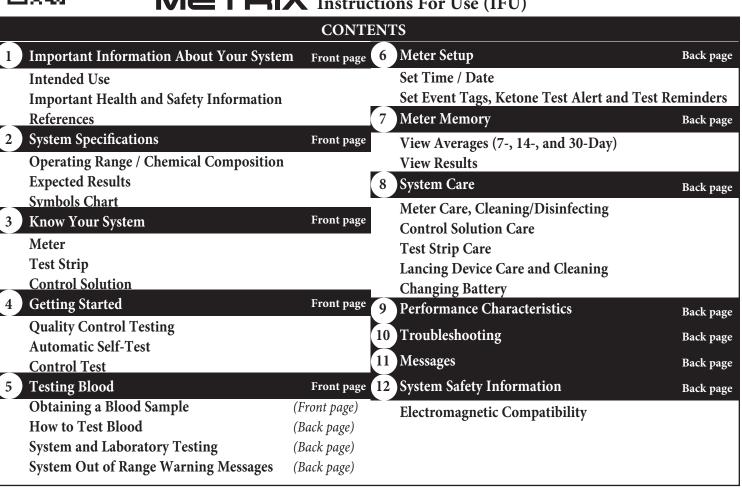
RE4AUT16 Rev. 52





1 IMPORTANT INFORMATION ABOUT YOUR SYSTEM

INTENDED USE

The TRUE METRIX Blood Glucose Monitoring System is intended for the quantitative determination of glucose in human whole blood taken from the fingertip or forearm (capillary) or from the vein (venous). The System may not be used for neonates. The System is intended for at-home use (self-testing) and for use by Healthcare Professionals in both physicians' offices and in acute and convalescent-care bedside testing facilities in order to assist in the management of diabetes.

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

IMPORTANT HEALTH and SAFETY INFORMATION

- For the most accurate results using TRUE METRIX:
- Read <u>all</u> product instructions for use before testing.
- Use of TRUE METRIX in a manner not specified in this System Instructions For Use is not recommended and may affect ability to determine true blood glucose levels.
- TRUE METRIX is an *in vitro* (outside body) **IVD** quantitative system that is used for self-testing of human whole blood only. • Alternative site (forearm) testing should not be used for insulin dose calculations. Alternative site testing should not be used to calibrate continuous glucose monitors (CGMs).
- Use only TRUE METRIX Test Strips and TRUE METRIX Control Solution with the TRUE METRIX Meter.
- Remove only one test strip at a time from test strip vial. Recap vial immediately. NEVER reuse test strips. NEVER wipe test strips with water, alcohol or any cleaner. DO NOT attempt to remove blood or
- control sample from test strips or clean test strips and re-use. Reuse of test strips will cause inaccurate results. NEVER add a second drop of sample to test strip. Adding more sample gives an error message.
- Perform Control Tests **before** performing a blood glucose test for the first time.
- Perform Control Tests with more than one level of TRUE METRIX Control Solution. Three levels of control solution are
- available for Control Tests. Contact place of purchase or contact for assistance to obtain control solution. ALL parts of the TRUE METRIX Blood Glucose Monitoring System could carry blood-borne pathogens after use, even after
- cleaning and disinfecting.² Cleaning the lancing device and the meter destroys most, but not necessarily all, blood-borne pathogens.
- 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. It is important to keep the meter and the lancing device clean. For instructions on how to clean the meter and lancing
- device, see Meter Care, Cleaning/Disinfecting and Lancing Device Care and Cleaning. 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.
- The system should be used only on one person and not shared, even with family members. Lancing devices are for single person use only and SHOULD NOT be shared, even with family members.
- Reuse of devices labeled for single-use may result in product contamination and patient infection.
- If there are symptoms of low or high blood glucose, check blood glucose immediately. If the result does not match the way you feel, repeat the test. If the results still do not match the way you feel, contact a Doctor or Healthcare Professional.
- Low blood glucose (hypoglycaemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and - High blood glucose (hyperglycaemia) symptoms may be intense thirst, a need to urinate often, dry mouth, vomiting, and
- Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in neonates.
- Do not use during xylose absorption testing, as xylose may produce falsely elevated glucose results during a xylose absorption test for diagnostic evaluation of malabsorption. Please check with a Doctor before using the System.
- Ascorbic acid (Vitamin C) greater than normal or therapeutic levels may cause significant interference resulting in
- 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.
- DO NOT perform capillary blood glucose testing on the critically ill. Capillary blood glucose levels when critically ill with reduced peripheral blood flow may not reflect the true physiological state. Reduced peripheral blood flow may result from the following conditions (for example):³
- shock, ~ severe hypotension, ~ severe dehydration, ~hyperglycaemia with hyperosmolarity, with or without ketosis. 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 laboratory instrument (Yellow Springs Instrument (YSI) recommended) and not to another meter brand.

