TRUEresult mini

BLOOD GLUCOSE MONITORING SYSTEM

NO CODING

For assistance, please call
1 800 451 737.

Nipro Australia Pty Ltd.
Suite 3, 500 Pacific Highway
St Leonards, NSW 2065

support@niproaustralia.com.au

NIPRO DIAGNOSTICS
2400 NW 55th Ct
Fort Lauderdale FL 33309 U.S.A.

N4IAU03FD Rev. 20

TRUEresult mini

BLOOD GLUCOSE MONITORING SYSTEM

Owner's Booklet

NO CODING

- FAST RESULTS
- EASY TO USE
- TINY SAMPLE SIZE

NIPRO

LIFETIME WARRANTY

TRUEresult mini

BLOOD GLUCOSE MONITORING SYSTEM

Fast Test Guide

Two simple steps

1 INSERT TEST STRIP

2 APPLY BLOOD SAMPLE

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.

Expected Results for people without diabetes:[1]

	Plasma Blood Glucose Result
Before eating	< 6.1 mmol/L
Two hours after meals	< 7.8 mmol/L

The TRUEresult mini 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.

Notes:

INTRODUCTION:

TRUEresult mini Blood Glucose Monitoring System

TRUEresult mini 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 mini 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 mini in a manner not specified in this Owner's Booklet is not recommended and may affect ability to determine true blood glucose levels.

FOR PATIENTS
IMPORTANT HEALTH and SAFETY INFORMATION:

WARNING!

- **NEVER** reuse Test Strips. **NEVER** wipe Test Strips with water, alcohol or any cleaner. **DO NOT** attempt to remove blood or Control Solution 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 Strip. Adding more sample gives an error message.

The TRUEresult mini Blood Glucose Monitoring System is for one person use **ONLY. DO NOT** share your Meter or your Lancing Device with anyone, including family members. **DO NOT** use on more than one person. **ALL** parts of your Blood Glucose Monitoring System could carry blood-borne pathogens after use, even after cleaning and disinfection.[2,3]

For cleaning and disinfecting your Meter, see Meter Care, Cleaning/Disinfection. For cleaning and disinfecting your Lancing Device see the Instructions for Use.

We suggest cleaning the Meter when visibly dirty. Wash your hands thoroughly with soap and warm water after handling the Meter, Lancing Device, or Test Strips as contact with blood presents an infection risk.

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.

Other Important Information for Healthcare Professionals:

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 mini and a laboratory system, perform a TRUEresult mini blood test within 30 minutes of laboratory test. Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is less than 4.2 mmol/L, and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L or higher.[1] If patient has recently eaten, fingerstick results from TRUEresult mini can be up to 3.9 mmol/L higher than venous laboratory results.[5]

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):[6]

- shock
- severe hypotension
- severe dehydration
- hyperglycaemia with hyperosmolarity, with or without ketosis

IMPORTANT INFORMATION:

For the most accurate results using TRUEresult mini:

IVD

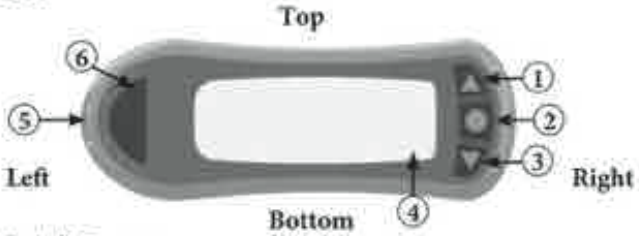
- **Read all instructions** before testing.
- TRUEresult mini is an *in vitro* (outside body) quantitative system that is used for self-testing and point-of-care (bedside) testing of human whole blood only.
- **Meter displays results as *Plasma* values.**
- **Use only TRUEresult** Test Strips and TRUEresult Control Solution with TRUEresult mini 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).
- When carrying your TRUEresult mini System with you, do not leave it where the storage temperature printed on vial label may be exceeded (car, boot, briefcase, etc).

Note: *Three levels of TRUEresult 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 Control Solution.*

- **Remove only one Strip at a time from vial when testing. Recap vial immediately after removing Strip.**
- **Do not use TRUEresult mini System during a xylose absorption test. This may falsely raise TRUEresult glucose results. Please check with your Doctor before using TRUEresult mini.**[7]
- **Ascorbic acid concentrations at or above 0.28 mmol/L may cause elevated meter glucose results.**[7]
- TRUEresult mini Blood Glucose Monitoring System is for one person use **ONLY. DO NOT** share your Meter or your lancing device with anyone, including family members. **DO NOT** use on more than one person. **ALL** parts of your Blood Glucose Monitoring System could carry blood-borne pathogens after use, even after cleaning and disinfection.[2]

Know Your System

Meter



① **" ▲ " Button**
Increase numbers in Time/Date Set Up;
add ALT Symbol; move forward by date/time when viewing results in Memory.

