on the blood glucose meter display</li> </ol>

Problems arisen	Solution
Temperature icon appears on the blood glucose meter display	<ol style="list-style-type: none"> <li>1. Blood glucose meter and test strips should be placed in an environment of 10°C to 40°C and used about 20 minutes later.</li> <li>2. If the temperature icon is always present, please contact Yuwell customer service staff.</li> </ol>
The test strip is in the insert state, but the meter does not start	<ol style="list-style-type: none"> <li>1. Confirm whether the test strip is fully inserted into the slot</li> <li>2. Confirm whether the positive and negative direction of the battery are correct.</li> <li>3. Replace with new battery</li> </ol>

Note: if the above situation can not be ruled out during use, or unexpected failures occur, please contact Yuwell customer service center!

Mailing address:

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To: Customer Service Management Center, JIANGSU YUYUE MEDICAL EQUIP-  
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Zip Code: 212300

Our company reserves the right to change the technology and appearance of this product, which is subject to change without notice and your understanding will be appreciated.



Authorized representative in the European Community  
Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany

Index

Preparation for Use of Blood Glucose Meter.....	06
Testing Blood Glucose.....	16
Check records.....	18
Quality control detection.....	23
Storage and maintenance.....	25
Technical parameters.....	27
Precautions.....	35
Common troubles and elimination methods.....	38