

metene

Blood Glucose Monitoring System



Owner's Manual

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Location: Moldova



Dear metene System Owner:

Thank you for choosing the **metene** TD-4116 Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the local customer service or place of purchase.

Intended Use

The **metene** TD-4116 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The **metene** TD-4116 Blood Glucose Monitoring System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

AST in this system can be used only during steady-state blood glucose conditions described in the section of “Alternative Site Testing (AST).”

IMPORTANT SAFETY PRECAUTIONS

READ BEFORE USE

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit

1. "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

<http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

2. "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

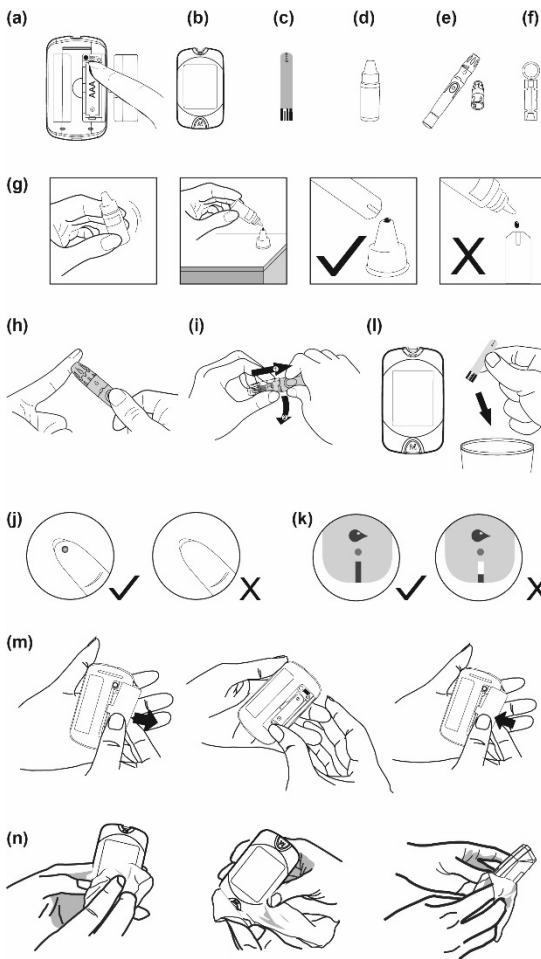
1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer.
3. Do **NOT** use the device if it is not working properly or if it is damaged.

4. Do NOT use the equipment in places where aerosol sprays are being used, or where oxygen is being administered.
5. Do NOT under any circumstances use the device on neonates or infants.
6. This device does NOT serve as a cure for any symptoms or diseases. The data measured is for reference only.
7. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
8. Keep the device and testing equipment away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
9. Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as this may interfere with the accurate operation.
10. Proper maintenance and periodically control solution test are essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact your local customer service or place of purchase for help.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

TABLE OF CONTENTS

BEFORE YOU BEGIN	1
Important Information	1
Test Principle	3
Contents of System	3
Meter Overview	4
Display Screen	5
Test Strip	5
SETTING THE METER	6
THE FOUR MEASURING MODES	7
BEFORE TESTING	8
Control Solution Testing	8
Performing a Control Solution Test	8
TESTING WITH BLOOD SAMPLE	10
Preparing the Lancing Device for Blood Testing	10
Preparing the Puncture Site	10
Performing a Blood Glucose Test	12
Alternative Site Testing	14
METER MEMORY	16
Reviewing Test Results	16
Reviewing Blood Glucose Day Average Results	16
DOWNLOADING RESULTS TO A COMPUTER	17
Data transmission via cable	17
MAINTENANCE	18
Battery	18
Caring for Your Meter	19
Disinfecting Procedures	20
Caring for Your Test Strips	21
Important Control Solution Information	22
MEASUREMENT RESULT READINGS	23
Result Readings	23
Reference Values	24
Comparing Meter and Laboratory Results	24
SYSTEM TROUBLESHOOTING	26
Error Messages	26
Troubleshooting	27
SPECIFICATIONS	28



BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh whole blood samples to test your blood glucose. Using other substances will lead to inaccurate results.
- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- The device should not be used on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

- Limitation

The device should not be used on individuals in hyperglycemic-hyperosmolar state, with or without ketosis; not for neonatal use; not for use on critically ill patients.

