



TRUEyou Blood Glucose Monitoring System

Instructions For Use (IFU)

CONTENTS

1 Important Information About the System	Front page	5 Testing Blood	Back page
Intended Use		Obtaining a Blood Sample	
Importance of Blood Glucose Monitoring		How to Test Blood Glucose	
Important Health and Safety Information		System Out of Range Warning Messages	
References		System and Laboratory Testing	
2 System Specifications	Front page	6 Memory	Back page
Operating Range / Chemical Composition		View Averages (7-, 14-, and 30-Day)	
Expected Results		View Results	
Symbols Chart		7 Meter Setup	Back page
3 Know the System	Front page	8 System Care	Back page
Meter		Changing Battery	
Test Strip		9 Performance Characteristics	Back page
Control Solution		10 Troubleshooting	Back page
4 Getting Started	Front page	11 Display Messages	Back page
Quality Control Testing		12 EMC Safety Information	Back page
Automatic Self-Test			
Control Test			

1 IMPORTANT INFORMATION ABOUT THE SYSTEM

INTENDED USE

The TRUEyou 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 a Doctor or Healthcare Professional 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.

IMPORTANCE OF BLOOD GLUCOSE MONITORING

- Use of TRUEyou Blood Glucose Monitoring System in a manner not specified in this System IFU is not recommended and may affect your ability to determine true blood glucose levels.
- The TRUEyou System is an in vitro (outside body) quantitative system that is used for self-testing and point-of-care testing of only human whole blood.
- The most accurate results come from using fresh whole blood taken from the fingertip or forearm (capillary) or from the vein (venous).
- Read all product instructions for use before testing.
- Use only TRUEyou Test Strips and TRUEyou GDH-FAD Control Solution with TRUEyou Meter.
- To help prevent false high results, wash hands before using the System to test blood, especially after handling fruit or other foods containing sugar.
- Perform Control Tests before performing a blood glucose test for the first time (see *Control Test*).
- Remove only one Test Strip at a time from vial when testing. Recap vial immediately after removing Test Strip.
- NEVER reuse Test Strips. NEVER wipe Test Strips with water, alcohol or any cleaner. DO NOT attempt to clean and re-use Test Strips. Reuse of Test Strips will cause inaccurate results.
- NEVER add a second drop of sample to Test Strip. Adding more sample to the Test Strip gives an error message.
- Venous whole blood collected in sodium heparin or lithium heparin blood collection tubes may be used for testing by a Doctor or Healthcare Professional. Mix tube contents gently before using.
- All meters 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.
- NEVER change a treatment plan without consulting with a Doctor or Healthcare Professional.

IMPORTANT HEALTH and SAFETY INFORMATION

The System should be used only on one person and not shared, even with family members.

We suggest cleaning the Meter when visibly dirty or if blood is on the Meter. Wash your hands thoroughly with soap and warm water before and after handling the Meter, Lancing Device or Test Strips as contact with blood presents an infection risk. For cleaning and disinfecting the Meter, see *Meter Care, Cleaning/Disinfecting*. For cleaning the Lancing Device, see the Lancing Device instructions for use. All parts of the System could carry blood-borne pathogens after use, even after cleaning and disinfection.^{1,2}

-FOR PATIENTS-

- The System is for one person use **ONLY**. DO NOT share your Meter or your Lancing Device with anyone, including family members.
- WARNING!** Upon opening the test strip carton, examine the product for missing, damaged or broken parts. Ensure the test strip vial cap is securely closed. If the product is damaged or the vial cap is not closed, DO NOT use the test strips for testing; product may give inaccurate results. Contact Trividia Health Customer Care for replacement and assistance.

