

yuwell

Blood Glucose Meter

Specification model: 582

User's Manual

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



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Welcome to use Yuwell series blood glucose meter

The scope of application: The blood glucose meter is matched with the Yuyue blood glucose test strip produced by Jiangsu Yuyue Medical Equipment Co., Ltd. It is used to measure the glucose concentration in capillary whole blood in hospitals and homes.

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For important information, please read this instructions in detail to ensure safe use and accurate detection.

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.
- If you have any questions about the use of Yuwell blood glucose meters, please call the National Service Hotline: 400-828 7768
- Yuwell blood glucose meter provides replacement within 5 years and lifetime warranty service. Please complete your valid information in our warranty card, and return it to selling pharmacies, distributors or Yuwell, you will become a member of Yuwell Healthy Home to enjoy a full range of Yuwell member services.

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Description

The yuwell 582 blood glucose meter includes: yuwell 582 blood glucose meter, two AAA batteries, user manual, a blood sampling pen.

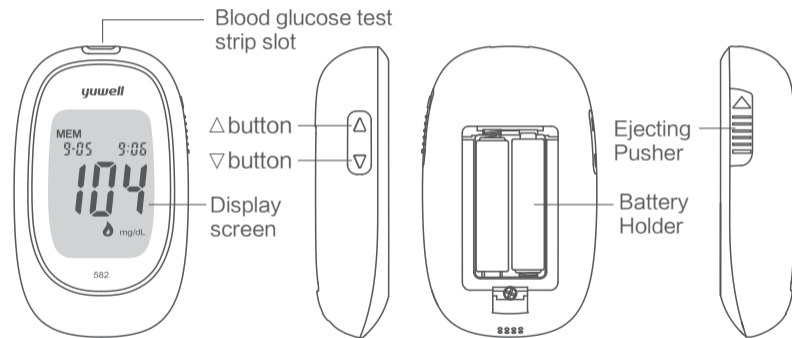
Intended Use

The yuwell 582 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.

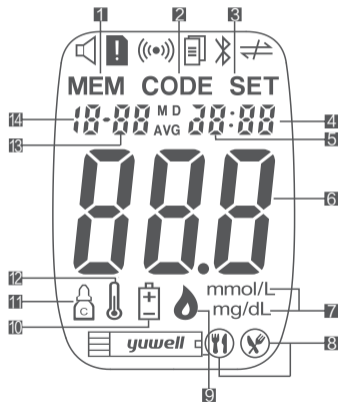
This system is for in vitro diagnostic use only.

The yuwell 582 blood glucose meter can only be used with the yuwell blood glucose test strip.

The yuwell blood glucose control solution is used with the yuwell 582 blood glucose meter and blood glucose test strip to check that the meter and test strip are working together properly. A control test also helps you practice proper testing technique.



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



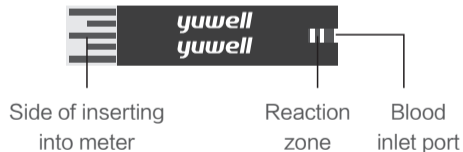
1. Display the storage results
2. Display the correction code
3. In the setting mode
4. Display minutes
5. Display hours
6. Display the test value
7. Unit of measurement
8. Before-meals and after-meals icons
9. Strip and blood icon – add blood or control into the strip
10. Low battery icon
11. Control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

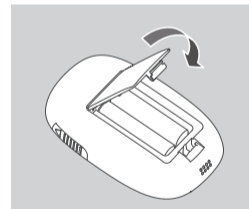
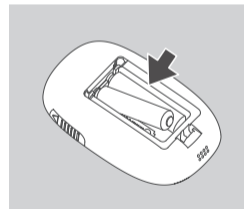
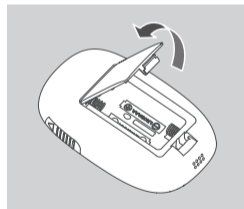
This product uses electrochemical principle. The blood glucose test strip is inserted into the blood glucose meter. When the blood droplets come into contact with the blood inlet port of the blood glucose test strip, blood will automatically siphon into the reaction zone. The Glucose oxidase catalyzes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

Note: please purchase Yuwell blood test strips and a blood sampling pen, which need to be used with the blood glucose meter!



Battery installation

1. Open the battery back cover.
2. Press the spring with the battery negative pole, insert the battery, install the battery back cover.
3. Press the battery positive pole with fingernail, and you can remove the battery.



Note: the battery septum should be withdrawn when using this product for the first time.

