BLOOD GLUCOSE MONITORING SYSTEM

- PRECISE, FAST RESULTS
- EASY TO USE
- TINY SAMPLE SIZE

Owner’s Booklet

For assistance, please call 1 800 451 737.
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E4AU03FD Rev. 20
Fast Test Guide

**TWO simple steps**

1. INSERT TEST STRIP
2. APPLY BLOOD SAMPLE

Notes:

The TRUEresult Blood Glucose Monitoring System is intended for the quantitative determination of glucose in human whole blood taken from the finger or forearm (capillary or 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 Type I, Type II, and gestational diabetes.

For quick reference only, not intended as a substitute for complete instructions. Please read entire Owner’s Booklet and product Instructions for Use before testing.
INTRODUCTION:
TRUEresult Blood Glucose Monitoring System
TRUEresult is a simple, accurate way to test whole blood glucose (sugar) level, anytime, anywhere. Our goal is to provide quality healthcare products and dedicated customer service. For questions about TRUEresult products, please see cover for phone number.

⚠️ Please read complete Owner’s Booklet and all product Instructions for Use.

IMPORTANCE OF BLOOD GLUCOSE MONITORING
The more you know about diabetes, the better you will be able to care for yourself. A Doctor or Diabetes Healthcare Professional will determine how often you should test and what your target ranges are for blood glucose results. Having most results within your target ranges show how well a treatment plan is working to control glucose levels. Keeping results within your target ranges helps slow or stop complications from diabetes. NEVER change your treatment plan without consulting a Doctor or Diabetes Healthcare Professional.
Use of TRUEresult in a manner not specified in this Owner’s Booklet is not recommended and may affect ability to determine true blood glucose levels.

SYMBOLS:

- 🚫 Caution
- 🌧️ Rain
- 🏟️ Sterile
- ⚖️ Control
- ☀️ Keep Dry
- 📡 For in vitro Diagnostic Testing Only
- 🍀 For Assistance Call
- 📝 Instructions for Use
- 🔄 Serial Number
- 🌋 Temperature Range
- 📆 Use By Date
- ☑️ Control Level
- 📜 Authorized Representative
- 🔍 Lot Number
- 🍀 Single Use Only
- 🎁 Manufactured By
FOR PATIENTS
IMPORTANT HEALTH and SAFETY INFORMATION:
If you have symptoms of low or high blood glucose, check your blood glucose immediately. If your result does not match the way you feel, repeat the test. If your results still do not match the way you feel, call 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.
Important Information:
The most accurate results come from using fresh, capillary whole blood from the fingertip or forearm. Venous whole blood collected into sodium or lithium heparin vacutainer tubes may be used for testing by healthcare professionals. Use of EDTA vacutainer tubes (purple top) is not recommended and may cause low results. Mix tube contents gently before using.

When comparing results between TRUEresult and a laboratory system, perform a TRUEresult blood test within 30 minutes of laboratory test. Results from the TRUEresult System are considered accurate if within 20% of laboratory results.¹ If the patient has recently eaten, fingerstick results from the TRUEresult System can be up to 3.9 mmol/L (70 mg/dL) higher than venous laboratory results.²

Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis.

DO NOT test critically ill patients with a blood glucose meter.¹
IMPORTANT INFORMATION:
For the most accurate results using TRUEresult:

- **Read all instructions** before testing.
- TRUEresult is an *in vitro* (outside body) quantitative system that is used for self-testing and point-of-care (bedside) testing of human whole blood only.
- Meter displays results as *Plasma* values.
- Use only TRUEresult Test Strips and TRUEresult Glucose Control with TRUEresult Meter.
- Do not use for diagnosis of diabetes or for testing blood glucose in newborns.
- Perform Control Tests *before* performing a blood glucose test for the first time (see *Getting Started*).

*Note:* Two levels of TRUEresult Glucose Control Solution are available for Quality Control Testing. Call for availability using the number located on the cover of this Owner’s Booklet for information on obtaining different levels of TRUEresult Glucose Control Solution.