-FOR DOCTOR OR HEALTHCARE PROFESSIONALS-

- The System can be used on multiple patients, provided a Doctor or Healthcare Professional always wear gloves and follow the *Cleaning/Disinfecting* section and/or adhere to the infection control policies and procedures approved by the facility.
- The Test Strips and Lancets are for single-use. Lancing Device is restricted to be used on one patient only.
- Reuse of devices labeled for single-use may result in product contamination and patient infection.
- Do not use the System for the diagnosis of diabetes or for testing blood glucose in neonates (newborns).
- DO NOT perform capillary blood glucose testing on critically ill patients.** Capillary blood glucose levels in critically ill patients 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 hyperosmolality, with or without ketosis.
- Do not use the System during a xylose absorption test. This may falsely raise glucose results.⁴ Please check with your Doctor or Healthcare Professional before using the System.

REFERENCES

- FDA Public Health Notification: *Use of Fingertick 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>.
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- U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter*. [Electronic Version]. Retrieved July 6, 2009 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm>.
- 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.
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2 SYSTEM SPECIFICATIONS

Result Range: 1.1 - 33.3 mmol/L
Sample Size: Minimum 0.5 microliter (0.5 µL)
Sample: Fresh capillary whole blood, venous blood drawn in sodium heparin or lithium heparin blood collection tubes, or Control Solution
Test Time: Results in as fast as 4 seconds
Result Value: Plasma values
Assay Method: Electrochemical
Power Supply: One 3V lithium battery #CR2032 (non-rechargeable)
Battery Life: Approximately 2146 tests or 1.5 years
Automatic shut-off: After two minutes of non-use
Weight: 47 grams
Size: 89 x 55 x 17 mm
Memory Size: 500 blood results and one control result

Operating Range (For Blood Testing)

Relative Humidity: 10-90% (Non-condensing)
Temperature: 10°C-40°C
Haematocrit: 20-55%
Altitude: 3094 metres
Note: Use within specified environmental conditions only.

Chemical Composition

Test Strips: Glucose dehydrogenase-FAD (*Acinetobacter calcoaceticus*), mediators, buffers and stabilisers.
Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

EXPECTED RESULTS

Expected Blood Glucose Results for people without diabetes:⁵

	Plasma Blood Glucose Result
Before breakfast	< 5.6 mmol/L
Two hours after meals	< 7.8 mmol/L

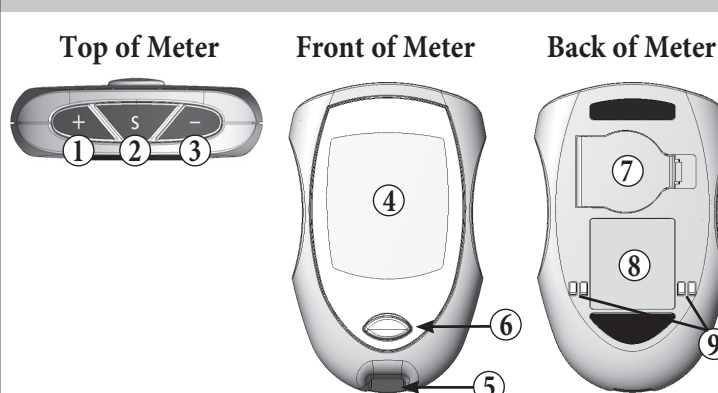
A Doctor or Healthcare Professional will determine target ranges for blood glucose results and how often to test. Having most results within the target ranges shows how well a treatment plan is working to control glucose levels. Keeping results within the target ranges helps slow or stop complications of diabetes. NEVER change a treatment plan without consulting with a Doctor or Healthcare Professional.

