

GlucoRx TD-4230

BLOOD GLUCOSE MONITORING SYSTEM



Owner's Manual

311-4230200-003
Version 1.0 2009-11

Dear GlucoRx TD-4230 System Owner:

Thanks for choosing our GlucoRx TD-4230 system. This manual provides extremely important information which helps you operate this meter smoothly. Before using this product, please read the following contents thoroughly and carefully.

The most prominent feature of this system is its **strip-ejection function**, which helps you take out the used strip without touching used test strip. This may prevent any cross-contamination of potential biohazardous materials.

Another unique feature is its **alarm function**, which alerts you to perform blood glucose test at the designated time. This thoughtful design helps you routinely check your daily blood glucose.

This design not only greatly simplifies the process of glucose testing, but also provides you and your doctor with more precise test results.

IMPORTANT SAFETY INSTRUCTIONS
READ THIS BEFORE USE

The following basic safety precautions should always be taken.

1. This device does NOT serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your physician to have the results interpreted.
2. Use the device only for the intended use described in this manual.
3. Do not use accessories which are not supplied by the manufacturer.
4. Keep the equipment and its flexible cord away from hot surfaces.
5. Do not use the equipment where aerosol sprays are being used, or where oxygen is being administered.
6. Do not use the device if it is not working properly or has been damaged.
7. Read all instructions thoroughly and practice the test before using the product to test your blood glucose. Do all quality control checks as directed and consult with a diabetes healthcare professional.
8. Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets, vial caps are choking hazards.

KEEP THESE INSTRUCTIONS

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● IMPORTANT INFORMATION

- ▶ Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- ▶ If you get your blood glucose results lower or higher than usual, and do not have symptoms, first repeat the test. If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.
- ▶ Apply only capillary whole blood sample to the absorbent hole. Applying other substances to the absorbent hole will cause inaccurate results.
- ▶ If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all instructions described in this owner's manual, call your healthcare professional.
- ▶ A red blood cell count (hematocrit) that is very high (above 60%) or very low (below 20%) can cause false results.
- ▶ The following **WILL NOT** affect results:
Elevated blood triglyceride, reducing substances such as uric acid and ascorbic acid when occurring in expected blood concentration, or acetaminophen, dopa, methyldopa, L-dopa and tolbutamide occurring in expected blood concentrations.
- ▶ This system may be used at altitudes up to 10,742 feet (3,275 m) without an effect on test results.
- ▶ Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

● ABOUT ALTERNATIVE SITE TESTING (AST)

Important: There are limitations for doing AST. Please consult your healthcare professional before you do AST.

What is AST?

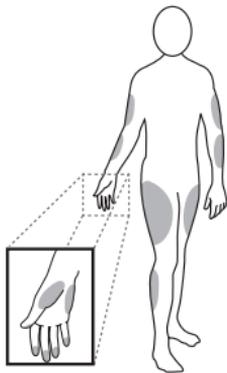
Alternative site testing (AST) means that people use parts of the body other than fingertips to check their blood glucose levels. This system allows you to test on the palm, the forearm, the upper arm, the calf, and the thigh with the equivalent results to fingertip testing.

What's the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings are not so condensed, you will not feel as much pain as at the fingertip.

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore when testing blood glucose during or immediately after meal, physical exercise, or any other events, **take blood sample from your finger only.**



We strongly recommend you do AST **ONLY** in the following intervals:

- ▶ In a pre-meal or fasting state (more than 2 hours since the last meal).
- ▶ Two hours or more after taking insulin.
- ▶ Two hours or more after exercise.

Do **NOT** use AST if:

- ▶ You think your blood glucose is low.
- ▶ You are unaware of hypoglycaemia.
- ▶ Your AST results do not match the way you feel.
- ▶ You are testing for hyperglycaemia.
- ▶ Your routine glucose results are often fluctuating.

How to increase the accuracy?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the finger.

Please follow suggestions below before getting a drop of blood:

- ▶ Rub the puncture site about 20 seconds before penetration.
- ▶ Use a clear cap (included in the kit) instead while setting the lancing device.

● GETTING STARTED

■ Intended Use

The system is intended for use outside the body (in vitro diagnostic use). It should be used only for testing glucose (sugar) and only with fresh capillary whole blood samples taken from the finger and the alternative sites including the palm, forearm, upper arm, calf and thigh. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for testing in newborns.

AST in this system can be used only during steady-state blood glucose conditions described in the section of "About AST".

■ Principle of Measurement

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent in the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

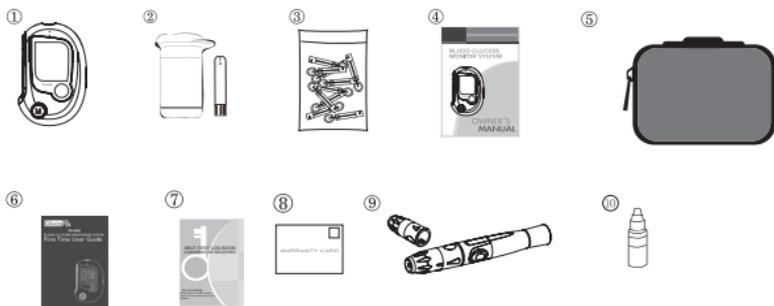
■ Contents of the System

The three main parts are included in this system: the blood glucose meter, test strips, and a control solution. These products have been designed, tested, and proven to work together as a system to measure the concentration of your blood glucose precisely.

Always use the same brand name of test strips and TaiDoc control solution with the blood glucose meter.

Your system includes:

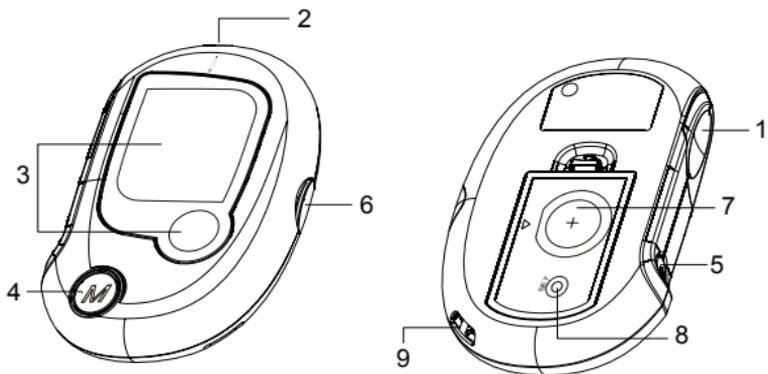
- ① A meter
- ② Test strips
- ③ Sterile lancets
- ④ Owner's manual
- ⑤ Sporty carrying case
- ⑥ Your first time user guide
- ⑦ Daily log book
- ⑧ Warranty card
- ⑨ Lancing device with clear cap for Alternative Site Testing
- ⑩ Control solution



NOTE

- ▶ Please make sure that all products listed above are contained and sealed in the package before using this system. If you find any imperfection in our products, please return the whole system to the place of purchase.
- ▶ There are 3 levels for TaiDoc control solutions: low, normal and high. Please note that the other two levels are optional and are not included in the standard kit. Please ask your local agent for availability.