Mode setting

Enter mode setting

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



Date and time setting

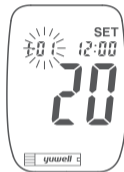
1. The year flashes, press the button Δ to set the year (This unit only displays the last two digits of the year, i.e., 20=2020), press the button ∇ to confirm the year and switch to the month setting.
2. The month flashes, press the button Δ to set the month, press the button ∇ to confirm the month and switch to the date setting.
3. The date flashes, press the button Δ to set the date, press the button ∇ to confirm the date and switch to the hour setting.
4. The hour flashes, press the button Δ to set the hour (this device uses a 24-hour system), press the button ∇ to confirm the hour and switch to the minute setting.
5. The minute flashes, press the button Δ to set the minute, press the button ∇ , the minute is set and switch to the clock mode.
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



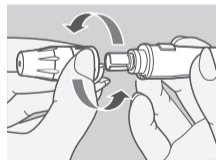
Hour setting



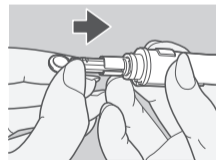
Minute setting

Use of blood sampling pen

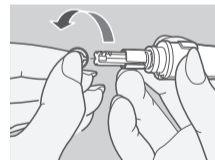
1. Unscrewing the cap of the blood sampling pen.(or Transparent protective cover)
2. Put the lancet and push the lancet to the bottom of the blood sampling pen holder.
3. Twist the protection cap from the lancet (Do not shake it left or right to prevent the needle from bending). Never throw away the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



1

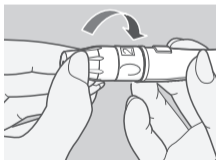


2

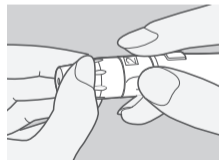


3

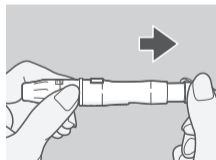
4. Install the blood sampling pen cap.
5. Adjust blood sampling depth. Recommended depth 2, users with thicker skin can adjust deeper appropriately.
6. Pull the handle of the blood sampling pen backward and let it open after hearing the clicking sound or unable to pull. At this point, the blood sampling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



4

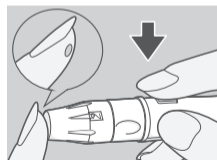


5



6

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.



7



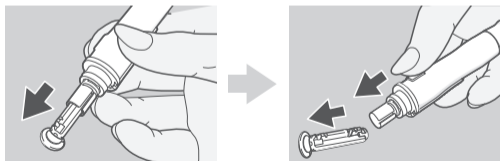
8

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.

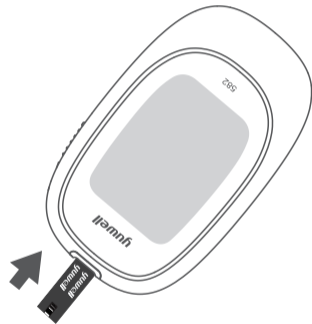




9

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 (if the blood glucose meter has buzzer), 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.)



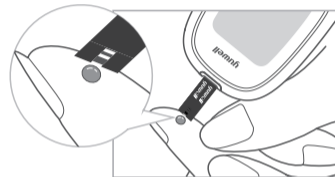
3. When the blood drop symbol  on the screen flashes, it indicates that blood is being collected. At this time, the date, time and Calibration code flash alternately on the screen. Set the pre-meal, post-meal and quality control solution by pressing the button .

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

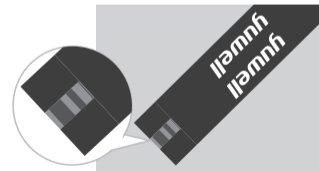


Test of Blood Glucose

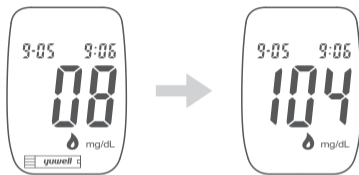
1. Lightly touch the blood inlet port with blood sample, and blood droplets will be automatically sucked. Do not drip blood on the test strip.



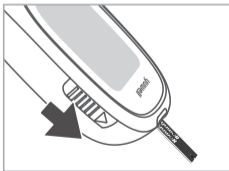
2. Confirm that the blood volume is sufficient. We can observe the color of entire test strip reaction becomes darker.



3. The screen displays the blood glucose test results for 8 seconds. Do not shake the instrument 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 Δ key, the screen displays the latest test results. Press Δ 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 Δ key for 3 seconds in the off state to display the average blood glucose for



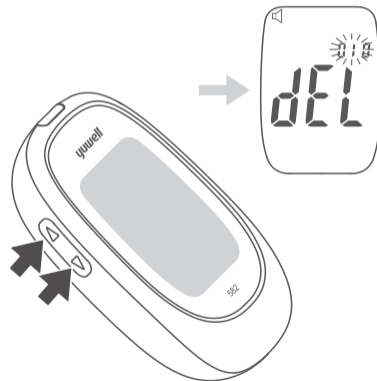
7 days. Press Δ key again to display the average blood glucose for 14 days, 30 days, 2 months, 3 months, 7 days before meals, 14 days before meals, 30 days before meals, 2 months before meals, 3 months before meals, 7 days after meals, 14 days after meals, 30 days after meals, 2 months after meals, and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