FOR HEALTHCARE PROFESSIONALS:

- The system can be used on multiple patients, provided Healthcare Professionals always wear gloves and follow the Cleaning/ Disinfecting section and/or adhere to the infection control policies and procedures approved by their facility.
- The test strips and lancets are for single-use. Lancing device is restricted to be used on one patient only.
- Venous whole blood drawn into only a sodium heparin blood collection tube must be used for testing. Mix well before use.
- DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause inaccurate results.

REFERENCES

© 09/2019 Trividia Health, Inc.

- 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.

 Atkin, S. H., Dasmahapatra, A., Jaker, M.A., Chorost, M. I., Redd, S., Fingerstick Glucose Determination in Shock. Annals of Internal Medicine, 114:1020-1024, 1991.

 U.S. Food and Drug Administration. Blood Glucose Meters, Getting the Most Out of Your Meter. [Electronic Version]. Retrieved July 6, 2009: 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.

 European Committee for Standardization. In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus. Reference number EN ISO 15197:2015 (E). Brussels: European Committee for Standardization; 2015.

 Data on file.
- A TRIVIDIA

TRIVIDIA HEALTH, INC. 2400 N.W. 55TH COURT FORT LAUDERDALE, FL 33309 U.S.A. Australian sponsor: Trividia Health Australia Pty. Ltd 58 Gipps Street

Result Range: 1.1 - 33.3 mmol/L

2 SYSTEM SPECIFICATIONS

Sample Size: 0.5 microliter $(0.5 \mu L)$ Sample: Fresh capillary whole blood, venous whole blood collected in sodium heparin blood collection tubes, or control solutio

Test Time: Results in as fast as 4 seconds Result Value: Plasma values Assay Method: Amperometric **Power Supply:** One 3V lithium battery #CR2032 (non-rechargeable)

Battery Life: Approximately 1000 tests or 1 year **Automatic shut-off:** After two minutes of non-use Weight: 47 grams **Size:** 8.7 x 5.5 x 1.7 cm **Memory Size:** 500 glucose results and 1 control result

salts, dye and preservatives.

Operating Range (Meter & Test Strips For Blood Testing) Relative Humidity: 10-90% (Non-condensing) **Temperature:** 5°C-40°C

Haematocrit: 20%-70% Altitude: Up to and including 3109 metres

Note: Use within specified environmental conditions only. **Chemical Composition**

Test Strips: Glucose dehydrogenase-FAD (Aspergillus sp.), mediators, buffers and stabilizers. Control Solution: Water, d-glucose, buffers, viscosity enhancing agent,

EXPECTED RESULTS

METER

①" **◄** " Button

feature on).

2 "•" Button

Meter Set Up.

Display Screen

③ Strip Release Button

Battery Door

Meter Label

Data Contacts

Full

Display

Screen

Result is from Memory

Alternate Site (ALT) Symbol

4. Result is from 7-, 14-, or 30-Day Average

Event Tag Symbols

Control Symbol

10. Temperature Symbol

13. Units of Measure

11. Test Reminder Symbol

12. Ketone Test Alert Symbol

Battery Symbol

Time, Date

Test Result

mark results (if feature on).

Front of Meter

" ► " Button

Expected Blood Glucose Results for people without diabetes:1

Top of Meter

Decrease numbers in Meter Set Up; add ALT Symbol; move

backward by date/time when viewing results and Averages

in Memory; scroll through Event Tags to mark results (if

Turn meter on to view Average values, to view results in

Increase numbers in Meter Set Up; remove ALT

Insert Test Strip here, contact blocks facing up

Releases test strip after testing for disposal.

positive ("+") side up (see Changing Battery).

M88:88RM

Contains serial number of meter.

Memory, to access Meter Set Up, to turn on Event Tags in

Symbol; move forward by date/time when viewing results

and view Averages in Memory; scroll through Event Tags to

Back of Meter

4

Before breakfast < 5.6 mmol/L Two hours after meals < 7.8 mmol/L

Importance of Blood Glucose Monitoring A Doctor or Healthcare Professional determines how often to test and what the target ranges are for blood glucose results. Having most blood glucose results within target range shows how well a treatment plan is working to control glucose levels. Keeping results within target range helps slow or stop complications from diabetes. NEVER change a treatment plan without consulting a Doctor or Healthcare Professional.

> 3 KNOW YOUR SYSTEM TEST STRIP **Top of Test Strip**

> > ① **Contact End** - Insert into Test Port with contact blocks

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 Humidity Range

Diagnostic Testing Only

EC REP Authorised Representative

Manufactured By

(🔌 Single Patient Use Only

M Date of Manufacture

Storage Temperature Range

1 2 3 Control Level

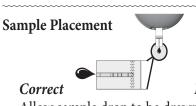
Caution!

Keep Dry

LOT Lot Number

② **Sample Tip** - Touch Tip to top of drop of sample (fresh blood or control solution) after Drop Symbol appears in the Display.

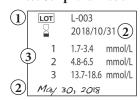
Note: Insert test strip into meter <u>before</u> touching Sample Tip to blood or control solution drop.



