

TRUE METRIX[®] PRO

Professional Monitoring
Blood Glucose System

Owner's Booklet

Use only with TRUE METRIX[®] PRO
Blood Glucose Test Strips

Call for assistance
Monday - Friday,
8AM-8PM Eastern Standard Time
English or Spanish
1-800-803-6025
www.trividiahealth.com



Manufactured by:



Fort Lauderdale, FL 33309 U.S.A.

© 2021 Trividia Health, Inc.

TRUE METRIX PRO and the Trividia Health
logo are trademarks of Trividia Health, Inc.

RE4TVHP03 Rev. 54



INTRODUCTION:

TRUE METRIX®

Self Monitoring Blood Glucose System

TRUE METRIX is a simple, accurate way to test your whole blood glucose (sugar) level, anytime, anywhere. Our goal is to provide quality healthcare products and dedicated customer service. For questions about TRUE METRIX products, visit our web site at:

www.trividiahealth.com.

The TRUE METRIX Self Monitoring Blood Glucose System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm. The TRUE METRIX Self Monitoring Blood Glucose System is intended to be used by a single person and not to be shared.

The TRUE METRIX Self Monitoring Blood Glucose 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.

The TRUE METRIX Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The TRUE METRIX Self Monitoring Test Strips are for use with the TRUE METRIX Self Monitoring Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm. The TRUE METRIX Self Monitoring Meter measures the current, detects, analyzes and corrects for hematocrit and temperature and calculates the glucose result.

The TRUE METRIX Control Solution is for use with the TRUE METRIX Self Monitoring Meter and TRUE METRIX Self Monitoring Test Strips to check that the meter and the test strip are working together properly and the test is performing correctly.

Importance of Blood Glucose Monitoring

The more you know about diabetes, the better you will be able to care for yourself. A Doctor or Healthcare Professional determines how often you should test and what your target ranges are for blood glucose results.

Having most blood glucose results within your target range shows how well your treatment plan is working to control glucose levels. Keeping results within your target range helps slow or stop complications from diabetes.

NEVER change your treatment plan without consulting a Doctor or Healthcare Professional.

IMPORTANT INFORMATION:

For the most accurate results using TRUE METRIX Self Monitoring Blood Glucose System:

- Read all product instructions for use before testing.
- Use of TRUE METRIX Self Monitoring Blood Glucose System in a manner not specified in this Owner's Booklet is not recommended and may affect ability to determine true blood glucose levels.
- TRUE METRIX Self Monitoring Blood Glucose System is an *in vitro* (outside body) quantitative system that is used for self-testing of human whole blood only.
- Alternative site (forearm) testing should not be used to calibrate continuous glucose monitors (CGMs).
- Alternative site (forearm) testing should not be used for insulin dose calculations.
- Use only TRUE METRIX Self Monitoring Blood Glucose Test Strips and TRUE METRIX Control Solution with the TRUE METRIX Self Monitoring Blood Glucose Meter.
- Remove only one test strip at a time from test strip vial. Recap vial immediately.
- NEVER reuse test strips. NEVER wipe test strips with water, alcohol or any cleaner. DO NOT attempt to remove blood or control solution from test strips or clean test strips and re-use. Reuse of test strips will cause inaccurate results.
- NEVER add a second drop of sample to test strip. Adding more sample gives an error message.
- Perform Control Tests ***before*** performing a blood glucose test for the first time.

IMPORTANT INFORMATION (cont.):

- Perform Control Tests with more than one level of control solution. Three levels of TRUE METRIX Control Solution are available for Control Tests. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for assistance in obtaining control solution.
- The TRUE METRIX Self Monitoring Blood Glucose System is for one person use **ONLY**. **DO NOT** share your meter or lancing device with anyone, including family members. Do not use on multiple patients!!
- **ALL** parts of your blood glucose monitoring system could carry blood-borne pathogens after use, even after cleaning and disinfecting.^{2,3}
- Cleaning and disinfecting the lancing device and the meter destroys most, but not necessarily all, blood-borne pathogens.
- Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips as contact with blood presents an infection risk.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- It is important to keep the meter and the lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see *Meter Care, Cleaning and Disinfecting* and *Lancing Device Cleaning and Disinfecting*.

IMPORTANT INFORMATION (cont.):

- If you have symptoms of low or high blood glucose, check your blood glucose immediately. If your result does not match the way you feel, repeat the test. If your results still do not match the way you feel, call your Doctor or Healthcare Professional immediately.
- ~ Low blood glucose (hypoglycemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and trouble speaking.
- ~ High blood glucose (hyperglycemia) symptoms may be intense thirst, a need to urinate often, dry mouth, vomiting, and headache.
- Do not use for diagnosis of or screening of diabetes or for neonatal use.
- Inaccurate results may occur in severely hypotensive individuals or in dehydrated patients or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.

WARNING: Upon opening the test strip carton, examine the product for missing, damaged or broken parts. Ensure the test strip vial cap is securely closed. If the product is damaged or the vial cap is not closed, DO NOT use the test strips for testing; product may give inaccurate results. Contact Trividia Health Customer Care at 1-800-803-6025 for replacement and assistance.

