



# TRUE METRIX GO Blood Glucose Monitoring System

## Instructions For Use (IFU)

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## 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.**

<b>Color Codes:</b>		
<b>Pink - Caution:</b>	<b>Yellow - Important:</b>	<b>Blue - 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

**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. 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.

**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**

- 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>.
- FDA Public Health Notification: *Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication Update 1/12/2010* [Electronic Version]. Retrieved February 22, 2012 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
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- Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests*. Scand J Clin Lab Invest 36:805-808, 1976.
- Data on file.
- 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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1. Joslin Diabetes Center. <i>Goals for Blood Glucose Control</i> [Electronic Version]. Retrieved June 8, 2015 from <a href="http://www.joslin.org/Info/Goals-for-Blood-Glucose-Control.html">http://www.joslin.org/Info/Goals-for-Blood-Glucose-Control.html</a> .	
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4. Larsson-Cohn U: <i>Difference between capillary and venous blood glucose during oral glucose tolerance tests</i> . Scand J Clin Lab Invest 36:805-808, 1976.	
5. Data on file.	
6. European Committee for Standardization. <i>In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus</i> . Reference number EN ISO 15197:2015(E). Brussels: European Committee for Standardization; 2015.	

## 2 SYSTEM SPECIFICATIONS

<b>Result Range:</b>	1.1-33.3 mmol/L
<b>Sample:</b>	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.
<b>Test Time:</b>	Results in as little as 4 seconds
<b>Result Value:</b>	Plasma equivalent values
<b>Assay Method:</b>	Electrochemical
<b>Power Supply:</b>	One 3V lithium battery #CR2032 (non-rechargeable)
<b>Battery Life:</b>	Approximately 1,000 tests or 1 year
<b>Automatic shut-off:</b>	After two minutes of non-use
<b>Weight:</b>	18 grams
<b>Size:</b>	4.1 cm x 3.5 cm x 2.2 cm
<b>Memory Size:</b>	500 results
<b>Operating Range (Meter &amp; Test Strips for Blood Testing)</b>	
<b>Relative Humidity:</b>	10%-90% (Non-condensing)
<b>Temperature:</b>	5°C-40°C
<b>Hematocrit:</b>	20%-70%
<b>Altitude:</b>	Up to and including 3109 metres <i>Use within specified environmental conditions only.</i>
<b>Chemical Composition</b>	
<b>Test Strips:</b>	Glucose dehydrogenase-FAD ( <i>Aspergillus species</i> ), mediators, buffers and stabilizers.
<b>Control Solution:</b>	Contents: water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.
<b>EXPECTED RESULTS</b>	
<b>Expected Blood Glucose Results for people without diabetes:</b>	
	<b>Plasma Blood Glucose Result<sup>1</sup></b>
Before breakfast	< 5.6 mmol/L
Two hours after a meal	< 7.8 mmol/L
<b>Importance of Blood Glucose Monitoring</b>	
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.	
<b>NEVER change a treatment plan without talking to a Doctor or Healthcare Professional.</b>	

## 3 KNOW YOUR SYSTEM

### 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.

### Test Strip Vial Label

**1** Lot Number (LOT) - Use for identification when contacting for assistance.  
**2** Use By Dates (U) -  
**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 U 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 U 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.**

### 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

### CONTROL SOLUTION

**1** Lot Number (LOT) - Use for identification when contacting for assistance.  
**2** Use By Dates (U) -  
**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 U on bottle label has passed, whichever comes first. Use of control solution past the Use By Dates U 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.

### 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.

### TO ATTACH/REMOVE METER TO TEST STRIP VIAL

**To attach:**

- Set 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.

*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.
- Lift off meter off the vial top.

## 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 U 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 U 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.

- Insert test strip into Test Port.
- Full Display appears. Check for missing segments.
- 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.**

### How To Test Control Solution, cont.

- 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.
- 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.