SYMBOLS:

- Biological Risk
- Sterile
- Do Not Resterilise
- Single Use Only
- Control Solution
- Control Level
- Serial Number
- Caution!
- Use By Date
- Keep Dry
- Attention! Read Instructions for Use.
- Storage Temperature Range
- Lot Number
- For in vitro Diagnostic Testing Only
- Authorised Representative
- Manufactured By
- Date of Manufacture
- Single Patient Use Only

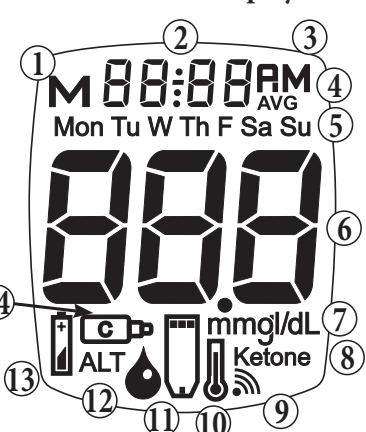
3 KNOW THE SYSTEM

METER



- “+” Button** - Increase numbers in Time/Date Set Up for Meter and Testing Reminders; turn on Testing Reminders and Ketone Test Alert; add ALT Symbol; move forward by date/time when viewing results in Memory.
- “S” Button** - Turn Meter on to view Average values, to view results in Memory, and to access Meter Set Up.
- “-” Button** - Decrease numbers in Time/Date Set Up for Meter and Testing Reminders; turn off Testing Reminders and Ketone Test Alert; remove ALT Symbol; move backward by date/time when viewing results in Memory.
- Display Screen** - Shows test results, messages, user prompts, other information.
- Test Port** - Insert Test Strip here.
- Strip Release Button** - Releases Test Strip after testing.
- Battery Door** - Use one non-rechargeable 3V lithium battery (#CR2032), positive (“+”) side up (see *Changing Battery*).
- Meter Label** - Contains serial number that identifies Meter when contacting for assistance.
- Docking Station Contacts** - Contacts used for uploading Meter results to a computer using a Docking Station. (Please contact for availability).

Full Screen Display

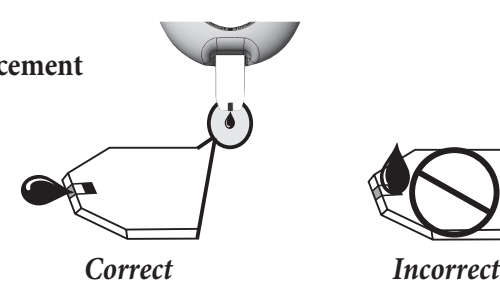


- Memory Symbol
- Time, Date
- AM/PM (*Note: Only seen on factory set 12 hour clock.*)
- Result is from 7-, 14-, or 30-day Average
- Day of Week
- Test Result
- Unit of Measure
- Ketone Test Alert Symbol
- Testing Reminder Symbol
- Temperature Symbol
- Drop Symbol - Apply blood or Control Solution
- Alternate Site (ALT) Symbol
- Battery Symbol
- Control Symbol

TEST STRIP

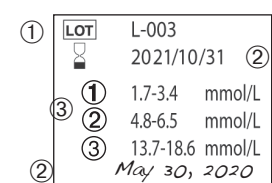
- Top of Strip**
- Contact End - Insert into Test Port with blocks (contacts) facing up.
 - Sample Tip - Touch to top of sample (fresh capillary or venous blood or Control Solution) after inserting Contact End into Meter.

Sample Placement



- Do not touch Sample Tip to drop of sample unless Contact End is inserted into Meter.
- Do not apply blood or Control Solution to top of Test Strip.
- Do not smear or scrape drop with Test Strip.
- Do not apply more sample to the Test Strip after testing begins.
- Do not insert Sample Tip with sample into Meter for testing. May damage Meter.

Test Strip Vial Label



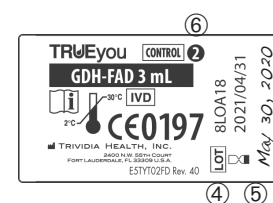
- Lot Number (LOT)** - Used for identification when contacting for assistance.
- Use By Dates ()** - Write date first opened on vial label. Discard vial and unused Test Strips if either 4 months after first opening or date printed next to on vial label has passed, whichever comes first.

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.