■ Appearance and Key Function of the Meter



1. STRIP-EJECTION BUTTON

is where the used strip will be ejected after you push up the button.

2. TEST SLOT

is where you insert the test strip. The meter will turn on automatically after insertion.

3. LCD DISPLAY

guides you through the test using symbols and simple messages.

4. MAIN BUTTON

located in front of the meter with "M" on it, is used to turn on the meter, enter the memory or control steps of setting.

5. C BUTTON

located at the side, is for control solution test.

6. DATA PORT

located at the side, is for cable connection to the PC.

7. BATTERY COMPARTMENT

8. SET BUTTON

located in the battery compartment, is used to set up the meter.

9. STRAP HOLE

■ LCD Display

LOW BATTERY SYMBOL

Appears when the battery power is low.

TEST RESULT AREA

Displays glucose results. A decimal point appears when the measurement unit is mmol/L.

KETONE WARNING

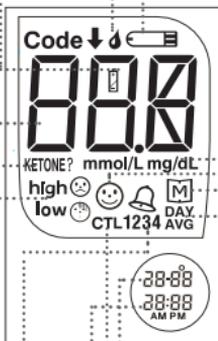
Appears when the test result is equal or higher than 15mmol/L (270 mg/dL)

FACE SYMBOL LOW/HIGH SYMBOL

Both are result indicators. They appear together with the test result if it exceeds the reference range.

ALARM FUNCTION INDICATOR

Blinking at first, appears when performing test. Four alarms can be set in this meter.



TEST STRIP SYMBOL

Appears when the meter is turned on.

BLOOD DROP SYMBOL

Flashes when it is ready to apply the sample.

MEASUREMENT UNIT

Appears with the test result either in mmol/L or in mg/dL.

SMILE SYMBOL

Appears when the test result is within reference range.

MEMORY SYMBOL

Appears when you review the memory.

DATE

DAY AVERAGE

Indicates that the displayed test result is an average.

TIME

CTL SYMBOL

Appears when doing a control test and indicates that the result will not be stored in the memory.

■ Appearance of the Test Strip

This system measures the amount of sugar (glucose) in whole blood. Blood is applied to the absorbent hole of the test strip and is automatically drawn into the reaction cell where the reaction takes place.

The test strip consists of the following parts:

Contact Bars

Insert this end of the test strip into the meter.
Push it in firmly until it will go no further.

Test Strip Handle

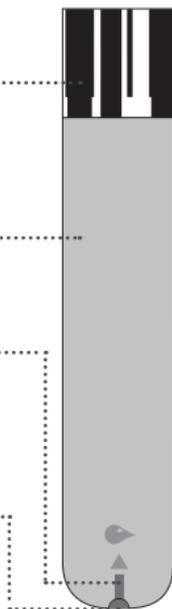
Hold this part to insert the test strip into the slot.

Confirmation Window

This is where you confirm if enough blood has been applied to the absorbent hole of the strip.

Absorbent Hole

Apply a drop of blood here, and
The blood will be sucked up automatically.



Please see pages 31~37, "Testing Your Blood", for complete instructions.

● PREPARATION BEFORE USE

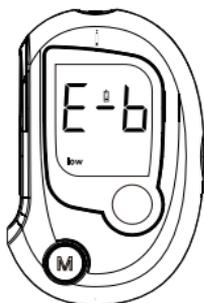
■ Battery Replacement

Your meter comes with one 3V CR2032 Lithium battery. The meter will alert you when the power is getting low by displaying two different messages:

1. When  symbol is displayed on the screen: the meter is functional and the result remains accurate, but it is time to change the battery.



2. When  symbol, low and E-b symbols are displayed the battery cannot provide enough power to do a test. You must change the battery immediately.



PLEASE NOTE

- ▶ Replacing the battery within 5 minutes does not affect the settings. Therefore, the settings do not need to be updated when the battery is changed.
- ▶ Batteries might leak chemicals if not used for a long time. Remove the battery if you are not going to use the device for an extended period (i.e., 3 months or more).
- ▶ Do not use the used battery. Use only the new one in required size and type.

To replace the battery, make sure that the meter is turned off.

STEP1 Press the buckle on battery cover and lift up to remove cover.

STEP2 Remove the old battery and replace with one 3V CR2032 Lithium battery.

STEP3 Close the battery cover.

STEP 1



STEP 2



STEP 3



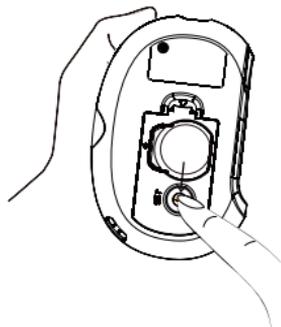
WARNING

As with all small batteries, the batteries should be kept away from small children who still put things in their mouths. If they are swallowed, promptly see a doctor for help.

■ Setting the Meter and Deleting the Memory

Your meter comes with the time, date, unit of measurement, memory deletion and alarm function setting. If you need to set these parameters, please follow below steps.

Start with the meter off. Then press the set button located in the battery compartment. The meter is now in the setting mode.



STEP 1. Set the Year

After pressing the set button, the year, a blinking number, will be shown on the screen. Press and release the M button plus one year. You can also keep pushing down the M button to proceed faster. When the correct year is displayed on the screen, press the set button and then a flashing number, which stands for the month, is shown.



STEP 2. Set the Month

Press and release the M button until you see the correct month. To move faster, keep pushing the M button down. When the desired month is displayed, press the set button and then the day will flash.



STEP 3. Set the Day

Press and release the M button until you see the correct day. To move faster, keep pushing the M button down. When the desired month is displayed, press the set button and the hour will be shown on the screen.



STEP 4. Set the Hour

Press and release the M button until you see the correct hour on the screen. To move faster, keep pushing the M button down. When the desired hour is displayed on the screen, press the set button and then the minute will flash.



STEP 5. Set the Minute

Press and release the M button to advance one minute. To move faster, keep pushing the M button down. When the desired minute is displayed, press the set button and then the memory deletion will appear.

