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<http://www.yuwell.com>
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1430162-2A 

yuwell

Blood Glucose Meter

Specification model: 660

User's Manual

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



Welcome to use Yuyue blood glucose meter

The scope of application: This blood glucose meter is matched with the Yuyue blood glucose test strip (Y350) produced by Jiangsu Yuyue Medical Equipment & Supply CO., LTD.. It is used to measure the glucose concentration in venous whole blood and fingertip fresh 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..
- Please use the instrument in accordance with the manufacturer's instructions, otherwise, the user should be responsible for the risk.
- 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.

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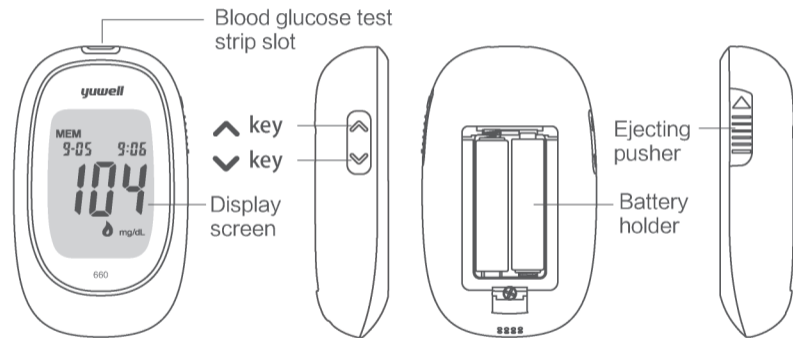
Description

This product may contain the following contents: Blood Glucose Meter (Model: 660), user manual, a blood sampling pen, two AAA batteries, 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 test strip (Y350), yuwell blood glucose control solution, lancets.

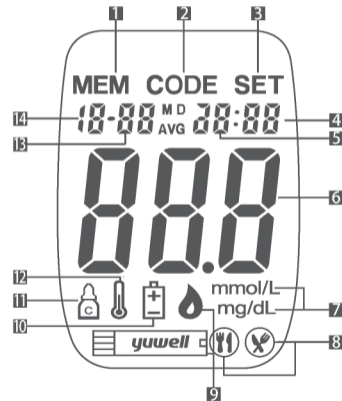
Intended use

- The yuwell 660 blood glucose monitoring system is intended for use in quantitative measurement of fingertip (capillary). It is intended to be used by lay person or clinical site by medical staff.
- This system is in vitro diagnostic medical device for self-testing.
- The yuwell 660 blood glucose meter can only be used with the yuwell Y350 blood glucose test strip.
- The yuwell blood glucose control solution is used with the yuwell 660 blood glucose meter and Y350 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.

Product descriptions



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

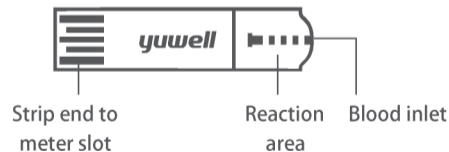


1. Display the storage results
2. Display the calibration code
3. In the setting mode
4. Display minutes
5. Display hours
6. Display the test value
7. Unit of measurement
8. Before-meals and after-meals icons
9. Strip and blood icon – add blood or control into the strip
10. Low battery icon
11. Control solution icon
12. Temperature icon
13. Display the date
14. Display the month

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

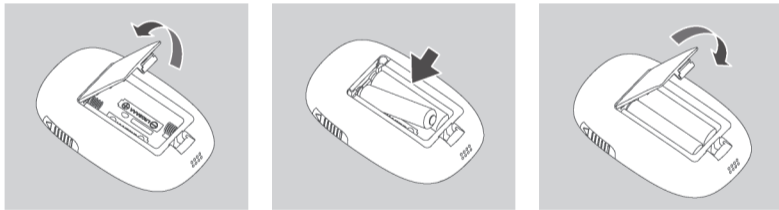
Blood glucose test strips

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 dehydrogenase 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 glucose meter, and then stored.



Battery installation


1. Open the battery back cover.
2. Press the spring with the battery negative pole, insert the battery.
3. Close the battery back cover and installation is complete.



The Meter is powered by 2 AAA alkaline batteries (LR03), which can be purchased and replaced by the user.