This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Test Principle

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Contents of System

Your new blood glucose monitoring system kit includes:

1. Meter
2. Owner's Manual
3. Protective Wallet
4. Quick Start Guide
5. Blood Glucose Test Strips
6. Lancing Device
7. Sterile Lancets
8. 1 x 1.5 V AAA alkaline batteries

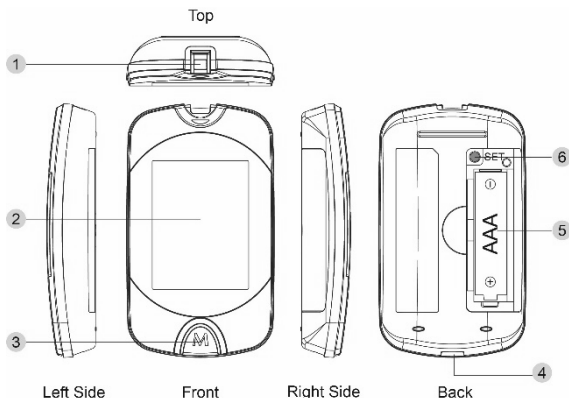
Test strips (c), control solutions (d), sterile lancets (e) or lancing device (f) are not included in the kit. They must be purchased separately. Please make sure you have those items needed for a blood glucose test beforehand.

The USB cable is not provided in the kit but an accessory for the data transmission feature connecting to your PC (see section Downloading Results onto your Computer). Please contact local customer services or the place of purchase for obtaining the cable.

NOTE:

If any items are missing from your kit or opened prior to use, please contact local customer services or place of purchase for assistance.

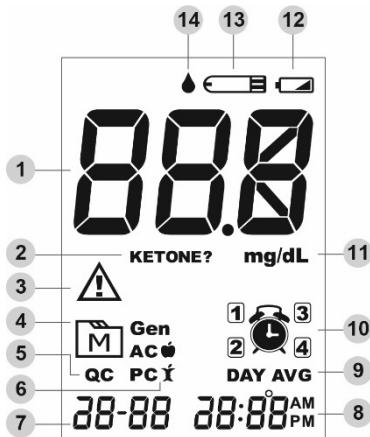
Meter Overview



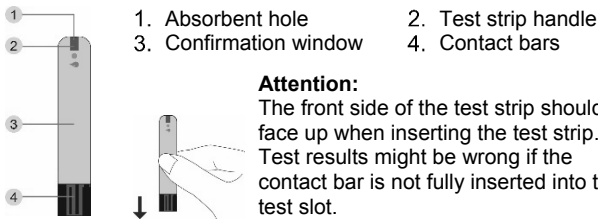
1. **Test Strip Slot & Strip Indicator**
Insert test strip here to turn the meter on for testing.
2. **Display Screen**
3. **M Button (M)**
Enter the meter memory and mute a reminder alarm.
4. **Data Port**
Transfer test results with a cable connection.
5. **Battery Compartment**
6. **SET Button (S)**
Enter and confirm the meter settings.

Display Screen

1. Test Result
2. Ketone warning
3. Error Warning
4. Memory symbol
5. Control solution mode
QC – control solution test
6. Measurement modes
AC – before meal
PC – after meal
Gen – any time of day
7. Date
8. Time
9. Day average
10. Reminder alarms
11. Measurement unit
12. Low battery symbol
13. Test strip symbol
14. Blood drop symbol



Test Strip



Attention:

The front side of the test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

The **metene TD-4116 Blood Glucose Meter** should only be used with **metene TD-4116 Blood Glucose Test Strips**. Using other test strips with this meter can produce inaccurate results

SETTING THE METER

Before using your meter for the first time or if you change the meter battery, you should check and update these settings.

Entering the Setting Mode (a)

Start with the meter off (no test strip inserted). Press **SET (S)**.

1. Setting the date

The sequence of the date setting is: YEAR → MONTH → DAY.
With the YEAR/MONTH/DAY flashing in sequence, press **M button (M)** until the correct year/month/day appears. Press **S**.

2. Setting the time format

Press **M** to select the desired time format (12h or 24h). Press **S**.

3. Setting the time

With the Hour/Minute flashing in sequence, press **M** until the correct hour/minute appears. Press **S**.

4. Deleting the memory

With "dEL" and a  symbol on the display, press **M** and select "no" to keep the results in memory then press **S** to skip. To delete all the results, press **M** and select "yes" to delete all memory records.

5. Setting the reminder alarm

Your meter has four reminder alarms. The meter will display "OFF" and "". If you don't want to set an alarm, press **S** to skip this step.

To set an alarm, press **M** to select "On", then press **S**. With the hour/minute flashing in sequence, press **M** to select the correct hour/minute. Press **S** and go to the next alarm setting.

When the alarm beeps, you can press **M** to silence it or insert a test strip to begin testing; if you ignore it, the meter will beep for 2 minutes then switch off.

Congratulations! You have completed all settings!

NOTE:

- These parameters can **ONLY** be changed in the setting mode.
- If the meter is idle for 3 minutes during the setting mode, it will switch off automatically.

