

Instructions For Use (IFU) CONTENTS 5 Testing Blood 1 Important Information About Your System Front page **Obtaining a Blood Sample Intended Use How to Test Blood Important Health and Safety Information System Out of Range Warning Messages** References **System and Laboratory Testing System Specifications** Meter Setup Operating Range / Chemical Composition Time/Date Setup **Expected Results** Meter Memory **Symbols Chart Know Your System** Front page View Averages (7-, 14-, -30 day) **View Memory** Meter **System Care** Test Strip **Control Solution Control Solution Care Blood Glucose Test Strip Care** To Attach/Remove Meter to Test Strip Vial Meter Care and Cleaning **Getting Started** Front page **Changing Battery Quality Control Testing Performance Characteristics Automatic Self-Test Control Test** 10 Troubleshooting 1 Messages

1 IMPORTANT INFORMATION ABOUT YOUR SYSTEM

12 System Safety Information

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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: Provides information that is important for user protection and about risks for inaccurate results. Yellow - **Important:**

Blue - Notes:

Provides important information on testing and Helpful hints other issues relating to testing.

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
- 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
- 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. \sim 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.

or 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 steadystate 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 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.
- 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. Larsson-Cohn U: Difference between capillary and venous blood glucose during oral glucose tolerance tests. Scand J Clin Lab Invest 36:805-808, 1976.
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Back page **Automatic shut-off:** After two minutes of non-use Operating Range (Meter & Test Strips For Blood Testing) **Relative Humidity:** 10%-90% (Non-condensing) Back page Back page **Chemical Composition** Back page **EXPECTED RESULTS** Before breakfast Two hours after a meal Back page Importance of Blood Glucose Monitoring Back page A Doctor or Healthcare Professional determines how often to test glucose and what the target ranges are for Back page Having most blood glucose results within the target range shows how well a treatment plan is working to Back page control glucose levels. To slow or stop the complications from diabetes, keep glucose results within the target

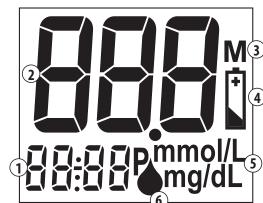
3 KNOW YOUR SYSTEM METER

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

Back of Meter Front of Meter

Display - Shows test results, messages, user prompts.

- **Test Port** Insert Test Strip here, with contact blocks facing up.
- **Set Button** Turns meter on to view Average values and scroll through Memory, sets up date/time, adds ALT Symbol, turns meter off.
- **Battery Tray** Holds battery (one non-rechargeable 3V lithium battery
- Meter Label Contains serial number used to identify meter when contacting 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.



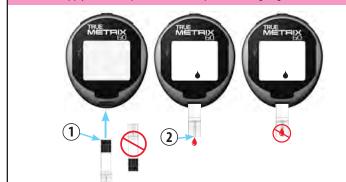
Meter Full Display Screen

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

TEST STRIP

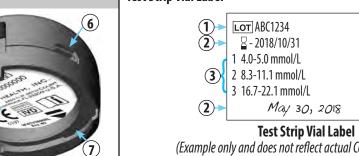
Insert test strip into meter before touching Sample Tip to top of blood or control solution drop. Allow drop to be drawn into the test strip until dashes appear in the

- ~ 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



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

SYMBOLS:

STERILE R Sterile

Biological Risk

Do Not Resterilise

Single Use Only

CONTROL Control Solution

SN Serial Number

☐ Use By Date

Attention!

Read Instructions for Use.

Storage Temperature Range

Storage Humidity Range

Diagnostic Testing Only

Authorised Representative

Manufactured By

(🔌 Single Patient Use Only

M Date of Manufacture

① ② ③ Control Level

Caution!

