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

CONTENTS

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.

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 all 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 and disinfecting 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 immediately.

~ Low blood glucose (hypoglycaemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and trouble speaking.

~ High blood glucose (hyperglycaemia) symptoms may be intense thirst, a need to urinate often, dry mouth, vomiting, and headache.

- Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in neonates.
- **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

1. Joslin Diabetes Center. *Goals for Blood Glucose Control* [Electronic Version]. Retrieved June 8, 2015 from http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html.
2. FDA Public Health Notification: *Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication Update 11/29/2010* [Electronic Version]. Retrieved February 22, 2012 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
3. 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.
4. 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.
5. Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests.* Scand J Clin Lab Invest 36:805-808, 1976.
6. 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.
7. Data on file.

2 SYSTEM SPECIFICATIONS

Result Range:	1.1 - 33.3 mmol/L
Sample Size:	0.5 microliter (0.5 µL)
Sample:	Fresh capillary whole blood, venous whole blood collected in sodium heparin blood collection tubes, or control solution
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

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, salts, dye and preservatives.

EXPECTED RESULTS

Expected Blood Glucose Results for people without diabetes:[1]

Plasma Blood Glucose Result	
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.

SYMBOLS:

- Biological Risk
- STERILE R — Sterile
- Do Not Resterilise
- Single Use Only
- CONTROL — Control Solution
- ① ② ③ Control Level
- SN — Serial Number
- Caution!
- Use By Date
- Keep Dry
- Attention! Read Instructions for Use.
- Storage Temperature Range
- Storage Humidity Range
- LOT — Lot Number
- IVD — For *in vitro* Diagnostic Testing Only
- EC REP — Authorised Representative
- Manufactured By
- Date of Manufacture
- Single Patient Use Only

3 KNOW YOUR SYSTEM

METER

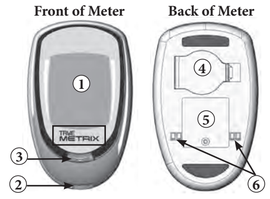
Top of Meter

① **" ◂ " Button**
Decrease numbers in Meter Set Up; remove ALT Symbol; move backward by date/time when viewing results and Averages in Memory; scroll through Event Tags to mark results (if feature on).

② **" • " Button**
Turn meter on to view Average values, to view results in Memory, to access Meter Set Up, to turn on Event Tags in Meter Set Up.

③ **" ▸ " Button**
Increase numbers in Meter Set Up; add ALT Symbol; move forward by date/time when viewing results and view Averages in Memory; scroll through Event Tags to mark results (if feature on).

Front of Meter **Back of Meter**



① **Display Screen**
Shows results, messages, user prompts, information.

② **Test Port**
Insert Test Strip here, contact blocks facing up.

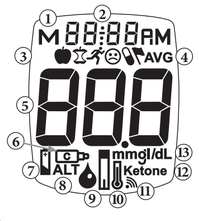
③ **Strip Release Button**
Releases test strip after testing for disposal.

④ **Battery Door**
Use one non-rechargeable 3V lithium battery (#CR2032), positive ("+") side up (see *Changing Battery*).

⑤ **Meter Label**
Contains serial number of meter.

⑥ **Data Contacts**
Connects meter with computer for data upload.

Full Display Screen



1. Result is from Memory
2. Time, Date
3. Event Tag Symbols
4. Result is from 7-, 14-, or 30-Day Average
5. Test Result
6. Control Symbol
7. Battery Symbol
8. Alternate Site (ALT) Symbol
9. Drop Symbol - Apply blood or control solution
10. Temperature Symbol
11. Test Reminder Symbol
12. Ketone Test Alert Symbol
13. Units of Measure
*(**Note:** Shows both mmol/L and mg/dL in full Display. Unit of measure is factory set and cannot be changed.)*

TEST STRIP

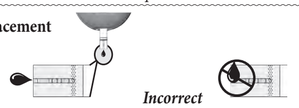
Top of Test Strip

① **Contact End** - Insert into Test Port with contact blocks facing up.