- Control Test Range** - Range of numbers in which Control Test result must fall to assure System is working properly.

CONTROL SOLUTION CONTROL

Control Solution Bottle Label



- Lot Number (LOT)** - Used for identification when contacting for assistance.
- 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.
- Control Solution Level (1, 2 or 3)** - Testing at least 2 levels of Control Solution is recommended. Use contact at the bottom of the page for information on obtaining Control Solution.

4 GETTING STARTED

The Meter comes with pre-set time and date. Ketone Test Alert and all Testing Reminders are off. Before using Meter for the first time or after battery is changed, check to make sure all of the Meter settings are correct and update if needed (see *Meter Set Up*).

The Meter turns on when a Test Strip is inserted into the Test Port or when “S” Button is pressed and released (see *Memory and Meter Set Up*). Meter turns off when the Test Strip is released from the Meter, “S” Button is pressed and held for 20 seconds, or after 2 minutes of non-use. Always check your supplies before using.

- Check Meter for damage (cracked Display, missing buttons, etc.). If damage is seen, do not use Meter. Contact for assistance.
- Check Test Strip vial for damage (cracked vial, broken vial, etc.). Discard damaged vial and all contents (Test Strips) and use a new vial of Test Strips for testing.
- Write date first opened on Test Strip vial. Check Use By Dates (written and printed) before using any Test Strips from the vial. Do not use if 4 months after first opening (written date) or if printed Use By Date has passed.
- Check Control Solution bottle for any leaks or broken cap. Discard bottle and open a new one for testing.
- Write date first opened on Control Solution bottle label. Check Use By Dates (written and printed) before using. Do not use if 3 months after first opening (written date) or if printed Use By Date has passed.

QUALITY CONTROL TESTING

To assure you are getting accurate and reliable results, the System offers two kinds of quality control tests. These tests let you know that the System is working properly and your testing technique is good.

AUTOMATIC SELF-TEST

An Automatic Self-Test ensures that the Meter is working correctly.

- Wash hands and dry thoroughly.
- Remove one Test Strip from the Test Strip vial and insert Test Strip into the Meter.
- Meter turns on. The full Display appears and is replaced by the time and the blinking Drop Symbol. The Meter is working correctly and is ready to perform a Control or blood test.

Do not use Meter if:

- The full Display does not appear (segments are missing),
- The blinking Drop Symbol does not appear, or
- An error message appears in the Display.

See *Troubleshooting* or contact for assistance (see contact information at the bottom of the page).

CONTROL TEST

The Control Test checks that the System is working correctly and testing technique is good. Use **ONLY** TRUEyou GDH-FAD Control Solution to perform Control Tests. Perform Control Tests:

- For practice before using the System for the first time,
- When opening a new vial of Test Strips,
- Occasionally as a vial of Test Strips is used,
- If a Test Strip vial has been left opened or left in extreme heat, cold, or humidity,
- Whenever a check on performance of the System is needed,
- If results seem unusually high or low,
- If Meter damage is suspected (Meter was dropped, crushed, wet, etc.).

Performing Control Tests with more than one level of Control Solution is recommended to ensure that the System is working properly. Three levels of TRUEyou GDH-FAD Control Solution are available. Use contact at the bottom of the page for more information on obtaining Control Solution.

Ranges printed on Test Strip vial label are for Control Test results only and are not suggested levels for your blood glucose. Do not drink Control Solution.

HOW TO TEST CONTROL SOLUTION

Use **ONLY** TRUEyou GDH-FAD Control Solution with the TRUEyou Meter.

- Check supplies. See *Getting Started*.
- Allow Control Solution, vial of Test Strips and Meter to adjust to room temperature (20°C-25°C).

Running a Control Test at temperatures outside the range listed above may cause Control Solution to read as a blood test.

- Wash hands. Dry thoroughly.
- Gently swirl or invert Control Solution bottle to mix. **DO NOT SHAKE!**
- Remove one Test Strip from vial. Close Test Strip vial immediately. Use Test Strip quickly after removal from vial.

