

yuwell



ACCUSURE 510

Blood Glucose Monitoring System

User's manual

Please read the user's manual closely!

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Accusure 510 blood glucose monitoring system

Welcome to use the blood glucose monitoring system of Yuwell series

Thank you for choosing Yuwell products. Jiangsu Yuyue Medical Equipment & Supply Co., Ltd., specializes in medical equipment R & D, manufacturing and marketing. "Quality casts brand" is the company's core value; quality culture is the core of the company culture. The company apart from the establishment of a complete quality control system, and through the ISO13485 quality system certification, all the major products has been certified by the FDA, CE quality certification, Japan SG security authentication international certification. With excellent quality and services, medical equipment Yuwell brand products have been known to the international counterparts, as the majority of domestic and international procurement of preferred brands.

The blood glucose monitoring system of Yuwell series will provide you with a more convenient and ergonomic monitoring measurement of blood glucose. You can get an accurate result only by following some simply procedures. Accusure 510 blood glucose monitoring system (The product, blood glucose monitoring system for short in the following content) is suitable for diabetics to test their blood glucose at home, it can also help health professional to monitor the effect of controlling diabetes.

Accusure 510 blood glucose monitoring system

Important information. Please read carefully

For the sake of safety and accuracy, be sure to read through the user's manual carefully before using the meter:

- This product is specific for blood glucose testing and only for testing fresh capillary whole blood samples. It can not be used for testing plasma or serum.
- This product can be used for hospital and homecare to test the blood glucose level in fresh capillary. It cannot be used for diagnosing of diabetes or a newly born baby.
- This product is exclusively used for testing blood glucose.
- You can not change the treatment only according to the test result without consulting doctors or diabetes professionals.

- To better care diabetics by using this blood glucose monitoring system, please consult doctors or diabetic professionals.

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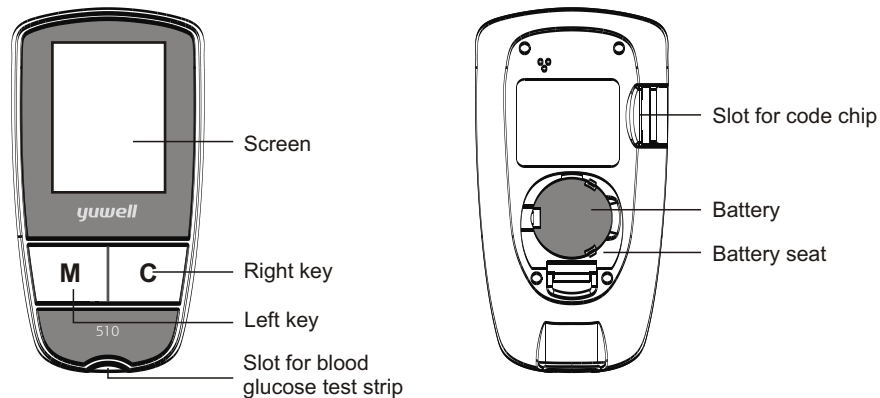
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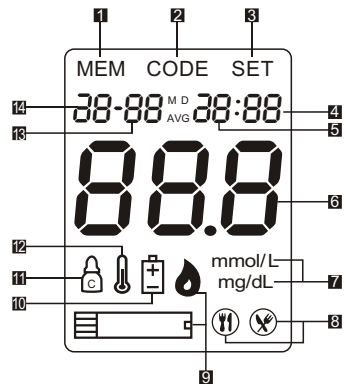
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Packing form

Blood glucose meter, lancing device, lithium battery (CR2032), potable bag, user's manual, quick instruction card.



Product descriptions



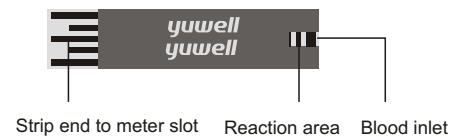
Note:The Accusure series has no before/after meal function

- 1 Memory: the stored records
- 2 Code: corresponding code
- 3 Setting: displaying set mode
- 4 Displaying minutes
- 5 Displaying hour
- 6 Displaying test result
- 7 Blood glucose units
- 8 Before/after meal
- 9 The flashing blood drop indicates it is ready to test
- 10 Low battery warning
- 11 Control solution
- 12 Temperature warning
- 13 Displaying date
- 14 Displaying month

Blood glucose test strip

Principles of electrochemistry are used here. The test strip is first inserted into the meter slot; a blood drop will be automatically sucked into the reaction area when it touches the strip edge. Then the glucose in the blood will be catalyzed by the oxidase to have redox reaction, generating micro-current that can be calculated, displayed and stored by the monitoring system.

Note: Please use Yuwell Blood glucose test strip, which exclusively match the blood glucose monitoring system.