② **" ● " Button**
Turn Meter on to view Average values; to view results in Memory and to access Time/Date Set Up.

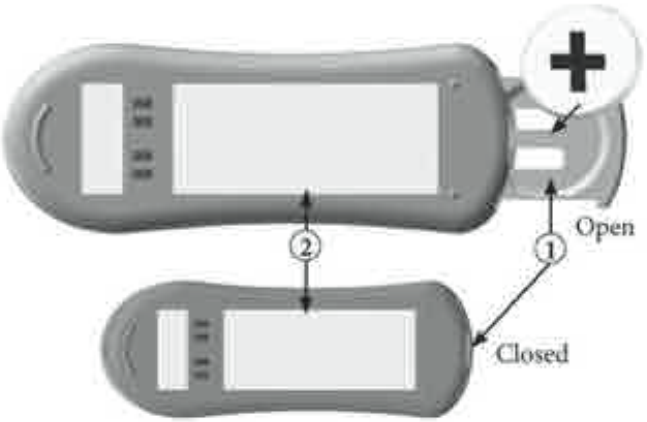
③ **" ▼ " Button**
Decrease numbers in Meter Set Up;
remove ALT Symbol; move backward by date/time when viewing results in Memory.

④ **Display Screen**
Shows results, messages, user prompts, information.

⑤ **Test Port**
Insert TRUEresult Test Strip here.

⑥ **Strip Release Button**
Press to release Strip after testing.

Back of Meter



① **Battery Tray**
Gently pull to slide open Battery Tray.
Use one non-rechargeable 3V lithium battery (#CR2032), positive ("+") side up (see *Changing Battery*).

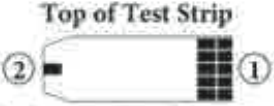
② **Meter Label**
Contains Serial Number of Meter.

Full Display Screen

Top

1. Result is from Memory
2. Low Battery Symbol
3. Test Result
4. Time, Date
5. Time is AM/PM
6. Units of Measure
   (Note: Factory set, cannot be changed by user.)
7. Result is from 7, 14 or 30 day Average
8. Control Symbol
9. Alternate Site (ALT) Symbol
10. Drop Symbol - Apply Blood or Control Solution sample

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 Control Solution) to edge of Tip.

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

Sample Placement

Correct Placement ***Incorrect Placement***

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

> ⚠ *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 Control Solution to top of Test Strip.*

Do not insert Sample Tip with sample into Meter for testing. May damage Meter.

Test Strip Vial Label

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

② **Use By Date ( )** - 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 Control Solution past the Use By Date may give incorrect test results. Discard out-of-date products and test with new products.*

③ **Control Solution Range** - Range of numbers in which Control Test result must fall to assure System is working properly.

Control Solution Bottle Label

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

② **Use By Date ( )** - Write date first opened on bottle label. Discard bottle if either 3 months after opening or date printed next to on bottle label has passed.

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

Getting Started

The Meter turns on when a Test Strip is inserted into the Test Port or when " ● " Button is pressed (see *Memory* and *Time and Date Set Up*). Meter turns off when the Strip is released from the Meter or after two minutes of non-use.

Meter comes with pre-set time and date. Before using the Meter for the first time or after a battery change, check the time and date. Update as needed (see *Time and Date Set Up*).

Quality Control Testing

To assure you are getting accurate and reliable results, TRUEresult mini offers two kinds of quality control tests. These tests let you know that your TRUEresult mini 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 right of the Display, and then
- the Drop Symbol begins to blink in the left side of Display.

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

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:

- For practice to ensure your testing technique is good,
- Occasionally as you use the vial of Test Strips,
- When opening a new vial of Strips,
- If results seem unusually low or high,
- If a vial has been left opened or exposed to extreme heat or cold, or humidity,
- If Meter damage is suspected (Meter was dropped, gotten wet, crushed, etc.).

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

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

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

*Ranges printed on 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

1. Allow Control Solution, vial of Strips and Meter to adjust to 20°C-25°C (room temperature). Write date first opened on Control Solution bottle label and Strip vial label.

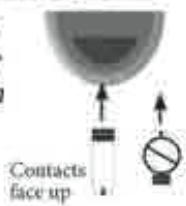
Note: *Running a Control Test at temperatures outside the range listed above may cause Control Solution to read as a blood test.*

2. Check dates on Control Solution label and Strip vial label. Do not use Control Solution or strips if Use By Date have passed (Control Solution - 3 months after opening or date next to on label, Strips - 4 months after opening or date next to on label). Discard expired products and use new products.
3. Swirl or invert bottle gently to mix Control Solution. **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.*



6. Wait until Drop Symbol appears in Display. Keep Strip in Meter until testing is finished.

Apply Sample

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

8. Gently squeeze a Control Solution 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 Solution. Allow drop to be drawn into Strip.