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.

- Insert Test Strip into Meter. Meter turns on and shows blinking Drop Symbol and time. Do not remove Test Strip.

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.

- With cap removed, turn Control Solution bottle upside down. Gently squeeze one drop of Control Solution onto a clean tissue. Wipe off bottle tip with the tissue.

Note: Do not put drop on top of the Test Strip.

- With Test Strip still in Meter, touch Sample Tip to top of the drop of Control Solution. Allow drop to be drawn into Test Strip. Remove Test Strip from drop when Meter beeps.

Dashes appear across the Display to show Meter is testing.

Note: If Meter does not beep or begin testing soon after drawing up sample, release and discard Test Strip. Repeat test with new Test Strip. If problem persists, see *Troubleshooting*.

- After testing is finished, the result appears in the display with the Control Symbol.

11. Compare result to Control Test Range printed on Test Strip vial label for Control Solution Level 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.

If result is still outside range after a second Control Test, System should not be used for testing blood. Contact for assistance.

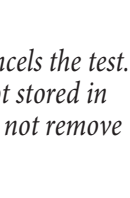
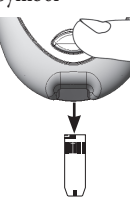
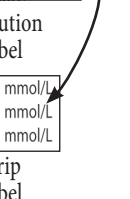
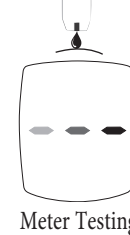
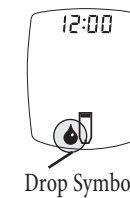
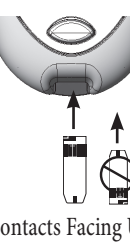
- After result is shown, Test Strip Release Button flashes. Hold Meter with Test Strip pointing down. Press Strip Release Button to release and discard Test Strip in appropriate container. Meter turns off. Recap Control Solution bottle tightly.

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.

LOT: BL0A18
2021/04/31

LOT: L003
2021/10/31

13.14 mmol/L
04.65 mmol/L
137.186 mmol/L
May 30, 2020



5 TESTING BLOOD

OBTAINING A BLOOD SAMPLE

Refer to lancet device's Instructions for Use for detailed instructions.

The lancet device is for single patient use ONLY. For cleaning your lancet device see lancet device's instructions for use. Wash your hands thoroughly with soap and warm water after handling the Meter, lancet device, or Test Strips. Contact with blood presents an infection risk.

- NEVER share lancets or lancet device.
- Lancets are for single use only. Do not reuse lancets.
- To help prevent false high results, wash hands before using the System to test blood, especially after handling fruit or other foods containing sugar.

FROM FINGERTIP

- Prepare fingertip by washing hands in warm, soapy water. Rinse well. Dry thoroughly.
- Place end of lancet device equipped with lancet against tip of finger. Lance fingertip.
- Set lancet device aside. To help blood drop form, lower hand to waist level, gently massage finger from palm to fingertip. Allow blood drop to form before attempting to apply to Test Strip.
- Recap and remove used lancet from lancet device. Discard used lancet into appropriate container.

Treat used Test Strips and lancets as a biological risk. Dispose used Test Strips and lancets in appropriate container.

FROM FOREARM

- Note: Some lancet devices include a special end cap for alternate site testing. Check lancet device's Instructions for Use.
- Select area to be lanced. Wash with soap and warm water, rinse and dry thoroughly.
 - Rub area vigorously or apply a warm dry compress to increase blood flow.
 - Place end of lancet device equipped with lancet firmly against forearm. Press trigger button. Apply firm pressure on lancet device for 10 seconds. Allow blood drop to form before attempting to apply to the Test Strip.
 - Recap and remove lancet from lancet device. Discard used lancet into appropriate container.