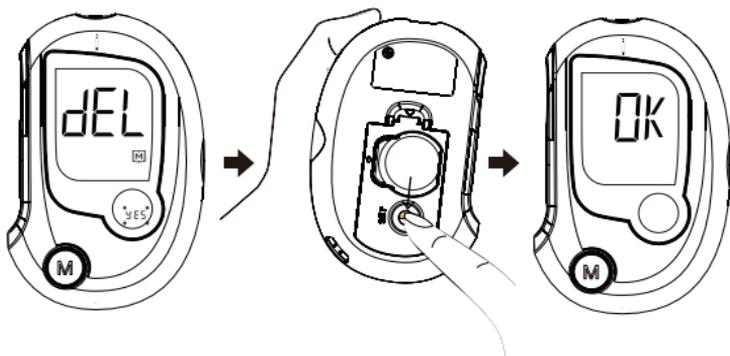


PLEASE NOTE

- ▶ The time and date can **ONLY be changed** in the setting mode. Therefore, when you perform a glucose testing, those parameters cannot be changed.
- ▶ The meter cannot automatically update Daylight Saving Time. You have to manually adjust the time in the meter according to the procedures. Please make sure the meter matches the time zone and adjust the Daylight Saving Time data if required.
- ▶ Your meter displays 7-, 14-, 21-, 28-, 60- and 90-day averages which you can access from the meter memory. These averages are calculated from results obtained during the 7-, 14-, 21-, 28-, 60- and 90-day preceding the current date and time settings. When the date and time are changed, the 7-, 14-, 21-, 28-, 60- and 90-day averages may change.
- ▶ While the meter is in the setting mode, it will turn off automatically without any action in three minutes.

STEP 6. Delete Memory

“dEL” and “M” and flashing Yes/no is displayed on the screen. If you do NOT want to delete memory, press the M button to select “no” and then press set button to go to step 7. If you’d like to delete ALL memory, press M button to select “yes”. Then **press set button to delete All memory**. “OK” is displayed in the meter, which means that all data stored is deleted. Go to step 7.

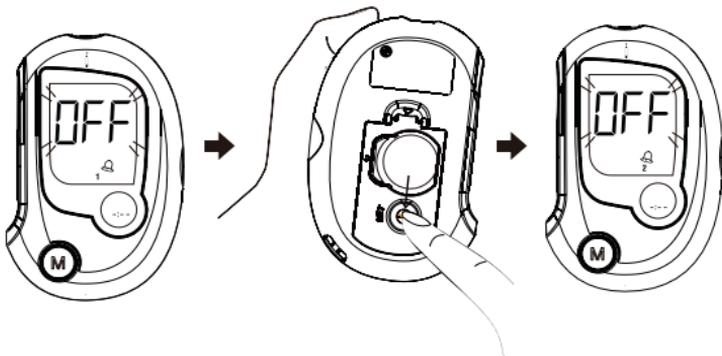


STEP 7. Select and Set Alarm Function

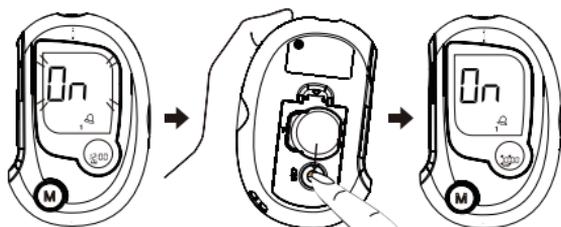
The meter provides four alarms. You are able to set four different alarm times a day. “On” or “OFF” and “A” are displayed on the screen firstly. Press the M button to turn on or turn off Alarm 1.

■ Alarm 1 setting

If you press the M button to select “OFF”, then press the set button to go to set Alarm 2.

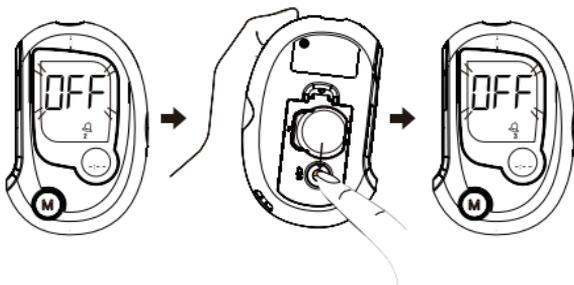


If you press the M button to select “On”, then press set button to set hour. While the hour is flashing, press the M button to plus an hour, and then press the set button. Blinking minute is displayed on the screen. Press the M button to advance one minute. To move faster, keep pushing the M button down. When the desired minute is displayed, press the set button to proceed to the next alarm setting.

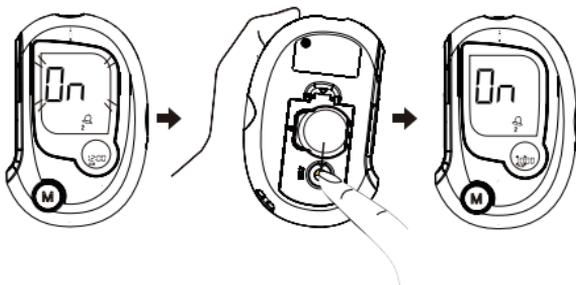


■ Alarm 2 setting

If you press the M button to select “OFF”, then press the set button to go to set Alarm 3.

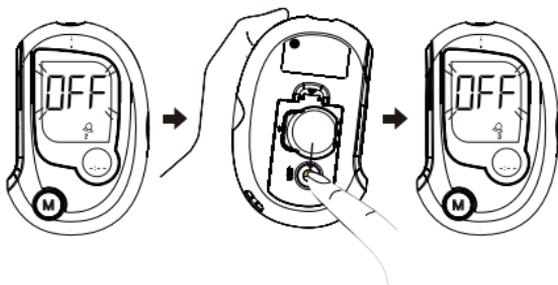


If you press the M button to select “On”, then press set button to set hour. Set hour and minute according to the instruction described in Alarm 1. Once finished, press the set button to go to set Alarm 3.

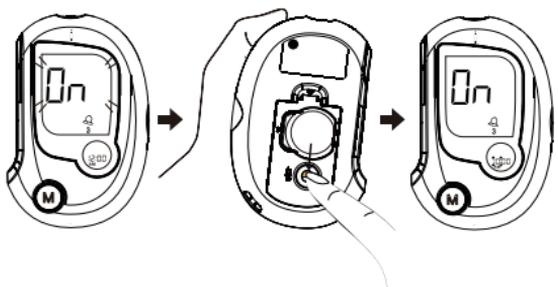


■ Alarm 3 setting

If you press the M button to select "OFF", then press the set button to go to set Alarm 4.

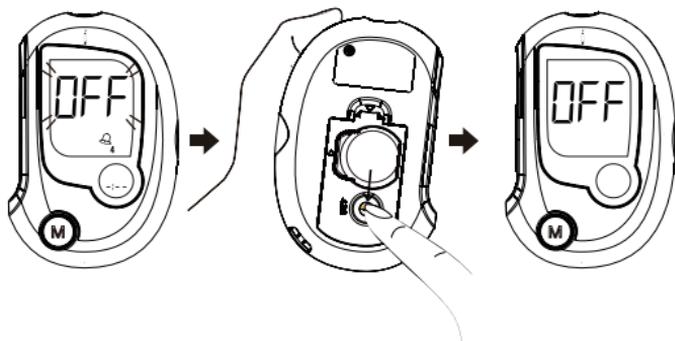


If you press the M button to select "On", then press set button to set hour. Set hour and minute according to the instruction described in Alarm 1. After finished, press the set button to go to set Alarm 4.