- Remove only one Strip at a time from vial when testing. Recap vial immediately after removing Strip.
- Do not use TRUEresult System during a xylose absorption test. Blood Samples containing xylose concentrations of > 7 mg/dL (0.38 mmol/L) may falsely raise TRUEresult glucose results. Please check with your Doctor before using TRUEresult.
Phone Number, Fast Test Guide ................................................................. see covers

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Know Your System

Meter

Top of Meter

① “+” Button
Increase numbers in Meter Set Up; add ALT Symbol; move forward by date/time when viewing results in Memory.

② “S” Button
Turn Meter on to view Average values, to view results in Memory, and to access Meter Set Up.

③ “-” Button
Decrease numbers in Meter Set Up; remove ALT Symbol; move backward by date/time when viewing results in Memory.
① **Display Screen**
Shows results, messages, user prompts, information.

② **Test Port**
Insert TRUEresult Test Strip here.

③ **Strip Release Button**
Releases Strip after testing.

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.
1. Result is from Memory
2. Time, Date
3. Time is AM/PM
4. Result is from 7, 14, or 30 day Average
5. Day of Week
6. Test Result
7. Units of Measure (Note: Factory set, cannot be changed by user.)
8. Ketone Test Alert
9. Testing Reminder
10. Temperature Symbol
11. Drop Symbol - Apply blood or Glucose Control
12. Alternate Site (ALT) Symbol
13. Battery Symbol
14. Control Symbol
Test Strip

① **Contact End** - Insert into Test Port with blocks (contacts) facing up.

② **Sample Tip** - Bring sample (fresh, capillary or venous blood or Glucose Control) to edge of Tip.

*Note:* Insert Strip into Meter before touching Sample Tip to blood or Control drop.

**Sample Placement**

- **Correct Placement**
  - Allow sample (blood or Glucose Control drop) to be drawn into Sample Tip until testing begins (dashes moving across Display).

- **Incorrect Placement**

![Diagram: Correct vs. Incorrect Sample Placement]

- Holding the Test Strip Sample Tip to the blood sample too long after the Meter begins testing may cause inaccurate results.

- Do not smear or scrape drop with Strip.
- Do not apply more sample to the Strip after testing begins.

*Note:* Do not apply blood or Glucose Control to top of Test Strip.

*Note:* Do not insert Sample Tip with sample into Meter for testing. May damage Meter.
Lot Number (LOT) - Used for identification when calling for assistance.

Expiry Dates ( □ ) - Write date first opened on vial label. Discard vial and unused Strips if either 4 months after opening or date printed next to □ on vial label has passed.

Use of Test Strips or Glucose Control past the Expiry Dates may give incorrect test results. Discard out-of-date products and test with new products.

Control Range - Range of numbers in which Control Test results must fall to assure the System is working properly.
Glucose Control Bottle Label

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

2 Expiry Dates (肟) - Write date first opened on bottle label. Discard bottle if either 3 months after opening or date printed next to肟 on bottle label has passed.

3 Control Level (1 or 2) - Two levels of TRUEresult Control are available. We recommend testing at least 2 levels of Control. Use the number on the front cover for information on how to obtain different levels of Control.
Getting Started

The Meter turns on when a Test Strip is inserted into the Test Port or when “S” Button is pressed (see Memory and Meter Set Up). Meter turns off when the Strip is released from the Meter or after 2 minutes of non-use.

Meter comes with pre-set time, date and all testing Alerts and Reminders off. Before using the Meter for the first time or after a battery change, check the time, date, Alerts and Reminders, and update as needed (see Meter Set Up).

We recommend performing Control Tests for practice before using your Meter for the first time to test your blood. Control Tests should also be performed:

• Occasionally as you use the vial of Test Strips,
• When opening a new vial of Strips,
• When Meter results seem unusually low or high, or
• If Meter damage is suspected,
  (Meter was dropped, crushed, gotten wet, etc.)

