RF4AUT16 Rev. 57

TRUE METRIX GO Blood Glucose Monitoring System Instructions For Use (IFU)

CONTENTS

1 IMPORTANT INFORMATION ABOUT YOUR SYSTEM

INTENDED USE

The TRUE METRIX GO Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm, or venous whole blood collected in only sodium heparin blood collection tubes.

The TRUE METRIX GO System is intended for self-testing outside the body (IVD) by people with diabetes at home and for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control.

The TRUE METRIX GO System should not be used for the diagnosis or screening of diabetes or for neonate (newborn) use. Alternate site (forearm) testing should be done only during steady-state times (when glucose is not changing rapidly).

The TRUE METRIX Test Strips are for use with the TRUE METRIX GO Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm and venous whole blood.

The TRUE METRIX Control Solution is for use with the TRUE METRIX GO Meter and TRUE METRIX 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 Meter measures the current, detects, analyzes and corrects for hematocrit and temperature, and calculates the glucose result.

Please read complete System IFU and all product Instructions for Use before using the System.

Color Codes:

Pink - **Caution:**	Yellow - **Important:**	Blue - **Notes:**
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

IMPORTANT HEALTH and SAFETY INFORMATION

- Use of the TRUE METRIX GO System in a manner not specified in this System Instructions for Use is not recommended and may affect the ability to determine true blood glucose levels.
- All meter brands perform differently. Test results from one meter brand to another may vary. This is why test results from your meter should only be compared to a lab instrument and not to another meter brand.
- Wash 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 the system could carry blood-borne pathogens after use, even after cleaning.[2] Cleaning the meter and lancing device destroys most, but not necessarily all, blood-borne pathogens.
- For instructions on how to clean the meter, see *Meter Cleaning*.
- If the meter is being operated by a second person who gives testing assistance, the meter and the lancing device should be cleaned 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.
- Alternate site (forearm) testing should not be used to calibrate continuous glucose monitors (CGMs) or used for insulin dose calculations.
- Alternate site (forearm) testing should be done only during steady-state times (when glucose is not changing rapidly).
- The System has not been tested with animals. Do not use to test blood glucose on pets.
- If there are symptoms of low or high blood glucose, check blood glucose immediately. If the result does not match how you feel, repeat the test. If the results still do not match the way you feel, call a 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, always have a backup meter.
- Do not use for diagnosis of or screening for diabetes or for neonatal use.
- Inaccurate results may occur in severely hypotensive individuals or in dehydrated patients or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Do not use the TRUE METRIX GO System during a xylose absorption test. Blood samples containing xylose concentrations >0.4 mmol/L may falsely raise glucose results.[5] Please check with a Doctor or Healthcare Professional before using the System.
- Ascorbic acid (Vitamin C) greater than normal or therapeutic levels may cause significant interference resulting in inaccurate result.
- Uric acid can interfere with this device at normal and disease levels, when uric acid concentrations are greater than 0.3 mmol/L. For people with diabetes, certain conditions (including gout or kidney disease) may cause the blood level of uric acid to rise. This may cause significant interference resulting in inaccurate glucose results and the blood glucose results may be not reliable. Please check with a Doctor or Healthcare Professional before using the System.
- **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 for replacement and assistance.

For best results using the TRUE METRIX GO System:

- Read **all** product instructions for use before testing.
- Perform a Control Test **before** performing a blood glucose test for the first time. Contact place of purchase or use the contact information at the bottom of the page for information on how to obtain different levels of control solution.
- Capillary whole blood from the fingertip or forearm may be used for testing with the TRUE METRIX GO System. Forearm testing should be used only during steady-state blood glucose conditions. Venous blood collected in only sodium heparin blood collection tubes may be used. Mix well before use.
- **DO NOT** use venous whole blood collected in sodium fluoride blood collection tubes. Blood samples containing sodium fluoride may cause false low glucose results or blood results may be read as control solution.
- Use only TRUE METRIX Test Strips and TRUE METRIX Control Solution with the TRUE METRIX GO Meter.
- Remove only one test strip at a time from the test strip vial. Recap vial immediately after removing the test strip.