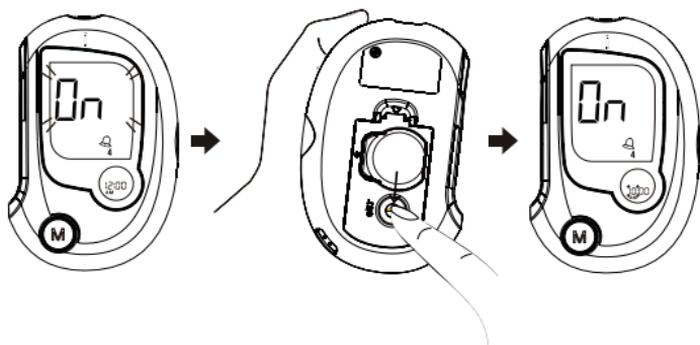


■ Alarm 4 setting

If you press the M button to select “OFF”, press the set button to turn off the meter.

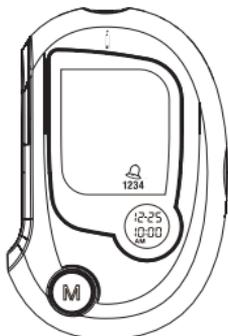


If you press the M button to select “On”, then press set button to set hour. Set hour and minute according to the instruction described in Alarm 1. After finished setting Alarm 4, press set button to turn off the meter.



■ Alarm Function

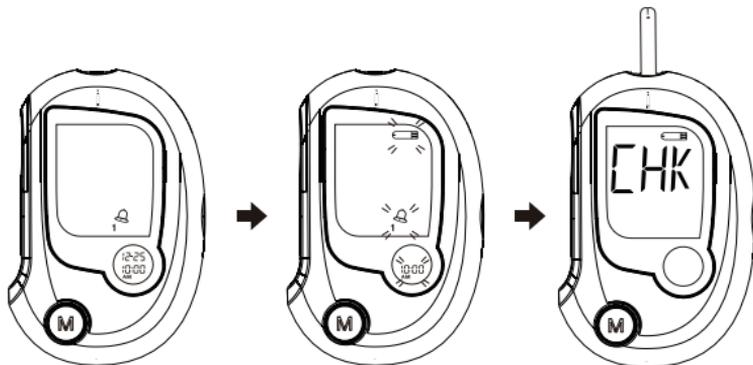
The meter provides four alarms. The alarm function alerts you to perform your blood glucose regularly. If you need to set alarm function, please refer to page 19 "Select and Set Alarm Function" for information.



If you have turned on the alarm function, the meter will auto-start at the time point you set with short beeps for two minutes.

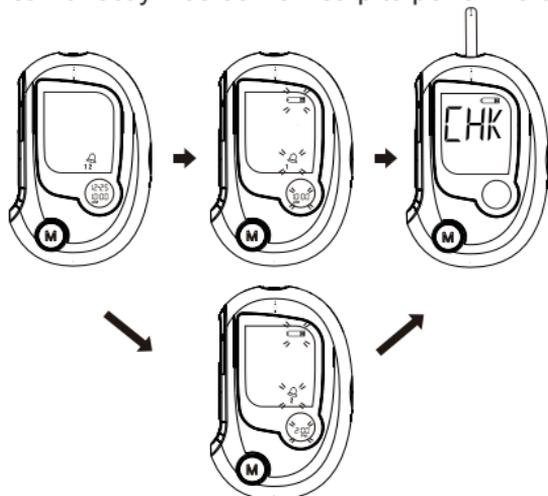
An example if set Alarm 1 at 10:00 AM

The meter automatically turns on at 10:00 AM everyday with beeping for two minutes, blinking "  " and "  ". You can directly insert a new strip to perform blood glucose test now.



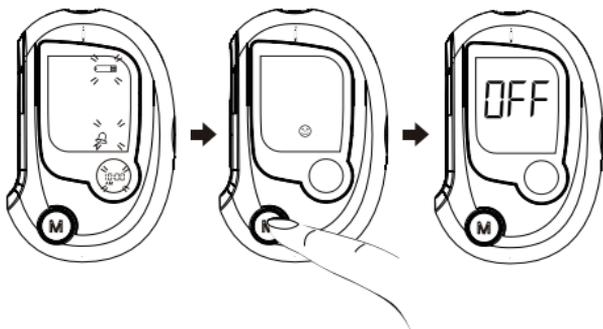
An example if set Alarm 1 at 10:00 AM and Alarm 2 at 2:00 PM

The meter automatically turns on at 10:00 AM first and next turns on at 2:00 PM. You can directly insert a new strip to perform a test.



If you don't want to perform a test after the meter turns on:

- ▶ Press the M button. “☺” and “OFF” displays and then the meter will turn off.



- ▶ Or you can leave the meter without pressing any button within two minutes. The meter will turn off automatically.

PLEASE NOTE

- ▶ If the alarm function is set, the alarm symbol will appear on the screen when the meter is off.
- ▶ Each alarm setting function is independent, you can set alarm function separately and the setting will not affect other alarm function.

● BEFORE TESTING

■ Checking the Display

Each time you insert a test strip, the meter displays "CHK" and "  ". This tells you that the system is checking if the meter and test strip can work together.



■ Checking with TaiDoc Control Solutions

TaiDoc control solutions contain a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, it is able to check that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

How often should the control solution test be performed?

- ▶ When you use this system to test your blood for the first time, practice the procedure using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
- ▶ To routinely check the meter and test strips, perform a single test for each level of control solution at least once a week.

When should the control solution test be performed?

- ▶ When you first get your Glucose Meter.
- ▶ When you begin using a new vial of test strips.
- ▶ Whenever you suspect that the meter or test strips are not working properly.
- ▶ When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
- ▶ When your test strips are exposed to extreme environmental conditions. (See **Storage** section of this manual).
- ▶ When you want to practice running the test.
- ▶ If you drop the meter.

■ Important Control Solution Information

- ▶ Use only TaiDoc control solutions.
- ▶ Check the expiry date on the control solution vial. Do not use if expired.
- ▶ Control solution, meter, and test strips should come to room temperature (2°C-25°C) before testing.
- ▶ Shake the vial, discard the first drop of control solution, and wipe off the dispenser tip to ensure a good sample and an accurate result.
- ▶ Use only for 3 months after first opening. Record the first opening date on the control solution vial. Discard after 3 months.
- ▶ Store the control solution tightly closed at temperatures 2°C to 30°C (36°F to 86°F). Do not freeze.

PLEASE NOTE

The control solution range printed on the test strip vial is for TaiDoc control solution only. It is used to test meter and test strip performance. It is not a recommended range for your blood glucose level.

