The Spanish Owner's Manual is located on Trividia Health.com

For Tips and Instructions visit TrividiaHealth.com for additional information







# **OWNER'S BOOKLET**

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.

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# **Fast Test Guide**

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 <sup>1</sup>
Before eating	< 100 mg/dL
2 hours after a meal	< 140 mg/dL

# 2 simple steps





# TRUE METRIX® GO Self Monitoring Blood Glucose System

The TRUE METRIX GO System 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 website at: <a href="https://www.trividiahealth.com">www.trividiahealth.com</a>.

## **System Components and Accessories**

TRUE METRIX GO Self Monitoring Blood Glucose Meter; TRUE METRIX Self Monitoring Blood Glucose Test Strips; TRUE METRIX Control Solution; Mini Lancing Device; Sterile Lancets Kits may contain one or more of the components and accessories above. To obtain components or accessories, call toll free 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

#### **Intended Use**

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

The TRUE METRIX GO 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 GO Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes, for neonate use or for alternative site testing.

The TRUE METRIX Self Monitoring Blood Glucose Test Strips are for use with the TRUE METRIX GO Self Monitoring Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

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

The TRUE METRIX GO Self Monitoring Blood Glucose Meter measures the current, detects, analyzes and corrects for hematocrit and temperature and calculates the glucose result.

#### Color Codes:

Pink - Caution:	Yellow - Important:	Blue - <b>Notes:</b>
Provides information that is important for user protection and about risks for inaccurate results.	Provides important information on testing and other issues relating to testing.	Helpful hints

# **Importance of Blood Glucose Monitoring**

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

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

#### **Caution!**

**NEVER** change your treatment plan without talking to your Doctor or Healthcare Professional.

#### **IMPORTANT INFORMATION**

- Use of the TRUE METRIX GO Self Monitoring Blood Glucose System in a manner not specified in this
  Owner's Booklet is not recommended and may affect the ability to determine true blood glucose levels.
- The TRUE METRIX GO Self Monitoring Blood Glucose System is for *in vitro* diagnostic use only.
- · For over-the-counter use.
- Not for neonate use.
- Not indicated for alternative site testing.
- · For single patient use only.
- The TRUE METRIX GO Self Monitoring Blood Glucose System is for one person ONLY. DO NOT share your
  meter or lancing device with anyone, including family members. Do not reuse lancets. Do not use on
  multiple patients!!
- 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.
- To help prevent false high results, wash hands before using the system to test blood, especially after fruit
  has been handled.

- ALL parts of your system could carry blood-borne pathogens after use, even after cleaning and disinfecting.<sup>2,3</sup> Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, blood-borne pathogens.
- For instructions on how to clean and disinfect the meter and lancing device, see *Meter Cleaning and Disinfecting*, pages 46 54.
- If the meter is being operated by a second person who gives testing assistance, the meter and the
  lancing device should be cleaned and disinfected before use by the second person. The second person
  should wear disposable gloves when performing testing. It is important to keep the meter and lancing
  device clean and disinfected.
- If any liquid gets into the test strip vial, discard vial and use a new vial for testing. Using test strips that may have been contaminated may result in incorrect results or error messages.
- If you have any liquids on your hands, especially blood, make sure you clean and completely dry your hands before opening the test strip vial.
- The System has not been tested with animals. Do not use to test blood glucose on pets.

- If you have symptoms of low or high blood glucose, check your blood glucose immediately. If your result
  does not match how 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.
- Since any meter may fail, break or be misplaced, you should always have a backup meter.
- 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.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.

**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.

# For best results using the TRUE METRIX GO Self Monitoring Blood Glucose System:

- Read **all** product instructions for use before testing.
- Perform a Control Test <u>before</u> performing a blood glucose test for the first time. Contact place of purchase or call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for information on how to obtain different levels of control solution.
- Capillary whole blood only from the fingertip may be used for testing with the TRUE METRIX GO Self Monitoring Blood Glucose System.
- Use only TRUE METRIX Self Monitoring Blood Glucose Test Strips and TRUE METRIX Control Solution with the TRUE METRIX GO Self Monitoring Blood Glucose Meter.
- Remove only one test strip at a time from the test strip vial. Recap vial immediately after removing the test strip.