⚠ *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.

REFERENCES

1. Joslin Diabetes Center. *Goals for Blood Glucose Control* [Electronic Version]. Retrieved June 8, 2015 from http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html.
2. FDA Public Health Notification: *Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication Update 11/29/2010* [Electronic Version]. Retrieved February 22, 2012 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
3. U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter.* [Electronic Version]. Retrieved July 6, 2009 from www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm.
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.
5. Data on file.
6. European Committee for Standardization. *In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.* Reference number EN ISO 15197:2015(E). Brussels: European Committee for Standardization; 2015.

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2 SYSTEM SPECIFICATIONS

Result Range:	1.1-33.3 mmol/L
Sample:	0.5 microliter (0.5 µL) fresh capillary whole blood from the fingertip or forearm and venous blood drawn in only sodium heparin blood collection tubes.
Test Time:	Results in as little as 4 seconds
Result Value:	Plasma equivalent values
Assay Method:	Electrochemical
Power Supply:	One 3V lithium battery #CR2032 (non-rechargeable)
Battery Life:	Approximately 1,000 tests or 1 year
Automatic shut-off:	After two minutes of non-use
Weight:	18 grams
Size:	4.1 cm x 3.5 cm x 2.2 cm
Memory Size:	500 results
Operating Range (Meter & Test Strips For Blood Testing)	
Relative Humidity:	10%-90% (Non-condensing)
Temperature:	5°C-40°C
Hematocrit:	20%-70%
Altitude:	Up to and including 3109 metres
	Use within specified environmental conditions only.

Chemical Composition

Test Strips: Glucose dehydrogenase-FAD *(Aspergillus species)*, mediators, buffers and stabilizers.
Control Solution: Contents: water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

EXPECTED RESULTS

Expected Blood Glucose Results for people without diabetes:

	Plasma Blood Glucose Result[1]
Before breakfast	< 5.6 mmol/L
Two hours after a meal	< 7.8 mmol/L

Importance of Blood Glucose Monitoring

A Doctor or Healthcare Professional determines how often to test glucose and what the target ranges are for blood glucose results.

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

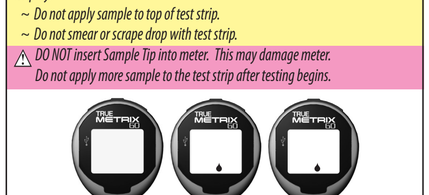
⚠ ***NEVER** change a treatment plan without talking to a Doctor or Healthcare Professional.*

SYMBOLS:

- Biological Risks
- STERILE R — Sterilized Using Irradiation
- Do Not Resterilize
- Single Use
- CONTROL — Control Solution
- ① ② ③ Control Level
- SN — Serial Number
- Caution
- Use-by Date
- Keep Dry
- Consult Instructions for Use
- Temperature Limit
- Humidity Limitation
- LOT — Lot Number
- IVD — *In vitro* Diagnostic Medical Device
- EC REP — Authorized Representative in the European Community
- Manufacturer
- Date of Manufacture
- Single Patient Use Only

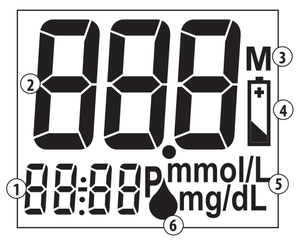
3 KNOW YOUR SYSTEM

METER



Front of Meter — Back of Meter

① **Display** - Shows test results, messages, user prompts.
② **Test Port** - Insert Test Strip here, with contact blocks facing up.
③ **Set Button** - Turns meter on to view Average values and scroll through Memory, sets up date/time, adds ALT Symbol, turns meter off.
④ **Battery Tray** - Holds battery (one non-rechargeable 3V lithium battery #CR2032).
⑤ **Meter Label** - Contains serial number used to identify meter when contacting for assistance.
⑥ **Micro USB Port** - Used with a cable to upload results to a computer.
⑦ **Vial Lip Cover** - Locks meter onto a vial of test strips.