Preparations before using

Battery installation

A: Open battery lid.



B: Put the positive pole "up" to install the battery, and then close the battery lid.



Note: Please insert the battery end with spring piece, push to the bottom and then push it.

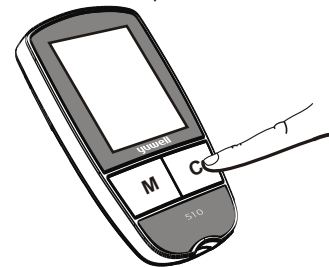
Preparations before using

Mode setting

Enter the mode setting

A: Installing a new battery or replacing the old one. Please see the battery installment.

B: Press "C" for three seconds to enter the setting mode with a beep sound.



C: Press to the inside along both sides of the trough, as shown in the picture, and then you can get the battery out.



Note: The battery spacer may be pulled out for the first time use.

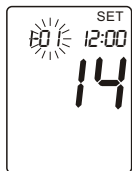
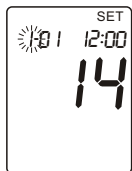
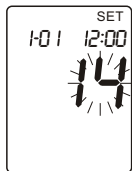
Time and date setting

A: When the year is flashing, press "M" to the current year(only the last two digits of the year is displayed, for example: 14=2014).

Press "C" to set the year and shift to the month setting.

B: When the month is flashing, press "M" to the current month. Press "C" to set the month and shift to the date setting.

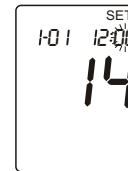
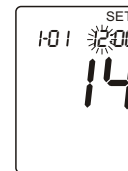
C: When the date is flashing, press "M" to the current date, press "C" to set the date and shift to the hour setting.



D: When the hour is flashing, press "M" to the current hour, press "C" to set the hour and shift to the minute setting.

E: When the minute is flashing, press "M" to the current minute, press "C" to set the minute.

F: In the setting mode, if no activity is conducted for 30 seconds, the blood glucose monitoring system will automatically turn off.



Preparations before using

Code chip matching

Take the new code chip from your test strip vial; make sure the number in the code chip matches the number on the test strip vial.

If these two do not match, stop using it and contact the supplier for the correct ones. Otherwise, you will get a false result.

If these two matches with each other insert the new code chip and test strip into the meter, it will automatically turn on and read the correct code.



Note: Discard the old code chip. Replace the new code chip which is provided in the new Yuwell blood glucose test strip box.

Blood glucose testing

Procedures to use the lancing device

A: Unscrew the end-cap from the lancing device.



B: Insert a lancet firmly.



C: Twist off the lancet cap; be sure not to discard it (see the procedure I).



Blood glucose testing

D: Screw the end-cap of the lancing device.



E: Adjust the depth for lancet shooting.



F: Pull the handle backward until the click is heard.



Blood glucose testing

Wash hands with warm soapy water and dry them well.

G: Press the top of the lancing device on the puncture site of your fingertip and press the release button for blood collecting. Wipe the first blood drop.

H: Use the second blood drop for blood glucose test.



I: Discard the used lancet: Unscrew the end-cap; protect needle with lancet-cap shown as figure then eject the used lancet.

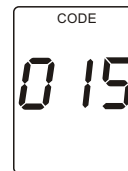
Note: The lancing device is for exclusively used and the lancet is for one time used only.



Preparation for blood glucose testing

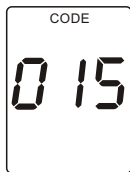
A: Confirm the code shown in the meter's screen with the code shown on the vial's (or pouch's) label. If they matched, continue to do the testing (Caution: re-cap the vial immediately after taking a test strip to avoid damp). If mis-matched, consult the store and replace a correct code. The test strip should be used for test within 5 minutes to avoid moisture which might degrade the strip performance.

B: Insert the test strip firmly.

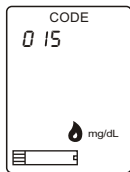


Blood glucose testing

C: Beep. Meter turns on, automatically. LCD screen shows the code number, first.



D: Screen shows flashing "💧" and code number, alternately.



Blood glucose testing

Blood glucose testing

A: Touch the tip of the test strip to the drop of blood. The blood is sucked into the test strip, automatically.

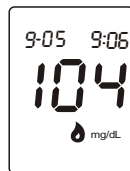
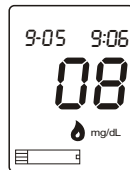


B: Make sure a sufficient blood to avoid any incorrect result.



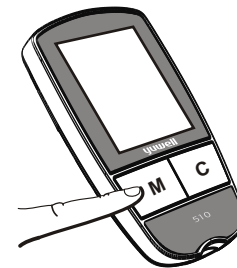
C: Blood glucose level will show in 8 seconds.