**1** Lot Number (LOT)  
**2** Use By Dates (U)  
**3** Control Solution Level (1, 2 or 3)

**Write date first opened on control solution bottle label. Discard bottle if either 3 months after first opening or date printed next to U has passed, whichever comes first.**

### 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

Use By Dates (U)

- Gather and check supplies. See *Getting Started - Testing Checklist*.
- Allow control solution, vial of test strips and meter to adjust to room temperature for 10 minutes.
- Wash hands. Dry thoroughly.
- Gently swirl or invert control solution bottle to mix.
- Remove one test strip from vial. Close vial immediately.

**DO NOT SHAKE.** Use test strip quickly after taking it out of the vial.

## 5 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\*

- 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. 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.

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

#### From Fingertip or From Forearm

- Place end of lancing device equipped with lancet against fingertip. Lance fingertip.
- Rub area vigorously or apply a warm dry compress to increase blood flow.

- Set lancing device aside. To help blood drop form, lower hand to waist level and gently massage from palm to fingertip.
- Place end of lancing device equipped with a lancet firmly against forearm. Press trigger button. Apply firm pressure on lancing device for 10 seconds.

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 into an appropriate waste container.

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

### HOW TO TEST BLOOD

Test Strip Label Use By Dates  
 LOT: ABC1234  
 2018/10/31  
 1 - 4: <math>\pm 0.5\text{ mmol/L}</math>  
 2 - 8: <math>\pm 1.1\text{ mmol/L}</math>  
 3 - 16: <math>\pm 2.2\text{ mmol/L}</math>  
 (May 30, 2018)

- Check supplies (see Getting Started - Testing Checklist).
- Allow vial of test strips and meter to adjust to room temperature for 10 minutes.
- Wash hands (and forearm for alternate site testing) in warm, soapy water. Rinse well and dry thoroughly.
- Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after taking it out of the vial.

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

## 6 METER SETUP

### 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.
- 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.

- After the correct hour appears, the number flashes for about 10 seconds before going to the minutes.
- Repeat steps 2-3 to set up minutes, month, day and year.

### 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.
- 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.

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

### 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.

- After meter displays the Averages, press and release Set Button again.
- The most recent result is shown with the Memory Symbol.

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

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

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.

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

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

## 7 METER MEMORY

### VIEW AVERAGES (7-, 14-, 30-DAY)

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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.

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- The most recent result is shown with the Memory Symbol.

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

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

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.

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

- Insert test strip firmly into Test Port. Meter turns on.
- 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 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  $\square$  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  $\square$  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.

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

- Wipe meter with a clean, lint-free cloth dampened with 70% isopropyl alcohol.
- Let meter air dry thoroughly before using to test.
- 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.

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

- Remove meter from top of test strip vial by holding the vial and twisting the meter ¼ turn counterclockwise. Lift meter from vial top.
- Turn meter over until the meter label is facing up. Pull Battery Tray out until battery is exposed.
- 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.
- 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.

## 9 PERFORMANCE CHARACTERISTICS\*

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  $\pm 0.83\text{ mmol/L}$  of the medical laboratory values at glucose concentrations below  $5.55\text{ mmol/L}$  and within  $\pm 15\%$  of the medical laboratory values at glucose concentrations at or above  $5.55\text{ mmol/L}$ . 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  $\pm 0.83\text{ mmol/L}$  of the YSI results at glucose levels  $< 5.55\text{ mmol/L}$  and within  $\pm 15\%$  at glucose levels  $\geq 5.55\text{ mmol/L}$ .

Fingertip Capillary Samples (HCP vs. YSI) for glucose concentrations  $< 5.55\text{ mmol/L}$

Within $\pm 0.28\text{ mmol/L}$	Within $\pm 0.56\text{ mmol/L}$	Within $\pm 0.83\text{ mmol/L}$
94 / 156 (60.3%)	146 / 156 (93.6%)	155 / 156 (99.4%)

Fingertip Samples (HCP vs. YSI) for glucose concentrations  $\geq 5.55\text{ mmol/L}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 0.83\text{ mmol/L}$ or $\pm 15\%$
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  $\pm 0.83\text{ mmol/L}$  of the YSI results at glucose levels  $< 5.55\text{ mmol/L}$  and within  $\pm 15\%$  at glucose levels  $\geq 5.55\text{ mmol/L}$ .