Meter Full Display Screen

① **Time, Date, Control Symbol (-C-), Alternate Site Symbol (-A-), Average Symbol (7-, 14-, or 30-day)**
② **Test Result**
③ **Memory Result**
④ **Battery Symbol**
⑤ **Units of measure** -
Factory set to mmol/L or mg/dL, cannot be changed by user.
⑥ **Drop Symbol**

TEST STRIP

Insert test strip into meter before touching Sample Tip to top of blood or control solution drop. Allow drop to be drawn into the test strip until dashes appear in the Display.
~ Do not apply sample to top of test strip.
~ Do not smear or scrape drop with test strip.

⚠ *DO NOT insert Sample Tip into meter. This may damage meter.*
Do not apply more sample to the test strip after testing begins.

1. **Contact End -** Insert test strip into meter with contacts (blocks) facing up.
2. **Sample Tip -** Touch Tip to top of drop of sample ***after*** Drop Symbol appears in the meter Display.

Test Strip Vial Label

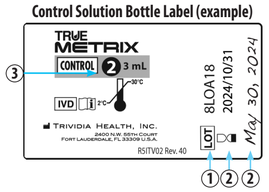
Test Strip Vial Label
(Example only and does not reflect actual Control Test ranges)

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

⚠ *Write date first opened on vial label. Discard vial and unused test strips if either the open vial Use By date or the date printed next to on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial Use By date. Use of test strips past the Use By 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 blood glucose.*

CONTROL SOLUTION CONTROL

Control Solution Bottle Label (example)



1. **Lot Number (LOT) -** Use for identification when contacting for assistance.
2. **Use By Dates ( )**
3. **Control Solution Level (1, 2 or 3)**

⚠ *Write date first opened on bottle label. Discard bottle and unused control solution if either 3 months after first opening or date printed next to on bottle label has passed, whichever comes first. Use of control solution past the Use By Dates may give incorrect test results. Discard out-of-date products and test with new products. Do not drink control solution.*

Use the contact information at the bottom of the page for information on how to obtain different levels of control solution.

TO ATTACH/REMOVE METER TO TEST STRIP VIAL

Please attach meter to the test strip vial and keep it attached until last test strip from the vial is consumed. Only remove meter from the test strip vial when a new test strip vial is needed for blood testing or when changing the battery, following the instructions below.

To attach:
1. 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.
3. 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.

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

FRONT PAGE

4 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. Use the contact information at the bottom of the page for assistance.*
✔ *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 Use By date or the date printed next to on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial Use By 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 for control solution sample drop 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 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

The Automatic Self-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.

1. Insert test strip into Test Port.

2. 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 contact for assistance.*

CONTROL TEST

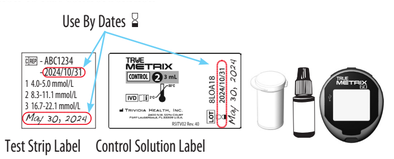
We recommend performing Control Tests:
- before using the meter for the first time,
- for practice to ensure your testing technique is good,
- when opening a new vial of test strips,
- occasionally as a vial of test strips is used,
- if results seem unusually high or low,
- if the test strip vial has 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. Use contact information at the bottom of the page for more information on how to obtain levels of control solution.

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

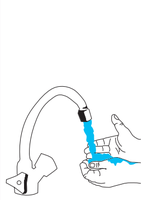
⚠ *Ranges printed on test strip vial label being used are for Control Test results only and **are not** suggested levels for blood glucose.*
Do not drink control solution.