Allow sample drop to be drawn into Sample Tip until testing begins (meter beeps and dashes move across Display).

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

Test Strip Vial Label



① Lot Number (Lot) - Used for identification when contacting for assistance.

② Use By Dates (\boxtimes) - 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 \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 or control solution past the Use By Dates may give incorrect test results. Discard out-ofdate products and test with new products.

③ Control Test Range - Range of numbers in which Control Test result must fall to assure the system is working properly.

CONTROL SOLUTION CONTROL

Control Solution Bottle Label



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

- ② Use By Dates () Write date first opened on bottle label. Discard bottle if either 3 months after first opening or date printed next to \(\sqrt{\text{o}} \) on bottle label has passed, whichever comes first.
- © Control Solution Level (1, 2, or 3) We recommend testing at least 2 levels of control solution. Use the contact information at the bottom of the page for information on how to obtain different levels of control solution.

4 GETTING STARTED

Meter comes with pre-set time and date. The Event Tags, Ketone Test Alert, and all Test Reminders are off. Before using the meter for the first time or after a battery change, check the time, date, Event Tags, Alert and Reminders, and update as needed (see *Meter Set Up*).

The meter turns on when a test strip is inserted into the Test Port or when " • " Button is pressed (see Meter Memory and Meter Set

Meter turns off when the test strip is released or removed from the meter, "•" Button is pressed, or after 2 minutes of non-use.

Turning the Ketone Test Alert on sets a reminder to check your ketones per your treatment plan when a blood glucose result is over 13.3 mmol/L.

Test Reminders are set like an alarm clock to sound a tone for 10 seconds to remind you to test. Up to four Test Reminders per day may be set.

Event Tags allow you to tag your blood glucose results to link to the following events:

- Before meal –test was taken just before a meal,
- ☆ After meal –test was taken after a meal,
- * Exercise test was taken during or just after exercise,
- Medications medication taken may have affected test result,
- Sick − test was taken when sick, or
- Other any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with this Event Tag in the meter Memory reminds you that there is more about this test result in your log book.

Cagging results helps track the effect specific events may have on your blood glucose test results. Event Tagging may assist you and your Doctor or Healthcare Professional with managing your diabetes.

QUALITY CONTROL TESTING

To assure accurate and reliable results, the System offers two kinds of quality control tests. These tests ensure that the System is working properly and testing technique is good.



An Automatic Self-Test is performed by the meter each time a test strip is inserted correctly into the Test Port. Insert a test strip into the Test Port.

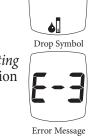
The meter is working properly if:

~ the full Display appears, then the time appears in the upper

part of the Display, and then,

the Drop Symbol begins to blink. If an error message appears in the Display, the

meter will not perform a test. See Troubleshooting or contact for assistance (see contact information at the bottom of the page).



888

Full Display

15:00

If any segments are missing in the Display when meter is first turned on, do not use the meter for testing. Contact for assistance.

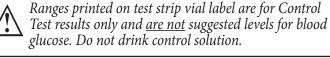
CONTROL TEST

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

Control Tests should be performed:

- To practice before using the system for the first time,
- For practice to ensure testing technique is good, • Occasionally when using a vial of test strips,
- When opening a new vial of test strips,
- If results seem unusually high or low,
- If a vial has been left opened or exposed to extreme
- heat or cold, or humidity, Whenever a check on performance of the system is needed, If meter damage is suspected (meter was dropped, crushed,

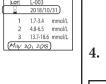
Note: It is important to perform Control Tests with more than one level of TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Use con tact information at the bottom the page for more information on how to obtain control solution



How to Test Control Solution Use **ONLY** TRUE METRIX Control Solution with the TRUE

METRIX Meter and TRUE METRIX Test Strips. 1. Check dates on control solution label and

test strip vial label. Do not use control solution or test strips if either Use By Date has passed (control solution - 3 months after first opening or date next to \square on bottle label; test strips - after open vial Use By Date (see Test Strip Instructions for Use) or date next to an vial label.) Discard expired products and use new products.



How To Test Control Solution, cont.

- 2. Allow control solution, vial of test strips and meter to adjust to room temperature. Write date first opened on both control solution bottle label and test strip vial label when using for the first time.
- Gently swirl or invert control solution bottle to mix.
- DO NOT SHAKE! 4. Remove one test strip from vial. Close test strip vial imme-

Insert Test Strip

Discard Control

Solution Drop on Tissue

12:00

15:00

- diately. Use test strip quickly after removal from vial. **5.** Insert test strip into Test Port. Meter
- **Note:** If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.
 - Wait until Drop Symbol appears in Display. Keep test strip in meter until testing

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

7. With cap removed, turn control solution bottle upside down. Squeeze one drop of control solution onto a clean tissue. Wipe off bottle tip and discard tissue.