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

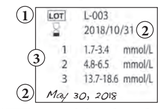
Note: *Insert test strip into meter before touching Sample Tip to blood or control solution drop.*

Sample Placement



- 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.

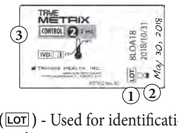
② **Use By Dates** ( ) - Write date first opened on vial label. Discard vial and unused test strips if either the open vial Use By date or the date printed next to on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial Use By date.

Use of test strips or control solution past the Use By Dates may give incorrect test results. Discard out-of-date 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 on bottle label has passed, whichever comes first.

③ **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 Up*).

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.

Tagging 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.

AUTOMATIC SELF-TEST

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).

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

We 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, wet, etc.)

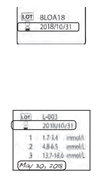
Note: It is important to perform Control Tests with more than one level of TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Use contact information at the bottom the page for more information on how to obtain control solution.

Ranges printed on test strip vial label 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 **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 on bottle label; test strips - after open vial Use By Date (see Test Strip Instructions for Use) or date next to on vial label.) Discard expired products and use new products.

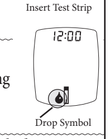


How To Test Control Solution, *cont.*

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.
3. Gently swirl or invert control solution bottle to mix. **DO NOT SHAKE!**
4. Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.
5. Insert test strip into Test Port. Meter turns on.

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.*

6. Wait until Drop Symbol appears in Display. Keep test strip in meter until testing is finished.

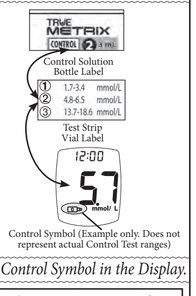


Note: *If test strip is removed before testing is finished, an error message appears. Release and discard old test strip. Use new test strip for testing.*

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.

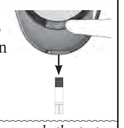
11. Compare meter result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, system can be used for testing blood. If result does not fall within range, repeat test using a new test strip.



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 instructions.

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 handled.

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.
3. 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.
4. 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.

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FRONT PAGE

Obtaining a Blood Sample, *cont.*

Tips for Forearm Sampling

Important Notes Regarding Forearm Testing[4]

- 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 from the finger.
- Use finger for testing instead of forearm for more accurate results:

~ 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.

1. Select area. Clean the area with soap and warm water, rinse or use an approved disinfectant. Dry thoroughly.
2. Rub area vigorously or apply a warm, dry compress to increase blood flow.
3. Lance forearm. Apply sample to Sample Tip.
4. Discard all biohazard materials into appropriate container.

Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets into approved biohazard container.

From Vein

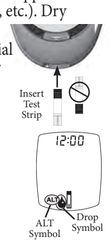
Venous whole blood drawn into only a sodium heparin blood collection tube must be used for testing. Mix well before use.

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

1. 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.
2. Clean hands and area to be lanced with an approved disinfectant (i.e. alcohol, soap and water, etc.). Dry thoroughly.
3. Remove one test strip from vial. Close vial immediately. Use test strips quickly after removal from vial.
4. 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.*

5. Wait until Drop Symbol appears in Display. Obtain a blood sample. Allow drop to form (see *Obtaining a Blood Sample*).
6. 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.

7. Dashes appear across Display to show meter is testing.
8. After the test is finished, result is displayed. The Strip Release Button flashes.

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.

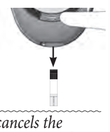
Note: *Event Tag must be marked prior to the removal of test trip from meter.*

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.

9. 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 date and time.



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

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

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 for testing.

DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause inaccurate results.

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/Lof 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.

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 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*).

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.*

1. 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.
3. The minutes flash. To change, press " ► " or " ◄ " Button to select the minutes. Press " • " Button to set.
4. Repeat Step 3 for the month, day and year.