How To Test Control Solution



Test Strip Label — Control Solution Label

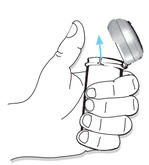
1. Gather and check supplies. See *Getting Started -Testing Checklist.*



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.

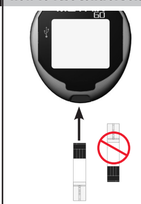


5. Remove one test strip from vial. Close vial immediately.

DO NOT SHAKE.

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

How To Test Control Solution, *cont.*



6. Insert test strip firmly into Test Port. Meter turns on.
Keep test strip in meter until testing is finished. Do not add control solution to test strip before inserting into meter.

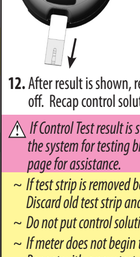
7. Remove cap from control solution bottle. Gently squeeze a drop onto a clean tissue. Wipe off bottle tip and discard tissue. Gently squeeze a drop onto a small piece of unused aluminum foil, clear plastic wrap, or waxed paper for testing.

8. With test strip still in meter, touch Sample Tip to top of drop. Allow drop to be drawn into test strip.

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

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

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



11. Compare result to Control Test Range printed on the test strip vial label for the 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.

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

⚠ *If Control Test result is still outside range after a second Control Test, do not use the system for testing blood. Use the contact information at the bottom of the page for assistance.*
~ 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.
~ 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.

5 SYSTEM SAFETY INFORMTION

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
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 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 Blood Glucose Monitoring Meter • TRUE METRIX Blood Glucose Test Strips
• TRUE METRIX Control Solution • Lancing Device • Sterile Lancet

Kit may contain one or more of the components above.
To obtain components, contact place of purchase of original kit.
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.

6 TESTING BLOOD

OBTAINING A BLOOD SAMPLE

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

Important Notes Regarding Forearm Testing[3]

- *Forearm testing results cannot be used for continuous glucose meter calibration or for insulin dose calculations.*
- *Check with a Doctor or Healthcare Professional to see if forearm testing is appropriate.*
- *Results from forearm are not always the same as results from fingertip.*
- *Some lancing devices include a special end cap for alternate site (forearm) testing. Check lancing device* Instructions for Use.
- *Use fingertip instead of forearm for more accurate results:*
  - *Within 2 hours of eating, exercise, or taking insulin,*
  - *If blood sugar may be rising or falling rapidly,*
  - *If routine results are often fluctuating,*
  - *If the patient is ill or under stress,*
  - *If forearm results do not match how you feel,*
  - *If blood sugar may be low or high,*
  - *If symptoms of low or high blood sugar are not evident.*

Wash hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets or test strips.

If the meter or lancing device is being operated by a second person who gives testing assistance, the meter and the lancing device should be cleaned before use by another person.

For instructions on how to clean the meter, see Meter Cleaning.

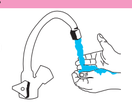
***ALL** parts of the system could carry blood-borne pathogens after use, even after cleaning.*[2] *Cleaning the meter and lancing device destroys most, but not necessarily all, blood-borne pathogens.*

Do not reuse lancets.
Reuse of devices labeled for single-use may result in product contamination and infection.

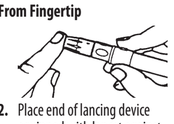
Used test strips and lancets are considered biohazardous.
Dispose used test strips and lancets carefully into an appropriate waste container.

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

1. Select area to be lanced. Wash hands (and forearm for alternate site testing) with soap and warm water, rinse and dry thoroughly.



From Fingertip



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

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

or

From Forearm

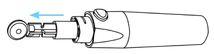
2. Rub area vigorously or apply a warm dry compress to increase blood flow.

3. Place end of lancing device equipped with a lancet firmly against forearm. Press trigger button. Apply firm pressure on lancing device for 10 seconds.

then

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

4. After testing, recap and remove used lancet from lancing device. Discard used lancet into an appropriate waste container.

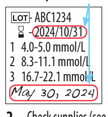


The used lancet may be biohazardous. Please discard it carefully into an appropriate waste container.