THE FOUR MEASURING MODES

The meter provides you with four modes for measuring, General, AC, PC and QC. You can switch between each mode by:

1. Start with the meter switched off. Insert a test strip to turn on the meter. The screen will display a flashing blood drop and "Gen".
2. Press M button to switch between General, AC, PC and QC mode.

BEFORE TESTING

Control Solution Testing

Our Control Solution contains a known amount of glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

Do a control solution test when:

- You first receive the meter
- At least once a week to routinely check the meter and test strips
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process
- You have dropped or think you may have damaged the meter

Performing a Control Solution Test

To perform a control solution test, you will need: (b), (c) and (d).

1. Insert the test strip into the meter. There will be a strip light indicating the test strip is inserted into the test slot. Wait for the meter to display “” and “”.
2. Press M button to mark this test as a control solution test
3. With “**QC**” displayed, the meter will store your test result in memory under “**QC**”. If you press **M** again, the “**QC**” will disappear and this test is no longer a control solution test.

WARNING:

When doing the control solution test, you have to mark it so that the test result will NOT mix with the blood glucose TEST RESULTS stored in the memory. Failure to do so will mix up the blood glucose test results with the control solution test results in memory.

4. Apply Control Solution (g)

Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap. Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down. To avoid contaminating the control solution, do not directly apply control solution onto a strip

5. Read and Compare the Result

After counting down to 0, the control solution test result will appear on the display. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See **MAINTENANCE** section for important information about your control solutions.

TESTING WITH BLOOD SAMPLE

WARNING:

To reduce the chance of infection:

- Never share a lancet or the lancing device.
- 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.
- Wash and dry your hands thoroughly after handling the meter, lancing device and test strips to prevent infection. For more information, please refer to the “Cleaning and Disinfection” section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.

Sharing the lancing device and lancets may increase the risk of contracting infectious diseases. Lancing device must not be used for more than one person.

Preparing the Lancing Device for Blood Testing

Please refer to the manufacturer's instructions for the lancing device to collect a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction significantly reduces variations between measurements.

Please follow the suggestions below before obtaining a drop of blood:

- Wash and dry your hands before starting.
- Select the puncture site at fingertips or another body parts (please see section “Alternative Site Testing” (AST) on how to select the appropriate sites).
- Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.
- Rub the puncture site for about 20 seconds before penetration.
- Use a clear cap (included in the kit) while setting up the lancing device.

Fingertip testing (h)

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

Blood from sites other than the fingertip (i)

Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, or hand, avoid lancing the areas with obvious veins because of excessive bleeding.

NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- Please consult your healthcare professional before you begin AST.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Performing a Blood Glucose Test

To perform a blood glucose test, you will need: meter (b), strip (c), sterile lancet (f) and lancing device (e).

1. Insert the test strip to turn on the meter

Wait for the meter to display “” and “”.

2. Select the appropriate measuring mode by pressing **M**.

3. **Obtaining a blood sample (j)**

Use the pre-set lancing device to puncture the desired site. Wipe off the first appeared drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. The volume of blood sample must be at least 0.7 microliter (μL) of volume. ( actual size). Be careful **NOT** to smear the blood sample.

4. **Apply the Sample (k)**

Gently apply the drop of blood to the absorbent hole of the test strip at a tilted angle. Confirmation window should be completely filled if enough blood sample has been applied. Do NOT remove your finger until you hear a beep sound.

NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- 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 start a new test.
- The confirmation window should be filled with blood before the meter begins to count down. **NEVER** try to add more blood to the test strip after the drop of blood has moved away. **Discard the used test strip and retest with a new one.**
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

5. Read Your Result

The result of the blood glucose test will appear after the meter counts down to 0. This blood glucose result will automatically be stored in the memory.

6. Remove the used test strip and lancet (I)

Remove the test strip by hand; throw the strip into a disposal container. The meter will turn itself off automatically after the test strip is removed.

Always follow the instructions in the lancing device package insert when removing the lancet.

WARNING:

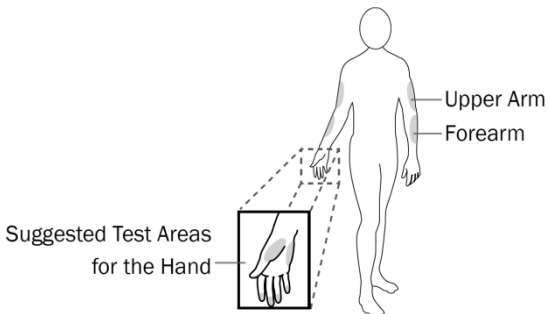
- The used lancet and test strip may be biohazards. Please follow your healthcare provider's recommendations for proper disposal.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device and test strips to avoid contamination. For more information, please refer to the "Cleaning and Disinfection" section.

Alternative Site Testing

When you are doing alternative site testing, only samples from the palm, upper arm and forearm should be used.