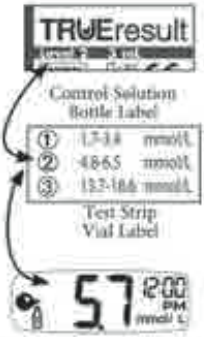
10. Dashes appear across the Display to show Meter is testing.

Meter Testing

Note: *If Meter does not 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 Solution Range printed on 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 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.*

12. After result is shown, hold Meter with Test Strip pointing down. Press Strip Release Button to release and discard Strip in appropriate container. Meter turns off.

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.

Note: *Used Strips and lancets are considered biohazardous. Dispose used Strips and lancets in approved biohazard container.*

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 the 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 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. Recap 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 use, an error message appears upon insertion of the Strip into the Meter. Release and discard old Strip. Use new Strip for testing.*

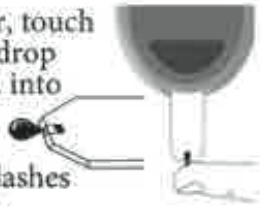
Note: *To mark test as alternate site result, press "▲" Button. ALT Symbol appears in Display. Press "▼" to remove ALT Symbol.*

5. Wait until Drop Symbol appears in Display.

ALT Symbol

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 dashes appear across Meter Display.



> ⚠ *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 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. Record result in log book.

10. Turn Meter so that the Strip is pointing down. Press the Strip Release Button to discard Strip in an appropriate container. Result is stored in Memory with 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.

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 your Doctor or Diabetes 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.*

Time and Date Set Up

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

1. Press and hold " ● " until the Full Display appears and the screen goes blank. Release " ● ". The Meter goes into Set Up.

Full Display

Set Time/Date

2. The hour flashes. To change, press " ▲ " or " ▼ " 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 " ● " 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 " ● " to set.

4. The month (number) flashes. To change, press " ▲ " or " ▼ " to select the month. Press " ● " to set.

5. The day (number) flashes. To change, press " ▲ " or " ▼ " to select the day. Press " ● " to set.

6. The year flashes. To change, press " ▲ " or " ▼ " to select the year. Press " ● " to set.

Exit Set-Up

Press and hold " ● " until Meter turns off. Set-up choices are saved.

Memory

Viewing Averages

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 range (see* How to Test Control Solution*), the Control Solution may read as a blood test and be included in the Averages.*

7-day Average

14-day Average

To review Averages:

1. Start 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.

30-day Average

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

No Average Result Available

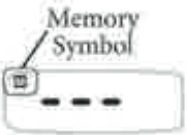
Viewing Results

Memory stores 500 results. When the Memory is full, the oldest result is replaced with the newest result. Only one Control Test is shown in Memory.

1. Press and release " ● " Button. Meter displays 7, 14 and 30-day Averages. Press and release " ● " again to view most recent Control Test result in Memory. If there are no results in Memory, dashes appear with Memory symbol.
2. Press " ▲ " and release to advance to the first blood test. Press " ▲ " to scroll forward through results or " ▼ " to scroll backwards through results.

Test results marked as alternate site display **ALT** Symbol.

Control Test result is displayed with the Control Symbol. If no Control Test has been done, Display shows dashes and the Control Symbol.



No Memory

Result From Memory

Alternate Site Result

Control Test Result

No Control Result

Caring for TRUEresult mini

- 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/Disinfection

Cleaning removes blood and soil, disinfecting removes infectious agents.

- We suggest cleaning your Meter when visibly dirty. Never put Meter in liquids or allow any liquids to enter the Test Port.
- Wipe Meter with a clean, lint-free cloth dampened with 70% Isopropyl alcohol.
- Let Meter air dry thoroughly before using to test.
- Do not use bleach to clean the Meter.

TRUEresult Control Solution Care

- Write date opened on Control Solution 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 close tightly.
- Store at 2°C-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 first opened on Strip vial. Discard unused Strips from 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 in a dry place at below 30°C (room temperature).

DO NOT REFRIGERATE OR FREEZE.

- Do not reuse Strip.
- 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 and then turns off.

To replace battery:

1. Gently slide Battery Tray open by pulling out using the slot at the top of the Meter.
2. Turn Meter upside down and tap gently to allow battery to drop out.
3. Discard old battery into appropriate container.
4. Insert new battery, positive ("+") facing up into Battery Tray. Slide Battery Tray closed. If Battery Tray does not close easily, reposition the battery and try to slide Tray closed again. Do not force Tray closed.