Keep Dry

LOT Lot Number

IVD

For in vitro

- **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 $\frac{1}{2}$ 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 \square 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



- **1. Lot Number (Lot)** Use for identification when contacting for assistance.
- 2. Use By Dates (∑)
- 3. Control Solution Level (1, 2 or 3)
- Mrite date first opened on bottle label. Discard bottle and unused control solution if either 3 months after first opening or date printed next to $\frac{1}{2}$ 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



FRONT PAGE

1. Set test strip vial on flat surface with

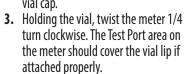


attached properly. The meter may also be used for testing

vial lip facing to the left.



Meter must be seated flat on top of



vithout attaching to the vial.

- Holding the vial, twist the meter 1/4 turn counterclockwise.
- **2.** 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:

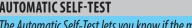
- ~ the test strip is released from the meter,
- ~ the Set Button is pressed and held for 3 seconds, or
- ~ after 2 minutes of non-use.

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
- ✓ 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 \square 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 \square has passed, whichever comes

QUALITY CONTROL TESTING

To assure accurate and reliable results, TRUE METRIX GO offers two kinds of quality ontrol 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.



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.



2. Full Display appears. Check for missing segments.



f an error message appears, the meter will not perform a test. See Troubleshooting or contact for assistance.

3. Drop Symbol

begins to blink.

Meter may be

used for testing.

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
- whenever a check on the performance of the system is needed,
- if meter damage is suspected (meter was dropped, crushed, wet, etc.).

CONTROL 2 2 MA

IVD [] to

erforming a Control Test with more than one level of control solution is ecommended 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. Λ 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 ☐





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

meter to adjust to room temperature for 10 minutes

2. Allow control solution,

vial of test strips and



- thoroughly.
- **4.** Gently swirl or invert control solution bottle to mix.
 - test strip from vial. Close vial immediately.

5. Remove one

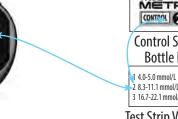
DO NOT SHAKE.

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

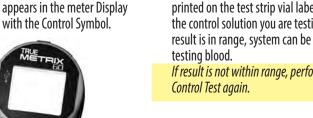


7. Remove cap from control solution bottle. Gently squeeze a drop onto a clean tissue. Wipe off bottle tip and discard tissue. Gently squeeze a drop onto a small piece of unused aluminum foil, clear plastic wrap, or

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



(Examples only and do not represent actual Control Test ranges) 11. Compare result to Control Test Range **0.** After testing is finished, result





- **12.** After result is shown, remove test strip from meter and discard. Meter turns
- \ 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
- If test strip is removed before testing is finished, an error message appears.
- Do not put control solution drop on top of 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



How To Test Control Solution, cont.

6. Insert test strip firmly into Test

Keep test strip in meter until

testing is finished. Do not add

control solution to test strip

before inserting into meter.

Port. Meter turns on.











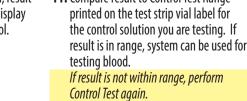






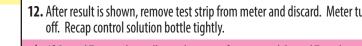








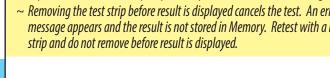
strip.



page for assistance.

Discard old test strip and retest using a new test strip.

- If meter does not begin testing soon after drawing up sample, discard test strip.







2400 N.W. 55TH COURT

UK: 0800 689 5035

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 Blood Glucose Results for people without diabetes:** Plasma Blood Glucose Result¹

 $< 5.6 \, \text{mmol/L}$

< 7.8 mmol/L

2 SYSTEM SPECIFICATIONS

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.

Result Range: 1.1-33.3 mmol/L

Assay Method: Electrochemical

Weight: 18 grams

Memory Size: 500 results

Temperature: 5°C-40°C

Hematocrit: 20%-70%

Test Time: Results in as little as 4 seconds

Battery Life: Approximately 1,000 tests or 1 year

Size: 4.1 cm x 3.5 cm x 2.2 cm

Altitude: Up to and including 3109 metres

Use within specified environmental conditions only.