IMPORTANT:

There are limitations with AST (Alternative Site Testing). Please consult your health care professional before you perform AST. AST should not be used for calibrating continuous glucose monitors (CGMs). AST should not be used for insulin dose calculations. AST can be used only during steady-state blood glucose conditions.



When to use AST?

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

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or fasting state (more than 2 hours since 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 hypoglycemia.
- You are testing for hyperglycemia.
- Your AST results do not match the way you feel.
- Your routine glucose results often fluctuate.

METER MEMORY

The meter stores the 450 most recent blood glucose test results along with respective dates and times in its memory. To enter the meter memory, **start with the meter switched off.**

Reviewing Test Results

1. Press and release **M**. “ ” will appear on the display. Press **M** again, and the first reading you see is the last blood glucose result along with date, time and the measurement mode.
2. Press **M** to recall the test results stored in the meter each time you press. After the last test results, press **M** button again and the meter will be turned off.

Reviewing Blood Glucose Day Average Results

1. Press and release **M**. When “ ” appears on the display, keep pressing **M** for 3 seconds until the flashing “**DAY AVG**” appears. Release **M** and then your 7-day average result measured in general mode will appear on the display.
2. **Press M to review** 14-, 21-, 28-, 60- and 90- day average results stored in each measuring mode in the order of Gen, AC, and then PC.
3. **Exit the meter memory.** Keep pressing the **M** button and the meter will turn off after displaying the last test result.

NOTE:

- Any time you wish to exit the memory, keep pressing **M** button for 5 seconds or leave it without any action for 3 minutes. The meter will switch off automatically.
- Control solution results are **NOT** included in the day average.

DOWNLADING RESULTS TO A COMPUTER

Data transmission via cable

You can use the meter with the USB cable and the Health Care Software System to view test results on your personal computer. To learn more about the Health Care Software System or to obtain the USB cable separately, please contact local customer services or the place of purchase for assistance.

1. Obtaining the required cable and installing the software.

To download the Health Care Software System, please visit the metenecare, website at <http://metene.com>.

2. Connecting to a personal computer

Connect the cable to the USB port on your computer. With the meter switched off, connect the other end of the USB cable to the meter data port. "USB" will appear on the meter display, indicating that the meter is in communication mode.

3. Data transmission

To transmit data, follow the instructions provided with the software. Results will be transmitted with date and time. Remove the cable and the meter will automatically switch off.

WARNING:

While the meter is connecting to the PC, it will be unable to perform a blood glucose test.

MAINTENANCE

Battery

Your meter comes with one 1.5 V AAA size alkaline battery.

Low Battery Signal

The meter will display one of the messages below to alert you when the meter power is getting low.

1. The “” symbol appears along with display messages:
The meter is functional and the result remains accurate, but it is time to change the batteries.
2. The “” symbol appears with E-b and “ **LOW**”:
The power is not enough to do a test. Please ~~change~~ change the batteries immediately.

To replace the batteries, make sure that the meter is turned off.
(m)

1. Press the edge of the battery cover and lift it up to remove.
2. Remove the old batteries and replace with one 1.5 V AAA size alkaline battery.
3. Close the battery cover. If the battery is inserted correctly, you will hear a "beep" afterwards.

NOTE:

- Replacing the batteries does not affect the test results stored in the memory.
- As with all small batteries, these batteries should be kept away from small children. If swallowed, promptly seek medical assistance.
- Batteries might leak chemicals if unused 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).

- Properly dispose of the batteries according to your local environmental regulations.
- After replacing the battery, the meter will enter the setting mode.

Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash hands thoroughly with soap and water before and after use.

Why the cleaning and disinfection should be performed

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

When to clean and disinfect the meter

Clean the meter when you see any dirt on it. You should disinfect the meter at least once a week to prevent infection.

How to clean and disinfect the meter

The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt or blood or any other body fluid with the wipe. Use a second wipe to disinfect the meter. **Do NOT use organic solvents to clean the meter.**

- We recommend for meter cleaning and disinfection you should use the disinfecting wipes/towelettes

Disinfecting Procedures

1. Wipe all meter's exterior surface display and buttons by three passes vertically and three passes horizontally with a folded disinfecting towelette. Hold the meter with the test strip slot pointing down and wipe the area around the test slot but be careful not to allow excess liquid to get inside. Keep meter wet with disinfection solution contained in the wipe for a minimum of 2 minutes for Micro-Kill+™ wipes. (n)
2. Remove the wipe. Allow the meter surface to dry completely.
3. Discard the used wipes and never reuse them. Users should wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

This device has been validated to withstand up to 10950 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 10 cleaning and disinfection cycles per day over 3 years. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Stop using the meter if you see any signs of deterioration. For example:

- Meter cannot be turned on
- LCD display cracks or becomes cloudy
- Buttons no longer function
- Meter outer casing cracks
- Data cannot be transmitted to pc
- Color or paint/printing on housing is abnormal
- Scratches or abrasions on meter are higher than acceptable

Please contact the customer service for a replacement meter if any of the signs of deterioration are noticed.

