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:
TRIVIDIA HEALTH®
Fort Lauderdale, FL 33309 U.S.A.

RE4TVHP03 Rev. 57

TRUE METRIX® PRO
Professional Monitoring Blood Glucose System

Fast Test Guide

2 simple steps

For quick reference only, not intended as a substitute for complete instructions. Please read entire Owner's Booklet and product Instructions for Use before testing.

Expected Results for people without diabetes:

	Plasma Blood Glucose Result[1]
Before eating	< 100 mg/dL
2 hours after eating	< 140 mg/dL

Notes

INTRODUCTION:

TRUE METRIX® PRO
Professional Monitoring Blood Glucose System

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

Trividia Health, Inc. recognizes the importance of practicing safe and reliable testing using the TRUE METRIX PRO. Each patient should have specific blood glucose target ranges that are determined by their Doctor or Diabetes Healthcare Professional. Having most blood glucose results within the patient's target range shows how well a treatment plan is working to control glucose levels. Keeping results within the patient's target range helps slow or stop complications from diabetes.

The TRUE METRIX PRO Professional Monitoring Test Strips are for use with the TRUE METRIX PRO Professional Monitoring Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm, or venous whole blood collected only in sodium heparin vacutainer tubes. The TRUE METRIX PRO meter measures the current, detects, analyzes and corrects for hematocrit and temperature, and calculates the glucose result.

IMPORTANT SAFETY INFORMATION:

For the most accurate results using TRUE METRIX PRO:

- Read all product instructions for use before testing.
- Use of TRUE METRIX PRO 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 PRO is an *in vitro* (outside the body) quantitative system for multiple patient use testing of human whole blood only.
- Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in newborns.
- ONLY use auto-disabling single use lancing devices/ lancets to obtain capillary blood sample.
- 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.
- DO NOT use venous whole blood collected in sodium fluoride (grey top), lithium heparin, or EDTA vacutainer tubes for testing, as this may cause inaccurate results.

- Use ONLY TRUE METRIX PRO Test Strips and TRUE METRIX Control Solution with the TRUE METRIX PRO 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 sample 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.
- 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.

IMPORTANT INFORMATION (cont.):

WARNING!

Healthcare Professionals should adhere to standard precautions and disinfection procedures when handling or using this device for testing. ALL parts of the TRUE METRIX PRO Professional Monitoring Blood Glucose System are considered potentially infectious, and capable of transmitting blood-borne pathogens between patients and healthcare professionals.[2,3] Only use auto-disabling, single-use lancing devices/lancets to obtain capillary blood. For more information on standard precautions and practices please refer to http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.

- Multiple patient use devices such as blood glucose meters should be used on only one patient and not shared. If dedicating blood glucose meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines found in *Meter Care, Cleaning/Disinfecting*.
- Healthcare Professionals should wear gloves when cleaning and disinfecting the meter. Wash hands after taking off gloves. A new pair of gloves should be worn before testing each patient.

IMPORTANT INFORMATION (cont.):

- If the patient is showing symptoms of low or high blood glucose, check their blood glucose. If any result seems higher or lower than expected, repeat the test with a new test strip. Contact the Doctor or Diabetes Healthcare Professional with any unusual results.

~ Low blood glucose (hypoglycemia) symptoms may include trembling, sweating, intense hunger, nervousness, weakness or trouble speaking.

~ High blood glucose (hyperglycemia) symptoms may include intense thirst, a need to urinate often, a dry mouth, vomiting, or headache.

- **This device has not been validated for use in the critically ill.**
- 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.
- Follow facility protocols to verify blood glucose results with laboratory results for patients who are unresponsive or unable to communicate.

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.

Description of System

Meter

Top of Meter

① **“ ◄ ” Button**

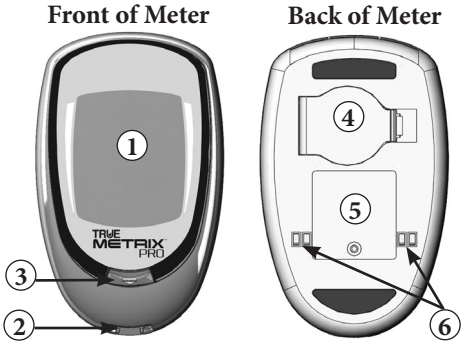
Decrease numbers in Meter Set Up; remove ALT Symbol; move backward by date/time when viewing results and Averages in Memory; scroll through Event Tags to mark results (if feature on).