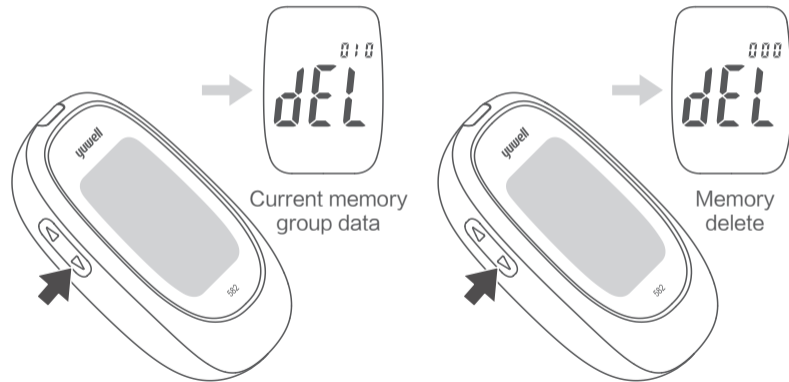


Clear records (Handle with Care)

Whole group deleting

Press the two Δ ∇ 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 national 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 "Test of Blood Glucose".




Storage and maintenance


- Use a non-toxic detergent and warm water to clean the blood sampling pen adjustment head and dry thoroughly after cleaning. It can also be disinfected with medical 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	mmol/L
Measuring range	1.1 ~ 33.3 mmol/L (20~600mg/dL)
Target bloods	Fingertip fresh capillary whole blood
Calibration standard	Plasma calibration
Blood volume	Reference test strip manual
Hematocrit	30% ~ 60%
Testing time	<10s
Number of memory groups	Measurement results of 250 groups
Automatic shut-down	15second to 3 minutes
Display screen	LCD
Equipment operation mode	Continuous operation
Supply voltage	DC 3.0V
Battery life	2 AAA alkaline batteries can measure about 1,000 times

Equipment type	Internal power supply equipment, non-AP/APG equipment (equipment that cannot be used in the presence of flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide)
Service life	5 years (Except for wearing parts)
Electrical safety classification	BF application section 
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 result deviation between the blood glucose monitoring system and the biochemical instrument (clinical lab) is within 95%, which shall follow below:

Precision:

Test range	Accuracy
≤ 4.2 mmol/L (≤ 75 mg/dL)	Not more than ± 0.83 mmol/L (± 15 mg/dL)
> 4.2 mmol/L (>75 mg/dL)	Not more than $\pm 20\%$

Accuracy:

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

Control objectives 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!

Status	Ideal	General	Poor
Fasting (mg/dL)	79–110	≤126	>126
Non-fasting (mg/dL)	79–144	≤180	>180
Glycated hemoglobin (%)	<6.5	6.5–7.5	>7.5

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 1.1 and 33.3mmol/L. when the test result is lower than 1.1mmol/L, “**LO**” is displayed. when the test result is higher than 33.3mmol/L, “**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
	Blood glucose test strips have been contaminated or used	Replace it with a new one to re-measure.
	Calibration code error	Please re-insert the test strip and confirm that the test strip matches with the machine.
	System error	Please detect with new glucose test strip; if the problem persists, please contact with dealer or manufacturer.
	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"> 1. Confirm whether the test strip is fully inserted into the slot 2. Check whether there is foreign matter on the test strip 3. Blood should be sucked into the blood inlet port of the test strip correctly 4. Please do not add blood sample before the blood droplet icon flickers
Abnormal test results	<ol style="list-style-type: none"> 1. Check whether there is foreign matter on the test strip 2. Check whether the test strip is within the validity period 3. Check whether the test strip is exposed for a long time 4. Confirm whether the calibration code of the blood glucose meter is consistent with that of the test strip. 5. Check whether the thermometer icon appears on the blood glucose meter display

Problems arisen	Solution
Thermometer icon appears on the blood glucose meter display	<ol style="list-style-type: none"> 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. 2. If the thermometer icon is always present, please contact Yuwell customer service staff.
The test strip is in the insert state, but the meter does not start	<ol style="list-style-type: none"> 1. Confirm whether the test strip is fully inserted into the slot 2. Confirm whether the positive and negative direction of the battery are correct. 3. Replace with new battery

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

Value-added services

All you need to do is submit or mail a clear, complete warranty card to Yuwell Customer Service Center. Once we have contacted you and verified the information, you will become a member of Yuwell Healthy Home and enjoy a range of member value-added services.

Mailing address:

Yunyang Industrial Park, Danyang City, Jiangsu Province

To: Customer Service Management Center, JIANGSU YUWELL MEDICAL EQUIPMENT & SUPPLY CO., LTD.

Zip Code: 212300