NOTE:

- Do NOT clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do NOT allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry

Caring for Your Test Strips

- Storage conditions: 39.2°F ~ 104°F (4°C ~ 40°C), relative humidity between 10% ~ 85%. Do not freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands.
- Use each test strip immediately after removing it from the vial.
- Do not use test strips after the expiration date. This may cause inaccurate results.
- 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.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only **metene** Control Solutions with your meter.
- Do not use the control solution after the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature (68°F ~ 77°F / 20°C ~ 25°C). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 35.6°F ~ 86°F (2°C ~ 30°C). Do **NOT** freeze.

MEASUREMENT RESULT READINGS

Result Readings

MESSAGE	WHAT IT MEANS
	Appears when your result is below measurement limit, which is less than 20 mg/dL (1 mmol/L). This indicates hypoglycemia (low blood glucose). You should seek medical assistance immediately.
	Appears when your result is equal to or higher than 240 mg/dL (13.3 mmol/L). This indicates the possibility of ketone accumulation for type 1 diabetes. Please seek medical assistance immediately. The User's blood glucose level has exceeded 240 mg/dL (13.3 mmol/L), possible of ketoacidosis. Please consult with the healthcare professionals for further inspection. Source: Abbas E. Kitabchi et al., Diabetes Care. 2009 Jul; 32(7): 133532(7): 1335–1343.
	Appears when your result is higher than the limit of measurement, which is higher than 600 mg/dL (33.3 mmol/L).

Reference Values

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining **blood glucose levels close to normal** can reduce the risk of diabetes complications by up to 60%*¹. The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes.

Time of day	Normal plasma glucose range for people without diabetes (mg/dL)
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

*1: American Diabetes Association. Standards of Medical Care in Diabetes- 2018 Jan; 41(Supplement 1): S1-S2.

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

Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. 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.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

While staying at the lab:

Make sure that the samples for both tests 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 gray-top test tube.
- Use fresh capillary or venous blood only.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, 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 prick can be up to 70 mg/dL (3.9 mmol/L) 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 (dehydration) may also cause a meter result to be different from a laboratory result.

*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.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please contact your local customer service. Do not attempt to repair yourself and never try to disassemble the meter under any circumstances.

Error Messages

MESSAGE	WHAT IT MEANS	ACTION
E-b	Appears when the battery cannot provide enough power for a test.	Replace the battery immediately.
E-U	Appears when a used test strip is inserted	Repeat the test with a new test strip.
E-E	Problem in operation.	Repeat the test with a new test strip. If the meter still does not work, please contact the customer service for assistance.
E-0		
E-A		
E-C		
E-F	Appears when test strip is removed while counting down, or other problems in operation.	Repeat the test with a new test strip.
E-t	Appears when ambient temperature is below or above system operation range.	System operation range is 46.4°F ~ 113°F (8°C ~ 45°C). Repeat the test after the meter and test strip are in the above temperature range.

Troubleshooting

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

POSSIBLE CAUSE	WHAT TO DO
Battery exhausted.	Replace the battery.
Test strip inserted upside down or incompletely.	Insert the test strip with contact bars end first and facing up.
Defective meter or test strips.	Please contact customer services.

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

POSSIBLE CAUSE	WHAT TO DO
Defective test strip.	Repeat the test with a new test strip.
Sample applied after automatic switch-off (3 minutes after last user action).	Repeat the test with a new test strip. Apply sample only when flashing "💧" appears on the display.
Defective meter.	Please contact customer services.

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

POSSIBLE CAUSE	WHAT TO DO
Error in performing the test.	Read instructions thoroughly and repeat the test again.
Control solution vial was poorly shaken.	Shake the control solution vigorously and repeat the test again.
Expired or contaminated control solution.	Check the expiry date of the control solution.
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature (68°F ~ 77°F / 20°C ~ 25°C) before testing.
Defective test strip.	Repeat the test with a new test strip.
Meter malfunction.	Please contact customer services.
Improper working of meter and test strip.	Please contact customer services.

SPECIFICATIONS

Model No: TD-4116

Dimension: 89.8 (L) x 52.4 (W) x 17.3 (H) mm

Weight: 46.6 g

Power Source: One 1.5 V AAA alkaline batteries

Display: LCD

Memory: 450 measurement results with respective date and time

External output: USB Cable

Auto electrode insertion detection

Auto reaction time count-down

Auto switch-off after 3 minutes without action

Temperature Warning

Operating Condition: 50°F ~ 104°F (10°C ~ 40°C), 10% to 85% R.H. (non-condensing)

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

Strip Storage / Transportation Conditions: 39.2°F ~ 104°F (4°C ~ 40°C), 10% to 85% R.H. (non-condensing), up to 24 months for unopened vial

Measurement Units: mg/dL

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

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

metene

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metene limited.