② **“ • ” Button**

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

③ **“ ► ” Button**

Increase numbers in Meter Set Up; add ALT Symbol; move forward by date/time when viewing results and Averages in Memory; turn on Event Tags in Meter Set Up.



① **Display Screen**
Shows results, messages, user prompts, information.

② **Test Port**
Insert TRUE METRIX PRO Test Strip here, contact blocks facing up.

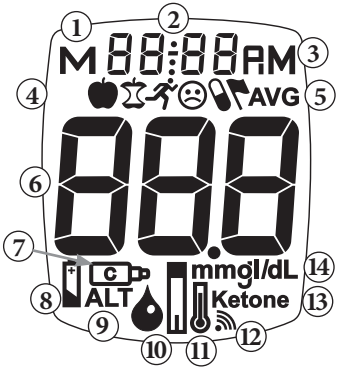
③ **Strip Release Button**
Releases test strip after testing for disposal.

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** - Touch Tip to top of drop of sample (blood or control solution) ***after*** Drop Symbol appears in the Display.

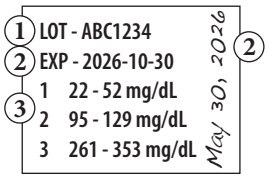
Note: *Insert test strip into meter before touching Sample Tip to blood or control solution drop.*

Sample Placement

Correct ***Incorrect***

- 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 Sample Tip after testing begins.
- Do not apply blood or control to top of test strip. Do not insert Sample Tip with sample into Test Port. May damage meter.

Test Strip Vial Label



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.

Control Solution (Control)

Control Bottle Label

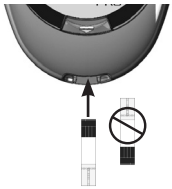
① **Lot Number (LOT)** - Used for identification when calling for assistance.

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. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for assistance in obtaining different levels of control solution.

Quality Control Testing

To assure accurate and reliable results, TRUE METRIX PRO offers two kinds of Quality Control Tests. These tests ensure that TRUE METRIX PRO is working properly and testing technique is good.



Contact Blocks Face Up

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 for assistance *(see Booklet cover for phone number)*.

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 for assistance.*

Control Test

We recommend performing Control Tests to check the performance of the system.

Control Tests should be performed:

- Before using the System for the first time,
- For practice to ensure testing technique is good,
- When opening a new vial of test strips,
- If results seem unusually high or low, based on patient's condition,
- If a vial has been left opened or exposed to extreme heat or cold, or humidity,
- Whenever a check on the performance of the system is needed,
- If meter damage is suspected (meter was dropped, crushed, wet, etc.).

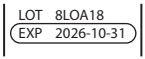
Note: *It is important to perform Control Tests with more than one level of control solution. Three levels of TRUE METRIX Control Solution are available for Control Tests. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for assistance in obtaining different levels of control solution.*

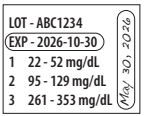
Caution! *Ranges printed on test strip vial label are for Control Test results only and are not to be used for management of patient's blood glucose. Do not drink control solution.*

How to Test Control Solution

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

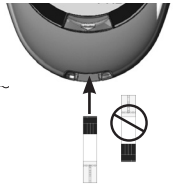
1. Check dates on control solution label and test strip vial label. Do not use control solution or test strips if Expiration Dates have passed. (Control solution - 3 months after first opening or date next to **EXP** on bottle label; test strips – after open vial expiration date (see test strip Instructions 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.
3. Gently swirl or invert control solution bottle to mix.
   DO NOT SHAKE!
4. Remove one test strip from vial. Close strip vial immediately. Use test strip quickly after removal from vial.