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 Reminders off.

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

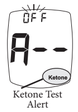
Event Tags are used to mark a test result that was taken during a specific event.

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/L, 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.

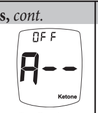


When a Ketone Test Alert Symbol appears, it does not mean that ketones have been detected in your blood. Perform a ketone test per the treatment plan, as prescribed by the Doctor or Healthcare Professional.

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

Test Reminder

Up to four Test Reminders per day may be set. 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 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.
2. When "on" is chosen, press " • " Button. The hour flashes. Press " ► " or " ◄ " Button to set the hour. Press " • " Button to set.
3. The minutes flash. Press " ► " or " ◄ " Button to set the minutes. Press " • " Button to set. Meter goes to the next Test Reminder.
4. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).

Exit Set-Up

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

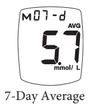
Note: *If Test Reminders are set, the Test Reminder Symbol appears in all Displays.*

7 METER MEMORY

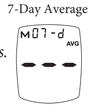
VIEW AVERAGES (7-, 14-, AND 30-DAY)

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.



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



VIEW RESULTS

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.
2. 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.

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 humidity (Non-condensing). **DO NOT FREEZE.**
- Allow system to sit at room temperature for 10 minutes before testing.

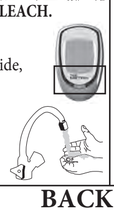
METER CARE, CLEANING/DISINFECTING

- 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 needed 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 disinfecting (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.**

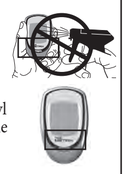
3. Rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, left side, right side, top and bottom of the meter. Make sure no liquids enter the Test Port or any other opening in the meter. Discard used wipes.
4. Verify that the meter is working properly by performing an Automatic Self-Test. See Automatic Self-Test on how to perform.



Meter Care, Cleaning/Disinfecting, *cont.*

To Disinfect the Meter:

1. Clean the Meter before disinfecting (see *To Clean the Meter*).
2. 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.**
3. Let meter air dry thoroughly before using to test.
4. Wash hands thoroughly again after handling meter.
5. 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 ⌧ 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.
- Write date first opened on test strip vial label. Discard vial and unused test strips if either the open vial Use By date or the date printed next to ⌧ on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial Use By date. Use of test strips past the Use By dates may give incorrect results.
- Close vial immediately after removing test strip.
- Store in a dry place at room temperature (4°C-30°C) at 10%-80% relative humidity (Non-condensing). **DO NOT FREEZE.**
- Do not reuse test strip.
- 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.

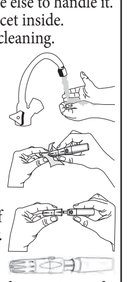
LANCING DEVICE CARE AND CLEANING

Clean immediately after getting any blood on the lancing device or if lancing device is dirty.

- Clean lancing device before allowing anyone else to handle it.
- Do not clean lancing device if there is a lancet inside. Remove lancet from lancing device before cleaning.

To Clean the Lancing Device:

1. Wash hands thoroughly with soap and water.
2. Remove End Cap. Clean with cleaning agent. Repeat as needed until all surfaces are visibly clean.
3. Let lancing device air dry thoroughly before using to test. Replace End Cap. Gently pull back Arming Barrel and press the Trigger Button. A click will be heard if the lancing device is functioning properly.
4. Wash hands thoroughly again after handling the lancing device.

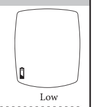


Use contact information at the bottom of page for assistance if:

- Markings on lancing device are coming off,
- Trigger button hard to push,
- End Cap does not go back on,
- Arming Barrel does not click when gently pulled back.