■ Doing a Control Solution Test

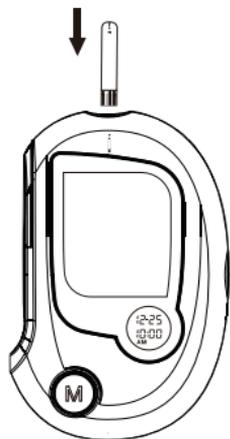
TAKE A TEST STRIP OUT WITH CLEAN AND DRY HANDS FIRST.

STEP 1. Insert the Test Strip

Insert a test strip with contact bars end first and facing up into the test slot. The meter turns on automatically and displays the following in sequence:

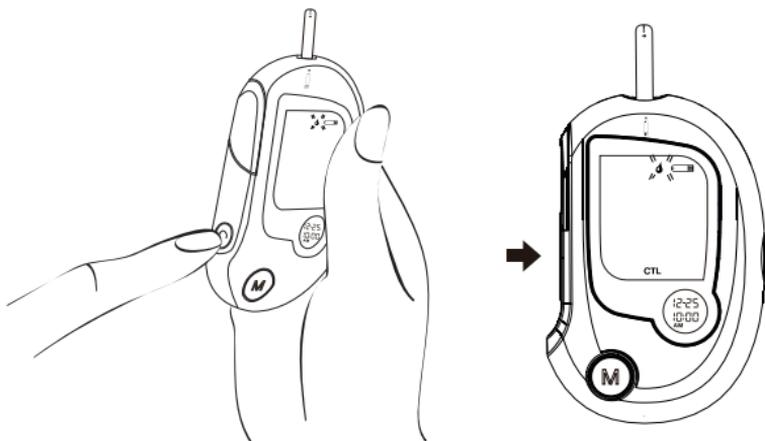
→ “CHK” and “”

→  and flashing “” with date and time.



STEP 2. Press the C button

While the “” symbol appears on the display, press the C button and then “CTL” will appear on the display. With the “CTL” sign on the display, the meter will not store your test result in memory. If you decide not to perform a control solution test, press the C button again, and the “CTL” sign will disappear.



WARNING

- ▶ Contact bars must be inserted all the way into the meter or you may get an inaccurate test result.
- ▶ Every time you perform a control solution test, you must enter into the “CTL” test mode so that the test result will not be stored in the meter memory. Failure to do so will confuse the blood glucose test result with the control solution test result in memory.

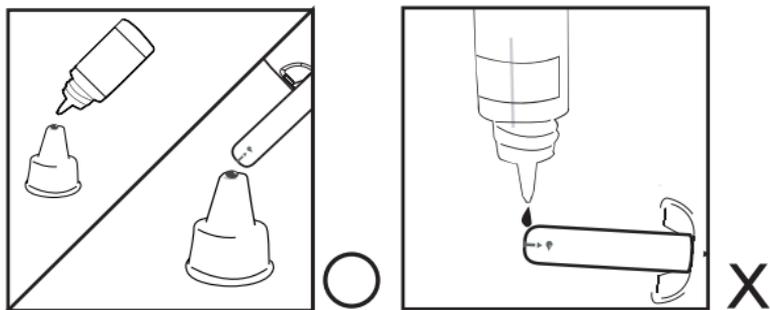
STEP 3. Obtain Control Solution.

Shake the control solution vial well. Remove the cap from the control solution bottle. Place cap on flat surface. Squeeze the vial, discard the first drop, and wipe off the dispenser tip to prevent contamination. Squeeze the vial again to get another drop and apply the drop to the top of cap.

STEP 4. Apply Control Solution.

While holding the meter, move the absorbent hole of the test strip to touch the drop of control solution. Then the drop will be automatically drawn into the test strip. Make sure the confirmation window fills completely. The meter begins to count down.

To avoid contaminating the control solution with the content of the test strip, you have to place a drop of control solution on a clean surface. Do not directly apply control solution into a strip.



STEP 5. Read and Compare the Result

After counting to 0, the test result of control solution is shown on the screen. Compare this result with the range printed on the test strip vial. It should fall within this range.



Out-of-range results

If test results fall outside the range printed on the test strip vial, check the section "Problem in Operation" in troubleshooting guide and repeat the test. If you continue to get out-of-range results, it means that the system may not be working properly. Do NOT test your blood. Please call your local agent for help.

● TESTING YOUR BLOOD

Be sure to read this section and the test strip package insert found in the test strip box carefully before testing. Make sure you have all items needed to test:

- A. Blood Glucose Meter
- B. Test Strip
- C. Lancing Device
- D. Sterile Lancet
- E. Clear Cap (For AST use)



WARNING

To reduce the chance of infection:

- ▶ Never share a lancet or the lancing device with others.
- ▶ Always use a new, sterile lancet. Lancets are for single use only.
- ▶ Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.

■ Testing Procedure

Wash and dry your hands first before testing.

STEP 1. Set the Lancing Device

Pull off the cap of the lancet device.



Insert a lancet into the lancet holder and push down firmly until it is fully in place.



Twist the protective disk off from the lancet.



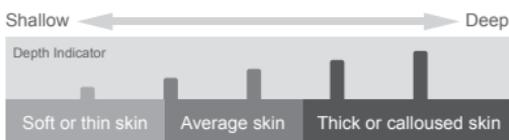
Replace the cap by aligning the arrow on the cap with the release button.



Select the depth of penetration by turning the adjustable tip in either direction so that the arrow on the cap points to the appropriate depth.



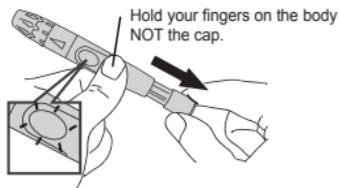
This Lancing Device offers you 5 depths of skin penetration:



The longer the length of the indicator line, the greater the depth of penetration.

Pull the cocking control back until it clicks. You will see a color change inside the release button when it is ready.

► If it does not click the device may have been cocked when the lancet was inserted.



► Blood from sites other than the fingertip

Replace the lancing device cap with the clear cap for alternative site testing. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, hand, thigh, or calf, avoid lancing the areas with obvious veins for excess bleeding.



The lancing device is now ready for use. Set aside for later use.

STEP 2. Insert Test Strip

Insert a test strip with contact bars end first and facing up into the test slot. The meter turns on automatically and displays the followings in sequence:

→ “CHK” and “”

→  and flashing “” with date and time.



STEP 3. Get a Drop of Blood

Select the puncture site either in finger or in other parts (AST). Clean the puncture site with 70% alcohol cotton and **let it air-dry**.

► Fingertip

Press the lancing device's tip firmly against the side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.



► Sites other than fingertip

Please refer to the section of "About AST" for available punctured sites.

After penetration, discard the first drop of blood with a clean tissue paper or cotton. Then gently squeeze the punctured area to obtain blood. But be attention **NOT to smear the blood sample**.



The volume of blood sample must be at least 0.7 microliter (° actual size).