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Toll Free: +12133786121

(7:00 am - 6:00 pm PST, Mon.-Fri.)

For assistance outside of these hours, please contact your healthcare professional.

www.metene.com

For Self-testing.
Read instructions before use.

metene TD-4116

For over the counter use

Blood Glucose Test Strips

ver 6.0 2019/06
322-3223001-xox

Important Safety Instructions

- For **in vitro** diagnostic use (for use outside of the body only).
- For single use only.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even if you have performed cleaning and disinfection.
- Please read this sheet and your Blood Glucose Monitoring System Owner's Manual before you use this test strip.
- Use only metene TD-4116 Test Strips with metene TD-4116 Blood Glucose Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- This system is not for use in patients with abnormally low blood pressure or those who are in shock.
- This system is not for use in patients in hyperglycemic-hyperosmolar state, with or without ketosis.
- This system should not be used on critically ill patients.
- This system should not be used on patients with impaired peripheral circulation, severe dehydration as a result of diabetic ketoacidosis or severe hyperglycemia, hypersmolar non-ketotic coma or shock.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

For more information, please visit:
"FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmittable Bloodborne Pathogens: Initial Communication" (2010)
<http://wayback.archive-it.org/7933/20170111013014http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
"CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmittable Bloodborne Pathogens" (2010)
<http://www.cdc.gov/injectionsafety/Fingertick-DevicesBGM.html>

Intended Use

metene TD-4116 Test Strip, when used together with **metene TD-4116 Blood Glucose Monitoring System** to quantitatively measure glucose (sugar) in fresh capillary whole blood from the finger and alternative sites (palm, forearm and upper arm). This system is intended for single-patient use (lay-users at home) and should not be shared. It should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

Limitations

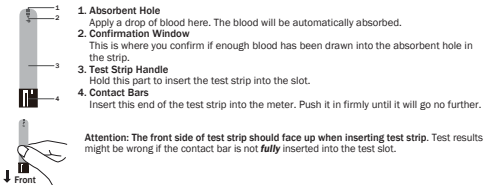
- Hematocrit: The hematocrit level is limited to between 20% and 60%. Please ask your healthcare professional if you do not know your hematocrit level.
- Neonatal Use: These test strips are not for use with newborns.
- Exogenous substances: Dopamine, L-Dopa, methyldopa, tolazamide, ascorbic acid (vitamin C), acetaminophen and mannose may cause inaccurate results if concentrations of these substances greater than therapeutic/physiologic concentrations.
- Endogenous substance: Uric acid may cause inaccurate results if concentration of the substance greater than therapeutic/physiologic concentration.
- There is no significant interference in the presence of galactose, maltose, or fructose observed in blood glucose tests.
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- Mannitol: Up to 5000 mg/dL do not affect the results significantly, but may cause inaccurate results at higher level.
- Lipemic Effects: Blood triglycerides up to 3000 mg/dL do not affect the results significantly, but may affect results at higher level.
- Glutathione reduced and paldoxime iodide: Do not test blood glucose during or soon after a glutathione reduced or paldoxime iodide treatment. The two compounds within the therapeutic/physiologic concentration range (Glutathione: 47 - 100 mg/dL. Paldoxime iodide: ~ 10 mg/dL) may affect the glucose results.
- Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Storage and Handling

IMPORTANT: Do not use the test strips if they have expired.

- Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it. (For strip vial only)
- Store the test strips in a cool, dry place between 39.2°F and 104°F (4°C and 40°C) and 10% to 85% relative humidity.
- Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers.
- Do not touch the test strips with wet hands.
- Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.
- Keep the vial closed at all times.
- Do not bend, cut, or alter the test strip.

Strip Appearance



About Alternative Site Testing (AST)

IMPORTANT: There are limitations for performing AST. Please read the metene TD-4116 Blood Glucose Monitoring System Owner's Manual and consult your doctor before you perform AST.

Alternative site testing (AST) is when individuals check their blood glucose levels using areas of the body other than the fingertip. Only samples from the palm, upper arm and forearm should be used. We strongly recommend that you perform AST ONLY at the following times:

- During 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 may not notice if you are hypoglycemic.
- Your AST results are inconsistent with the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results often fluctuate.
- The results are to be used to calibrate continuous glucose monitors (CGMs).
- The results are to be used in insulin dosing calculations.

To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds before following the procedures of "Testing Your Blood Glucose".

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTS.

CAUTION: Lancing devices should never be used for more than one person.



100
mg/dL

Please refer to your Owner's Manual for more information.