Quality Control Testing

To assure you are getting accurate and reliable results, TRUEresult offers three kinds of quality control tests. These tests let you know that your TRUEresult System is working properly and your testing technique is good.
Automatic Self-Test

An Automatic Self-Test is performed by the Meter each time a TRUEresult Test Strip is inserted correctly into the Test Port.

Insert a 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 call for assistance (see cover for phone number).

⚠️ If any segments are missing in the Display when Meter is first turned on, do not use the Meter for testing. Call for assistance.
Control Test

Control Tests check that the System is working properly and your testing technique is good.

Use **ONLY** TRUEresult Glucose Control to perform Control Tests.

There are two levels of TRUEresult Glucose Control Solution available that contain known amounts of glucose. It is important to perform Control Tests with more than one level of Control. See front cover for phone numbers to call for more information on obtaining different levels of Control.

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

*Do not drink Glucose Control.*
How to Test Glucose Control

1. Allow Control, vial of Strips and Meter to adjust to 15-30ºC (room temperature). Write date first opened on Control bottle label and Strip vial label.

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

2. Check dates on Control label and Strip vial label. Do not use Control or Strips if Expiry Dates have passed. (Control - 3 months after opening or date next to on label; Strips - 4 months after opening or date next to on labels.) Discard expired products and use new products.

3. Swirl or invert bottle gently to mix Control. **DO NOT SHAKE!**

4. Remove one Strip from vial. Close Strip vial immediately.

   **Note:** Use Strip quickly after removal from vial.

5. Insert Strip into Test Port. Meter turns on.

   **Note:** If Strip has been out of the vial too long before testing, an error message appears upon insertion of the Strip into the Meter. Release and discard old Strip. Use new Strip for testing.
6. Wait until Drop Symbol appears in Display. Keep Strip in Meter until testing is finished.

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

7. Turn Control bottle upside down. Squeeze one drop of Control onto a clean tissue. Wipe off bottle tip.

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

9. With Strip still in Meter, touch edge of Sample Tip to drop of Control. Allow drop to be drawn into Strip. Remove Strip from drop when Meter beeps.

10. 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 Strip. Repeat test with new Strip. If problem persists, see Troubleshooting.
11. Compare result to Control Range printed on Strip vial label for Control 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 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. Call for assistance (see front cover for phone number).


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

Refer to Lancing Device “Instructions for Use” for detailed instructions.

• **Never** share a lancet or lancing device.
• Lancets are for single use only. Do not reuse lancets.

From Fingertip

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

2. Place end of Lancing Device against tip of finger. Lance fingertip.

3. Set Lancing 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.

Always remove and discard used Lancet in appropriate container when testing is complete.
From Forearm

1. Select area to be lanced. Wash with soap and warm water, rinse and dry thoroughly.

2. Rub area vigorously or apply a warm dry compress to increase blood flow.

3. Place end of Lancing Device firmly against forearm. Press trigger button. Apply firm pressure on lancing device for 10 seconds.

Note: Some lancing devices include a special end cap for alternate site testing. Check lancing device Instructions for Use.

Important Notes Regarding Forearm Testing

• Check with your Doctor or Diabetes Healthcare Professional to see if forearm testing is right for you.

• Results from forearm are not always the same as results from finger.

• Use finger 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.
How to Test Blood Glucose

1. Check dates on Test Strip vial being used. Do not use if either 4 months after opening or after date printed next to 🗓 on label.

2. Wash hands (and forearm for alternate site testing). Rinse well and dry thoroughly.

3. Remove one Strip from vial. Close vial immediately.

   **Note:** Use 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 Strip in Meter until testing is finished.

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

   **Note:** To mark test as alternate site result, press “ + ” Button. ALT Symbol appears in Display. Press “ - ” to remove ALT Symbol.