#### Caution!

NEVER reuse test strips.

NEVER try to wipe test strips with water, alcohol or any cleaner to remove blood or control solution to reuse test strips. Reuse of test strips will cause inaccurate results.

NEVER add a second drop of sample (blood or control solution) to the test strip. Adding more sample to the test strip after testing begins gives an error message.

Do not bend, cut or alter test strips in any way.

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#### **KNOW YOUR SYSTEM**

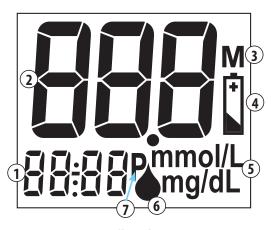
#### Meter

- ① **Display** Shows test results, messages, user prompts.
- ② **Test Port** Insert TRUE METRIX Test Strip here, contact blocks facing up.
- 3 Set Button Turns meter on to view Average values and scroll through Memory, sets up date/time, turns meter off.
- Battery Tray Holds battery (one non-rechargeable 3V lithium battery #CR2032).
- Meter Label Contains serial number used to identify meter when calling for assistance.
- Micro USB Port Used with a cable to upload results to a computer.
- **Vial Lip Cover** Locks meter onto a vial of test strips.





**Back of Meter** 



**Meter Full Display Screen** 

- ① Time, Date, Control Symbol (-C-), Average Symbol (7-, 14-, or 30-day)
- 2 Test Result
- **3** Memory Result
- Battery Symbol
- S Unit of measure -Factory set to mg/dL, cannot be changed by user.
- **6** Drop Symbol
- **7** Time is PM

AM does not show

# **Test Strip**

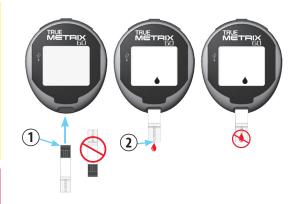
Insert test strip into meter before touching Sample Tip to blood or control solution drop. Allow sample drop to be drawn into the Sample Tip until dashes appear in the Display.

- ~ Do not apply sample to top of test strip.
- ~ Do not smear or scrape drop with test strip.

#### Caution!

DO NOT insert Sample Tip into meter. This may damage meter.

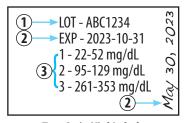
Do not apply more sample to the test strip after testing begins.



- Contact End Insert test strip into meter with contacts (blocks) facing up.
- Sample Tip Bring Tip of test strip to top of sample drop (blood or control solution) <u>after</u> Drop Symbol appears in the Display.

# **Test Strip Vial Label**

- **1. Lot Number (LOT)** Use for identification when calling for assistance.
- 2. Expiration Dates (EXP)
- Control Test Range Range of numbers where Control Test result must fall to assure the system is working properly.



Test Strip Vial Label (Example only and does not reflect actual Control Test ranges)

## **Caution!**

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. Use of test strips past the Expiration Dates may give incorrect test results. Discard out-of-date products and test with new products.

Ranges printed on test strip vial label are for Control Test results only and are not suggested levels for your blood glucose.

#### **Control Solution (Control)**

- Lot Number (LOT) Use for identification when calling for assistance.
- 2. Expiration Dates (EXP)
- Control Solution Level (1, 2 or 3)

### **Control Solution Bottle Label (example)**



#### Caution!

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. Use of control solution past the Expiration Dates may give incorrect test results. Discard out-of-date products and test with new products. Do not drink control solution.

We recommend testing at least 2 levels of control solution. Contact place of purchase or call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for assistance with obtaining different levels of control solution.