Phone Number, Fast Test Guide, Expected Results	Cover
Introduction and Important Information	1
Know Your System	
Meter	7
Test Strip	10
Control Solution	12
Getting Started	
Quality Control Testing	15
Automatic Self Test	15
Control Test	16
How to Test Control Solution	17
Testing Blood	
Obtaining a Blood Sample	21
How to Test Blood	25
TRUE METRIX System and Laboratory Testing	29
System Out of Range Warning Messages	30
Meter Set Up	
Set Time / Date	31
Set Event Tags, Ketone Test Alert and Test Reminders	33
Meter Memory	
View Averages (7-, 14-, and 30-day)	36
View Memory	37
Care, Cleaning/Disinfecting and Troubleshooting	
Caring for TRUE METRIX	38
Changing Battery	44
Troubleshooting	45
Messages	46
System Safety Information and Electromagnetic Compatibility...	49
System Specifications/Chemical Composition	51
Meter Warranty	52
References	52

Know Your System

Meter

Top of Meter



① “ ◀ ” Button

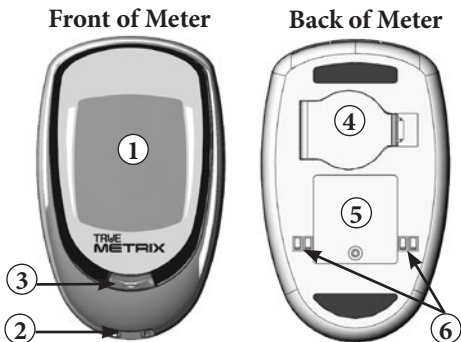
Decrease numbers in Meter Set Up; remove ALT Symbol; move backward by date/time when viewing results and Averages in Memory; scroll through Event Tags to mark results (if feature on).

② “ • ” Button

Turn meter on to view Average values, to view results in Memory, to access Meter Set Up, to turn on Event Tags in Meter Set Up.

③ “ ▶ ” Button

Increase numbers in Meter Set Up; add ALT Symbol; move forward by date/time when viewing results and view Averages in Memory; scroll through Event Tags to mark results (if feature on).



① Display Screen

Shows results, messages, user prompts, information.

② Test Port

Insert TRUE METRIX Test Strip here, contact blocks facing up.

③ Strip Release Button

Releases test strip after testing for disposal.

④ Battery Door

Use one non-rechargeable 3V lithium battery (#CR2032), positive (“+”) side up (see *Changing Battery*).

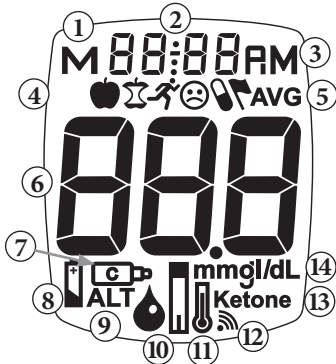
⑤ Meter Label

Contains serial number of meter.

⑥ Data Contacts

Connects meter with computer for data upload.

Full Display Screen



1. Result is from Memory
2. Time, Date
3. Time is AM/PM
4. Event Tag Symbols
5. Result is from 7, 14, or 30 day Average
6. Test Result
7. Control Symbol
8. Battery Symbol
9. Alternate Site (ALT) Symbol
10. Drop Symbol - Apply blood or control solution
11. Temperature Symbol
12. Test Reminder Symbol
13. Ketone Test Alert Symbol
14. Unit of Measure (**Note:** Factory set to mg/dL, cannot be changed by user.)

Test Strip

Top of Test Strip



- ① **Contact End** - Insert into Test Port with contact blocks facing up.
- ② **Sample Tip** - Bring Tip of test strip to top of sample drop (blood or control solution) **after** Drop Symbol appears in the Display.

Note: Insert test strip into meter before touching Sample Tip to blood or control solution drop.

Sample Placement



- Allow sample drop to be drawn into Sample Tip until testing begins (meter beeps and dashes move across Display).
- Do not smear or scrape drop with test strip.
- Do not apply more sample to test strip after testing begins.
- Do not apply blood or control solution to top of test strip. Do not insert Sample Tip with sample into Test Port. May damage meter.

Test Strip Vial Label

①	LOT - ABC1234	May 30, 2022	②
②	EXP - 2022-10-30		
③	1 22 - 52 mg/dL		
	2 95 - 129 mg/dL		
3 261 - 353 mg/dL			

- ① **Lot Number (LOT)** - Used for identification when calling for assistance.
- ② **Expiration Dates (EXP)** - Write date first opened on vial label. Discard vial and unused test strips if either the open vial expiration date or the date printed next to **EXP** on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial expiration date.

Caution! *Use of test strips or control solution past the Expiration Dates may give incorrect test results. Discard out-of-date products and test with new products.*

- ③ **Control Test Range** - Range of numbers in which Control Test result must fall to assure the system is working properly.

Note: *Examples only. Do not represent actual Control Test ranges.*

Control Solution (Control)

Control Solution Bottle Label



- ① **Lot Number (LOT)** - Used for identification when calling for assistance.
- ② **Expiration Dates (EXP)** - Write date first opened on bottle label. Discard bottle if either 3 months after first opening or date printed next to **EXP** on bottle label has passed, whichever comes first.
- ③ **Control Solution Level (1, 2, or 3)** - We recommend testing at least 2 levels of control solution. Contact 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for assistance with obtaining different levels of control solution.