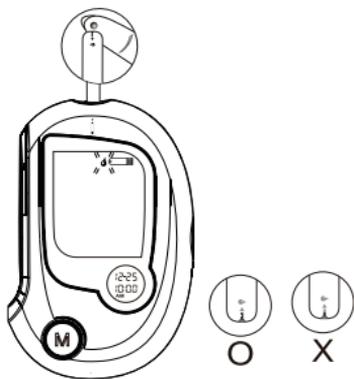


PLEASE NOTE

- Choose a different spot each time you test. Repeated punctures in the same spot may cause soreness and calluses.
- Before you decide to do AST, please consult your health professional firstly.
- Since the first drop of blood usually contains tissue fluid and serum, which may affect the test result, it is recommended to discard it.

STEP 4. Apply Blood into the Test Strip

When “**4**” is flashing on the screen, apply your blood to the absorbent hole of the test strip until the confirmation window is **fully covered** with blood. The meter then begins to count down automatically.



STEP 5. Obtain an Accurate Result in 7 Seconds

The result of your blood glucose test is shown after the meter counts to 0. This reading is automatically stored in the meter.

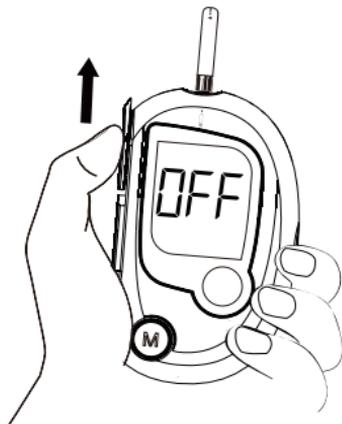


PLEASE NOTE

- ▶ Do not push your finger (with blood on it) against the test strip or try to apply a smeared sample on the test strip.
- ▶ If you do not apply a blood sample to the test strip within 3 minutes, the meter will automatically turn off. You must remove and reinsert the test strip to restart the test procedure.
- ▶ The blood should completely fill the confirmation window before the meter begins to count down. If you find that the confirmation window is not filled with blood when the meter is counting, **NEVER** try to add more blood to the test strip. **Discard the test strip and retest with a new one.**
- ▶ If you have trouble filling the test strip, please contact customer services for help.

STEP 6. Eject the Used Test Strip

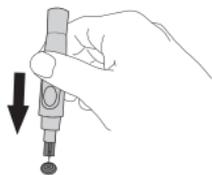
After finishing the measurement, you can either take out the used strip by simply pushing up the Strip-Ejection button or remove the test strip directly by your hand. "OFF" is shown after the used strip is ejected and the meter will turn off automatically afterwards.



STEP 7. Remove the Lancet

Always use caution when removing the lancet.

Remove the lancet by pulling the cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface, and pushing the exposed tip into the disk.



Slide the ejector forward to remove the used lancet. Dispose of the lancet according to your local regulations.

► For collecting blood samples from sites other than the fingertip, use the clear cap.



WARNING



The used lancet and the used test strip may be potentially biohazardous. Please discard it carefully according to your local regulations.

■ Expected Test Results

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that **keeping blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%* . The results you get with the GlucoRx TD-4230 system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

	Time of day	
	Fasting and before meals	2 hours after meals
Plasma glucose range (mmol/L) for people without diabetes	3.5-5.5 mmol/L	Less than 8 mmol/L
Children with Type 1 diabetes (NICE 2004)	4-8 mmol/L	Less than 10 mmol/L
Adults with Type 1 diabetes (NICE 2004)	4-7 mmol/L	Less than 9 mmol/L
Type 2 diabetes (NICE 2008)	4-7 mmol/L	Less than 8.5 mmol/L

* Diabetes UK's reference:

http://www.diabetes.org.uk/Guide-to-diabetes/Treatment__your_health/Monitoring/Blood_glucose/Blood-glucose-target-ranges/

Please work with your doctor to determine a target range that works best for you.

*1: American Diabetes Association position statement on the Diabetes Control and Complications Trial (1993).

● COMPARING METER AND LABORATORY RESULTS

Test results from the meter and laboratory are both expressed in whole blood equivalent units. However, the result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way. (See test strip package insert for typical accuracy and precision data, and for important information on Limitations.) To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before going to the lab:

- ▶ Perform a control solution test to make sure that the meter is working properly.
- ▶ It is best to fast for at least eight hours before doing comparison tests.
- ▶ Take your meter with you to the lab.

While staying the lab:

Make sure that the samples for both tests (the meter test and the lab test are taken and tested within 15 minutes of each other).

- ▶ Wash your hands before obtaining a blood sample.
- ▶ Never use your meter with blood that has been collected in a grey-top test tube.
- ▶ Use fresh capillary blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods, especially if you have recently eaten, exercised, taken medication, or experienced stress*². In addition, if you have eaten recently, the blood glucose level from a finger stick can be up to 3.9 mmol/L(70 mg/dL) higher than blood drawn from a vein (venous sample) used for a lab test*³.

Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (severe dehydration) may also cause a meter result to be different from a laboratory result.

References

*2: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

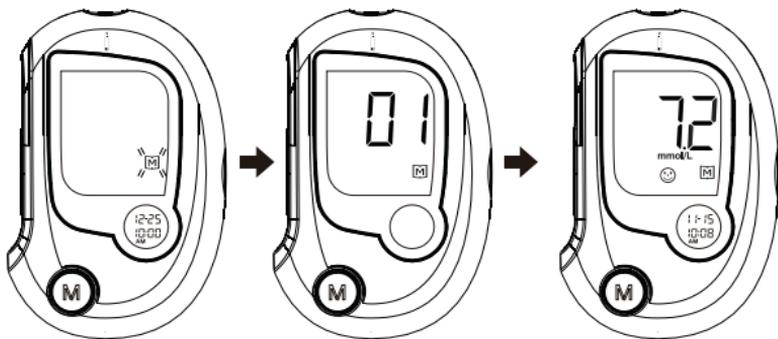
*3: Sacks, D.B.:“Carbohydrates. “Burtis, C.A.,and Ashwood, E.R.(ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

● USING THE METER MEMORY

Your meter stores the latest 450 results of your blood glucose with date and time in its memory. It also automatically calculates the averages of your blood glucose in the intervals of 7, 14, 21, 28, 60 and 90 days. You can review the results easily by the following steps.

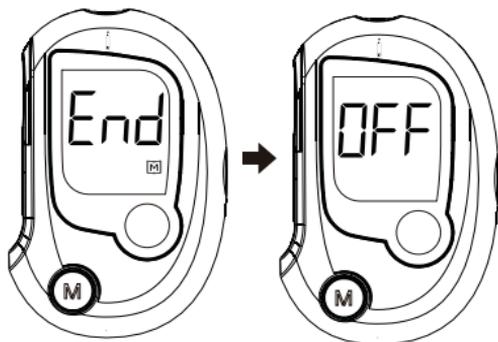
1. Recall the Stored Test Results

STEP 1. When the meter is off, press and release the M button. The screen shows “M”. Press the M button again, “01” appears first and then the latest glucose result along with date and time will be shown on the screen.