# To Attach/Remove Meter to Test Strip Vial



#### To attach:

- Set test strip vial on flat surface with vial lip facing to the left.
- 2. With Test Port facing front, place bottom of meter firmly on vial top. Meter must be seated flat on top of vial cap.
- Holding the vial, twist the meter 1/4 turn clockwise. The Test Port area on the meter should cover the vial lip if attached properly.

The meter may also be used for testing without attaching to the vial.



#### To remove:

- Holding the vial, twist the meter 1/4 turn counterclockwise.
- 2. Lift off meter off the vial top.

#### **GETTING STARTED**

The meter comes with pre-set time and date. Before using the meter for the first time or after a battery change, check time and date and update as needed.

#### The meter turns on when:

- ~ a test strip is inserted into the Test Port, or
- ~ when Set Button is pressed and released (see *Meter Memory* and *Time/Date Set Up*).

#### Meter turns off when:

- ~ the test strip is released from the meter,
- ~ the Set Button is pressed and held for 3 seconds, or
- ~ after 2 minutes of non-use.

# **Testing Checklist:**

- ✓ Check meter for damage (cracked Display, missing button, etc.). If damage is seen, do not use meter. Call 1-800-803-6025, Monday Friday, 8AM-8PM EST.
- Check test strip vial for damage (cracked or broken vial). Discard damaged vial and contents (test strips). Use a new vial of test strips for testing.
- ✓ 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.
- ✓ For Control Test, make sure you have clean tissues available. A small piece of plastic wrap, aluminum foil or waxed paper may be used to hold the control solution sample drop used in the Control Test.
- Check control solution bottle for any leaks or broken cap. Discard damaged bottle and open a new one for testing.
- ✓ Write date first opened on control solution 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.

# **Quality Control Testing**

To assure accurate and reliable results, TRUE METRIX GO offers two kinds of quality control tests, an Automatic Self-Test and a Control Test. 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 each time a test strip is inserted correctly into the Test Port. The Test lets you know if the meter and the Display are working properly. The Automatic Self-Test **does not** take the place of running a Control Test.



appears. (
Insert test strip for missin into Test Port. segments



Full Display appears. Check for missing segments.



3. Drop Symbol begins to blink. Meter may be used for testing.

If an error message appears, the meter will not perform a test. See Troubleshooting or call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

#### **Caution!**

If any segments are missing in the Display when test strip is inserted, **do not** use meter for testing. Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

#### **Control Test:**

We recommend performing Control Tests:

- · before using your meter for the first time,
- for practice to ensure your testing technique is good,
- · when opening a new vial of test strips,
- · occasionally as a vial of test strips is used,
- if results seem unusually high or low,
- if the test strip vial has been left opened, exposed to extreme heat, 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.).

Performing a Control Test with more than one level of control solution is recommended to ensure that the system is working properly. Three levels of TRUE METRIX Control Solution are available. Contact place of purchase or call 1-800-803-6025, Monday - Friday, 8AM-8PM EST, for more information on how to obtain levels of control solution.

Use **ONLY** TRUE METRIX Control Solution for Control Test.

#### **Caution!**

Ranges printed on test strip vial label being used are for Control Test results only and <u>are not</u> suggested levels for your blood glucose. Do not drink control solution.

#### **How To Test Control Solution**

# **Expiration Dates**



Test Strip Label Control Solution Label

**1.** Gather and check supplies. See *Getting Started -Testing Checklist* (page 17). 2. Allow control solution, vial of test strips and meter to adjust to room temperature for 10 minutes.



3. Wash hands. Dry thoroughly.









**4.** Gently swirl or invert control solution bottle to mix.

 Remove one test strip from vial. Close vial immediately. **6.** Insert test strip into Test Port. Meter turns on.

7. Remove cap from control solution bottle. Gently squeeze one drop onto a clean tissue. Wipe off bottle tip and discard tissue.

DO NOT SHAKE.