Cleaning and disinfection of your meter are required to reduce the risk of bloodborne pathogen transmission. The meter must be cleaned prior to the disinfection. Use one disinfecting wipe to clean exposed surfaces of the meter thoroughly and remove any visible dirt, blood, or any other body fluid with the wipe. Use a second wipe to disinfect the meter by following the disinfecting procedure. Please refer to your Owner's Manual for more information about the cleaning and disinfection procedures with a disinfecting wipe.

The used lancet and test strip are potentially biohazardous. Please follow your healthcare provider's recommendations for proper disposal.

Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in milligrams of glucose per deciliter of blood (mg/dL) or millimoles per liter of blood (mmol/L). The measurement range of this meter is 20–600 mg/dL (1.1–33.3mmol/L).

Reference values

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meals	Less than 100 mg/dL (5.6 mmol/L)
2 hours after a meal	Less than 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association. Standards of Medical Care in Diabetes- 2018 Jan; 41(Supplement 1): S1-S2.

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

Questionable or inconsistent results

- If your test results are unusual or inconsistent with how you are feeling:
- Make sure the confirmation window of the test strip is completely filled with blood.
- Check the expiration date of the test strips.
- Check the performance of your meter and test strip with the control solutions.

PLEASE NOTE: Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our Blood Glucose Control Solutions contain a known amount of glucose that can react with test strips. Do a control solution test when:

- You first receive the meter
- At least once a week to routinely check the meter and test strips
- You begin using a new vial of test strips
- You suspect the meter or test strips are not working properly
- Your blood glucose test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process
- You have dropped or think you may have damaged the meter

You can check the performance of meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial. Checking regularly can ensure your test results are accurate. If the quality control check fails, conduct the quality control check again or contact customer service if the quality control check continues to fail. Please refer to the Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of the control solutions may vary with each new vial of test strips. Make sure you check the range on the label of your current vial.

Chemical Components

- > Glucose oxidase: 10%
- > Electron shuttle: 50%
- > Enzyme protector: 8%
- > Non-reactive ingredients: 32%

Accuracy

■ **Capillary Blood Study**

Within ± 15 mg/dL at glucose concentration < 75 mg/dL and within $\pm 20\%$ at glucose concentration ≥ 75 mg/dL. Studies were conducted using capillary blood and the results are as below:

Performance Characteristics

- Sample Size: 0.7 µL
- Reaction Time: 7 seconds
- System Measurement Range: 20 to 600 mg/dL
- Hematocrit Range: 30% to 55%

N= 244
y=1.007x+1.013
R=0.990
Range=31-566 mg/dL

Additional Information of Accuracy for Professionals

The metene TD-4116 system was tested on 244 capillary blood samples, and the results were compared to the YSI-2300 laboratory method. The table below show how well the two methods compared: The tables show differences in glucose values between this system and YSI-2300. Table 1 and Table 2 represent samples for glucose results lower than (<) 75mg/dL and greater than ($\geq$) 75 mg/dL.

Table 1

Difference range in values between the laboratory value and the meter's value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL*	Within 20 mg/dL
The number (and percent) of samples for which the difference between the meter's and laboratory value were within the difference range shown in the top row.	41/48 (85%)	47/48 (98%)	48/48 (100%)	48/48 (100%)

Table 2

Difference range in values between the laboratory value and the meter's value	Within 5%	Within 10 %	Within 15 %	Within 20 % *
The number (and percent) of samples for which the difference between the meter's and laboratory value were within the difference range shown in the top row.	98/196 (50%)	179/196 (91%)	194/196 (99%)	196/196 (100%)

*Acceptance criteria in ISO15197 are that 95% of all differences in glucose values (i.e., YSI-2300 glucose value minus the meter's glucose value) should be within 15 mg/dL of for glucose values less than 75 mg/dL, and within 20% for glucose values greater than 75 mg/dL.

Note: When metene TD-4116 glucose results are compared to the laboratory results, difference values below 75 mg/dL are expressed in mg/dL, while those above 75 mg/dL are compared in percent.

• User performance study

Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a YSI-2300 laboratory method when the glucose concentration is less than 75 mg/dL and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. Table 3 displays how often the meter achieves this goal in the hand of lay user.

Table 3

For glucose results lower than 75 mg/dL, the number (and percent) of meter results that match the laboratory method within 15 mg/dL	48/48 (100%)
For glucose results at 75 mg/dL or higher, the number (and percent) of meter results that match the laboratory method within 20%.	196/196 (100%)

Note: When meter results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

• Alternative site testing study

120 subjects were tested on the finger and the alternative sites: the palm, the forearm and the upper arm. The tables show differences in glucose values between alternative sites and finger. Table 4 and Table 5 represent samples for glucose results lower than (<) 75 mg/dL and greater than ($\geq$) 75 mg/dL.