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



Contact Blocks Face Up

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.*

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

Drop Symbol

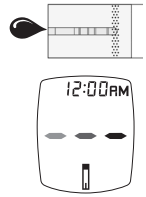
Note: *If Strip is removed before testing is finished, an error message appears. Release and discard old test strip. Use new test strip for testing.*

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.

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.



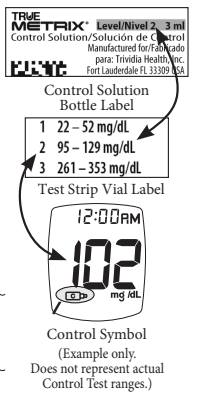
Meter testing

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.

Note: *Meter reads glucose levels from 20-600 mg/dL. If control test result is less than 20 mg/dL, "Lo" appears in Display. If control test result is greater than 600 mg/dL, "Hi" appears in Display.*

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 or meter displays "Lo" or "Hi", repeat test using a new test strip.

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



(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 or meter displays "Lo" or "Hi", the system should not be used for testing blood. Call for assistance (see Booklet cover for phone number).*

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.*

Blood Glucose Testing
Obtaining a Blood Sample

Refer to your facility approved method for lancing to obtain a blood sample for blood glucose testing. Follow the facility's precautions for blood-borne pathogens or refer to Biosafety in Microbiological and Biomedical Laboratories (BMBL) practice guidelines at http://www.cdc.gov/biosafety/publications/bmbl5/ .

"Protection of Laboratory Workers From Occupationally Acquired Infections, Approved Guidelines - Third Edition." Clinical and Laboratory Standards Institute (CLSI) M29-A3.

Venous whole blood collected only in sodium heparin tubes may be used for testing. Mix well before use.

DO NOT use sodium fluoride (grey top) vacutainer tubes. This may cause false low glucose results.

Caution!

- *ALL parts of the TRUE METRIX PRO blood glucose monitoring system could carry blood-borne pathogens after use, even after cleaning and disinfecting.*[2]
- *You should clean and disinfect the meter after each use to prevent the transmission of blood-borne pathogens.*
- *ONLY use auto-disabling single use lancing devices/lancets to obtain capillary blood sample.*
- *A new pair of gloves should be worn before obtaining blood sample from each patient.*

Tips for Fingertip Sampling

1. Select fingertip. Clean and disinfect the area with an approved disinfectant. Dry thoroughly.
2. Lance finger.
3. To help blood drop form, lower the hand to a level below the heart and gently massage the finger from palm to fingertip. Allow the blood drop to form before attempting to apply the test strip. Apply sample to Sample Tip.
4. Discard all biohazard materials into appropriate container. Wash hands after taking off gloves.

Tips for Forearm Sampling

Important Notes Regarding Forearm Testing[4]

- Check with the patient's Doctor or Diabetes Healthcare Professional to see if forearm testing is appropriate for the patient.
- Results from the forearm are not always the same as results from the finger.
- Use finger for testing instead of forearm for more accurate results:

~ Within 2 hours of eating, exercise, or taking insulin,
~ If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate,
~ If the patient is ill or under stress,
~ If the glucose result may be low or high,
~ If symptoms of low or high glucose levels are not evident.

1. Select area. Clean and disinfect the area with an approved disinfectant. Dry thoroughly.
2. Rub area vigorously or apply a warm, dry compress to increase blood flow.
3. Lance forearm. Apply sample to Sample Tip.
4. Discard all biohazard materials into appropriate container. Wash hands after taking off gloves.

Caution! *Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets into approved biohazard container.*

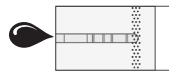
How to Test Blood

1. Check Meter time and date before each glucose test. With meter off, press and hold the " • " Button until the full Display is shown and a series of beeps sound. Release " • " Button. If time and date are incorrect, see Meter Set Up to set the correct time and date.
2. 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.
3. Clean the area to be lanced with an approved disinfectant. Dry thoroughly.
4. Remove one Strip from vial. Close vial immediately. Use test strips quickly after removal from vial.
5. 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 alternate site (forearm) result, press " ► " Button. ALT Symbol appears win Display. Press " ◄ " Button to remove ALT Symbol.
6. 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.*

7. Obtain the blood sample. Allow drop to form *(*see *Obtaining a Blood Sample).*

8. With test strip still in meter, touch Tip of test strip to top of blood drop and allow blood to be drawn into test strip. Remove Sample Tip from blood drop immediately after the meter beeps and dashes appear across the meter Display.