5. Wait until Drop Symbol appears in Display.

6. Lance fingertip or forearm. Allow drop to form (see *Obtaining a Blood Sample*).
7. With Test Strip still in Meter, touch edge of Sample tip to blood drop and allow blood to be drawn into Strip. Remove Test Strip Sample Tip from sample drop immediately after the Meter beeps and dashes appear across Meter Display.

![Warning]

Holding the Test Strip Sample Tip to the blood sample too long after the Meter begins testing may cause inaccurate results.

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

8. Dashes appear across Display to show Meter is testing.

9. After the test is finished, result is displayed. The Strip Release Button flashes. Record result in log book.

10. Hold Meter with Strip pointing down. Press Strip Release Button to discard Strip in the appropriate container. Meter turns off. Result is stored in Memory with day, date and time.

**Note:** Removing Strip before result displays cancels the test. An error message appears and result is not stored in Memory. Retest with a new Strip and do not remove before result is displayed.
System Out of Range Warning Messages

⚠️

Meter reads blood glucose levels from 1.1-33.3 mmol/L (20-600 mg/dL).

If blood test result is less than 1.1 mmol/L (20 mg/dL), “Lo” appears in Meter Display.

If blood test result is greater than 33.3 mmol/L (600 mg/dL), “HI” appears in Meter Display.

ALWAYS repeat test to confirm Low (“Lo”) and High (“HI”) results. If results still display “Lo” or “HI”, call your Doctor or Diabetes Healthcare Professional immediately.

Note: “Lo” results are included in the Average as 1.1 mmol/L (20 mg/dL). “HI” results are included as 33.3 mmol/L (600 mg/dL).

If blood glucose test result is greater than 13.3 mmol/L (240 mg/dL), and Ketone Testing Alert is turned on, “Ketone” appears in Display with glucose result (see Ketone Testing Alert).

Note: Ketone Testing Alert can be turned on or off during Meter Set-up.
Meter Set Up

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. Press and hold “S” until the full Display is shown and a tone sounds (around 30 seconds). Release “S”. Meter goes into Set Up.

Set Time/Date

2. The hour flashes. To change, press “+” or “-” on top of the Meter to select the hour. Like many alarm clocks, to set “AM” or “PM”, scroll through the hours until “AM” or “PM” appears in the Display. Press “S” to set.

Note: “AM” or “PM” does not display if Meter is factory set to 24-hour clock.

3. The minutes flash. To change, press “+” or “-” to select the minutes. Press “S” to set.
4. The month (number) flashes. To change, press “+” or “-” to select the month. Press “S” to set.

5. The day (number) flashes. To change, press “+” or “-” to select the day. Press “S” to set.

6. The year flashes. To change, press “+” or “-” to select the year. Press “S” to set.

**Note:** Day of the week (Mon, Tue, Wed, Thu, Fri, Sat, Sun) self-adjusts when month, day or year are changed.

**Note:** Meter beeps every time a setting is confirmed (“S” is pressed).
Setting Alert
Ketone Testing Alert

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

When a blood glucose result is over 13.3 mmol/L (240 mg/dL), the Ketone Testing Alert is a reminder to check your ketones per your treatment plan.

1. After setting year, press “+” or “-” to turn Alert on or off. Press “S” to set.

⚠️ When a Ketone Testing Alert sounds, it does not mean that ketones have been detected in your blood. Perform a ketone test per your health plan, as prescribed by your Doctor or Healthcare Professional.
**Testing Reminder**

Up to four Testing Reminders per day may be set. Reminder sounds at set time for 10 seconds.

To set the Testing Reminders:

1. After pressing “S” to set Ketone Testing Alert, Display shows first Reminder setting (A-1). Press “+” (on) or “-” (off) to turn Reminder on or off.

2. If “on” is chosen, press “S”. The hour flashes. Press “+” or “-” to set the hour. To set AM/PM, scroll (press “+” or “-”) until “AM” or “PM” is next to correct time. Press “S” to set.