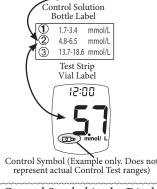
8. Gently squeeze a drop of control solution onto a small piece of unused aluminum foil or clear plastic wrap. Dispose after use.

9. With test strip still in meter, touch Sample Tip of test strip to top of drop of control solution. Allow drop to be drawn into test strip. Remove test strip from drop when meter beeps and begins testing.

10. Dashes appear across the Display to show meter is testing.

Note: If meter does not beep and begin testing soon after drawing up sample, release and discard test strip. Repeat test with new test strip. If problem persists, see Troubleshooting. TRUE METRIX (ONTROL 2) 3 mL

11. Compare meter result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, system can be used for testing blood. If result does not fall within range, repeat test using a new test strip.



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

If Control Test result is outside range, test again. If result is still outside range, system should not be used for testing blood. Contact for assistance (see contact information at the bottom of the page).

12. After result is shown, Strip Release Button flashes. Hold meter with test strip pointing down. Press Strip Release Button to release and discard test strip into appropriate container. Meter turns off.

Note: Removing test strip before result displays cancels the test. An error message appears and the result is not stored in *Memory. Retest with a new test strip and do not remove* before result is displayed.

5 TESTING BLOOD

OBTAINING A BLOOD SAMPLE

Refer to lancing device Instructions for Use for detailed in-

The lancing device is for single patient use ONLY. For cleaning your lancing device see lancing device's Instructions for Use. Wash your hands thoroughly with soap and warm water after handling the meter, lancing device, or test strips. Contact with blood presents an *infection risk.*

 Never share lancets or lancing device. Lancets are for single use only. Do not re-use.

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

From Fingertip

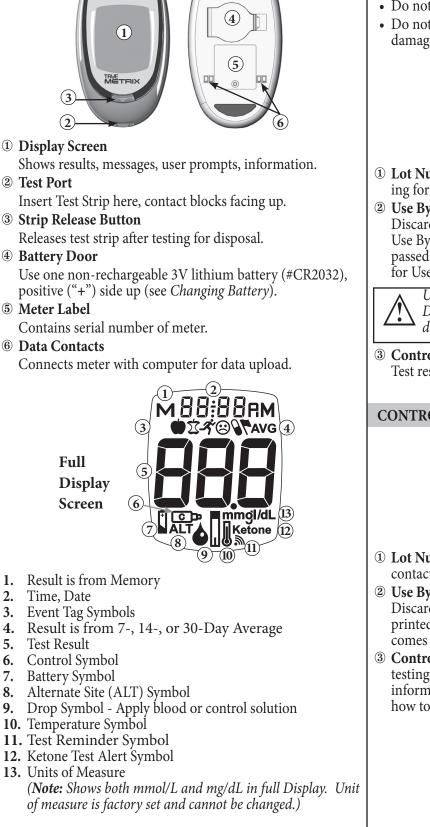
1. Prepare fingertip by washing hands in warm, soapy water. Rinse well. Dry thoroughly.

2. Place end of lancing device equipped with a

lancet against tip of finger. Lance fingertip. Set lancing device aside. To help blood drop form, lower hand to waist level, gently massaging finger from palm to fingertip. Allow blood drop to form for testing. Apply sample to test strip Sample Tip.

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

Treat used lancets as a biological risk. Dispose used lancets in approved container.



Tips for Forearm Sampling

Important Notes Regarding Forearm Testing4

- Check with the Doctor or Diabetes Healthcare Professional to see if forearm testing is appropriate. Results from the forearm are not always the same as results
- Use finger for testing instead of forearm for more accurate resul
- Within 2 hours of eating, exercise, or taking insulin,
- If blood glucose may be rising or falling rapidly or their results often fluctuate,
- If the patient is ill or under stress,
- If the glucose result may be low or high, If symptoms of low or high glucose levels are not evident.
- Select area. Clean the area with soap and warm water, rinse or use an approved disinfectant. Dry thoroughly,
- Rub area vigorously or apply a warm, dry compress to increase blood flow.
- Lance forearm. Apply sample to Sample Tip. 4. Discard all biohazard materials into appropriate contained
- 🙀 Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets into approved biohazard container.

From Vein

Venous whole blood drawn into only a sodium heparin blood collection tube must be used for testing. Mix well before use. DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing. This may cause inaccurate results

Used lancets and test strips are considered biohazardous. Please discard them according to the Healthcare Professional's instructions.

HOW TO TEST BLOOD

- Check dates on test strip vial being used. Do not use 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. Clean hands and area to be lanced with an approved
- disinfectant (i.e. alcohol, soap and water, etc.). Dry thoroughly. Remove one test strip from vial. Close vial
- immediately. Use test strips quickly after removal from vial. With meter off, insert test strip Contact End (blocks facing up) into Test Port.

Meter turns on. Keep test strip in meter

until testing is finished. To mark test as alternate site (forearm) result, press " ▶ " Button. ALT Symbol appears in Display. Press " ◀ " Button to remove ALT Symbol.

Note: If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.