Use test strip quickly after taking it out of the vial. Keep test strip in meter until testing is finished. Do not add control solution to test strip before inserting into meter.





9.





8. Gently squeeze a drop onto a small piece of unused aluminum foil, clear plastic wrap, or waxed paper. Wipe off bottle tip and discard tissue.

With test strip still in meter, bring Tip of test strip to top of sample drop after Drop Symbol appears in the Display. Allow drop to be drawn into test strip. 10. Remove test strip from drop when dashes appear across the meter Display. Meter is testing.

 After testing is finished, result appears in the meter Display with the Control Symbol.



# Control Solution Bottle Label

1 22 – 52 mg/dL

2 95 – 129 mg/dL

3 261 – 353 mg/dL

# Test Strip Vial Label (Examples only and do not represent actual Control Test ranges)

12. Compare result to Control Test Range printed on the test strip vial label for the level of control solution you are testing. If result is in range, system can be used for testing blood.

If result is not within range, perform Control Test again.



13. After result is shown, remove test strip from meter and discard. Meter turns off. Recap control solution bottle tightly.

#### Caution!

If Control Test result is still outside the range after a second Control Test, do not use the system for testing blood. Call 1-800-803-6025, Monday - Friday, 8AM-8PM FST.

- If test strip is removed before testing is finished, an error message appears. Discard old test strip and retest using a new test strip.
- ~ Do not put control solution drop on top of test strip.
- ~ Do not add sample drop to test strip and insert that end into the meter. Meter will be damaged.
- If meter does not begin testing soon after drawing up sample, discard test strip. Repeat with a new test strip. If problem persists, see Troubleshooting.
- ~ Removing the test strip before result is displayed 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**

#### **Caution!**

*Use* **ONLY** *capillary whole blood from the fingertip for testing*.

**DO NOT** use venous blood or capillary whole blood obtained from alternative site for testing.

Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets or test strips. Make sure your hands are completely dry before opening the test strip vial.

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 Cleaning and Disinfecting and Lancing Device Cleaning and Disinfecting in this Owner's Booklet (pages 46 - 54).

- ~ If blood gets on the meter or lancing device, clean and disinfect the meter and lancing device before anyone else touches them.
- ~ 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.

**ALL** parts of your system could carry blood-borne pathogens after use, even after cleaning and disinfecting.<sup>2,3</sup> Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, blood-borne pathogens.

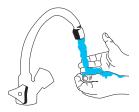
**DO NOT** share your meter or lancing device with anyone, including family members.

Lancets are for one time (single) use only. Do not re-use lancets as this may result in infection.

Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets carefully according to your Doctor or Healthcare Professional's instructions.

To help prevent false high results, wash hands before using the system to test blood, especially after fruit has been handled.

# Refer to lancing device's Instructions for Use for more detailed instructions on using the lancing device.



1. Select area to be lanced. Wash with soap and warm water, rinse, and dry thoroughly. Disinfect the clean skin with an antiseptic (e.g., 70% alcohol).

#### **From Fingertip**



**2.** Place end of lancing device equipped with lancet against fingertip. Lance fingertip.

#### Caution!

Use **ONLY** capillary whole blood from the fingertip for testing. **DO NOT** use venous blood or capillary whole blood obtained from alternative site for testing.



Set lancing device aside. To help blood drop form, lower hand to waist level and gently massage from palm to fingertip.

Allow blood drop to form before attempting to apply to the test strip.



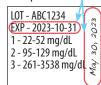
 After testing, recap and remove used lancet from lancing device. Discard used lancet.

#### **Caution!**

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

#### **How to Test Blood**

Test Strip Label Expiration Dates



2. Check supplies (see Getting Started Testing Checklist, page 17).



3. Allow vial of test strips and meter to adjust to room temperature for 10 minutes.



Wash hands in warm, soapy water. Rinse well and dry thoroughly.

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 begins to blink. Release"•"

Button. If time and date are incorrect, see Time/Date Set Up to see the correct time and date.