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

Result Value: Plasma equivalent values

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 Testing³

- 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
- 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

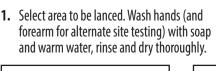
after cleaning.² Cleaning the meter and lancing device destroys most, but not necessarily all, blood-borne pathogens.

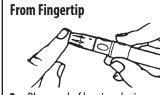
Do not reuse lancets. ③

Reuse of devices labeled for single-use may result in product contamination and Used test strips and lancets are considered biohazardous.

Dispose used test strips and lancets carefully into an appropriate waste To help prevent false high results, wash hands before using the system to test

blood, especially after fruit has been handled.





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



help blood drop form, lower hand to waist level and gently massage from palm to or | From Forearm

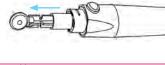


a warm dry compress to increase blood flow.



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.



2. Allow vial of test strips and

meter to adjust to room

temperature for 10 minutes.

4. Remove one test strip from vial.

out of the vial.

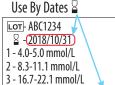
Close test strip vial immediately.

Use test strip quickly after taking it

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

HOW TO TEST BLOOD

Test Strip Label



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

May 30, 2018



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

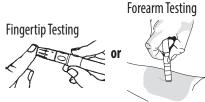


 Insert test strip firmly into Test Port. Meter turns on.



6. Wait until Drop Symbol appears in the 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.



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



8. 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.



9. Remove test strip from

Meter is testing.

11. Remove test strip from meter and

drop when dashes appear

across the meter Display.

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

discard into an appropriate waste container. Meter turns off. Result is stored in the Memory. If you wish to mark the result as alternate site, press the Set Button

before the meter turns off. -Aappears in the meter Display.

- 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

- ~ "**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

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.

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 he 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.

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

7 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.

30-Day 14-Dav

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.

. After meter displays the Averages, press and release Set Button again. with the Memory Symbol.



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



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.

8 SYSTEM CARE

from liquids, dust and dirt. Store in a dry place at room temperature 4°C-30°C and 4°Cat 10%-80% relative humidity (Non-condensing). DO NOT FREEZE. Allow system to sit at room temperature for

Store system (meter, control solution, test strips) in carrying case to protect

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.** RUE 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 Close vial immediately after removing test strip. Store in a dry place at room temperature 4°C-30°C and at

METER CARE AND CLEANING

leaning 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 ~ Do not clean the meter during a test.

10%-80% relative humidity (Non-condensing). **DO NOT FREEZE.**

How to Clean the Meter



. Wash hands thoroughly with soap and water or wear disposable

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.

♠ 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



meter from vial top.





7. Wash hands

thoroughly after

cleaning the meter.

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.

f 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.

5. Turn meter back over and

press Set Button to turn

9 PERFORMANCE CHARACTERISTICS⁵

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

2.1 4.1 7.7 11.4 16.4 27.6 Mean (mmol/L) 1.3 0.05 0.08 0.13 0.25 0.38 0.53 0.75 SD (mmol/L) 4.2 3.8 3.2 3.3 3.3 3.2 Intermediate Precision: N=100 Mean (mmol/L) 2.1 6.4 SD (mmol/L) 0.1 0.2 0.6 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 0.83 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

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 $\pm 15\%$ at glucose levels \geq 5.55 mmol/L. ingertip Capillary Samples (HCP vs. YSI) for glucose concentrations <5.55 mmol/L

<u>+</u> 0.28 mmol/L	#0.56 mmol/L	within <u>+</u> 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%								
Within ± 5%	Within <u>+</u> 10%	Within <u>+</u> 15%						
Within ± 5% 227 / 444 (51.1%)	Within ± 10% 383 / 444 (86.3%)	Within ± 15% 442 / 444 (99.5%)						

Within +0.83 mmol/L or +15%

597/600 (99.5%) Parkes Error Grid: 100% of individual fingertip glucose measured values performed by realthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

within ± 0.83 mmol/L of the YSI results at glucose levels <5.55 mmol/L and within $\pm 15\%$ at glucose levels \geq 5.55 mmol/L. orearm Capillary Samples (HCP vs. YSI) for glucose concentrations <5.55 mmol/L