*Note:* “AM” or “PM” will not display if the Meter is factory set to 24-hour time format.

If “off” is chosen and the “S” is pressed, the Meter goes to the next Testing Reminder.

3. Press “+” (on) or “-” (off) to turn Reminder on or off.

4. The minutes flash. Press “+” or “-” to set the minutes. Press “S” to set.
5. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).

6. Press and hold “S” when finished to turn off Meter. Meter turns off after 2 minutes of non-use.

**Note:** If Alert or Testing Reminders are set, the Alert Symbol appears in all Displays.

**Note:** If battery dies or is replaced, Alerts and Testing Reminders may have to be reset.

**Exit Set-Up**
Press and hold “S” until Meter turns off. Set-up choices are saved.
Viewing Averages (7, 14 and 30-Day)

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

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

You can review the average of your glucose results from the last 7, 14, or 30 days.

1. Start with Meter off. Press and release “S” 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.
Viewing Results in Memory

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

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

2. Press “ + ” and release to advance to the first Control Test. Press “ + ” to scroll forward through blood results or “ - ” 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 (240 mg/dL) display Alert Symbol, when Ketone Testing Alert is turned on during user Meter Set Up.
Caring for TRUEresult
• Store System (Meter, Glucose Control, Test Strips) in Carrying Case to protect from liquids, dust and dirt.
• Store in a dry place at 2-30°C (room temperature).
DO NOT REFRIGERATE OR FREEZE.

Meter Care
• Wipe Meter with clean, lint-free cloth dampened with mild detergent/soap or 10% household bleach and water.
• Never put Meter in liquids or allow any liquids to enter Test Port.
• Do not use alcohol to clean Meter. Cleaning the Meter with alcohol WILL cause damage.

TRUEresult Glucose Control Care
• Write date opened on Control label. Discard if either 3 months after opening or after date printed next to □ on label has passed.
• After use, wipe bottle tip clean and recap tightly.
• Store at 2-30°C (room temperature).
DO NOT REFRIGERATE OR FREEZE.
TRUEresult Test Strip Care

- Store Strips in original vial only. Do not transfer old Strips to new vial or store Strips outside of vial.
- Write date opened on Strip vial. Discard unused Strips in vial if either 4 months after opening or after date printed next to ☑️ on label has passed. Use of Strips past either date may give incorrect results.
- Close vial immediately after removing Strip. Store Strip vial in a dry place below 30°C (room temperature). **DO NOT REFRIGERATE OR FREEZE.**
- Do not reuse Strips.
- Do not bend, cut or alter 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:

1. Lift tab on Battery Door.
2. Turn Meter over, tap 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 ("+") facing up. Close Battery Door.

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

5. Press "S" Button to turn Meter on and check time, date, and Testing Alerts and Reminders. (see Meter Set Up). 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". Call for assistance if problem persists.
Batteries 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.
# Troubleshooting

**1) After inserting Test Strip, Meter does not turn on.**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strip inserted upside down or backwards</td>
<td>Remove Strip. Re-insert correctly.</td>
</tr>
<tr>
<td>Strip not fully inserted</td>
<td>Remove Strip. Re-insert Strip fully into Meter.</td>
</tr>
<tr>
<td>Strip Error</td>
<td>Repeat with new Strip.</td>
</tr>
<tr>
<td>Dead or no battery</td>
<td>Replace battery.</td>
</tr>
<tr>
<td>Battery in backwards</td>
<td>Battery positive (“+”) side must face up.</td>
</tr>
<tr>
<td>Meter Error</td>
<td>Call for assistance.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Reason</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample drop too small</td>
<td>Repeat test with new Strip and larger drop.</td>
</tr>
<tr>
<td>Sample applied after two minute shut-off</td>
<td>Repeat test with new Strip. Apply sample within 2 minutes of inserting Strip.</td>
</tr>
<tr>
<td>Problem with Strip</td>
<td>Repeat with new Strip.</td>
</tr>
<tr>
<td>Problem with Meter</td>
<td>Call for assistance.</td>
</tr>
</tbody>
</table>