Remove one test strip from vial. Close test strip vial immediately.

Use test strip quickly after taking it out of the vial.

6. Insert test strip firmly into Test Port. Meter turns on.

7. Wait until Drop Symbol appears in the Display.

Keep test strip in meter until testing is finished. Do not add blood to test strip before inserting into meter.





8. Lance fingertip.
Allow blood drop to form (see *Obtaining a Blood Sample*, pages 24-27).



9. With test strip in Meter, bring to top of blood drop after Drop Symbol appears in the Display. Allow blood to be drawn into the test strip.



10. Remove test strip from drop when dashes appear across the meter Display. Meter is testing.



11. After testing is finished, result appears in the meter Display. Record result in log book.



12. Remove test strip from meter and discard according to your Doctor or Healthcare Professional's instructions. Meter turns off. Result is stored in the Memory.

#### **Caution!**

Used test strips and lancets may be considered biohazardous. Please discard them carefully according to your Doctor or Healthcare Professional's instructions.

- ~ If test strip is removed before testing is finished, an error message appears. Discard old test strip and retest using a new test strip.
- ~ Do not place blood drop on top of test strip.
- ~ Do not add blood drop to test strip and insert that end into meter. Meter will be damaged.
- Removing the test strip before result is displayed cancels the test. An error message appears. Result is not stored in Memory. Retest with a new test strip. Do not remove before result is displayed.

# **TROUBLESHOOTING**

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

Reason	Action
Test strip inserted upside down or backwards	Remove test strip from meter. Re-insert test strip correctly into the meter.
Test strip not fully inserted	Remove test strip from meter. Re-insert test strip correctly into the meter.
Test strip error	Remove test strip from meter. Repeat with new test strip.
Meter is dead or there is not a battery in the meter	Remove test strip from meter. Replace battery in meter. Use new test strip for testing.
Battery in the meter backwards	Battery must be placed in meter with positive ("+") side facing up.
Meter error	Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

# 2. After applying sample, meter does not begin testing.

Reason	Action
Sample drop too small	Repeat test with new test strip and larger sample drop.
Sample applied after two minute shut-off	Repeat test with new test strip. Apply sample within 2 minutes of inserting test strip into the meter.
Problem with test strip	Repeat with new test strip. If meter still does not begin testing, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
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
E-0	Invalid Hematocrit	Repeat with new test strip, using capillary whole blood from the finger. If error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
<b>E-</b>	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.
E-2	Sample Not Detected or Sample Drop on Top of Test Strip	Retest with new test strip and larger sample. Make sure Sample Tip of test strip touched top of sample drop.

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
<b>E-3</b>	Used Test Strip, Test Strip Outside of Vial Too Long.	Repeat with new test strip. If error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
E-4	Meter Error	Call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
E-5	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.

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
E-6	Test Strip Removed During Test or Micro USB Cable Connected while Testing	Unplug Micro USB cable. Repeat with new test strip. Make sure result is displayed before removing test strip. If error persists, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.
<b>E-9</b>	Meter 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 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.
H, mg/dL	WARNING!! Out of Range - High Results > 600 mg/dL Out of Range - Low Results < 20 mg/dL	WARNING!!  Retest with new test strip.  If result is still "Hı" (High) or "Lo" (Low)  contact Doctor or Healthcare Professional  immediately.

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.

# **Results Out of System Range Warning Messages**

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

#### **Caution!**

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



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



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

- ~ "Lo" results are included in the Average as 20 mg/dL.
- ~ "**Hı**" results are included as 600 mg/dL.

# **TRUE METRIX GO System and Laboratory Testing**

When comparing results between TRUE METRIX GO System and a laboratory system, TRUE METRIX GO blood tests should be performed within 30 minutes of a laboratory test. If you have recently eaten, fingerstick results from the TRUE METRIX GO System can be up to 70 mg/dL higher than venous laboratory results.<sup>4</sup>

## **TIME/DATE SET UP**

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



 Start with the meter off. Press and hold the Set Button until the full Display appears and begins to blink. Release Set Button.