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

9. Dashes appear across Display to show meter is testing.

10. After the test is finished, result is displayed. The Strip Release Button flashes. Record result as required by your facility.

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

12. Discard all biohazard materials into appropriate container. Wash hands after taking off gloves.

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! *Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets in approved biohazard container.*

TRUE METRIX PRO System and Laboratory Testing

The most accurate glucose results come from using fresh, capillary whole blood from the fingertip or forearm. Venous whole blood drawn into only sodium heparin (green top) tubes may also be used. Mix well before use.

DO NOT use venous whole blood collected in sodium fluoride (grey top), lithium heparin, or EDTA vacutainer tubes for testing, as this may cause inaccurate results.

When comparing results between TRUE METRIX PRO and a laboratory system, TRUE METRIX PRO blood tests should be performed within 30 minutes of laboratory test. If a patient has recently eaten, fingerstick results from the TRUE METRIX PRO System can be up to 70 mg/dL higher than venous laboratory results.[5]

System Out of Range Warning Messages

WARNING!

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

If blood test result is less than 20 mg/dL, "**Lo**" appears in Display.

If blood test result is greater than 600 mg/dL, "**Hi**" appears in Display.

ALWAYS repeat test to confirm Low ("**Lo**") and High ("**Hi**") results. If results still display "**Lo**" or "**Hi**", contact Doctor or Diabetes Healthcare Professional ***immediately***.

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

Ketone Test Alert

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*).

Caution! *When a Ketone Test Alert is shown in the meter Display, it does not mean that ketones have been detected in the patient's blood. The Ketone Test Alert is a reminder to perform a ketone test as prescribed by the Doctor or Diabetes Healthcare Professional.*

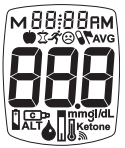
Note: *Ketone Test Alert can be turned on or off during Meter Set Up.*

Meter Set Up

Note: *Setting up the time, date, Event Tags, Ketone Test Alert and Test Reminders may not be suitable for a multiple patient use of the system. Check with the facility procedures and policies before performing 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. Press and hold " • " Button until the full Display is shown and a tone sounds (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.


Top of Meter

1. After setting the year, press " ▶ " or " ◀ " Button to turn Event Tags on or off. Press " • " Button to set. The meter goes to set Ketone Test Alert.

Event Tags may be used after each blood glucose result. 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).

Ketone Test Alert

When a blood glucose result is over 240 mg/dL, the Ketone Test Alert is a reminder to check the patient's ketones per the treatment plan prescribed by the Doctor or Diabetes Healthcare Professional.

Ketone Test Alert

2. Press " ▶ " or " ◀ " Button to turn Alert on or off. Press " • " Button to set. Meter goes to set Test Reminder.

Caution! *When a Ketone Test Alert is shown in the meter Display, it does not mean that ketones have been detected in the patient's blood. Perform a ketone test per the treatment plan, as prescribed by their Doctor or Diabetes 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:

Test Reminder

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. Meter goes to the next 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.*

Test Reminder Symbol

Meter Memory

Note: *The use of the Memory features (Averages, test results) may not be suitable for a multiple patient use of the system. Check with the facility procedures/ policy before use.*

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

The Averages feature allows the viewing of the average of all blood glucose results performed on the meter within a 7-, 14-, or 30-day period. Control Test results are not included in the Averages.

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

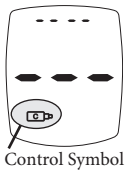
Meter Memory stores 500 results. Once Memory is full, the oldest result is replaced with the newest result.

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.

Care, Cleaning/Disinfecting and Troubleshooting

Caution! *Healthcare Professionals should wear gloves when cleaning and disinfecting the meter. Wash hands after taking off gloves as contact with blood presents a risk of infection.*

We recommend using only one meter per patient.