12:00

Meter Testing

12:30

Test Result

Event Tag

(Before Meal Icon - sh

TIPE

Top of Meter

Wait until Drop Symbol appears in Display. Obtain a blood sample. Allow drop to form (see Obtaining a Blood Sample).

With test strip still in meter, touch Sample Tip of test strip to top of blood drop and allow blood to be drawn into test strip. Remove Sample Tip from blood drop immediately after the meter beeps and begins testing.

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

Dashes appear across Display to show meter is testing. After the test is finished, result is

displayed. The Strip Release Button To mark the result with an Event Tag, Event Tags must be turned on (see

Set Event Tags, Ketone Alert and Test Reminders). The Event Tag icons flash. **Note:** Event Tag must be marked prior to

the removal of test trip from meter. Press "▶" or "◄" Button to go to the correct Event Tag. Press "•" Button to mark the test result with an event (icon

stops flashing).

Event Tags are as follows:

• Before meal –test was taken just before a meal,

☐ After meal –test was taken after a meal,

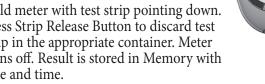
* Exercise – test was taken during or just after exercise,

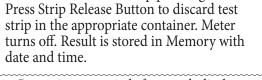
Medications – medication taken may have affected test result, ⊗ Sick – test was taken when sick,

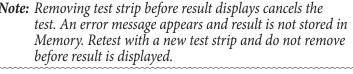
Other – any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with this Event Tag in the meter Memory reminds you that there is more about this test result in the log book. Record result in log book.

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

Professional's instructions.







Used lancets and test strips are considered biohazard-

ous. Please discard them according to the Healthcare

SYSTEM AND LABORATORY TESTING

The most accurate glucose results come from using fresh, capillary whole blood from the fingertip. Capillary whole blood taken from the forearm or venous whole blood drawn into only a sodium heparin blood collection tube must be used DO NOT use venous whole blood collected in sodium fluoride

blood collection tubes for testing, as this may cause inaccurate When comparing results between TRUE METRIX and a

laboratory system, TRUE METRIX blood tests should be performed within 30 minutes of a laboratory test. If you have recently eaten, fingerstick results from the TRUE METRIX System can be up to 3.9 mmol/L higher than venous laboratory results.⁵ Diabetes experts have suggested that 95% of glucose meter results agree within 0.83 mmol/L of a laboratory system when the glucose concentration is less than 5.55 mmol/L, and within 15% of a laboratory system when the glucose concentration is 5.55 mmol/L or higher.6

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.

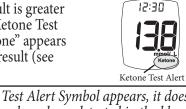
33.3 mmol/L, "Hi" appears in meter Display. ALWAYS repeat test to confirm Low ("Lo") and High ("Ĥi") results. If results still

If blood test result is greater than

display "Lo" or "Hi", call the Doctor or Healthcare Professional immediately.

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

If blood glucose test result is greater than 13.3 mmol/L and Ketone Test Alert is turned on, "Ketone" appears in Display with glucose result (see Ketone Test Alert).



12:00

12:00

H,

888

Top of Meter

LO

When a Ketone Test Alert Symbol appears, it does not mean that ketones have been detected in the blood. Perform a ketone test per the treatment plan, as prescribed by the Doctor or Healthcare Professional.

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

6 METER SETUP

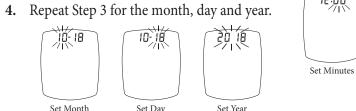
Note: If the meter turns off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.

With meter off, press and hold "•" Button until the full Display is shown and a series of beeps sound (after about 10 seconds). Release "•" Button. Meter goes into Set Up.

SET TIME/DATE

2. The hour flashes. To change, press "▶" or "◄" Button on top of the meter to select the hour. Press "•" Button to set.

The minutes flash. To change, press "▶" or "
Button to select the minutes. Press "•" Button to set.



Note: Meter beeps every time a setting is confirmed ("•" Button is pressed).

SET EVENT TAGS, KETONE ALERT AND TEST REMINDERS Meter comes with Event Tags, Ketone Test Alert and all Test

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

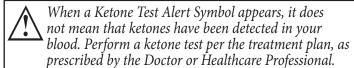
Event Tags are used to mark a test result that was taken during a specific event.

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

Ketone Test Alert

When a blood glucose result is over 13.3 mmol/, the Ketone Test Alert is a reminder to check your ketones per the treatment plan.

2. Press "▶" or "◄" Button to turn Alert on or off. Press "•" Button to set, then the Meter goes to set Test Reminder.



Set Event Tags, Ketone Alert and Test Reminders, cont.

Test Reminde

000

Set Hour

Set Minutes

M07-d

08:30

Test Reminder Symbol

Reminder sounds at set time for 10 seconds. Meter comes with all Test Reminders off. To set the Test Reminders: 1. After pressing "•" Button to set Ketone Test

Up to four Test Reminders per day may be set.