2. The time appears and the hour begins flashing. Change the number by pressing the Set Button until the desired number appears.

Pressing and releasing the Set Button only makes the numbers increase by one. Once the number reaches its limit, it resets to the lowest number. Pressing and holding the Set Button increases the numbers quickly. Release Set Button when the number you want is reached.



3. After the correct hour appears, the number flashes for about 10 seconds before going to the minutes.



**4.** Repeat steps 2-3 to set up minutes, month, day and year.

## **METER MEMORY**

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

Averages allows you to view the average of all blood glucose results within a 7-, 14-, or 30 day period.



 With meter off, press and release Set Button.



2. Display scrolls through the 7-, 14-, and 30-day Averages. Meter turns off after 2 minutes if Set Button is not pressed.

If there are no average values, three dashes are displayed for 7-, 14-, and 30-day Averages.

## **View Memory**

Memory stores 500 results which are displayed from most recent to oldest. When Memory is full, the oldest result is replaced with the newest result.



1. After meter displays the Averages, press and release Set Button again.



The most recent result is shown with the Memory Symbol.



**3.** Continue to press and release the Set Button to scroll through results.



~ Blood test results are shown with the Memory Symbol, the time and date.



~ Only the last Control Test is saved in Memory. The Control Test result is shown with the Control Symbol in the Display.

## **SYSTEM CARE**

# **Caution!** Do not share your meter or lancing device with anyone, including family members.

- 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.**
- Allow system to sit at room temperature for 10 minutes before testing.

## **TRUE METRIX Control Solution Care**

- Write date first opened on control solution 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.
- After each use, wipe bottle tip clean and recap tightly.
- Discard any control solution bottles that appear cracked or leaking.
- Store at room temperature (36°F-86°F). **DO NOT FREEZE.**

# TRUE METRIX Self Monitoring Blood Glucose 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 the expiration dates
  may give incorrect results.
- Discard any test strip vials that appear cracked or broken. DO NOT transfer test strips to a new vial or store
  outside of the vial.

 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.

# **Meter Cleaning and Disinfecting**

Cleaning and disinfecting the meter is a two step process. The first step is **Cleaning**. Cleaning removes any blood, liquids, dust or dirt from the meter. **Cleaning must be done before Disinfecting**.

The second step is **Disinfecting**. Disinfecting removes most, but not all possible infectious agents (bacteria or viruses) from the meter, including blood-borne pathogens.

#### **Caution!**

- ~ Before you attach the meter to a new test strip vial, clean and disinfect the meter, including the bottom of the meter that attaches to the test strip vial cap.
- ~ If blood gets on the meter or outside of the test strip vial, make sure that the vial is **completely** closed to clean and disinfect it before anyone else touches it.
- ~ If someone is helping you test your blood or performs a test on you, do the cleaning and disinfecting before allowing anyone else to handle them.
- ~ Do not clean the meter during a test.
- ~ If blood or cleaning solution gets into the test strip vial, discard vial and use a new vial for testing. Using test strips that may have become contaminated may result in incorrect results or error messages if used for testing.
- ~ If you have any liquids on your hands, especially blood, make sure you clean and completely dry your hands before opening the test strip vial.

# How to Clean the Meter



 Wash hands thoroughly with soap and water or wear disposable gloves.



Make sure that the meter is off and a test strip is not inserted. Remove the meter from the empty vial by holding the vial and twisting the meter 1/4 turn counter clockwise. Lift off meter off the vial top.

## **Caution!**

After removing the empty vial, we recommend cleaning and disinfecting the meter before attaching it to a new vial. If meter remains attached to the test strip vial for cleaning/disinfecting, make sure that the vial cap is **completely** closed!