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 begins to blink. Release "▪" Button. If time and date are incorrect, see Time/Date Set Up to set the correct time and date.

Test Strip Label
Use By Dates

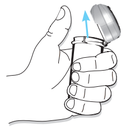


2. Check supplies (see *Getting Started - Testing Checklist*).

4. Wash hands (and forearm for alternate site testing) in warm, soapy water. Rinse well and dry thoroughly.

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

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

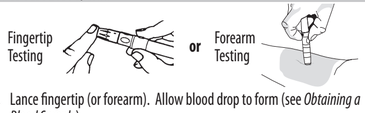


5. Remove one test strip from vial. Close test strip vial immediately. *Use test strip quickly after taking it out of the vial.*

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

How to Test Blood, *cont.*



8. Lance fingertip (or forearm). Allow blood drop to form (see *Obtaining a Blood Sample*).

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

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

If you wish to mark the result as alternate site, press the Set Button before the meter turns off. -A- appears in the meter Display.

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

12. Remove test strip from meter and discard into an appropriate waste container. Meter turns off. Result is stored in the Memory.

Used test strips and lancets may be considered biohazardous. Please discard them carefully into an appropriate waste container.

- *If test strip has been out of the vial too long before testing, an error message appears. Remove and discard old test strip. Use new test strip for testing.*
- *Do not place blood drop on top of test strip.*
- *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.*

SYSTEM OUT OF RANGE WARNING MESSAGES

Meter reads blood glucose levels from 1.1-33.3 mmol/L.
If blood test result is less than 1.1 mmol/L, "**Lo**" appears in meter Display. If blood test result is greater than 33.3 mmol/L, "**Hi**" appears in meter Display.

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

- *"**Lo**" results are included in the Average as 1.1 mmol/L.*
- *"**Hi**" results are included as 33.3 mmol/L.*

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 3.9 mmol/L higher than venous laboratory results.[4]

7 METER SETUP

TIME/DATE SET UP

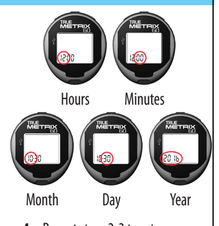
If meter turns off at any time during Set Up, go back to Step #1 and begin again.

1. 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 scrolls the numbers. Release Set Button when desired number 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.

8 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.

1. 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.

2. 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 will show the Control Symbol in the lower left corner of the Display.

~ Alternate Site Blood Test results are shown with the Alternate Site Symbol in the lower left corner of the Display.

9 SYSTEM CARE

- 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 4°C-30°C and at 10%-80% relative humidity (Non-condensing). **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 and unused control solution if either 3 months after first opening or date printed next to ⌛ on label has passed, whichever comes first.
- After each use, wipe bottle tip clean and recap tightly.
- Store at room temperature 2°C-30°C. **DO NOT FREEZE.**

TRUE METRIX 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 Use By date or the date printed next to ⌛ on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial Use By date. Use of test strips past the Use By dates may give incorrect results.
- Close vial immediately after removing test strip. Store in a dry place at room temperature 4°C-30°C and at 10%-80% relative humidity (Non-condensing). **DO NOT FREEZE.**

METER CARE AND CLEANING

Cleaning removes blood and soil from the meter.

~ If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned prior to use by the second person.
~ Do not clean the meter during a test.

How to Clean the Meter

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

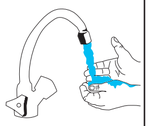
2. To Clean: Make sure that the meter is off and a test strip is not inserted. Remove meter from test strip vial.

Meter may remain attached to the test strip vial during cleaning. Ensure that vial cap is completely closed before attempting to clean the system.

3. Wipe meter with a clean, lint-free cloth dampened with 70% isopropyl alcohol.
4. Let meter air dry thoroughly before using to test.
5. Do not use bleach to clean the meter. For assistance use the contact information at the bottom of the page.