D: The blood glucose monitoring system will automatically store the testing records and turn off after the strip is removed.



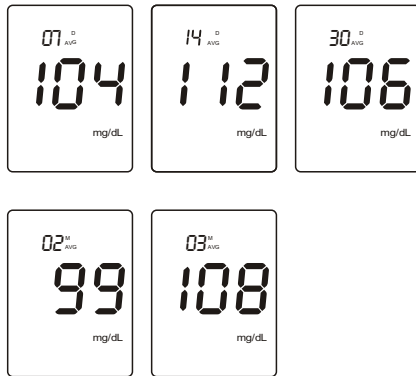
Showing record

With the meter off, press "M" to view the latest result. Press "M" again to view the previous records. Meter will turn off if there is no activity in 15 seconds.



Check the average results

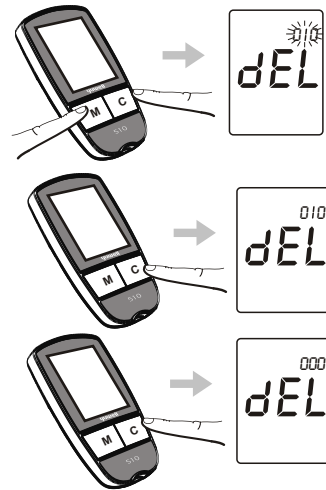
- Check the average results of the blood glucose for 7 days, 14 days, 30 days, 2 months or 3 months.
- When the meter is off, press "M" for 3 seconds to view the average blood glucose in the latest 7 days. Press "M" again to see results in the latest 14 days, 30 days, 2 months and 3 months, respectively. The meter will turn off automatically if there is no further operation for 15 seconds.



Delete records (caution to use)

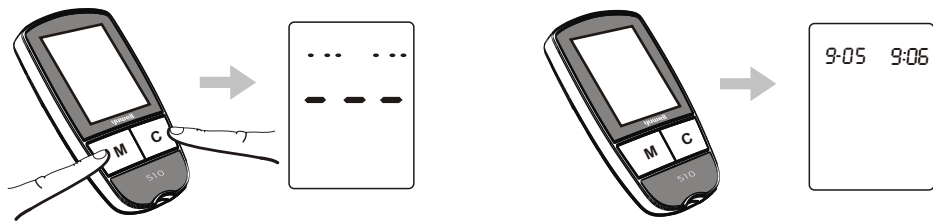
Erase entire records

When the meter is off or being viewed, presses "M" and "C" simultaneously for 3 seconds. The screen displays "dEL" and a flashing numbers indicating memories set is shown on the top right corner. Press "C" twice to erase entire records and flashing number shows 0 which means the memory is reset completely.



Delete the current measured results

When finishing the test and before pulling the tested strip out, press "M" and "C" simultaneously for 2 seconds, the current result will be erased.



Quality control

If you want to know whether your blood glucose monitoring system is working properly, please contact the customer service to test it for you.

Caution: Please follow the local government's regulation to dispose the used meter, strip, battery and accessories.

Control solution

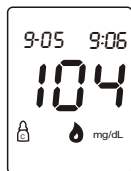
Flag the quality control result

Quality control solution is used to validate the whole system working properly when the solution result falls on the control range.

A: Use quality control solution to test: Replace blood drop with solution and follow the blood glucose test procedure A, B, C.

B: Press again, it appears "A". Pull the tested strip to finish the control solution test.

Note: The meter will turn off if there is no operation in 15 seconds.



Storage and maintenance

Storage and maintenance

- Wash the end-cap of the lancing device with non-toxic detergent in warm water and dry it well. Medicinal alcohol can also be used for disinfection.
- Lancing device is for exclusively use, hospital using is not recommended.
- The storage of testing strip shall follow the test strip's instruction.
- Battery shall be removed if the meter has not been used for a long time.
- The meter shall be kept in dry, clean and ventilate place, avoid exposing it to excessive heat, cold or light.

- Storage and Transportation:
Ambient Temperature: -10°C~50°C
Relative Humidity: <90% and no condensation
- Use lint-free tissue or 75% alcohol to clean the meter. Bleach and strong detergent are forbidden.
- To ensure the meter is in good condition, check it, regularly. Call our service center and stop using it immediately, once found broken.
- The product is maintained by our service center, solely. Please don't hit it or open it.