CHANGING BATTERY

A meter with a low battery displays Battery Symbol while continuing to function. A meter with a dead battery displays Battery Symbol, beeps, and then turns off. To replace battery:



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

1. Lift tab on Battery Door.
2. Turn meter over. While holding meter in one hand with Battery Door facing down, tap meter gently on the palm of your other hand to loosen and remove battery.
3. Discard old battery into appropriate container.
4. Insert new battery, positive ("+") side facing up. Close Battery Door.
5. 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.

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

Battery might explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local regulations.

9 PERFORMANCE CHARACTERISTICS

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

Repeatability: N=100					
Mean (mmol/L)	2.4	4.8	8.0	11.3	17.8
SD (mmol/L)	0.09	1.16	0.24	0.39	0.49
%CV	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		
%CV	4.3	3.2	3.4		

SYSTEM ACCURACY: Diabetes experts have suggested that 95% of glucose meter results should agree within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L. 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 Instrument (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 ≥ 5.55 mmol/L.

Fingertip 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
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%
207/444 (46.6%)	364/444 (82%)	441/444 (99.3%)

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

Within ± 0.83 mmol/L or ± 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).

100% 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 ≥ 5.55 mmol/L.

Forearm 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
13/41 (31.7%)	26/41 (63.4%)	41/41 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
17/59 (28.8%)	38/59 (64.4%)	59/59 (100%)

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

Within ± 0.83 mmol/L or ± 15%
100/100 (100%)

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

Venous Blood

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 ≥ 5.55 mmol/L.

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

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
16/50 (32%)	39/50 (78%)	50/50 (100%)

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

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 ± 0.83 mmol/L or ± 15%
216/224 (96.4%)

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

FOR CONSUMERS

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

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

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
9/18 (50%)	17/18 (94.4%)	18/18 (100%)

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

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/L

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

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

98% of TRUE METRIX forearm values performed by users fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

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

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
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%	Within ± 15%
21/59 (35.6%)	39/59 (66.1%)	57/59 (96.6%)

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

Within ± 0.83 mmol/L or ± 15%
98/100 (98%)

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

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

10 TROUBLESHOOTING

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

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

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

REASON	ACTION
Sample drop too small	Repeat test with new test srip and larger drop.
Sample applied after two minute shut-off	Repeat test with new test strip. Apply sample within 2 minutes 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

Display	Reason	Action
E-0	Invalid Haematocrit	Repeat with new test strip, using capillary whole blood from the finger, forearm or venous whole blood collected only in a sodium heparin blood collection tube. If error persists, contact for assistance.
E-1	Temperature error • Too cold/ Too hot	Move meter and test strips to area between 5°C-40°C; wait 10 minutes for system to reach room temperature before testing.
E-2	Sample not detected or using wrong test strip	Retest with new test strip and larger sample.
E-3	Used test strip; Test strip outside of vial too long; Sample on top of test strip.	Repeat with new test strip. Make sure Sample Tip of test strip touched top of sample drop. If error persists, contact for assistance.
E-4	Meter error	Contact for assistance.
E-5	Test strip error or very high blood glucose result (higher than 33.3 mmol/L)	Retest with new test strip. If error persists, contact for assistance. If symptoms such as fatigue, excess urination, thirst, or blurry vision are found, follow a Doctor or Healthcare Professional's advice for high blood glucose.
E-6	Test strip removed during test	Retest with new test strip. Make sure result is displayed before removing test strip.
E-9	Communication error	Contact for assistance.
	Low or dead battery	Low: About 50 tests can be done before battery dies. Dead: Battery Symbol appears and beeps before meter turns off.
---	Broken Display	Do not use meter for testing. Contact for assistance.
12:00 Hi	⚠ **Out of range - High results** > 33.3 mmol/L	⚠ Retest with new test strip. If result is still "Hi" (High) or "Lo" (Low) contact a Doctor or Healthcare Professional ***immediately***.
12:00 Lo	**- Low results** < 1.1 mmol/L	

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

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.

BACK PAGE