Getting Started

Meter comes with pre-set time and date. The Event Tag feature, Ketone Test Alert, and all Test Reminders are off. Before using the meter for the first time or after a battery change, check the time, date, Event Tags, Alert and Reminders, and update as needed (see *Meter Set Up*).

The meter turns on when a test strip is inserted into the Test Port or when “ • ” Button is pressed (see *Memory and Meter Set Up*).







Meter turns off when the test strip is released or removed from the meter, “ • ” Button is pressed, or after 2 minutes of non-use.

Turning the Ketone Test Alert on sets a reminder to check your ketones per your treatment plan when a blood glucose result is over 240 mg/dL.

Test Reminders are set like an alarm clock to sound a tone for 10 seconds to remind you to test. Up to four Test Reminders per day may be set.

Getting Started (cont.)

Event Tags allow you to tag your blood glucose results to link to the following events:

-  Before meal – test was taken just before a meal,
-  After meal – test was taken 2 hours after the start of a meal,
-  Exercise – test was taken during or after exercise,
-  Medications – medication taken may have affected test result,
-  Sick – test was taken when sick,
-  Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with an Event Tag in the meter Memory reminds you that there is more about this test result in your log book.

Tagging results helps track the effect specific events may have on your blood glucose test results. Event Tagging may assist you and your Doctor or Health-care Professional with managing diabetes.

Quality Control Testing

To assure you are getting accurate and reliable results, TRUE METRIX offers two kinds of quality Control Tests. These tests let you know that your System is working properly and your testing technique is good.

Automatic Self-Test

An Automatic Self-Test is performed by the meter each time a test strip is inserted correctly into the Test Port.

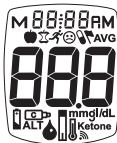
Insert a test strip into the Test Port.

The meter is working properly if:

- ~ the full Display appears, then
- ~ the time appears in the upper part of the Display, and then,
- ~ the Drop Symbol begins to blink.

If an error message appears in the Display, the meter will not perform a test.

See *Troubleshooting* or call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.



Full Display



Drop Symbol



Error Message

Caution! *If any segments are missing in the Display when meter is first turned on, do not use the meter for testing. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.*

Control Test

We recommend performing Control Tests for practice before using your meter for the first time to test your blood.

Control Tests should be performed:

- For practice to ensure your testing technique is good,
- Occasionally as you use a vial of test strips,
- When opening a new vial of test strips,
- If results seem unusually high or low,
- If a vial has been left opened or exposed to extreme heat or cold, or humidity,
- Whenever a check on performance of the system is needed,
- If meter damage is suspected (meter was dropped, crushed, wet, etc.)

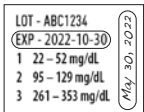
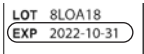
Note: It is important to perform Control Tests with more than one level of control solution. Three levels of TRUE METRIX Control Solution are available for Control Tests. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for assistance in obtaining different levels of control solution.

Caution! *Ranges printed on test strip vial label are for Control Test results only and are not suggested levels for your blood glucose. Do not drink control solution.*

How to Test Control Solution

Use **ONLY TRUE METRIX** Control Solution with the TRUE METRIX Self Monitoring Meter and Test Strips.

1. Check dates on control solution label and test strip vial label. Do not use control solution or test strips if expiration dates have passed. (Control solution - 3 months after first opening or date next to **EXP** on bottle label; test strips - after open vial expiration date (see test strip Instructions for Use) or date next to **EXP** on vial label.) Discard expired products and use new products.



2. Allow control solution, vial of test strips and meter to adjust to room temperature. Write date first opened on both control solution bottle label and test strip vial label when using for the first time.
3. Gently swirl or invert control solution bottle to mix.
DO NOT SHAKE!
4. Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.

5. Insert test strip into Test Port.
Meter turns on.

Note: If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.



Contact Blocks
Face Up



Drop Symbol

6. Wait until Drop Symbol appears in Display. Keep test strip in meter until testing is finished.

Note: If test strip is removed before testing is finished, an error message appears. Release and discard old test strip. Use new test strip for testing.

7. With cap removed, turn control solution bottle upside down. Squeeze one drop of control solution onto a clean tissue. Wipe off bottle tip and discard tissue.
8. Gently squeeze a drop of control solution onto a small piece of unused aluminum foil or clear plastic wrap. Dispose after use.



Discard Control
Solution Drop on
Tissue

9. With test strip still in meter, touch Sample Tip of test strip to top of drop of control solution. Allow drop to be drawn into test strip. Remove test strip from drop when meter beeps.
10. Dashes appear across the Display to show meter is testing.



Meter testing

Note: *If meter does not beep and begin testing soon after drawing up sample, release and discard test strip. Repeat test with new test strip. If problem persists, see Troubleshooting.*

11. Compare meter result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, System can be used for testing blood. If result does not fall within range, repeat test using a new test strip.



Control Solution
Bottle Label

1	22 – 52 mg/dL
2	95 – 129 mg/dL
3	261 – 353 mg/dL

Test Strip
Vial Label

Note: *Control Test result shows the Control Symbol in the Display.*



Control Symbol
(Example only.)

Does not represent actual
Control Test ranges.)

Caution! *If Control Test result is outside range, test again. If result is still outside range, system should not be used for testing blood. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.*

12. After result is shown, Strip Release Button flashes. Hold meter with test strip pointing down. Press Strip Release Button to release and discard test strip into appropriate container. Meter turns off.