Forearm Capillary Samples (HCP vs. YSI) for glucose concentrations  $< 5.55\text{ mmol/L}$

Within $\pm 0.28\text{ mmol/L}$	Within $\pm 0.56\text{ mmol/L}$	Within $\pm 0.83\text{ mmol/L}$
28 / 62 (45.2%)	53 / 62 (85.5%)	60 / 62 (96.8%)

Forearm Capillary Samples (HCP vs. YSI) for glucose concentrations  $\geq 5.55\text{ mmol/L}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 0.83\text{ mmol/L}$ or $\pm 15\%$
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  $\pm 0.83\text{ mmol/L}$  of the YSI results at glucose levels  $< 5.55\text{ mmol/L}$  and within  $\pm 15\%$  at glucose levels  $\geq 5.55\text{ mmol/L}$ .

Venous Samples (HCP vs. YSI) for glucose concentrations  $< 5.55\text{ mmol/L}$

Within $\pm 0.28\text{ mmol/L}$	Within $\pm 0.56\text{ mmol/L}$	Within $\pm 0.83\text{ mmol/L}$
61 / 90 (67.8%)	85 / 90 (94.4%)	90 / 90 (100%)

Venous Samples (HCP vs. YSI) for glucose concentrations  $\geq 5.55\text{ mmol/L}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 0.83\text{ mmol/L}$ or $\pm 15\%$
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  $\pm 0.83\text{ mmol/L}$  of the YSI results at glucose levels  $< 5.55\text{ mmol/L}$  and within  $\pm 15\%$  at glucose levels  $\geq 5.55\text{ mmol/L}$ .

Fingertip Samples (User vs. YSI) for glucose concentrations  $< 5.55\text{ mmol/L}$

Within $\pm 0.28\text{ mmol/L}$	Within $\pm 0.56\text{ mmol/L}$	Within $\pm 0.83\text{ mmol/L}$
13 / 17 (76.5%)	17 / 17 (100%)	17/17 (100%)

Fingertip Samples (User vs. YSI) for glucose concentrations  $\geq 5.55\text{ mmol/L}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 0.83\text{ mmol/L}$ or $\pm 15\%$
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  $\pm 0.83\text{ mmol/L}$  of the YSI results at glucose levels  $< 5.55\text{ mmol/L}$  and within  $\pm 15\%$  at glucose levels  $\geq 5.55\text{ mmol/L}$ .

Forearm Samples (User vs. YSI) for glucose concentrations  $< 5.55\text{ mmol/L}$

Within $\pm 0.28\text{ mmol/L}$	Within $\pm 0.56\text{ mmol/L}$	Within $\pm 0.83\text{ mmol/L}$
13 / 31 (41.9%)	22 / 31 (71.0%)	31/31 (100%)

Forearm Samples (User vs. YSI) for glucose concentrations  $\geq 5.55\text{ mmol/L}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
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 $\pm 0.83\text{ mmol/L}$ or $\pm 15\%$
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  $\pm 0.83\text{ mmol/L}$  of the medical laboratory values at glucose concentrations below  $5.55\text{ mmol/L}$  and 98.8% within  $\pm 15\%$  of the medical laboratory values at glucose concentrations at or above  $5.55\text{ mmol/L}$ .

## 10 TROUBLESHOOTING

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.

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

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.

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

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.
H <sub>i</sub>	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	Out of Range - Low Results < 1.1 mmol/L	WARNING! Retest with new test strip. If result is still "Hi" (High) or "Lo" (Low) contact a Doctor or Healthcare Professional immediately.

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

## 11 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	