Test Reminder

Alert, Display shows first Reminder setting (A-1). To turn Reminder on, press "▶" Button. Press " ◀ " Button to turn Reminder back to off. Press "• "Button to set. When "on" is chosen, press "•" Button. The

hour flashes. Press "▶" or "◄" Button to set the hour. Press "•" Button to set. . The minutes flash. Press "▶" or "◄" Button to set the minutes. Press "•" Button to set.

4. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed). Exit Set-Up

Meter goes to the next Test Reminder.

Press and hold "•" Button until meter turns off. Meter also turns off after 2 minutes of non-use. Set-up choices are saved.

Note: If Test Reminders are set, the Test Reminder Symbol appears in all Displays.

7 METER MEMORY VIEW AVERAGES (7-, 14-, AND 30-DAY)

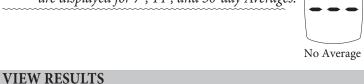
The Averages feature allows you to view the average of all blood glucose results within a 7-, 14-, or 30-day period. Control Test results are not included in the Averages.

1. With meter off press and release "•" Button. Display scrolls through 7-, 14-, and 30-day Average values.

2. Meter turns off after 2 minutes

if no buttons are pressed

7-Day Average **Note:** If there are no Average values, three dashes are displayed for 7-, 14-, and 30-day Averages.



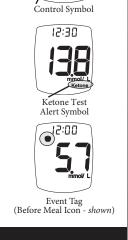
Meter Memory stores 500 results. Once Memory is full, the oldest result is replaced with the newest result.

1. Press and release "•" Button. Meter displays 7-, 14-, and 30-day Averages. Press and release " • " Button again to view most recent Control Test result in Memory. If there are no results in Memory, dashes appear with the Memory Symbol.

Press " ▶ " Button and release to advance to the most recent blood test. Press " ▶ " Button to scroll forward through results or " ◀ " Button to scroll backwards through results. Test results marked as alternate site

display **ALT** Symbol. Control Test results display the Control Symbol. If no Control Test has been done, Display shows dashes and the Control Symbol.

Test results above 13.3 mmol/L display Ketone Test Alert Symbol, when Ketone Test Alert is turned on during Set Up. Tests marked with an Event Tag shows the Event Tag icon in the Display



Memory Symbol

(M)10-28

8 SYSTEM CARE

• Store system (meter, control solution, test strips) in carrying case to protect from liquids, dust and dirt. Do not keep system in an area where it may be crushed (i.e. back pocket,

drawer, bottom of bag, etc.). Store in a dry place at room temperature (4°C - 30°C) and at 10%-80% relative 4°C humidity. **DO NOT FREEZE.**

• Allow system to sit at room temperature for 10 minutes before testing METER CARE, CLEANING/DISINFECTING

Cleaning removes blood and soil,

disinfecting removes infectious agents. Clean immediately after getting any blood on the meter or if meter is dirty. Wipe meter with a clean, lint free cloth dampened with 70% isopropyl alcohol. Repeat if need-

ed until all meter surfaces are visibly clean. Clean and disinfect the meter before allowing anyone else to handle it.

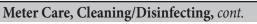
Do not clean the meter during a test. Cleaning (see *To Clean the Meter*) must occur before disin-

fecting (see *To Disinfect the Meter*). Never put meter in liquids or allow any liquids to enter the Test Port. • Let meter air dry thoroughly before using to test.

To Clean the Meter: 1. Wash hands thoroughly with soap and water. 2. Make sure meter is off and a test strip is not inserted. Using a lint-free cloth

dampened with 70% isopropyl alcohol, wipe outside of meter until clean. **DO NOT USE BLEACH.** Rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, left side, right side, top and bottom of the meter. Make sure no liquids enter the Test Port or any other

opening in the meter. Discard used wipes. Verify that the meter is working properly by performing an Automatic Self-Test. See Automatic Self-Test on how to perform.



To Disinfect the Meter:

Clean the Meter before disinfecting (see *To Clean the Meter*).

Using a cleaning/disinfecting agent wipe with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%) wipe the outside of the meter, make sure that all outside surfaces of the meter remain wet for 2 minutes. DO NOT USE BLEACH. Let meter air dry thoroughly before using to test.

Wash hands thoroughly again after handling meter.

Verify that the meter is working properly by performing an Automatic Self-Test. See

Automatic Self-Test on how to perform. Stop using the Meter and use the contact information at the

bottom of the page for assistance if: Meter display appears cloudy or any display segments are missing.

 Markings on meter, including back meter label, are coming off or are missing, • Buttons are hard to push on the meter or do not work,

 Unable to insert test strip into Test Port, Automatic Self-Test gives an error message.

CONTROL SOLUTION CARE

• Write date first opened on control solution bottle label.

Discard if either 3 months after first opening or date printed next to \square on bottle label has passed, whichever comes first. Store at room temperature (2°C-30°C). **DO NOT FREEZE.**

• After each use, wipe bottle tip clean and recap tightly.