Note: *Removing test strip before result displays cancels the test. An error message appears and the result is not stored in Memory. Retest with a new test strip and do not remove before result is displayed.*

Testing Blood

Obtaining a Blood Sample

WARNING!

- The TRUE METRIX Self Monitoring Blood Glucose System is for one person use **ONLY**. **DO NOT** share your meter or lancing device with anyone, including family members. Do not use on multiple patients!!
- **ALL** parts of your blood glucose monitoring system could carry blood-borne pathogens after use, even after cleaning and disinfecting.²
- Cleaning and disinfecting the lancing device and the meter destroys most, but not necessarily all, blood-borne pathogens.
- Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips as contact with blood presents an infection risk.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- It is important to keep the meter and the lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see *Meter Care, Cleaning and Disinfecting* and *Lancing Device Cleaning and Disinfecting*.

Obtaining a Blood Sample (cont.)

Refer to lancing device Instructions for Use for detailed instructions.

- Never share lancets or lancing device. Lancets are for single use only. Do not re-use.
- Do not use venous blood for testing.
- To help prevent false high results, wash hands before using the system to test blood, especially after fruit has been handled.

From Fingertip

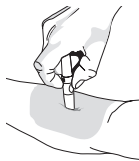
1. Prepare fingertip by washing hands in warm, soapy water. Rinse well. Dry thoroughly.
2. Place end of lancing device equipped with a lancet against tip of finger. Lance fingertip.
3. Set lancing device aside. To help blood drop form, lower hand to waist level, gently massaging finger from palm to fingertip. Allow blood drop to form before attempting to apply to the test strip. Apply sample to test strip Sample Tip.
4. Recap and remove used lancet from lancing device. The used lancet may be biohazardous. Please discard it carefully according to your Doctor or Healthcare Professional's instructions.



From Forearm

Important Notes Regarding Forearm Testing⁴

- Check with your Doctor or Healthcare Professional to see if forearm testing is right for you.
 - Results from forearm are not always the same as results from fingertip.
 - Use fingertip instead of forearm for more accurate results:
 - ~ Within 2 hours of eating, exercise, or taking insulin,
 - ~ If your blood sugar may be rising or falling rapidly or your routine results are often fluctuating,
 - ~ If you are ill or under stress,
 - ~ If your forearm test results do not match how you feel,
 - ~ If your blood sugar may be low or high,
 - ~ If you do not notice symptoms when blood sugar is low or high.
1. Select area to be lanced. Wash with soap and warm water, rinse and dry thoroughly.
 2. Rub area vigorously or apply a warm dry compress to increase blood flow.
 3. Place end of lancing device equipped with a lancet firmly against forearm. Press Trigger Button. Apply firm pressure on lancing device for 10 seconds. Apply sample to test strip Sample Tip.



4. Recap and remove lancet from lancing device.

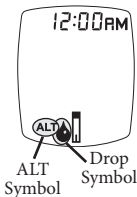
Caution! *The used lancet may be biohazardous. Please discard it carefully according to your Doctor or Healthcare Professional's instructions.*

How to Test Blood

1. Check dates on test strip vial being used. Do not use if either the open vial expiration date (see test strip Instructions for Use) or the date printed next to **EXP** on vial label has passed, whichever comes first.
2. Wash hands (and forearm for alternative site testing). Rinse well and dry thoroughly.
3. Remove one test strip from vial. Close vial immediately. Use test strips quickly after removal from vial.
4. With meter off, insert test strip Contact End (blocks facing up) into Test Port. Meter turns on. Keep test strip in meter until testing is finished.

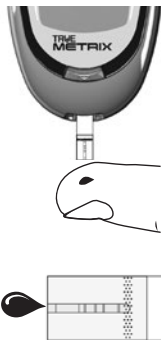


To mark test as alternative site (forearm) result, press “▶” Button. ALT Symbol appears in Display. Press “◀” Button to remove ALT Symbol. Wait until Drop Symbol appears in Display.



Note: *If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.*

5. Lance fingertip or forearm.
Allow drop to form
(see *Obtaining a Blood Sample*).
6. With test strip still in meter, touch
Sample Tip of test strip to top of
blood drop and allow blood to be
drawn into test strip. Remove test
strip from blood drop immediately
after the meter beeps and dashes
appear across the Display.



Note: *If meter does not begin testing soon after touching drop to test strip, discard test strip. Repeat test with new test strip and new blood drop. If problem persists, see Troubleshooting.*

Dashes appear across Display to show meter is testing.



7. After the test is finished, result is displayed. The Strip Release Button flashes.

To mark the result with an Event Tag, make sure that Event Tags are turned on (see *Set Event Tags, Ketone Alert and Test Reminders*). The Event Tag icons flash.

Press "▶" or "◀" Button to go to the correct Event Tag. Press "•" Button to mark the test result with an event (icon stops flashing).

Event Tags are as follows:

- 🍏 Before meal – test was taken just before a meal,
- 🕒 After meal – test was taken 2 hours after the start of a meal,
- 🏃 Exercise – test was taken during or after exercise,
- 💊 Medications – medication taken may have affected test result,
- 😷 Sick – test was taken when sick,
- 🚩 Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with an Event Tag in the meter Memory reminds you that there is more about this test result in the log book.



Test Result



Event Tag
(Before Meal Icon
- shown)



Top of Meter

Record result in log book.