Mode setting

Enter mode setting

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



Date and time setting

1. The year flashes, press the \wedge key to set the year (This device only displays the last two digits of the year, that is, 22=2022), press the \vee key to confirm the year and switch to the month setting.
2. The month flashes, press the \wedge key to set the month, press the \vee key to confirm the month and switch to the date setting.
3. The date flashes, press the \wedge key to set the date, press the \vee key to confirm the date and switch to the hour setting.
4. The hour flashes, press the \wedge key to set the hour (this device uses a 24-hour system), press the \vee key to confirm the hour and switch to the minute setting.
5. The minute flashes, press the \wedge key to set the minute, and press the \vee key to confirm the minute.
6. If there is no operation on the blood glucose meter in the setting state within 3 minutes, it will automatically shut down.



Year setting



Month setting



Date setting



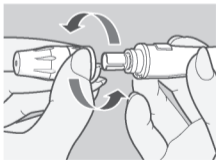
Hour setting



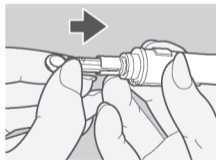
Minute setting

Use of blood sampling pen

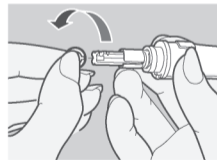
1. Unscrew the cap of the blood sampling pen. (or Transparent protective cover)
2. Put the lancet and push the lancet to the bottom of the blood sampling pen holder.
3. Twist the protection cap from the lancet (Do not shake it left or right to prevent the needle from bending). Never throw away the protection cap (see procedure 9: Processing instructions after sampling blood).



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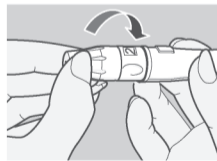


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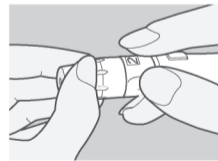


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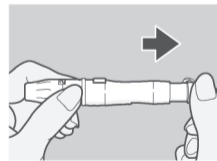
4. Install the blood sampling pen cap.
5. Adjust blood sampling depth. Recommended depth 2, users with thicker skin can adjust deeper appropriately.
6. Pull the handle of the blood sampling pen backward and let it open after hearing the clicking sound or unable to pull. At this point, the blood sampling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



4



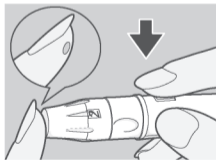
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7. Place the top of the prepared blood sampling pen on the part where the blood is to be collected, then press the ejection button to collect the blood. Take away the blood sampling pen after the completion of blood collection.

8. When taking fingertip blood, it is recommended to wipe off the first drop of blood, and use the second drop.



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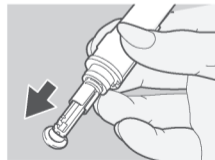
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Before blood collection, please wash your hands with soap and warm water and dry thoroughly.

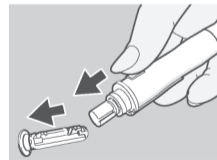
9. Properly dispose of used lancet:

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.



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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. (Note: 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. When the blood drop symbol  on the screen flashes, it indicates that blood is being collected. At this time, the date, time and calibration code flash alternately on the screen. Set the before-meal, after-meal and quality control solution by pressing the  key.

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

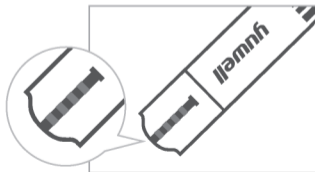


Test of blood glucose

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 there is enough blood volume on the test strip, and observe that the reaction area of the entire test strip becomes darker.



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


3. The reading will be shown in 10 seconds. Do not shake the instrument and remove the strip while measuring and counting down.



4. After obtaining the test results, push the ejecting pusher to eject the test strip. The meter will automatically store the measurement results and shut down.





Display records

In the off state, press  key, the screen displays the latest test results. Press 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  key for 3 seconds in the off state to display the average blood glucose for