Specification and execution standard

Technical parameters

Metering unit	mg/dL
Testing range	20mg/dL - 600mg/dL
Type of blood sample	Fresh capillary whole blood
Rectification standard	Blood plasma rectification
Blood volume	1ul (microliter)
Hematocrit	30%-60%
Testing time	8 seconds
Memory group number	250 results
Auto power-off	15 seconds to 3 minutes
Equipment operation	Continuous operation

Specification and execution standard

Battery life	CR2032 the lithium battery can test about 1000 times
Working condition	Ambient temperature range: 10°C~40°C Relative humidity range: <85%
Electromagnetic interference	Interference of electromagnet from other equipment has not yet been found. To avoid electrostatic discharge, do not use the blood glucose monitoring system close to cell phone, computer and other home appliances.

Specification and execution standard

Standard and Regulation

- The result deviation between the blood glucose monitoring system and the biochemical instrument (clinical lab) is within 95%, which shall follow below:

Precision:

Testing range	Precision
< 75mg/dL	No more than ± 15 mg/dL
> 75mg/dL	No more than $\pm 20\%$

Accuracy:

Testing range	Accuracy
< 100mg/dL	SD < 7.5mg/dL
≥ 100 mg/dL	CV < 7.5%

Self- monitoring time, frequency and control target of the blood glucose

Self-monitoring time

Diabetics shall regularly test to observe the change of blood glucose level. Your doctor will give specific advice for the time and frequency. While the following time for test is just for reference only.

- Wake up and before meal
- After breakfast
- 1-2 hours after breakfast
- Before lunch
- 1-2 hours after lunch
- Before and after exercise
- Before dinner
- 1-2 hours after dinner
- Before sleeping at night
- After having deserts
- 2-3 am (if inject the Insulin)

Self- monitoring time, frequency and control target of the blood glucose

Frequency of self-monitoring

- Poor blood glucose control patients and critical patients shall test 3 days in a week with 5-7 times for each day until the blood glucose is under control.
- 3 days a week with twice for each day is enough if illness has become stable and the blood glucose has met the target range.
- Those treated with insulin have to perform the test 5 times every day, and then turn to 2-4 times when the treatment has achieved the target range.
- Those treated with oral medicines shall perform the test 2-4 times every week.

Self- monitoring time, frequency and control target of the blood glucose

Criteria for the Diagnosis of Diabetes mg/dL(mmol/L)

Criteria for the Diagnosis of Diabetes mg/dL(mmol/L)			
	Fasting plasma glucose	2-h plasma glucose during an OGTT	A random plasma glucose
Normal	70~100(3.9~5.6)	<140(7.8)	-
Glucose Impaired	101~125(5.6~6.9)	140~199(7.8~11.0)	-
Diabetes	$\geq 126(\geq 7.0)$	$\geq 200(\geq 11.1)$	$\geq 200(\geq 11.1)$

Amrcn_Dbts_Assctn_Cmplt_Gud_to_Dbts.pdf

American Diabetes Association Complete Guide to Diabetes, 4th Ed., ISBN 1-58040-237-2, 2005

The dos and don'ts






- This product is only used to test blood glucose, it is not for diagnosing blood glucose, nor can it be used for testing glucose relating to metabolic disorders.

- Expired, damaged or polluted test strips are forbidden to use. Test shall be performed by strictly following the rules; otherwise, false result might be caused.

- Lancing device can only be used for one person; lancet can not be repeatedly used.
- Keep the lancing device free of lotion, oil and dust.
- Lancing device is not to be soaked in any liquid.

- The result is between 20 and 600 mg/dL.
If the result is lower than 20 mg/dL, " **LO** " is in display.
If the result is higher than 600 mg/dL, " **HI** " is in display.

Some symbols and their meaning

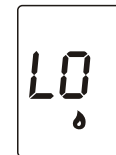
Symbols	Meaning
	This side up
	Fragile
	Damp proof
	Caution(refer to accompanying documents)
	Blood drop symbol

Errors and trouble remove



The result is higher than the measuring range

It means that you have serious hyperglycemia, consult your doctor's instruction for a recheck or treatment.



The result is lower than the measuring range

It means that you have hypoglycemia, consult your doctor's instruction for a recheck or treatment.



Test strip has been used or damaged

Change the test strip and perform a new test.



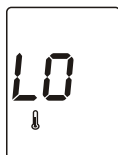
Temperature is higher than 40°C

Move the meter to a 10°C ~40°C environment and perform the test after 30 minutes.



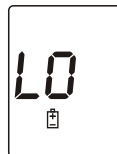
Code chip is wrong

Insert the correct code chip.



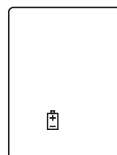
Temperature is lower than 10°C

Move the meter to a 10°C ~40°C environment and perform the test after 30 minutes.



Battery power is low, the equipment will turn off automatically

Change the battery immediately.



Battery power is low

Change the battery immediately.

Note: If you can not solve the problems, or even meet with other problems, please contact our service center.