Caring for TRUE METRIX PRO

- 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 keep meter in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).
- Allow System to sit at room temperature for 10 minutes before testing.

Meter Care, Cleaning and Disinfecting

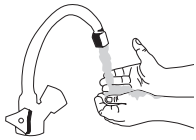
Cleaning *removes blood and soil from the meter.*

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.
- Meter should be cleaned and disinfected between patients.
- Clean and disinfect the meter before allowing anyone else to handle it.
- Do not clean the meter during a test.

To Clean and Disinfect the Meter:

1. Wash hands thoroughly with soap and water. Wear a clean pair of gloves.



2. Make sure meter is off and a test strip is not inserted. With **ONLY** Super Sani-Cloth® Wipes (or any disinfectant product with the EPA* reg. no. of 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. Repeat as needed until all surfaces are visibly clean. Discard used wipes.
   (*Environmental Protection Agency.)

3. 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 any other opening in the meter.

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

- Amazon.com,
- Officedepot.com or visit your local Office Depot store
- Walmart.com

4. Let meter air dry thoroughly before using to test.
5. 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 10,950 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the meter 10 times per day for a 3 year period. The use life of the meter is 3 years.*

TRUE METRIX Control Solution Care

- Write date opened on control solution label. Discard if either 3 months after first opening or date printed next to **EXP** on bottle label has passed, whichever comes first.
- After 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 PRO Test Strip Care

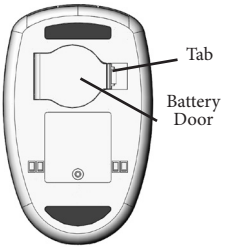
- Store test strips in original vial only. Do not transfer old test strips to new vial or store test strips outside of vial.
- Write date opened on test strip vial. Discard vial and unused test strips if either the open vial expiration date (see test strip Instructions for Use) or the date printed next to **EXP** on vial label has passed, whichever comes first. 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


Low

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. While holding meter in one hand with Battery Door facing down, tap meter 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.



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

5. Press " • " Button to turn meter on and check time, date, and Testing Alerts and Reminders (see *Meter Set Up*). If meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery and turn meter on by pressing " • " Button. Call for assistance 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! *Battery 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 for assistance.

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 for assistance.

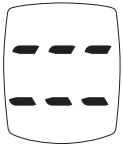
For assistance, see cover for phone number.

Messages

Display	Reason	Action
	Invalid Hematocrit	Repeat with new test strip, using capillary whole blood from the finger or forearm or venous whole blood collected with sodium heparin. If error persists, call for assistance.
	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 TRUE METRIX PRO 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 is touched to edge of test strip (not top). If error persists, call for assistance.
	Meter Error	Call for assistance.

Display	Reason	Action
	**Very high blood glucose result (higher than 600 mg/dL),** or Test Strip Error	**WARNING!!** **Retest with a new test strip. If the error persists and the patient has symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately.** If the patient has no symptoms, retest with a new test strip. If the error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST for assistance.
	Test Strip Removed During Test	Retest with new test strip. Make sure result is displayed before removing test strip.
	Communica-tion Error	Call for assistance.
	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 for assistance.

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

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call for assistance.

System Safety Information and Electromagnetic Compatibility

The TRUE METRIX PRO 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 PRO 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 PRO meter in a very dry environment, especially one in which synthetic materials are present.

Do not use the TRUE METRIX PRO 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 PRO meter, including cables specified by the manufacturer.

Blood Glucose Monitoring System Components

- TRUE METRIX PRO Self Monitoring Blood Glucose Meter
- TRUE METRIX PRO 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 PRO meter are fully enclosed.

System Specifications

Result Range: 20-600 mg/dL
Sample Size: 0.5 microliter (0.5 µL)
Sample: Fresh capillary whole blood from the finger or forearm, venous blood drawn in sodium heparin tubes, 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 PRO 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 PRO Limited Lifetime Warranty

Trividia Health, Inc. provides the following Warranty to the original purchaser of the TRUE METRIX PRO 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.