⚠️ For assistance, see cover for phone number.
<table>
<thead>
<tr>
<th>Messages Display</th>
<th>Reason Temperature Error</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-1</td>
<td>Too Cold/Too Hot</td>
<td>Move Meter and Strips to area between 10-40ºC; wait 10 minutes for System to reach room temperature before testing.</td>
</tr>
<tr>
<td>E-2</td>
<td>Sample Not Detected or Using Wrong Test Strip</td>
<td>Retest with new TRUEresult Test Strip and larger sample.</td>
</tr>
<tr>
<td>E-3</td>
<td>Used Strip or Test Strip Outside of Vial Too Long</td>
<td>Repeat with new Strip. If error persists, call for assistance.</td>
</tr>
<tr>
<td>E-4</td>
<td>Meter Error</td>
<td>Call for assistance.</td>
</tr>
<tr>
<td>E-5</td>
<td>Test Strip Error</td>
<td>Retest with new Strip. If error persists, call for assistance.</td>
</tr>
<tr>
<td>Display</td>
<td>Reason Strips Removed During Test</td>
<td>Action</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>E-6</td>
<td>Retest with new Strip. Make sure result is displayed before removing Strip.</td>
<td></td>
</tr>
<tr>
<td>E-8</td>
<td>Test Strip Error Wrong Test Strip used. Use only TRUEresult Test Strips.</td>
<td></td>
</tr>
<tr>
<td>E-9</td>
<td>Communication Error Call for assistance.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

**Out of Range - High Results**

>33.3 mmol/L (600 mg/dL)

**Out of Range - Low Results**

<1.1 mmol/L (20 mg/dL)

⚠️ Retest with new Strip. If result is still “HI” (High) or “Lo” (Low) contact Doctor immediately.

*If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call for assistance.*
FOR CONSUMERS • Performance Characteristics

Accuracy: Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L (15 mg/dL) of a laboratory method when the glucose concentration is less than 4.2 mmol/L (75 mg/dL), and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L (75 mg/dL) or higher. TRUEresult was tested by users at diabetes clinics, large urban hospitals, and diabetes care centers. The table below shows how often user TRUEresult fingertip values can achieve these goals. The fingertip data were compared to parallel results obtained on a Yellow Springs Instrument (YSI) Model 2300.

TRUEresult Finger Sample
< 4.2 mmol/L (75 mg/dL) (user finger vs. YSI)

| ±0.3 mmol/L (5 mg/dL) | 10/17 = 59% |
| ±0.6 mmol/L (10 mg/dL) | 15/17 = 88% |
| ±0.8 mmol/L (15 mg/dL) | 17/17 = 100% |

TRUEresult Finger Sample
≥ 4.2 mmol/L (75 mg/dL) (user finger vs. YSI)

| ±5%         | 155/359 = 43% |
| ±10%        | 281/359 = 78% |
| ±15%        | 330/359 = 92% |
| ±20%        | 354/359 = 99% |
The table below shows how often user TRUEresult forearm values achieve these goals when users’ glucose values are not fluctuating.

**TRUEresult Forearm Sample**
*< 4.2 mmol/L (75 mg/dL) (user forearm vs. finger)*

<table>
<thead>
<tr>
<th>Variation</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>±0.3 mmol/L (5 mg/dL)</td>
<td>3/6 = 50%</td>
</tr>
<tr>
<td>±0.6 mmol/L (10 mg/dL)</td>
<td>6/6 = 100%</td>
</tr>
<tr>
<td>±0.8 mmol/L (15 mg/dL)</td>
<td>6/6 = 100%</td>
</tr>
</tbody>
</table>