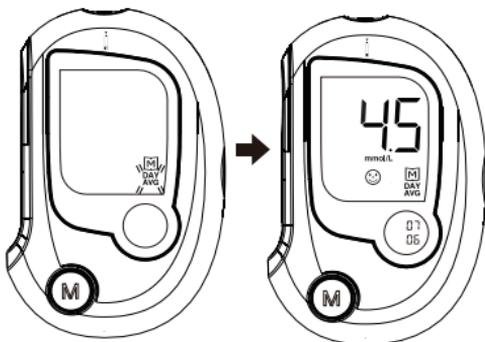
STEP 2. Press the M button once by once to recall the test results stored in the meter consecutively.

STEP 3. After the last test result, press the M button again and the meter will be turned off.



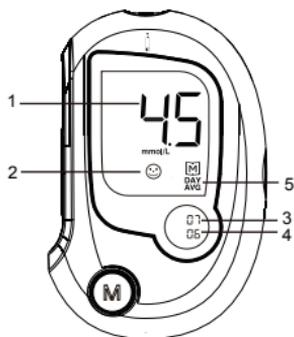
2. Read the Average of Blood Glucose Results:

STEP 1. When the meter is off, press and release the M button. The screen shows “M”. Keep pressing the M button for 2-3 seconds, until blinking “DAY AVG” appears. Release the M button and then the 7-day average result will appear on the screen.



The 7- day average is calculated from the blood glucose results obtained during the last 7 days.

- ① The **average** of glucose tests.
- ② Result indicator.
- ③ The average was calculated from the test results of the **last 7 days**.
- ④ **6 glucose tests** have been performed in the last 7 days.
- ⑤ You can interpret the figure as: The average of 6 glucose test in the last 7 days is 4.5 mmol/L.

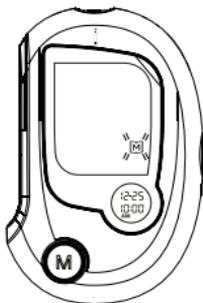


STEP 2. Press the M button once by once to review the 14-, 21-, 28-, 60- and 90- day average in order. Like the 7-day average, the 14-day average and the times of performing test in the past 14 days will be shown on the screen.

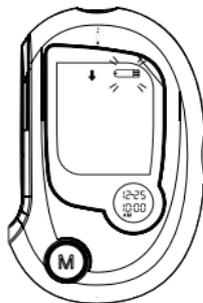
STEP 3. After the 90-day average, press the M button again and it will go to the most recent test result. Follow the steps in “Recall the Stored Test Results” to review individual result.

Please remember:

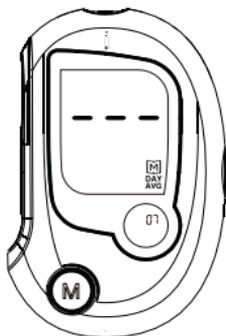
1. When pressing the M button to recall the stored test results, blinking “**M**” will be displayed on the screen first. If you do not press the M button within 5 seconds, the blinking “**⏏**” will appear. In the meantime, you can choose to insert a test strip to **start testing your blood** or to press the M button again to review the **stored test results**.



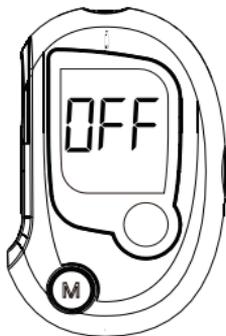
➔
Without actions in
5 seconds.



2. When using the meter for the first time, “---” is displayed when you recall the test results or review the average result. It means that there is no test result in memory.



3. Anytime when you want to exit the memory, keep pressing the M button for 3 seconds until “OFF” displays. The meter then automatically shuts down.



4. If no button is pressed within 2 minutes, the meter will show “OFF” and turn off automatically.
5. The control solution results are **NOT** stored in the memory (please also go to page 28 **WARNING** for information). The list of past results and the average result are for blood glucose results only.

● VIEWING RESULTS ON A PERSONAL COMPUTER

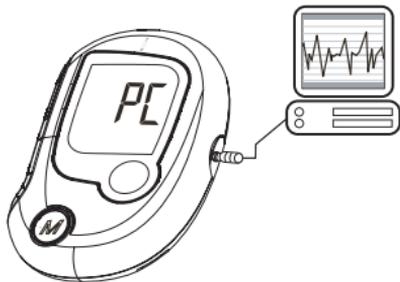
Results recorded in the meter can be transmitted to the personal computer. Health Care System Software and the Interface Cable are required before installation. You can download this software directly from the homepage of GlucoRx. The interface cable is an optional accessory. To learn more about Health Care System Software or to obtain an Interface Cable separately, please contact your local customer service.

STEP 1. Install Software

Install Health Care System Software on your computer by following the instructions provided at www.glucoRx.co.uk

STEP 2. Connect to Personal Computer

Connect the interface cable to a serial port of your computer. With the meter turned off, connect the Interface Cable to the Data Port of the meter. "PC" will appear on the display, indicating that the meter is ready to transmit data.



Step 3 Transmit Data

Follow the instructions provided in the software to transmit data. Results transmitted will include date and time. Remove the cable and the meter will automatically turn off.

PLEASE NOTE

While the meter is connected to the PC, it is unable to perform a blood glucose test.

● TAKE CARE OF YOUR METER AND STRIP

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

■ Cleaning

1. To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
2. Do not use organic solvents to clean the meter.

■ Storage

1. Meter Storage



- ▶ Storage condition: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.



- ▶ Always store or transport the meter in its original storage case.



- ▶ Avoid dropping and strong impact.

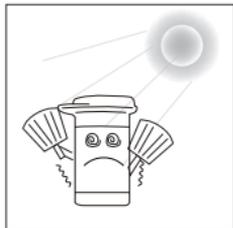


- ▶ Avoid direct sunlight and humidity.

2. Strip Storage



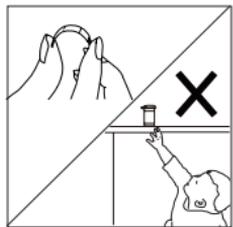
- ▶ Storage condition: 4°C to 40°C, below 85% relative humidity. Do not freeze.
- ▶ Store your test strips in their original vial only. Do not transfer to other container.



- ▶ Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
- ▶ After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
- ▶ Touch the test strip with clean and dry hands.



- ▶ Use each test strip immediately after removing it from the vial.
- ▶ Write the first opening date on the vial label when you first open it. Discard remaining test strips 3 months after first opening date.



- ▶ Do not bend, cut, or alter a test strip in any way.
- ▶ Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

3. Control solution storage



- ▶ Storage condition: Store the control solution tightly closed at temperatures 2°C to 30°C. Do not freeze.
- ▶ Record the first opening date on the control solution vial. Discard after 3 months.