8. Hold meter with test strip pointing down. Press test strip Release Button to discard test strip in the appropriate container. Meter turns off. Result is stored in Memory with date and time.



Note: *Removing test strip before result displays cancels the test. An error message appears and result is not stored in Memory. Retest with a new test strip and do not remove before result is displayed.*

Caution! *The used lancet and test strip may be biohazardous. Please discard them carefully according to your Doctor or Healthcare Professional's instructions.*

TRUE METRIX Self Monitoring Blood Glucose System and Laboratory Testing

When comparing results between TRUE METRIX Self Monitoring Blood Glucose System and a laboratory system, TRUE METRIX Self Monitoring Blood Glucose System blood tests should be performed within 30 minutes of a laboratory test. If you have recently eaten, fingerstick results from the TRUE METRIX Self Monitoring Blood Glucose System can be up to 70 mg/dL higher than venous laboratory results.⁵

System Out of Range Warning Messages

WARNING!

Meter reads blood glucose levels from 20-600 mg/dL.

If test result is less than 20 mg/dL, “Lo” appears in Display.

If test result is greater than 600 mg/dL, “Hi” appears in Display.

ALWAYS repeat blood tests to confirm Low (“Lo”) and High (“Hi”) results. If blood results still display “Lo” or “Hi”, call your Doctor or Healthcare Professional *immediately*.



Note: “Lo” results are included in the Average as 20 mg/dL.
“Hi” results are included as 600 mg/dL.

If blood glucose test result is greater than 240 mg/dL, and Ketone Test Alert is turned on, “Ketone” appears in Display with glucose result (see *Ketone Test Alert*).



Ketone Test Alert

Caution *When a Ketone Test Alert is shown in the meter Display, it does not mean that ketones have been detected in your blood. Perform a ketone test per your treatment plan, as prescribed by your Doctor or Healthcare Professional.*

Note: *Ketone Test Alert can be turned on or off during Meter Set Up.*

Meter Set Up

Note: If the meter turns off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.



1. With meter off, press and hold “•” Button until the full Display is shown and a series of beeps sound (after about 10 seconds). Release “•” Button. Meter goes into Set Up.



Set Time/Date

2. The hour flashes. To change, press “▶” or “◀” Button on top of the meter to select the hour. Like many alarm clocks, to set “AM” or “PM”, scroll through the hours until “AM” or “PM” appears in the Display. Press “•” Button to set.
3. The minutes flash. To change, press “▶” or “◀” Button to select the minutes. Press “•” Button to set.



4. The month (number) flashes.
To change, press “▶” or “◀”
Button to select the month.
Press “•” Button to set.



5. The day (number) flashes.
To change, press “▶” or “◀”
Button to select the day.
Press “•” Button to set.



6. The year flashes.
To change, press “▶” or “◀”
Button to select the year.
Press “•” Button to set.



Note: Meter beeps every time a setting is confirmed (“•” Button is pressed).

Set Event Tags, Ketone Alert and Test Reminders

Meter comes with Event Tags, Ketone Test Alert and all Test Reminders off.

Note: *If the meter turns off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.*

Event Tags

Event Tags are used to mark a test result that was taken during a specific event.

1. After setting the year, press “▶” or “◀” Button to turn Event Tags on or off. Press “•” Button to set, then the Meter goes to set Ketone Test Alert.

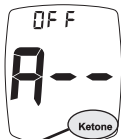


Top of Meter

Ketone Test Alert

When a blood glucose result is over 240 mg/dL, the Ketone Test Alert is a reminder to check your ketones per your treatment plan.

2. Press “▶” or “◀” Button to turn Alert on or off. Press “•” Button to set, then the Meter goes to set Test Reminder.



Ketone Test Alert

Caution! *When a Ketone Test Alert is shown in the Display, it does not mean that ketones have been detected in your blood. Perform a ketone test per your treatment plan, as prescribed by your Doctor or Healthcare Professional.*

Test Reminder

Up to four Test Reminders per day may be set.
Reminder sounds at set time for 10 seconds.
Meter comes with all Test Reminders off.

To set the Test Reminders:

1. After pressing “•” Button to set Ketone Test Alert, Display shows first Reminder setting (A-1). To turn Reminder on, press “▶” Button. Press “◀” Button to turn Reminder back to off. Press “•” Button to set.



Test Reminder

2. When “on” is chosen, press “•” Button. The hour flashes. Press “▶” or “◀” Button to set the hour. To set AM/PM, scroll (press “▶” or “◀” Button) until “AM” or “PM” is next to correct time. Press “•” Button to set.



3. The minutes flash. Press “▶” or “◀” Button to set the minutes. Press “•” Button to set. Meter goes to the next Test Reminder.



4. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).



Exit Set-Up

Press and hold “ • ” Button until meter turns off. Meter also turns off after 2 minutes of non-use. Set-Up choices are saved.

Note: *If Test Reminders are set, the Alert Symbol appears in all Displays.*

If battery dies or is replaced, Ketone Test Alert and Test Reminders may have to be reset.



Test
Reminder
Symbol

Meter Memory

View Averages (7-, 14-, and 30-day)

The Averages feature allows you to view the average of all your blood glucose results within a 7-, 14-, or 30-day period. Control Test results are not included in the Averages.

You can review the average of your glucose results from the last 7-, 14-, or 30-days.