- #### Important Notes Regarding Forearm Testing
- Check with your Doctor or Healthcare Professional to see if forearm testing is right for you.
 - Results from forearm are not always the same as results from fingertip.
 - Use fingertip instead of forearm for more accurate results:
 - Within 2 hours of eating, exercise, or taking insulin,
 - If your blood sugar may be rising or falling rapidly or your routine results are often fluctuating,
 - If you are ill or under stress,
 - If your forearm test results do not match how you feel,
 - If your blood sugar may be low or high,
 - If you do not notice symptoms when blood sugar is low or high.

6 MEMORY

HOW TO TEST BLOOD GLUCOSE

- Check supplies. See Getting Started.
- Wash hands (and forearm for alternate site testing). Rinse well and 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 Meter. Meter turns on and shows the Drop Symbol in the Display. Keep Test Strip in Meter until testing is finished.

ALTERNATE SITE TESTING

- To mark test as alternate site (forearm) result, press "+" Button. ALT Symbol appears in the 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.
- Lance fingertip or forearm. Allow drop to form (see Obtaining a Blood Sample).
 - With Test Strip still in Meter, touch Sample Tip to top of blood drop and allow blood to be drawn into Test Strip. Remove from blood drop immediately after the Meter beeps and dashes appear across Meter Display.

- Note: If Meter does not beep or begin testing soon after touching blood drop to Sample Tip, discard Test Strip. Repeat test with new Test Strip and new blood drop. If problem persists, see Troubleshooting.
- After the test is finished, result is displayed with time. The Test Strip Release Button flashes. Record result in log book.
 - Hold Meter with Test Strip pointing down. Press Test Strip Release Button to discard Test Strip in the appropriate container.

- 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.
- Meter turns off. Result is stored in Memory with day, date and time.
- Treat used Test Strips and lancets as a biological risk. Dispose used Test Strips and lancets in appropriate container.

SYSTEM OUT OF RANGE WARNING MESSAGES

Lo AND HI RESULTS

If you have symptoms of low or high glucose, check your blood glucose immediately. If your result does not match the way you feel, repeat test. If your results still do not match the way you feel, contact your Doctor or Healthcare Professional.

- 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, a dry mouth, vomiting, and headache.

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", contact your 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.

KETONE TEST ALERT

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 Set Ketone Test Alert).

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

SYSTEM AND LABORATORY TESTING

The most accurate results come from using fresh, capillary whole blood from the fingertip or forearm. Venous whole blood collected in EDTA, sodium heparin or lithium heparin blood collection tubes may be used for testing by Doctor or Healthcare Professionals. Mix tube contents gently before using. When comparing results between TRUeYou and a laboratory system, perform a TRUeYou blood test within 30 minutes of laboratory test. Diabetes experts have suggested that 95% of glucose meter results should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is less than 5.55 mmol/L, and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher.⁷ If the patient has recently eaten, fingerstick results from the TRUeYou System can be up to 3.9 mmol/L higher than venous laboratory results.⁸

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-, and 30-day period. Results marked as Control Test results are not included in the Averages.

Note: If a Control Test is performed outside the recommended testing temperature (see How to Test Control Solution), the Control Solution may read as a blood test and be included in the Averages.

Start with Meter off. Press and release "S" Button. Display scrolls through 7-, 14-, and 30-Day Average values.

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

VIEW RESULTS

Memory stores 500 total blood results and one Control Test result, which are displayed from most recent to oldest. When the Memory is full, the oldest result is replaced with the newest result.

- Press and release "S" Button. Meter displays 7-, 14-, and 30-day Averages.
- Press and release "S" Button again to view most recent result in Memory. If there are no results in Memory, dashes appear with the Memory Symbol.
- Press "+" Button and release to advance to the next result. Press "+" Button to scroll forward through blood results or "-" Button to scroll backwards through blood 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 Meter Set Up.

7 METER SETUP

Meter Set Up is to be used when changes need to be made to the pre-set time and date, to turn on the Ketone Test Alert and Testing Reminders, or if settings need to be reset because of battery change.