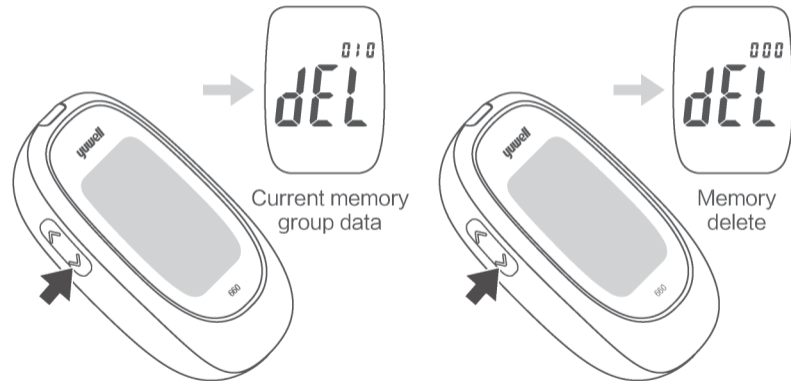
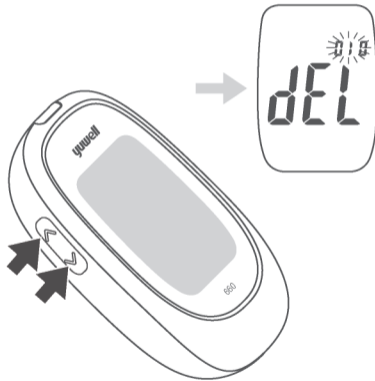
7 days. Press  key again to display the average blood glucose for 14 days, 30 days, 2 months, 3 months, 7 days before meals, 14 days before meals, 30 days before meals, 2 months before meals, 3 months before meals, 7 days after meals, 14 days after meals, 30 days after meals, 2 months after meals, and 3 months after meals. The blood glucose meter automatically shuts down after 15 seconds without operation.



Clear records (operate with care)

Whole group deleting

Press the two   keys together for 3 seconds during the shutdown state or in the memory check state, the "dEL" icon will appear, and the current memory group data will flash in the upper right corner. Press  key at this point and press again. The number of memory groups changes to 0, indicating that the entire memory has been cleared.







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, lancet, batteries and their accessories must comply with European Union laws and regulations.

Control solution icon settings

1. Use the control solution detection. After the insertion, press  key to display the before-meal icon, and press  key again to display the after-meal icon.
2. Press  key again to display the control solution icon  . A control solution test is performed at this point.
3. Replace the blood drop with 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 or venous whole blood
Calibration standard	Plasma calibration
Blood volume	Refer to the test strip manual
Hematocrit	10%~70%
Testing time	<10s
Number of memory groups	Measurement results of 500 groups
Automatic shut-down	15 second to 3 minutes
Display screen	LCD
Equipment operation mode	Continuous operation
Input power	DC 3.0V 100mA
Battery life	2 AAA alkaline batteries can measure about 1,000 times

Size	23mm(H)*91mm(L)*55mm(W)
Weight	About 50 g (Except for the battery)
Equipment type	Internal power supply equipment
Service life	5 years (Except for wearing parts)
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 dry battery provided with this machine is only used for testing when the device is turned on. It is recommended to replace the new alkaline dry 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–testing 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
$\leq 100\text{mg/dL}$ ($\leq 5.55\text{ mmol/L}$)	Not more than $\pm 15\text{mg/dL}$ ($\pm 0.83\text{mmol/L}$)
$> 100\text{mg/dL}$ ($> 5.55\text{mmol/L}$)	Not more than $\pm 15\%$

- 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 lancing device can only be used by one person and cannot be used by more than one person. The lancet is for one-time use only, please do not reuse it.
- Avoid contact with lotion, oil or dust on blood collection pen.
- Do not immerse the lancing device in any liquid.
- 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		Fragile, handle with care
	Keep dry		Blood drop symbol
	Pollution control mark of electronic information products, environmental protection service life is 10 years, consumables are not included		Caution, the accompanying document must be consulted in all cases where this symbol is marked

Common troubles and elimination methods

Code Error	Description	Solution
E02	Calibration code error	Retest with a new blood glucose test strip; if the problem persists, contact your dealer or manufacturer
E03	Insufficient blood volume	Retest with a new blood glucose test strip; add blood until the test window is full; if the problem persists, contact your dealer or manufacturer
E01 E07 E08	Blood glucose test strips have been contaminated or used	Retest with a new blood glucose test strip; if the problem persists, contact your dealer or manufacturer

Code Error	Description	Solution
E04 E05 E06 E09 E10 E11 E12	Internal standard detection error	Retest with a new blood glucose test strip; if the problem persists, contact your dealer or manufacturer

Code Error	Description	Solution
	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
	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

Code Error	Description	Solution
	The battery is not enough and the meter will turn off automatically	Please replace with new batteries immediately
	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!.