~ Make sure no liquids enter the Test Port or any other opening in the meter.
~ Do not spray meter with any cleaning agents.
~ If the meter remains attached to the test strip vial during cleaning, make sure that the vial cap is closed before cleaning.

6. Make sure that the system is working properly by performing an Automatic Self-Test. See *Automatic Self-Test* under *Getting Started*.



7. Wash hands thoroughly after cleaning the meter.

Do not use meter and contact for assistance if:
~ Meter Display appears cloudy or any display segments are missing,
~ Markings on meter, including back meter label, are 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.

CHANGING BATTERY

1. 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.

4. 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, use the contact information at the bottom of the page for assistance.

Battery 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.

⚠ WARNING

KEEP BATTERIES OUT OF REACH OF CHILDREN

- *Swallowing may lead to serious injury in as little as 2 hours or death, due to chemical burns and potential perforation of the esophagus.*
- *If you suspect your child has swallowed or inserted a button battery immediately call the 24-hour Poisons Information Centre on 13 11 26 for fast, expert advice.*
- *Examine your meter and make sure the battery compartment is correctly secured, i.e. the battery door is fully closed. If the battery compartment cannot be secured, remove the battery and keep away from children. Call Trividia Health Australia Customer Care 1 800 001 351 for assistance.*
- *Dispose of used button batteries immediately and safely. Flat batteries can still be dangerous.*
- *Tell others about the risk associated with button batteries and how to keep their children safe.*

10 PERFORMANCE CHARACTERISTICS[5]

PRECISION: Precision describes the variation between results. There are two types of precision results measured - repeatability (using blood) and intermediate precision (using control solution).

Repeatability: N=100

Mean (mmol/L)	1.3	2.1	4.1	7.7	11.4	16.4	27.6
SD (mmol/L)	0.05	0.08	0.13	0.25	0.38	0.53	0.75
%CV	4.2	3.8	3.2	3.3	3.3	3.2	2.7

Intermediate Precision: N=100

Mean (mmol/L)	2.1	6.4	17.7
SD (mmol/L)	0.1	0.2	0.6
%CV	4.2	3.4	3.3

SYSTEM ACCURACY: Diabetes experts have suggested that glucose meters should agree within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.[6] The tables below show how often healthcare professionals (HCP) and users achieve these goals using capillary fingertip, capillary forearm, and venous blood samples when glucose results are not fluctuating. The laboratory reference instrument is the Yellow Springs Instrument (YSI).

FOR HEALTHCARE PROFESSIONALS

99.5% of TRUE METRIX GO fingertip values performed by healthcare professionals (HCP) fell within ±0.83 mmol/L of the YSI results at glucose levels <5.55 mmol/L and within ±15% at glucose levels ≥5.55 mmol/L.

Fingertip Capillary Samples (HCP vs. YSI) for glucose concentrations <5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
94 / 156 (60.3%)	146 / 156 (93.6%)	155 / 156 (99.4%)

Fingertip Samples (HCP vs. YSI) for glucose concentrations ≥5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
227 / 444 (51.1%)	383 / 444 (86.3%)	442 / 444 (99.5%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ±0.83 mmol/L and ±15%
597/600 (99.5%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

98.2% of TRUE METRIX GO forearm values performed by healthcare professionals (HCP) fell within ±0.83 mmol/L of the YSI results at glucose levels <5.55 mmol/L and within ±15% at glucose levels ≥5.55 mmol/L.

Forearm Capillary Samples (HCP vs. YSI) for glucose concentrations <5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
28 / 62 (45.2%)	53 / 62 (85.5%)	60 / 62 (96.8%)

Forearm Capillary Samples (HCP vs. YSI) for glucose concentrations ≥5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
74 / 156 (47.4%)	132 / 156 (84.6%)	154 / 156 (98.7%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ±0.83 mmol/L and ±15%
214 / 218 (98.2%)

Parkes Error Grid: 99.1% of individual forearm glucose measured values performed by healthcare professionals fell within Zone A and 0.9% in Zone B of the Parkes Error Grid (PEG).