1. With meter off press and release “•” Button. Display scrolls through 7-, 14-, and 30-day Average values.
2. Meter turns off after 2 minutes if no buttons are pressed.

Note: *If there are no Average values, three dashes are displayed for 7-, 14-, and 30-day Averages.*



7-Day
Average



14-Day
Average



30-Day
Average



No Average

View Memory

Meter Memory stores 500 results. When Memory is full, the oldest result is replaced with the newest result.

1. Press and release “•” Button.
Meter displays 7-, 14- and 30-day Averages. Press and release “•” Button again to view most recent Control Test result in Memory. If there are no results in Memory, dashes appear with the Memory Symbol.
2. Press “▶” Button and release to advance to the most recent blood test. Press “▶” Button to scroll forward through results or “◀” Button to scroll backwards through results.

Test results marked as alternate site display ALT Symbol.

Control Test results display the Control Symbol. If no Control Test has been done, Display shows dashes and the Control Symbol.

Test results above 240 mg/dL display Ketone Test Alert Symbol, when Ketone Test Alert is turned on during Set Up.

Tests marked with an Event Tag shows the Event Tag icon in the Display.

Memory Symbol



Alternate Site Symbol



Control Symbol



Ketone Test Alert Symbol



Event Tag
(Before Meal Icon
- shown)

Care, Cleaning/Disinfecting and Troubleshooting

- Store System (meter, control solution, test strips) in Carrying Case to protect from liquids, dust and dirt.
- Store in a dry place at room temperature (40°F-86°F) at 10%-80% relative humidity. **DO NOT FREEZE.**
- Do not share your meter with anyone, including family members.
- Allow system to sit at room temperature for 10 minutes before testing.
- Do not keep meter in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).

Meter Care, Cleaning and Disinfecting

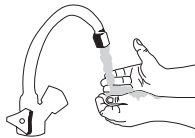
Cleaning removes blood and soil from the meter.

Disinfecting removes most, but not all possible infectious agents (bacteria or virus) from the meter, including blood-borne pathogens.

- Clean and disinfect immediately after getting any blood on the meter or if meter is dirty.
- Clean and disinfect meter at least once a week. Meter may be cleaned and disinfected once a week for up to 5 years.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned and disinfected prior to use by the second person. Do not clean the meter during a test.
- Cleaning (step #2) must occur before disinfecting (steps #3 and #4).

To Clean and Disinfect the Meter:

1. Wash hands thoroughly with soap and water.
2. **To Clean:** Make sure meter is off and a test strip is not inserted. With **ONLY** Super Sani-Cloth® Wipes (EPA* reg. no. 9480-4), rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, left side, right side, top and bottom of the meter. Discard used wipes. (*Environmental Protection Agency.)
3. **To Disinfect:** Using fresh wipes, make sure that all outside surfaces of the meter remain wet for 2 minutes. Make sure no liquids enter the Test Port or an other opening in the meter.



Super Sani-Cloths may be purchased at the following places:

- [Amazon.com](https://www.amazon.com),
 - [Officedepot.com](https://www.officedepot.com)
or visit your local Office Depot store,
 - [Walmart.com](https://www.walmart.com)
4. Let meter air dry thoroughly before using to test.

5. Wash hands thoroughly again after handling meter.
6. Verify that the System is working properly by performing an Automatic Self-Test (see *Getting Started*).



Stop using the meter and call Customer Care for assistance at 1-800-803-6025, Monday - Friday, 8AM-8PM EST, if:

- Meter display appears cloudy or any display segments are missing,
- Markings on meter, including back meter label, are coming off or are missing,
- Buttons are hard to push on the meter or do not work,
- Unable to insert test strip into Test Port,
- Automatic Self-Test gives an error message.

Note: *Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the meter. Use of disinfectants other than Super Sani-Cloth Wipes may damage meter.*

Note: *Super Sani-Cloth Wipes have been tested on the meter for a total of 260 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the meter once a week for a 5 year period. The use life of the meter is 5 years.*

Lancing Device Cleaning and Disinfecting

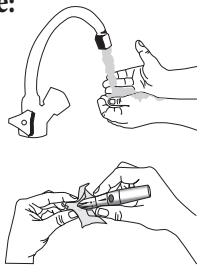
Cleaning removes blood and soil from the lancing device.

Disinfecting removes most, but not all possible infectious agents (bacteria or virus) from the lancing device, including blood-borne pathogens.

- Clean and disinfect immediately after getting any blood on the lancing device or if lancing device is dirty.
- Clean and disinfect the lancing device at least once a week. Lancing device may be cleaned and disinfected once a day for a 3 year period.
- If the lancing device is being operated by a second person who provides testing assistance, the lancing device should be cleaned and disinfected prior to use by the second person.
- Do not clean lancing device if there is a lancet inside. Remove lancet from lancing device before cleaning.
- Cleaning (step #2) must occur before disinfecting steps (#3 and #4).

To clean and disinfect the lancing device:

1. Wash hands thoroughly with soap and water.
2. **To Clean:** With **ONLY** Super Sani-Cloth Wipes (EPA* reg. no. 9480-4), rub the entire outside of the lancing device using 3 circular wiping motions with moderate pressure. Discard used wipes.
(*Environmental Protection Agency.)