Note: Meter turns off after 2 minutes of non-use. If Meter turns off at any time during Set Up, all settings are saved. The Meter takes you back to Step #1.

SET TIME/DATE

- Press and hold "S" Button until the full Display is shown and a tone sounds (around 5 seconds). Release "S" Button.
- The hour flashes. Press the "+" Button to scroll up the hour or the "-" Button to scroll down the hour. Release "+" or "-" Button when the correct hour displays. Press "S" Button and release to save the hour and go to the next step.
- The minutes flash. Slowly press the "+" Button to scroll minutes up or the "-" Button to scroll minutes down. Release "+" or "-" Button when the correct minutes are displayed. Press "S" Button and release to save the minutes and go to the next step.
- The month (number) flashes. Slowly press and release the "+" Button to increase the month and the "-" Button to decrease the month. Press and release "S" Button to save the month and go to the next step.
- Slowly press and release the "+" Button to increase the day and the "-" Button to decrease the day. Press and release "S" Button to save the day and go to the next step.
- Slowly press and release the "+" Button to increase the year or the "-" Button to decrease the year. Press and release the "S" Button to save the year.

Note: Day of the week (Mon, Tue, Wed, Thu, Fri, Sat, Sun) self-adjusts when month, day or year are changed. Meter beeps every time a setting is confirmed ("S" Button is pressed).

SET KETONE TEST ALERT

- After setting year, press "+" Button or "-" Button to turn Alert on or off. Press "S" Button to set and go to the Testing Reminders.

SET TESTING REMINDERS

- Up to four Testing Reminders per day may be set. Reminder sounds at set time for 10 seconds. To set the Testing Reminders:
- After pressing "S" Button to set Ketone Test Alert, Display shows first Reminder setting (A-1). Press "+" (on) or "-" (off) Button to turn Reminder on or off.
 - If "on" is chosen, press "S" Button. The hour flashes. Press the "+" Button to scroll up the hour or the "-" Button to scroll down the hour. Release "+" or "-" Button when the correct hour displays. Press "S" Button and release to save the hour and go to the minutes set up.
 - If "off" is chosen and the "S" Button is pressed, the Meter goes to the next Testing Reminder.
 - The minutes flash. Press "+" or "-" Button to set the minutes. Press "S" Button to set.
 - Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).
 - Press and hold "S" Button when finished to turn off Meter. Meter turns off after 2 minutes of non-use.

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

8 SYSTEM CARE

CARING FOR THE SYSTEM

- Store System (Meter, Control Solution, Test Strips) in Carrying Case to protect from liquids, dust and dirt.
- Store in a dry place at 2°C-30°C (room temperature). DO NOT REFRIGERATE OR FREEZE.

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 step #2 must occur before disinfecting steps #3 and #4.
- 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:

- Wash hands thoroughly with soap and water.
- Make sure meter is off and a test strip is not inserted.
- Using a lint free cloth dampened with 70% isopropyl alcohol, 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 wipe. DO NOT USE BLEACH.

To Disinfect the Meter:

- Clean the Meter before disinfecting (see To Clean the Meter).
- Using a fresh 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 System 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 opened on Control Solution label. Discard if either 3 months after first opening or after date printed next to the bottle label has passed, whichever comes first.
- Store at 2°C-30°C (room temperature). DO NOT REFRIGERATE OR FREEZE.
- After use, wipe bottle tip clean and recap tightly.

TEST STRIP CARE

- Store Test Strips in original vial only. Do not transfer old Test Strips to new vial or store Test Strips outside of vial.
- Write date opened on Test Strip vial. Discard unused Test Strips from vial if either 4 months after first opening or after date printed next to the vial label has passed, whichever comes first. Use of Test Strips past either date may give incorrect results.
- Close vial immediately after removing Test Strip.
- Store in a dry place below 30°C (room temperature). DO NOT REFRIGERATE OR FREEZE.
- Do not reuse Test Strip. NEVER wipe Test Strips with water, alcohol or any cleaner. DO NOT attempt to clean and re-use Test Strips. Reuse of Test Strips will cause inaccurate results.
- Do not bend, cut or alter Test Strips in any way.