 Discard any control solution bottles that appear cracked or leaking.

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.

and unused test strips if either the open vial Use By date or the date printed next to \(\subseteq \) 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.

• Store in a dry place at room temperature

(4°C-30°C) at 10%-80% relative humidity. **DO NOT FREEZE**.

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

• Discard any test strip vials that appear cracked or broken. DO NOT transfer test strips to a new vial or store outside of the vial.

or if lancing device is dirty. Clean lancing device before allowing anyone else to handle it

To Clean the Lancing Device: I. Wash hands thoroughly with soap and

Remove End Cap. Clean with cleaning are visibly clean.

Let lancing device air dry thoroughly before using to test. Replace End Cap. the Trigger Button. A click will be heard if the lancing device is functioning properly.

handling the lancing device. Use contact information at the bottom of page for assistance if: • Markings on lancing device are coming off,

Trigger button hard to push,

Arming Barrel does not click when gently pulled back.

bol while continuing to function. A meter with a dead battery displays Battery Symbol, beeps, and

then turns off. To replace battery:

. Lift tab on Battery Door.

one hand with Battery Door facing down, tap meter gently on the palm of your other hand to loosen and remove battery. Discard old battery into appropriate

container. Insert new battery, positive ("+") side facing up. Close Battery Door.

Press "•" Button to turn meter on. Check time, date, Event Tags, Ketone Test Alert and Test Reminders (see *Meter Set Up*). If meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery. Turn meter on by pressing "•" Button. Contact for assistance if problem persists.

original factory settings. Verify settings are correct after replacing battery by going into Meter Set Up and checking time, date, Ketone Testing Alert, and Testing Reminders. Change if needed. Results in Memory are not deleted and time and date on the results does not change if battery is dead or removed for any length of time.

Battery is not rechargeable. If you have a cable or a cradle for downloading results to a computer, DO NOT plug the USB cable end into an adaptor for an electrical outlet or use any other type of charger. Trying to recharge the battery or power the meter by plugging into an adaptor for an electrical outlet may cause meter to catch on fire and/or battery may explode.

Do not dispose of battery in fire. Do not take apart or attemp to recharge battery. Dispose according to local regulations.

CHANGING BATTERY, cont.

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 door is fully closed. 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.

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) 2.4 4.8 8.0 11.3 17.8

SD (mmol/L) 0.09 1.16 0.24 0.39 0.49 3.9 3.3 3.0 3.4 2.7 **Intermediate Precision:** N=100 Mean (mmol/L) 2.1 6.4 18.4 SD (mmol/L) 0.1 0.2 0.6

SYSTEM ACCURACY: Diabetes experts have suggested that 95% of glucose meter results should agree within ± 0.83 mmol/L of the medical laboratory value

at glucose concentrations below 5.55 mmol/L and within \pm 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L. The tables below show how often healthcare professionals (HCP) and users achieve these goals using capillary fingertip and forearm blood samples when glucose results are not fluctuating. The laboratory reference instrument is the Yellow Springs nstrument (YSI) FOR HEALTHCARE PROFESSIONALS

99,3% of TRUE METRIX 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 Fingertip Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within + 0.56 mmol/L 99/156 (63.5%) 135/156 (86.5%) 155/156 (99.4%) Fingertip Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L Within ± 5% Within + 10% Within ± 15% 364/444 (82%) 441/444 (99.3%) 207/444 (46.6%) Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L Within \pm 0.83 mmol/L or \pm 15%

596/600 (99.3%)

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

00% of TRUE METRIX 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

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

Within ± 0.83 mmol/L + 0.28 mmol/L ± 0.56 mmol/L 26/41 (63.4%) 41/41 (100%) 13/41 (31.7%) Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L Within ± 5% Within + 10% 38/59 (64.4%)

Within \pm 0.83 mmol/L or \pm 15%

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

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

96.4% of TRUE METRIX 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 Venous Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L Within Within

+ 0.28 mmol/L 16/50 (32%) 39/50 (78%) 50/50 (100%) enous Samples (HCP vs. YSI) for glucose concentrations > 5.55 mmol/ Within ± 5% Within + 10% Within + 15% 33/174 (19%) 100/174 (57.5%) 166/174 (95.4%) Venous Samples for glucose concentrations between 1.1-33.3 mmol/L Within \pm 0.83 mmol/L or \pm 15%

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

99% of TRUE METRIX 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

9/18 (50%) 17/18 (94.4%) 18/18 (100%) gertip Samples (User vs. YSI) for glucose concentrati Within ± 5% Within ± 10% Within ± 15% 39/82 (47.6%) 65/82 (79.3%) 81/82 (98.8%) Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/I Within \pm 0.83 mmol/L or \pm 15% 99/100 (99%)

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

98% of TRUE METRIX for earm 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 \geq 5.55 mmol/L.