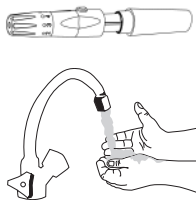


3. **To Disinfect:** Using fresh wipes, make sure that all outside surfaces of the lancing device remain wet for 2 minutes.

Super Sani-Cloths may be purchased at the following places:

- [Amazon.com](https://www.amazon.com),
- [Officedepot.com](https://www.officedepot.com) or visit your local store,
- [Walmart.com](https://www.walmart.com)

4. Let lancing device air dry thoroughly before using to test. Replace End Cap. Gently pull back Arming Barrel and press the Trigger Button. A click will be heard if the lancing device is functioning properly.



5. Wash hands thoroughly again after handling the lancing device.

Stop using the lancing device and call Customer Care for assistance at 1-800-803-6025, Monday - Friday, 8AM-8PM EST, if:

- Markings on lancing device are coming off,
- Trigger Button hard to push,
- End Cap does not go back on,
- Arming Barrel does not click when gently pulled back.

Note: Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the lancing device. Use of disinfectants other than Super Sani-Cloth Wipes may damage lancing device.

Note: Super Sani-Cloth Wipes have been tested on the lancing device for a total of 1095 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the lancing device once per day for a 3 year period. Lancing device may be cleaned and disinfected up to 7 cycles per week for 3 years.

TRUE METRIX Control Solution Care

- Write date opened on control solution bottle label. Discard if either 3 months after first opening or date printed next to **EXP** on bottle label has passed, whichever comes first.
- After each use, wipe bottle tip clean and recap tightly.
- Discard any control solution bottles that appear cracked or leaking.
- Store at temperatures between 36°F-86°F.
DO NOT FREEZE.

TRUE METRIX Self Monitoring Test Strip Care

- Store test strips in original vial only. Do not transfer test strips to new vial or store test strips outside of vial.
- Write date first opened on test strip vial label. Discard vial and unused test strips if either the open vial expiration date or the date printed next to **EXP** on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial expiration date. Use of test strips past expiration dates may give incorrect results.
- Discard any test strip vials that appear cracked or broken.
- Close vial immediately after removing test strip. Store in a dry place at room temperature (40°F-86°F) at 10%-80% relative humidity. **DO NOT FREEZE.**
- Do not reuse test strip.
- Do not bend, cut or alter test strips in any way.

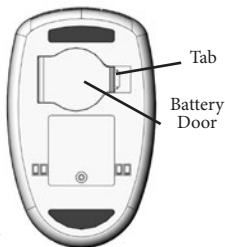
Changing Battery

A low battery displays Battery Symbol while continuing to function. A dead battery displays Battery Symbol, beeps, and then turns off. To replace battery:

1. Lift tab on Battery Door.
2. Turn meter over, tap gently on the palm of your other hand to loosen and remove battery.
3. Discard old battery into appropriate container.
4. Insert new battery, positive (“+”) side facing up. Close Battery Door.



Low



Note: Use non-rechargeable 3V lithium battery (#CR2032).

5. Press “•” Button to turn meter on. Check time, date, Ketone Test Alert and Test Reminders (see *Meter Set Up*). If meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery. Turn meter on by pressing “•” Button. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, if problem persists.

Warning! Battery is not rechargeable. If you have a cable or a cradle for downloading results to a computer, **DO NOT** plug the USB cable end into an electrical outlet. Trying to recharge the battery or power the meter by plugging into an electrical outlet will cause meter to catch on fire or melt.

Caution! Batteries might explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local regulations.

Troubleshooting

1. *After inserting test strip, meter does not turn on.*






Reason	Action
Test strip inserted upside down or backwards	Remove test strip. Re-insert correctly.
Test strip not fully inserted	Remove test strip. Re-insert test strip fully into meter.
Test strip error	Repeat with new test strip.
Dead or no battery	Replace battery.
Battery in backwards	Battery positive (“+”) side must face up.
Meter error	Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.





2. *After applying sample, test does not start/meter does not beep or begin testing.*

Reason	Action
Sample drop too small	Repeat test with new test strip and larger drop.
Sample applied after two minute shut-off	Repeat test with new test strip. Apply sample within 2 minutes of inserting test strip.
Problem with test strip	Repeat with new test strip.
Problem with meter	Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

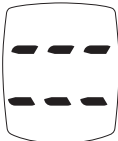

For assistance, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

Messages

Display	Reason	Action
	Invalid Hematocrit	Repeat with new test strip, using capillary whole blood from the finger or forearm. If error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
	Temperature Error • Too Cold/ Too Hot	Move meter and test strips to area between 41°F-104°F; wait 10 minutes for system to reach room temperature before testing.
	Sample Not Detected or Using Wrong Test Strip	Retest with new test strip and larger sample.
	Used Test Strip, Test Strip outside of vial too long, Sample on top of Test Strip.	Repeat with new test strip. Make sure Sample Tip of test strip touched top of sample drop. If error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
	Meter Error	Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

Display	Reason	Action
	Test Strip Error, or very high blood glucose result (higher than 600 mg/dL)	Retest with new test strip. If error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST. If you have symptoms such as fatigue, excess urination, thirst, or blurry vision follow your Doctor or Healthcare Professional's advice for high blood glucose.
	Test Strip Removed During Test	Retest with new test strip. Make sure result is displayed <u>before</u> removing test strip.
	Communication Error	Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
	Low or Dead Battery	Low: About 50 tests can be done before battery dies. Dead: Battery Symbol appears and beeps before meter turns off.