Venous Blood

99.1% of TRUE METRIX GO venous values performed by healthcare professionals (HCP) fell within ±0.83 mmol/L of the YSI results at glucose levels <5.55 mmol/L and within ±15% at glucose levels ≥5.55 mmol/L.

Venous Samples (HCP vs. YSI) for glucose concentrations <5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
61 / 90 (67.8%)	85 / 90 (94.4%)	90 / 90 (100%)

Venous Samples (HCP vs. YSI) for glucose concentrations ≥5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
66 / 130 (50.8%)	122 / 130 (93.8%)	128 / 130 (98.5%)

Venous Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ±0.83 mmol/L and ±15%
218/220 (99.1%)

Parkes Error Grid: 100% of individual venous glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

FOR CONSUMERS

99% of TRUE METRIX GO fingertip values performed by users fell within ±0.83 mmol/L of the YSI results at glucose levels <5.55 mmol/L and within ±15% at glucose levels ≥5.55 mmol/L.

Fingertip Samples (User vs. YSI) for glucose concentrations <5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
13 / 17 (76.5%)	17 / 17 (100%)	17/17 (100%)

Fingertip Samples (User vs. YSI) for glucose concentrations ≥5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
46 / 83 (55.4%)	73 / 83 (88.0%)	82/83 (98.8%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ±0.83 mmol/L and ±15%
99/100 (99.0%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

98.2% of TRUE METRIX GO forearm values performed by users fell within ±0.83 mmol/L of the YSI results at glucose levels <5.55 mmol/L and within ±15% at glucose levels ≥5.55 mmol/L.

Forearm Samples (User vs. YSI) for glucose concentrations <5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L
13 / 31 (41.9%)	22 / 31 (71.0%)	31/31 (100%)

Forearm Samples (User vs. YSI) for glucose concentrations ≥5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
34 / 78 (43.6%)	64 / 78 (82.1%)	76 / 78 (97.4%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ±0.83 mmol/L and ±15%
107/109 (98.2%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

USER PERFORMANCE EVALUATION: A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
100% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.8% within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

11 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	Contact for assistance.

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 meter.
Problem with test strip	Repeat with new test strip. If testing still has not begun, contact for assistance.
Problem with meter	Contact for assistance.

Use contact information at the bottom of the page for assistance.

12 MESSAGES

Display	Reason	Action
E-0	Invalid Hematocrit	Repeat with new test strip, using capillary whole blood from the finger or forearm or venous whole blood collected only in a sodium heparin blood collection tube. If error persists, contact for assistance.
E-1	Temperature Error • Too Cold/ Too Hot	Move meter and test strips to area between 5°C-40°C; 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.
E-3	Used Test Strip, Test Strip Outside of Vial Too Long	Repeat with new test strip. If error persists, contact for assistance.
E-4	Meter Error	Contact for assistance.
E-5	Test Strip Error or Very High Blood Glucose Result (higher than 33.3 mmol/L)	Retest with new test strip. If error persists, contact for assistance. If you have symptoms such as fatigue, excess urination, thirst or blurry vision, follow a Doctor or Healthcare Professional's advice for high blood glucose.
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, contact for assistance.
E-9	Meter Error	Contact for assistance.
	Low or Dead Battery	Low: About 50 tests can be done before battery dies. Dead: Battery Symbol appears before meter turns off. Change the battery.
---	Broken Display	Do not use meter for testing. Contact for assistance.
Hi mmol/L	**WARNING!!** Out of Range - High Results > 33.3 mmol/L	**WARNING!!** Retest with new test strip. If result is still "Hi" (High) or "Lo" (Low) contact a Doctor or Healthcare Professional ***immediately***.
Lo mmol/L	Out of Range - Low Results < 1.1 mmol/L	

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