98.2% of TRUE METRIX GO forearm values performed by healthcare professionals (HCP) fell

<u>+</u> 0.28 mmol/L	<u>+</u> 0.56 mmol/L	±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 <u>+</u> 10%	Within <u>+</u> 15%						
Within ± 5% 74 / 156 (47.4%)	Within ± 10% 132 / 156 (84.6%)	Within ± 15% 154 / 156 (98.7%)						

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 <u>+</u> 10%	Within <u>+</u> 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 <u>+</u> 0.28 mmol/L	Within <u>+</u> 0.56 mmol/L	Within ±0.83 mmol/L					
13 / 17 (76.5%)	17 / 17 (100%)	17/17 (100%)					
gertip Samples (User vs. YSI) for glucose concentrations ≥5.55 mmol/L							
Within + 5%	Within ± 10%	Within <u>+</u> 15%					

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 \pm 15% at glucose levels \geq 5.55 mmol/L.

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

99/100 (99.0%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users

Within ±0.28 mmol/L	Within <u>+</u> 0.56 mmol/L	Within ±0.83 mmol/L				
13 / 31 (41.9%)	22 / 31 (71.0%)	31/31 (100%)				
orearm Samples (User vs. YSI) for glucose concentrations ≥5.55 mmol/L						
	, 3					
Within ± 5%	Within <u>+</u> 10%					
• •	· ·					

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

Within ±0.83 mmol/L or ±15%

107/109 (98.2%)

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.

1. After inserting test strip, meter does not turn on. Action Reason Test strip inserted upside down Remove test strip from meter. Reor backwards insert test strip correctly into the Test strip not fully inserted Remove test strip from meter. Re-insert test strip correctly into the meter. Remove test strip from meter. Repeat Test strip error with new test strip. Meter is dead or there is not a Remove test strip from meter. Replace battery in meter. Use new battery in the meter test strip for testing. Battery must be placed in meter with Battery in the meter backwards positive ("+") side facing up.

Contact for assistance.

10 TROUBLESHOOTING

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 of	at the bottom of the page for assistance.		