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

Display	Reason	Action
	Broken Display	Do not use meter for testing. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
	<p><u>WARNING!!</u> Out of Range - High Results > 600 mg/dL</p> <p>- Low Results < 20 mg/dL</p>	<p><u>WARNING!!</u> Retest with new test strip. If result is still “Hi” (High) or “Lo” (Low) contact Doctor or Healthcare Professional <i>immediately</i>.</p>

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

System Safety Information and Electromagnetic Compatibility

The TRUE METRIX meter was tested and found to comply with the electromagnetic emission and immunity requirements as specified in IEC 60601-1-2 Edition 4.0. The meter's electromagnetic emission is low.

The TRUE METRIX has met the following requirements of 60601-1-2, Edition 4:

EMC Test	Compliance Information
Radiated Emissions	CISPR 11 Class B limits
Conducted Emissions Voltage	Not applicable
Radiated RF EM Fields	10v/m, 80 MHz – 2.7 GHz, 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	Per table 8.10
Power Frequency Magnetic Fields	30 A/m, 50 Hz and 60 Hz
Electrical Fast Transients / Bursts	Not applicable
Surges	Not applicable
Conducted Disturbances induced by RF fields	Not applicable
Voltage Dips and Voltage Interruptions	Not applicable
Electrostatic Discharge	+/-8kV contact ; +/-15kV air discharges.

Interference from the meter to other electronically driven equipment is not anticipated. The electromagnetic environment should be evaluated prior to operation of the device.

Do not use the TRUE METRIX meter in a very dry environment, especially one in which synthetic materials are present.

Do not use the TRUE METRIX meter close to sources of strong electromagnetic radiation, as these may interfere with the proper operation of the meter.

Do not use electrical equipment, including antennas, closer than 12 inches to any part of the TRUE METRIX meter, including cables specified by the manufacturer.

Blood Glucose Monitoring System Components

- TRUE METRIX Self Monitoring Blood Glucose Meter
- TRUE METRIX Self Monitoring Blood Glucose Test Strips
- TRUE METRIX Control Solution
- Lancing Device • Single Use Lancet

Kit may contain one or more of the components above. To obtain components, call 1-800-803-6025, Monday – Friday, 8AM-8PM EST.

Other accessories may negatively affect EMC performance.

No adverse events to the Patient and Operator are anticipated due to electromagnetic disturbances because all electrical components of the TRUE METRIX meter are fully enclosed.

System Specifications

Result Range: 20-600 mg/dL

Sample Size: 0.5 microliter (0.5 μ L)

Sample: Fresh capillary whole blood from the finger or forearm, or control solution

Test Time: Results in as little as 4 seconds

Result Value: Plasma values

Assay Method: Amperometric

Power Supply: One 3V lithium battery
#CR2032 (non-rechargeable)

Battery Life: Approximately 1000 tests or 1 year

Automatic shut-off: After two minutes of non-use

Weight: 1.66 ounces

Size: 3.44" x 2.16" x 0.69"

Memory Size: 500 glucose results

Operating Range (meter & test strips):

Relative Humidity: 10%-90% (Non-condensing)

Temperature: 41°F-104°F

Hematocrit: 20%-70%

Altitude: Up to and including 10,200 feet

Note: Use within specified environmental conditions only.

Chemical Composition

TRUE METRIX Test Strips: Glucose dehydrogenase-FAD (*Aspergillus species*), mediators, buffers and stabilizers.

TRUE METRIX Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

TRUE METRIX Self Monitoring Limited Lifetime Warranty

Trividia Health, Inc. provides the following Warranty to the original purchaser of the TRUE METRIX Self Monitoring Blood Glucose Meter:

1. Trividia Health Inc. warrants this meter to be free of defects in materials and workmanship at the time of purchase. If the meter is ever inoperative, Trividia Health, Inc. will replace the meter with an equivalent meter, at its option, at no cost to the purchaser. Failure of the meter due to abuse or use not in accordance with the instructions for use is not covered by this Warranty.
2. This Warranty does not include the battery supplied with the meter.
3. Do not take the meter apart. This action will void the Warranty and cause the meter to display false results.
4. The duration of any implied Warranty, including any implied Warranty of merchantability or fitness for a particular purpose shall be limited to the lifetime in use with the original user in accordance with any state law to the contrary.
5. Trividia Health, Inc. disclaims liability for incidental or consequential damages for breach of any expressed or implied Warranty, including any implied Warranty of merchantability or fitness for a particular use with respect to the meter. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusion may not apply.
6. This Warranty gives the user specific legal rights, and the user may also have other rights which vary state to state.

Your Trividia Health, Inc. Customer Care Representative will be able to provide detailed information regarding procedures for returning your meter, if necessary.

References

1. American Diabetes Association. *Diagnosis and Classification of Diabetes Mellitus*. Diabetes Care, Volume 37, Supplement 1, January 2014.
2. *FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication*. Available at <https://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
3. *Infection Prevention during Blood Glucose Monitoring and Insulin Administration*. Available at <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>.
4. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter*. [Electronic Version]. Retrieved December 22, 2009 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.html>.
5. Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests*. Scand J Clin Lab Invest 36:805-808, 1976.