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

+ 0.28 mmol/l + 0.56 mmol/I ± 0.83 mmol/L 21/41 (51.2%) 32/41 (78%) 41/41 (100%) Forearm Samples (User vs. YSI) for glucose concentrations > 5.55 mmol/L Within ± 5% Within + 10% 21/59 (35.6%) 39/59 (66.1%) 57/59 (96.6%) Forearm Samples for glucose conce Within \pm 0.83 mmol/L or \pm 15%

98/100 (98%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by users fell within USER PERFORMANCE EVALUATION: A study evaluating glucose values from fingertip capillary

100% within + 0.83 mmol/L of the medical laboratory values at glucose concentrations below

.55 mmol/L and 98.8% within \pm 15% of the medical laboratory values at glucose concentrations at or

lood samples obtained by 100 lay persons showed the following results:

Remove test strip. Re-insert correctly

Contact for assistance.

Test strip inserted upside down or backwards Remove test strip. Re-insert Test strip not fully inserted Test strip fully into meter. Test strip error Repeat with new test strip. Dead or no battery Replace battery. Battery positive ("+") side Battery in backwards must face up.

10 TROUBLESHOOTING

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

After applying sample, test does not start/meter does not beep or begin testing.

Meter error

Display

Repeat test with new Sample drop too small test srip and larger drop. Repeat test with new test strip. Sample applied after two apply sample within 2 minutes minute shut-off of inserting test strip. Test Strip Error Repeat with new test strip. Meter Error Contact for assistance.

Use contact information at the bottom of the page for assistance

11 MESSAGES Action Reason

Repeat with new test strip, using capillary whole blood from the Invalid finger, forearm or venous whole Haematocrit blood collected only in a sodium heparin blood collection tube. If error persists, contact for assistance. Move meter and test strips to Temperature area between 5°C-40°C; wait error 10 minutes for system to Too cold/ reach room temperature Too hot before testing. Sample not Retest with detected or new test strip and using wrong larger sample. test strip Used test strip; Repeat with new test strip. Make Fest strip outside sure Sample Tip of test strip of vial too long; ouched top of sample drop. If er-Sample on top` or persists, contact for assistance. fest strip. Meter Contact for assistance. Retest with new test strip. est strip error o error persists, contact for assistance. very high blood symptoms such as fatigue, excess uriglucose result nation, thirst, or blurry vision are found, (higher than 33.3 mmol/L) follow a Doctor or Healthcare Professional's advice for high blood glucose. Retest with new test strip. Test strip Make sure result is disremoved played <u>before</u> during test removing test strip. E-9 Communication Contact for assistance. error Low: About 50 tests can be done Low or before battery dies. dead Dead: Battery Symbol appears battery and beeps before meter turns off. Do not use meter Broken for testing. Display Contact for assistance. 15:00 Out of range Retest with new test strip. High results If result is still 33.3 mmol/L "Hi" (High) 15:00

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

Low results

< 1.1 mmol/

"Lo" (Low)

contact a Doctor or

Healthcare Professional

immediately.

12 SYSTEM SAFETY INFORMATION **ELECTROMAGNETIC COMPATABILITY**

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.

Write date first opened on test strip vial label. Discard vial

Close vial immediately after removing test strip.

• Do not reuse test strip.

LANCING DEVICE CARE AND CLEANING Clean immediately after getting any blood on the lancing device

• Do not clean lancing device if there is a lancet inside. Remove lancet from lancing device before cleaning.

agent. Repeat as needed until all surfaces Gently pull back Arming Barrel and press

Wash hands thoroughly again after

• End Cap does not go back on,

A meter with a low battery displays Battery Sym-

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

2. Turn meter over. While holding meter in

Note: If battery is out of meter or dead too long, meter may reset to

Battery might explode if mishandled or incorrectly replaced.

BACK PAGE

		ART INFORMATION	Colors:	Graphic Artist/Reviewer:	
ATRIVIDIA		DESIGNER: Mark		Artist/Date	Reviewer/Date
		_{DATE:} 13jun19 _{SIZE:} 24x19.875		mm13jun19	Reviewer/Date
GRAPHICS Packaging		SUBSTRATE/FORMAT:		mm23jul19	RW 07/23/19
		White Board/Box ☐ Shrink Sleeve/Label ☐		mm19sep19	RW 09/20/19
		Pressure Sensitive/Label ☐ IMAGES		Artist/Date	Reviewer/Date
Patricia	13jun19	IIVIAGES		Artist/Date	Reviewer/Date
INITIAL REQUESTOR	DATE	·		Artist/Date	Reviewer/Date
Notes:				Artist/Date	Reviewer/Date
00-00-00 Notes:				Artist/Date	Reviewer/Date
				Artist/Date	Reviewer/Date
			Process Colors Used in Art	Artist/Date	Reviewer/Date
			CMYK	Artist/Date	Reviewer/Date
			4 Color Process	Artist/Date	Reviewer/Date
			PANTONE" simulations used in this art may not match PANTONE-identified solid color standards. Use current PANTONE Color Reference Manuals for accurate color.	Artist/Date	Reviewer/Date