**TRUEresult Forearm Sample**
*≥ 4.2 mmol/L (75 mg/dL) (user forearm vs. finger)*

<table>
<thead>
<tr>
<th>Variation</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>±5%</td>
<td>180/370 = 49%</td>
</tr>
<tr>
<td>±10%</td>
<td>291/370 = 79%</td>
</tr>
<tr>
<td>±15%</td>
<td>335/370 = 91%</td>
</tr>
<tr>
<td>±20%</td>
<td>358/370 = 97%</td>
</tr>
</tbody>
</table>
FOR HEALTH-CARE PROFESSIONALS

Performance Characteristics

Accuracy: TRUEresult accuracy was assessed against the Yellow Springs Instrument (YSI) Model 2300. Studies were conducted at 4 clinical sites by Health-care Professionals.

Fingertip Capillary Blood (ISO15197: 2003 data finger vs. YSI):

N=376

Slope 0.98  y-intercept -0.14 mmol/L (-2.44 mg/dL)
$r^2$ 0.97  Range 3.2 - 26.4 mmol/L (57-475 mg/dL)

Venous Blood: N=342

Slope 1.02  y-intercept 0.12 mmol/L (2.07 mg/dL)
$r^2$ 0.98  Range 3.0 - 28.1 mmol/L (54 - 506 mg/dL)

98.4% of Health-care Professional (HCP) TRUEresult fingertip values fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 4.2 mmol/L (75 mg/dL) and within 20% at glucose levels ≥ 4.2 mmol/L (75 mg/dL).
Fingertip Capillary Blood  
< 4.2 mmol/L (75 mg/dL) (HCP finger vs. YSI)

<table>
<thead>
<tr>
<th>±0.3 mmol/L (5 mg/dL)</th>
<th>12/18 = 67%</th>
</tr>
</thead>
<tbody>
<tr>
<td>±0.6 mmol/L (10 mg/dL)</td>
<td>18/18 = 100%</td>
</tr>
<tr>
<td>±0.8 mmol/L (15 mg/dL)</td>
<td>18/18 = 100%</td>
</tr>
</tbody>
</table>

Fingertip Capillary Blood  
> 4.2 mmol/L (75 mg/dL) (HCP finger vs. YSI)

<table>
<thead>
<tr>
<th>±5%</th>
<th>182/358 = 51%</th>
</tr>
</thead>
<tbody>
<tr>
<td>±10%</td>
<td>297/358 = 83%</td>
</tr>
<tr>
<td>±15%</td>
<td>333/358 = 93%</td>
</tr>
<tr>
<td>±20%</td>
<td>352/358 = 98%</td>
</tr>
</tbody>
</table>

97.8% of Health-care Professional (HCP) TRUEresult forearm values fell within 0.83 mmol/L (15 mg/dL) of the fingertip results at glucose levels < 4.2 mmol/L (75 mg/dL) and within 20% at glucose levels ≥ 4.2 mmol/L (75 mg/dL) when users’ glucose values are not fluctuating.
**Forearm Capillary Blood**
*< 4.2 mmol/L (75 mg/dL) (HCP forearm vs. HCP finger)*

<table>
<thead>
<tr>
<th>±0.3 mmol/L (5 mg/dL)</th>
<th>6/9 = 67%</th>
</tr>
</thead>
<tbody>
<tr>
<td>±0.6 mmol/L (10 mg/dL)</td>
<td>8/9 = 89%</td>
</tr>
<tr>
<td>±0.8 mmol/L (15 mg/dL)</td>
<td>8/9 = 89%</td>
</tr>
</tbody>
</table>

**Forearm Capillary Blood**
*≥ 4.2 mmol/L (75 mg/dL) (HCP forearm vs. HCP finger)*

<table>
<thead>
<tr>
<th>±5%</th>
<th>176/367 = 48%</th>
</tr>
</thead>
<tbody>
<tr>
<td>±10%</td>
<td>293/367 = 80%</td>
</tr>
<tr>
<td>±15%</td>
<td>345/367 = 94%</td>
</tr>
<tr>
<td>±20%</td>
<td>360/367 = 98%</td>
</tr>
</tbody>
</table>
**Precision (Repeatability):** Precision describes the variation between results. Precision results were performed in a laboratory.