● PROBLEM-SOLVING GUIDES

If you get any problem in performing test with this meter, please refer to the following problem-solving guides. They help you to identify and solve certain problems, but not in all circumstances. Improper use may cause inaccurate results without showing any error message or symbol. In the event of a problem, refer to the information under action.

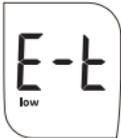
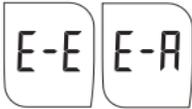
Never try to disassemble the meter under any circumstances. If you encounter any error messages not listed below or if you have followed the actions recommended below but the problem is unsolved, please call the local dealer for support.

■ Result Indicator

Special symbols and messages appear together with your test result.

Message	What it means
	Lo appears when your result is below measurement limit, which is less than 1.1 mmol/L (20 mg/dL)
	low ☹️ appears when your result is between 1.1 and 3.9 mmol/L (20 and 70 mg/dL). It indicates that the result is below reference range.
	☺️ appears when your result is in the reference range from 4.0 and 8.9 mmol/L (72 and 160 mg/dL)
<p>“Lo” or “low☹️” symbol indicates hypoglycaemia (low blood glucose.) You should contact with your healthcare professionals for further treatment immediately.</p>	
	high ☹️ appears when your result is equal or greater 9.0 mmol/L (162 mg/dL) . It indicates that the result is higher than reference range.
	KETONE? and high ☹️ are shown when your result is equal or higher than 15 mmol/L (270 mg/dL). This indicates the possibility of ketone accumulation for Type 1 diabetes. Please seek medical assistance immediately.
	Hi is displayed when your result is higher than the limit of the measurement, which is higher than 33.3 mmol/L (600 mg/dL)

■ Error Message

Message	What it means	Action
	Appear when the battery can not provide enough power for a test.	Replace the battery immediately.
	Appear when inserting a used test strip.	Test with a new test strip.
	Appear when environmental temperature is below system operation range: 10°C.	System operation range is 10°C to 40°C (50°F to 104°F). Repeat the test after the meter and test strip have reached the above temperature.
	Appear when environmental temperature is above system operation range: 40°C.	
	Remove the strip after applying blood to the absorbent hole.	Re-test with a new test strip.
	Problem with the meter.	Review the instructions and re-test with a new test strip. If the above steps do not work, please contact the dealer.

■ Problem in Operation

1. If the meter does not display a message after inserting a test strip:

PROBABLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Battery incorrectly installed or absent.	Check that the battery is correctly installed.
Test strip inserted upside down or incompletely.	Insert the test strip correctly with the contact bars end first and “  ” facing up .
Defective meter.	Please call the dealer for service.

2. If the test does not start after applying the sample:

PROBABLE CAUSE	WHAT TO DO
Insufficient blood sample.	Repeat the test using a new test strip with larger volume of blood sample.
Defective test strip.	Repeat the test with a new test strip.
Did not apply sample until “  ” is flashing.	Repeat the test with a new test strip. Apply sample only when flashing “  ” appears on the display.
Defective meter.	Please call the dealer for service.

3. If the control solution test result is out of range.

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read the instruction thoroughly and repeat the test again.
Do not shake the control solution vial very well.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date or the discarded date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should come to room temperature (20°C to 25°C/68°F to 77°F) before testing.
Test strip deterioration.	Repeat the test with a new test strip.
Meter malfunction.	Contact local customer service.

● SPECIFICATIONS

Model No.:TD-4230

Dimension&Weight: 88mm(L) x 53mm(W) x 15mm(H),
43.58g

Power source: one CR2032 battery

Memory: 450 measurement results with date and time

Power saving : Auto turn-off after 3 minutes without action

External output : Standard RS232 PC interface

Operating condition: 10°C to 40°C, below 85% R.H. (noncondensing)

Strip Storage/Transportation condition: 4°C to 40°C(39.2°F to 104°F),
below 85% R.H.

Meter Storage/Transportation condition:-20°C to 60°C(-4°F to 140°F),
below 95% R.H.

Measurement Range: 1.1 to 33.3 mmol/L (20 to 600 mg/dL)

Measurement Units: mmol/L

Result indicator : 😊 appears when glucose value is between 4.0 and 8.9
mmol/L (72 and 160 mg/dL)

low 😞 appears when glucose value is between 1.1 and 3.9
mmol/L (20 and 70 mg/dL)

L □ appears when glucose value is less than 1.1
mmol/L (20 mg/dL)

high 😡 appears when glucose value is equal to or
greater than 9.0 mmol/L (162 mg/dL)

KETONE? when glucose value is equal to or greater
than 15 mmol/L (270 mg/dL)

H | appears when glucose value is higher than 33.3
mmol/L (600 mg/dL)

This device has been tested to meet the electrical and safety requirements of: IEC 60601-1, EN 60601-1, IEC 61010-1, EN 61010-1, EN 61010-2-101, EN 60601-1-2, EN 61326.

● SYMBOL INFORMATION

Symbol	Referent
	For in vitro diagnostic use only
	Do not reuse
	Read instructions before use
	Keep away from sunlight
	Keep dry
	Temperature limitation
	Use by
	Batch code
	Manufacturer
	Serial number
	Caution, consult accompanying documents
	Biological risks
	Authorised representative in the European Community
	CE mark
	Do not use if package is damaged
	Use within 3 months after opening
	Sterilised using irradiation

● SUMMARY OF OPERATION

This summary is intended only for quick reference and can't be taken as the substitute for the owner's manual. Please read the entire manual before you begin doing test.

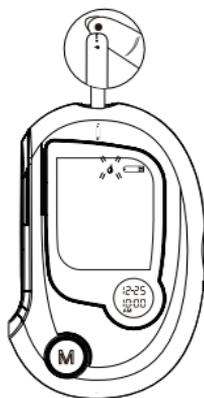
STEP 1. Insert test strip

The meter is automatically turned on.



STEP 2. Puncture and apply sample

Hold the drop of blood and make it fully contact to the absorbent hole of test strip until the confirmation window is completely filled.



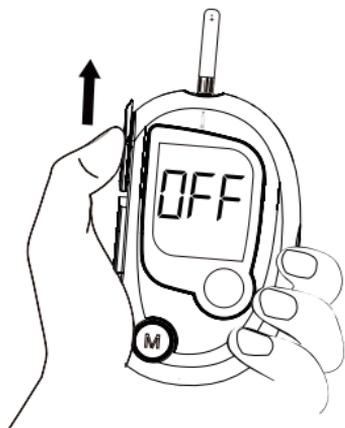
STEP 3. Obtain a result

The meter starts to count down. Never try to add any blood into the absorbent hole even if you find that the confirmation window is not fulfilled. Discard the strip and retest with a new strip.



STEP 4.

Eject the used strip by pushing the strip-ejection button.



STEP 5.

Discard the used strip and the lancet according to your local regulations.