use contact information at the bottom of the page for assistant

1 MESSAGES

Forearm Capillary Samples (HCP vs. YSI) for glucose concentrations <5.55 mmol/L					Display	Reason	Action	
	Within ±0.28 mmol/L	Within <u>+</u> 0.56 mmol/L	Within ±0.83 mmol/L		rn		Repeat with new test strip, using	
l	28 / 62 (45.2%)	28 / 62 (45.2%) 53 / 62 (85.5%) 60 / 62 (96.8%)					capillary whole blood from the fing	
Forearm Capillary Samples (HCP vs. YSI) for glucose concentrations ≥5.55 mmol/L						Invalid	or forearm or venous whole blood	
Within ± 5% Within ± 10%			Within <u>+</u> 15%			Hematocrit	collected only in a sodium heparin blood collection tube.	
l	74 / 156 (47.4%)	132 / 156 (84.6%)	154 / 156 (98.7%)				If error persists, contact for assistance	
l	Forearm Samples for glucose	concentrations between 1.1	-33.3 mmol/L			Temperature	Move meter and test strips to area	
		Within <u>+</u> 0.83 mmol/L or <u>+</u> 159	%			Error	between 5°C-40°C;	
l		214 / 218 (98.2%)			-	•	wait 10 minutes for system to reach	
		ndividual forearm glucose measi				Too Cold/Too Hot	room temperature before testing.	
	Venous Blood	thin Zone A and 0.9% in Zone B			E-2	Sample Not Detected or Sample Drop on	Retest with new test strip and larger sample. Make sure Sample Tip of test strip	
		ous values performed by healthc s at glucose levels <5.55 mmol,	are professionals (HCP) fell with /I and within +15% at glucose	in		Top of Test Strip	touched top of sample drop.	
	levels \geq 5.55 mmol/L.	s at gracose revers (5155 minor,	E una maini = 1370 de gracose			1	and the same of th	
l	Venous Samples (HCP vs. YS	I) for glucose concentrations	s < 5.55 mmol/L			Used Test Strip,	Repeat with new test strip.	
						Test Strip Outside of Vial Too Long	If error persists, contact for assistance.	
l	61 / 90 (67.8%)	85 / 90 (94.4%)	90 / 90 (100%)					
l	Venous Samples (HCP vs. YS	l) for glucose concentrations	5 <u>></u> 5.55 mmol/L					
l	Within ± 5%	Within <u>+</u> 10%	Within <u>+</u> 15%			Meter Error	Contact for assistance.	
l	66 / 130 (50.8%)	122 / 130 (93.8%)	128 / 130 (98.5%)					
l	Venous Samples for glucose	concentrations between 1.1	1-33.3 mmol/L 			1	Retest with new test strip. If error	
Within ±0.83 mmol/L or ±15%						Test Strip Error or	persists, contact for assistance.	
l		218/220 (99.1%)				Very High Blood	If you have symptoms such as	
		dividual venous glucose measur				Glucose Result	fatique, excess urination, thirst or	
l	healthcare professionals fell wi	thin Zone A of the Parkes Error C	arid (PEG).			(higher than	blurry vision, follow a Doctor or	
	FOR CONSUMERS	tin values nerformed by users fe	ll within ±0.83 mmol/L of the Y	ςι		33.3 mmol/L)	Healthcare Professional's advice for high blood glucose.	
		mmol/L and within ±15% at gl		"		Test Strip		
	-	YSI) for glucose concentratio			<u> </u>	Removed During	Unplug Micro USB cable. Repeat with new test strip. Make sure	
	Within <u>+</u> 0.28 mmol/L	Within <u>+</u> 0.56 mmol/L	Within <u>+</u> 0.83 mmol/L			Test or Micro USB Cable	result is displayed	

Connected while

Testing

Meter Error

Low or Dead

Battery

Broken Display

WARNING!!

Out of Range -

High Results

> 33.3 mmol/L

Out of Range -

Low Results

< 1.1 mmol/L

<u>F-9</u>

before removing test strip. If error

persists, contact for assistance.

Contact for assistance.

Low: About 50 tests can be done

before battery dies.

Dead: Battery Symbol appears

before meter turns off.

Change the battery.

Do not use meter for testing.

Contact for assistance.

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.

12 SYSTEM SAFETY INFORMTION **ELECTROMAGNETIC COMPATIBILITY**

This meter meets the electromagnetic immunity requirements as per EN ISO 15197:2015.

It meets the electromagnetic emissions requirements as per EN 61326 series. 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 meter close to sources of strong electromagnetic radiation, as these may interfere with the proper operation.

BACK PAGE

		ART INFORMATION	Colors:	Graphic Art	tist/Reviewer:
▲ TRIVIE	DIA EALTH.	DESIGNER: Mark DATE: 05 jun 19 SIZE: 24x19.8975		Artist/Date mm 05jun19	<u>Reviewer/Date</u> AK 06/12/19
GRAPHICS Packaging		SUBSTRATE/FORMAT: White Board/Box		Artist/Date Artist/Date Artist/Date	Reviewer/Date Reviewer/Date Reviewer/Date
HAMISH INITIAL REQUESTOR Notes: 00-00-00 Notes:	05jun19 _{DATE}	IMAGES (Artist/Date Artist/Date Artist/Date	Reviewer/Date Reviewer/Date Reviewer/Date
			Process Colors Used in Art	Artist/Date Artist/Date Artist/Date	Reviewer/Date Reviewer/Date Reviewer/Date
			4 Color Process PANTONE* simulations used in this art may not match PANTONE-dentified solid color standards. Use current PANTONE Golor Reference Manuals for accurate color.	Artist/Date Artist/Date Artist/Date	Reviewer/Date Reviewer/Date Reviewer/Date