- Wipe (EPA\* reg.no. 9480-4), wipe in circles every surface of the meter (front, back, left side, right side top and bottom) 3 times. Make sure that you go over the entire meter.
- **4.** Discard used wipe.
  - Make sure no liquids enter the Test Port or any other opening in the meter.
  - Do not spray meter with any cleaning agents.

\*Environmental Protection Agency

#### How to Disinfect the Meter



- 1. After cleaning the meter, use a fresh wipe to wet all the outside surfaces of the meter.
- Make sure no liquids enter the Test Port or any other opening in the meter.
- ~ Do not spray meter with any cleaning agents.

## **Caution!**

If the meter remains attached to the test strip vial during cleaning, make sure that the vial cap is **completely** closed before disinfecting.





2. Keep the meter wet for 2 minutes by rewiping all of the surfaces. Fresh wipes may be used if needed to keep the meter wet. Discard used wipes.

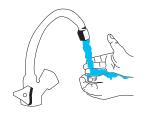
#### Caution!

Do not wrap or scrub the meter or the test strip vial with the wipe to keep the surfaces wet. Wrapping wipe around test strip vial or scrubbing can cause the label to become unreadable.

**3.** Allow meter to air dry for an additional 1 minute.



- **4.** Reattach meter to the new test strip vial by setting the test strip vial on flat surface with vial lip facing to the left.
  - With Test Port facing front, place bottom of meter firmly on vial top. Meter must be seated flat on top of vial cap.
  - Holding the vial, twist the meter 1/4 turn clockwise.
     The Test Port area on the meter should cover the vial lip if attached properly.



Wash hands thoroughly after cleaning/ disinfecting the meter. Make sure your hands are completely dry.

#### Caution!

If hands are not dry before removing a test strip from the vial, the vial may become contaminated. Test strips that have become contaminated may result in incorrect results or error messages.



6. Perform an Automatic Self-Test by removing a test strip from the vial. Insert test strip into Test Port. If the full Display appears with no missing segments followed by the blinking Drop Symbol, the meter may be used for testing.

## **Caution!**

If any segments are missing in the Display when test strip is inserted, do not use meter for testing. Call 1-800-803-6025, Monday - Friday, 8AM-8PM FST.

#### Caution!

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

Do not use meter or test strips 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 or test strip vial, including labels, are faded, coming off or missing,
- ~ Set Button is hard to push on meter or does not work (see Meter Memory),
- ~ Unable to insert test strip into Test Port.
- ~ If Automatic Self-Test gives an error message.

Only use Super Sani-Cloth Wipes to clean and disinfect the meter. Super Sani-Cloth Wipes may be purchased at the following places: • Amazon.com • Staples.com • Walmart.com

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 and disinfecting the lancing device is a two-step process. The first step is **Cleaning.** Cleaning removes any blood, liquids, dust or dirt. The second step is **Disinfecting**. Disinfecting removes most, but not all possible infectious agents (bacteria or viruses) including blood-borne pathogens. **Cleaning must be done before Disinfecting.** 

## **Caution!**

- ~ Clean and disinfect the lancing device at least once a week. Lancing device may be cleaned and disinfected once a day for up to 3 years.
- ~ If blood gets on the lancing device, clean and disinfect it before anyone else touches it.

2.

~ If someone is helping you test your blood or performs a test on you, do the cleaning and disinfecting before allowing anyone else to handle it.



1. Wash hands thoroughly with soap and water or wear disposable gloves.



**To Clean:** Using **ONLY** Super Sani-Cloth (EPA\* Reg. No. 9480-4), thoroughly wipe the entire outside surface of the lancing device with one cloth by wiping in circles 3 times. Discard the used cloth.