### Within Lot Precision (n=100)

<table>
<thead>
<tr>
<th>Mean (mmol/L)</th>
<th>2.7</th>
<th>4.8</th>
<th>7.1</th>
<th>12.7</th>
<th>19.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (mg/dL)</td>
<td>48</td>
<td>86</td>
<td>128</td>
<td>228</td>
<td>342</td>
</tr>
<tr>
<td>SD (mmol/L)</td>
<td>0.06</td>
<td>0.11</td>
<td>0.21</td>
<td>0.41</td>
<td>0.74</td>
</tr>
<tr>
<td>SD (mg/dL)</td>
<td>1.1</td>
<td>2.0</td>
<td>3.7</td>
<td>7.4</td>
<td>13.3</td>
</tr>
<tr>
<td>%CV</td>
<td>2.4</td>
<td>2.3</td>
<td>2.9</td>
<td>3.2</td>
<td>3.9</td>
</tr>
</tbody>
</table>

### Within-Vial Precision (n=10)

<table>
<thead>
<tr>
<th>Mean (mmol/L)</th>
<th>2.7</th>
<th>4.8</th>
<th>7.1</th>
<th>12.7</th>
<th>19.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (mg/dL)</td>
<td>48</td>
<td>86</td>
<td>128</td>
<td>228</td>
<td>342</td>
</tr>
<tr>
<td>SD (mmol/L)</td>
<td>0.06</td>
<td>0.10</td>
<td>0.21</td>
<td>0.32</td>
<td>0.68</td>
</tr>
<tr>
<td>SD (mg/dL)</td>
<td>1.0</td>
<td>1.8</td>
<td>3.7</td>
<td>5.7</td>
<td>12.3</td>
</tr>
<tr>
<td>%CV</td>
<td>2.1</td>
<td>2.1</td>
<td>2.9</td>
<td>2.5</td>
<td>3.6</td>
</tr>
</tbody>
</table>

### Glucose Control Precision (n=100)

<table>
<thead>
<tr>
<th>Mean (mmol/L)</th>
<th>2.4</th>
<th>7.2</th>
<th>17.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (mg/dL)</td>
<td>44</td>
<td>129</td>
<td>314</td>
</tr>
<tr>
<td>SD (mmol/L)</td>
<td>0.6</td>
<td>0.20</td>
<td>0.71</td>
</tr>
<tr>
<td>SD (mg/dL)</td>
<td>1.1</td>
<td>3.6</td>
<td>12.7</td>
</tr>
<tr>
<td>%CV</td>
<td>2.4</td>
<td>2.8</td>
<td>4.0</td>
</tr>
</tbody>
</table>
**Meter Specifications**

**Result Range:** 1.1-33.3 mmol/L (20-600 mg/dL)

**Sample Size:** Minimum 0.5 microlitre (0.5 µL)

**Sample:** Fresh capillary whole blood, venous blood drawn in sodium or lithium heparin tubes, or Glucose Control.

**Test Time:** Results in as little as 4 seconds

**Result Value:** Plasma values

**Assay Method:** Electrochemical

**Power Supply:** One 3V lithium battery

#CR2032 (non-rechargeable)

Total power when active at full battery = 8.6 mW

**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 glucose results

**System Operating Range (Meter & Test Strips):**

**Relative Humidity:** 10-90% (Non-condensing)

**Temperature:** 10-40ºC

**Haematocrit:** 25-60%

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

**Chemical Composition**

**TRUEresult Test Strips:** Glucose dehydrogenase-FAD (*Aspergillus sp.*), mediators, buffers and stabilisers.

**TRUEresult Glucose Control:** Contents: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.
References