Table 4

Difference range in values between the alternative sites' value and the finger's value	Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL*
Palm	9/21(43%)	15/21(71%)	20/21(95%)
Forearm	13/21(62%)	17/21(81%)	21/21(100%)
Upper arm	9/21(43%)	15/21(71%)	20/21(95%)

Table 5

Difference range in values between the alternative sites' value and the finger's value	Within 5%	Within 10 %	Within 15 %	Within 20 % *
Palm	32/99(32%)	67/99(68%)	91/99(92%)	98/99(99%)
Forearm	39/99(39%)	72/99(73%)	91/99(92%)	95/99(96%)
Upper arm	41/99(41%)	70/99(71%)	85/99(86%)	95/99(96%)

*Acceptance criteria in ISO15197 are that 95% of all differences in glucose values (i.e. finger glucose value minus an alternative site glucose value) should be within 15 mg/dL of for glucose values less than 75 mg/dL, and within 20% for glucose values greater than 75 mg/dL.

Note: When the alternative site results are compared to the finger results, difference values below 75 mg/dL are expressed in mg/dL, while those above 75 mg/dL are compared in percent.

Precision

CVs (%) of intermediate precision and repeatability were less than 5%.

Made in Taiwan
For in vitro diagnostic use.
For single use only.
Read instructions before use.
Store at 39.2–104°F.

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Emails: tai@metene.com

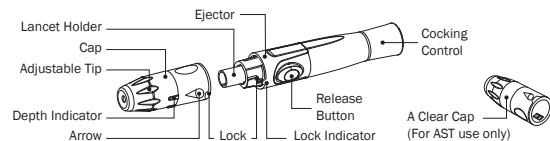
Use only with the metene TD-4116 Blood Glucose Monitoring System.

INSTRUCTIONS LANCING DEVICE AND STERILE LANCET

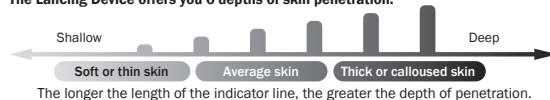
Ver 2.0 2019-07

318-5010200-134

Our Lancing Device allows you to collect your capillary blood from your fingertip (and alternative sites) easily and virtually pain free.



The Lancing Device offers you 6 depths of skin penetration:



WARNING

To reduce the chance of infection:

- ▶ Never share a lancet or the lancing device.
- ▶ 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.
- ▶ The used lancet may potentially be biohazardous. Please dispose of used lancets properly.

Setting up the Lancing Device

1. Twist and pull off the cap of the lancing device.
2. Insert a lancet into the lancet holder and push down firmly until it is fully secured.
3. Twist the protective disk off the lancet.
4. Replace and twist the cap to the right to close the lock as shown in the picture until you hear the click. When the lock is properly closed lock indicator is in the extreme right position.
5. Hold the cap to select the depth of penetration by turning the adjustable tip in either direction so that the arrow on the cap points to the desired depth.
6. 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.**

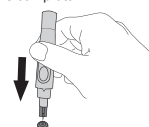
NOTE

Before collecting a drop of blood:

- ▶ Wash and dry your hands before you start.
- ▶ Select the puncture site at the fingertip.
- ▶ Rub the puncture site for about 20 seconds before penetration.
- ▶ Clean the site using cotton swab moistened with 70% alcohol and let it air dry.



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



9. Remove the lancet by twisting 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.

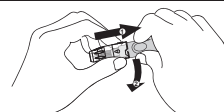


8. Remove the device from the puncture site. After penetration, remove the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample. Apply the blood to the test strip.



10. 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.**

Alternative Site Testing (AST)



NOTE

This option is not available for all devices. Refer to the **Intended Use** in your meter's Owner's Manual if you can perform AST with your device.

Testing on sites other than the fingertip is referred to as alternative site testing (AST). Please read the **Alternative Site Testing** section in your Owner's Manual before you perform AST. Substitute 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, or hand, you should avoid lancing the areas with obvious veins in order to prevent excess bleeding.

Cleaning and Disinfection

- The lancet is disposable and is intended for single use only.
- The lancing device is reusable.
- We recommend for lancing device cleaning and disinfection, you should use Micro-Kill+™ (Micro-Kill Plus™). Please refer to your Owner's Manual for more information about the cleaning and disinfection procedures with a disinfecting wipe.
- DO NOT rinse the device under water.
- Do NOT place the device in a dishwasher or use detergents.

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24888 New Taipei City, Taiwan
www.taidoc.com

Model No. of Sterile Lancet: TD-5084
Model No. of Lancing Device: TD-5010

For self-testing,
Do not re-use (Lancet only).
Sterilized using irradiation (Lancet only).
Read instructions before use.
Made in Taiwan