\*Environmental Protection Agency

- **3.** Repeat step 2 if the lancing device is not visually clean, or safely dispose of it according to your state/local regulations.
- **4. To Disinfect:** Remove a fresh Super Sani-Cloth and thoroughly wipe the entire outside surface of the lancing device by wiping in circles 3 times. Make sure that you go over the entire lancing device.
- 5. Using fresh cloths, if needed, make sure that all outside surfaces of the lancing device stay wet for 2 minutes by patting with the cloth. Discard used cloth. Let lancing device air dry completely before using.
- **6.** Gently pull back Arming Barrel and press the Trigger Button. You will hear a click if the lancing device is working properly.
- **7.** Wash hands thoroughly again.

#### **Caution!**

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 may damage lancing device.

Do not use 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 is hard to push,
- ~ End Cap does not go back on,
- ~ Arming Barrel does not click when gently pulled back.

Super Sani-Cloth may be purchased at  $: \bullet$  Amazon.com,  $\bullet$  Officedepot.com (or your local Office Depot store),

Walmart.com

Super Sani-Cloth has been tested on the lancing device for a total of 1,095 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the lancing device once a day for a 3-year period. Lancing device may be cleaned and disinfected up to 7 cycles per week for 3 years.

# **Changing Battery**



 Remove meter from top of test strip vial by holding the vial and twisting the meter ¼ turn counterclockwise. Lift meter from vial top.



- 2. Turn meter over until the meter label is facing up. Pull Battery Tray out until battery is exposed.
- 3. Holding the Battery Tray over your hand, press on edge of battery until battery drops out.



Insert new battery into Battery
 Tray with "+" side facing up. Slide
 Battery Tray back into meter.



5. Turn meter back over and press Set Button to turn meter on.

If meter does not turn on, open Battery Tray and check that the battery was inserted with the "+" side facing up. Close Battery Tray and repeat Step 5. If meter still does not turn on, call 1-800-803-6025, Monday - Friday, 8AM-8PM EST.

#### Caution!

Batteries may explode if mishandled. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local regulations.

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.

Time and date settings may need to be reset after changing the battery. See Time/Date Set Up on pages 40-41 to re-set time and date.

# **System Specifications**

**Result Range:** 20-600 mg/dL

**Sample:** 0.5 microliter (0.5 µL) Fresh capillary whole blood from the fingertip

**Test Time:** Results in as fast as 4 seconds **Result Value:** Plasma equivalent values

**Assay Method:** Electrochemical

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

**Battery Life:** Approximately 1,500 tests or 2 years

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

Weight: 0.58 ounces

**Size:** 1.6" x 1.4" x 0.85"

**Memory Size:** 500 results

Operating Range (Meter & Test Strips): Relative Humidity: 10%-90% (Non-condensing)

Temperature: 41°F - 104°F Hematocrit: 20%-70%

Life of the meter: 5 years
Life of the lancing device: 3 years

Hematocrit: 20%-70%
Up to and including 10,200 feet

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:** Contents: water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

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# **System Safety Information and Electromagnetic Compatibility**

The TRUE METRIX GO 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 GO 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

EMC Test	Compliance Information			
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.			

#### Caution!

To maintain electromagnetic interference within certified limits, the meter must be used with the data transfer cable supplied by Trividia Health, Inc. For assistance obtaining cable, please call 1-800-803-6025, Monday - Friday, 8AM-8PM EST. The use of cables other than those specified or supplied may result in increased emissions or decreased immunity of the system.

No modification of this device is allowed.

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 GO meter in a very dry environment, especially one in which synthetic materials are present. Do not use the TRUE METRIX GO 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 GO meter, including cables specified by the manufacturer.

# **Blood Glucose Monitoring System Components**

- TRUE METRIX GO 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.

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 GO meter are fully enclosed.

## TRUE METRIX GO Self Monitoring Limited Lifetime Warranty

Trividia Health, Inc. provides the following Warranty to the original purchaser of the TRUE METRIX GO 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. Classification and Diagnosis of Diabetes. Diabetes Care, Volume 39, Supplement 1, January 2016.
- 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. Larsson-Cohn U: Difference between capillary and venous blood glucose during oral glucose tolerance tests. Scand J Clin Lab Invest 36:805-808, 1976.