CHANGING BATTERY

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

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

- Lift tab on Battery Door.
- Turn Meter over, tap gently on the palm of your other hand to loosen and remove battery.
- Discard old battery into appropriate container.
- Insert new battery, positive (+) facing up. Close Battery Door.
- Press "S" Button to turn Meter on. If Meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery and turn Meter on by pressing "S" Button. Contact for assistance if problem persists.

Battery is not rechargeable. If you have a cable and/or a cradle for downloading results to a computer, DO NOT plug the 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/country specific regulations.

9 PERFORMANCE CHARACTERISTICS

Performance Characteristics⁴
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)	3.4	5.1	8.5	12.1	19.2
SD (mmol/L)	0.11	0.14	0.27	0.37	0.66
%CV	3.2	2.9	3.1	3.0	3.4

Intermediate Precision: N=100

Mean (mmol/L)	3.1	7.6	19.5
SD (mmol/L)	0.09	0.24	0.69
%CV	3.1	3.2	3.5

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 TRUeYou 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
74/180 (41%)	155/180 (86%)	178/180 (98.8%)

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

Within ± 5%	Within ± 10%	Within ± 15%
272/420 (65%)	395/420 (94%)	418/420 (99.5%)

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

Within ± 0.83 mmol/L and ± 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 TRUeYou 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
18/28 (64%)	26/28 (93%)	28/28 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
50/72 (69%)	64/72 (89%)	72/72 (100%)

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

Within ± 0.83 mmol/L and ± 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
99.6% of TRUeYou 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
10/28 (35.7%)	18/28 (64.3%)	28/28 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
126/214 (58.9%)	191/214 (89.3%)	213/214 (99.5%)

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

Within ± 0.83 mmol/L and ± 15%
241/242 (99.6%)

Parkes Error Grid: 99.6% of individual venous glucose measured values performed by healthcare professionals fell within Zone A and 0.4% fell within Zone B of the Parkes Error Grid (PEG).

FOR CONSUMERS
99.6% of TRUeYou 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
11/23 (48%)	21/23 (91%)	23/23 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
38/77 (49%)	66/77 (86%)	76/77 (99%)

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

Within ± 0.83 mmol/L and ± 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).

100% of TRUeYou 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
16/28 (57%)	23/28 (82%)	28/28 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
42/72 (58%)	61/72 (85%)	72/72 (100%)

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

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

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 99% 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 Strip 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 DISPLAY MESSAGES

DISPLAY	REASON	ACTION
E-1	Temperature Error Too Cold / Too Hot	Move Meter and Test Strips to area between 10°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 or Test Strip Outside of Vial Too Long	Repeat with new Test Strip. Make sure sample is touched to edge of Test Strip (not top). If error persists, contact for assistance.
E-4	Meter Error	Contact for assistance.
E-5	Test Strip Error Very high glucose result (higher than 33.3 mmol/L)	Retest with new Test Strip. If error persists, contact for assistance. If you have symptoms such as fatigue, excess urination, thirst, or blurry vision follow your 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-8	Meter Error	Contact for assistance.
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 beep sounds before Meter turns off. Change the battery.
H	Out of Range - High Results > 33.3 mmol/L	Retest with new Test Strip. If result is still "Hi" (High) or "Lo" (Low) contact your Doctor or Healthcare Professional immediately.
Lo	Low Results < 1.1 mmol/L	Retest with new Test Strip. If result is still "Hi" (High) or "Lo" (Low) contact your Doctor or Healthcare Professional immediately.

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

12 EMC SAFETY INFORMATION

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.