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

5. Press " ● " Button to turn Meter on and check time/date (*see* Time and Date 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 " ● ". 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

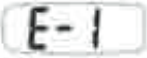
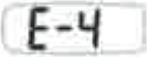
1) After inserting Test Strip, Meter does not turn on.

Reason	Action
Strip inserted upside down or backwards	Remove Strip. Re-insert correctly.
Strip not fully inserted	Remove Strip. Re-insert Strip fully into Meter.
Strip Error	Repeat with new Strip.
Dead or no battery	Replace battery.
Battery in backwards	Battery positive ("+") side must face up.
Meter Error	Call for assistance.

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

Reason	Action
Sample drop too small	Repeat test with new Strip and larger drop.
Sample applied after two minute shut-off	Repeat test with new Strip. Apply sample within 2 minutes of inserting Strip.
Problem with Strip	Repeat with new Strip.
Problem with Meter	Call for assistance.

For assistance, see cover for phone number.

Messages Display	Reason	Action
	**Temperature Error • Too Cold/ Too Hot**	Move Meter and Strips to area between 10°C - 40°C; wait 10 minutes for System to reach room temperature before testing.
	**Sample Not Detected or Using Wrong Test Strip**	Retest with new TRUEresult Test Strip and larger sample.
	**Used Strip or Test Strip Outside of Vial Too Long**	Repeat with new Strip. Make sure sample is touched to edge of Strip (not top). If error persists, call for assistance.
	**Meter Error**	Call for assistance.
	**Test Strip Error**	Retest with new Strip. If error persists, call for assistance.

Display	Reason	Action
	**Strip Removed During Test**	Retest with new Strip. Make sure result is displayed before removing Strip.
	**Memory Error**	Result was not recorded in Memory. Retest with new Strip. If error persists, call for assistance.
	**Communications Error**	Call for assistance.
	**Low or Dead Battery**	Low: About 50 tests can be done before battery dies. Dead: Battery Symbol appears before Meter turns off.
	**Out of Range High Results** > 33.3 mmol/L	⚠ Retest with new Strip. If result is still "HI" (High) or "Lo" (Low) contact Doctor ***immediately***.
	**Out of Range Low Results** < 1.1 mmol/L	

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

FOR CONSUMERS • Performance Characteristics[7]

Accuracy: Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is less than 4.2 mmol/L, and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L or higher.[4] TRUEresult mini was tested by users at diabetes clinics, large urban hospitals, and diabetes care centers. The table below shows how often user TRUEresult mini fingertip values can achieve these goals. The fingertip data were compared to parallel results obtained on a Yellow Springs Instrument (YSI) Model 2300.

TRUEresult mini Finger Sample
< 4.2 mmol/L (user finger vs. YSI)

±0.3 mmol/L	9/14 = 64%
±0.6 mmol/L	12/14 = 86%
±0.8 mmol/L	14/14 = 100%

TRUEresult mini Finger Sample
≥ 4.2 mmol/L (user finger vs. YSI)

±5%	145/330 = 44%
±10%	258/330 = 78%
±15%	314/330 = 95%
±20%	328/330 = 99%

The table below shows how often user TRUEresult mini forearm values achieve these goals when users' glucose values are not fluctuating.

TRUEresult mini Forearm Sample
< 4.2 mmol/L (user forearm vs. finger)

±0.3 mmol/L	9/13 = 69%
±0.6 mmol/L	10/13 = 77%
±0.8 mmol/L	13/13 = 100%

TRUEresult mini Forearm Sample
≥ 4.2 mmol/L (user forearm vs. finger)

±5%	172/329 = 52%
±10%	268/329 = 81%
±15%	309/329 = 94%
±20%	324/329 = 98%

FOR HEALTH-CARE PROFESSIONALS

Performance Characteristics[7]

Accuracy: TRUEresult mini accuracy was assessed against the Yellow Springs Instrument (YSI) Model 2300. Studies were conducted at 3 clinical sites by Health-care Professionals.

Fingertip Capillary Blood (ISO15197: 2003 data finger vs. YSI):[1] N=200

Slope 0.98 y-intercept -0.03 mmol/L
r^2 0.98 Range 1.3 - 27.7 mmol/L

Venous Blood: N=292

Slope 0.97 y-intercept 0.52 mmol/L
r^2 0.98 Range 2.0 - 29.2 mmol/L

100% of Health-care Professional (HCP) TRUEresult mini fingertip values fell within 0.83 mmol/L of the YSI results at glucose levels < 4.2 mmol/L and within 20% at glucose levels ≥ 4.2 mmol/L .

Fingertip Capillary Blood
< 4.2 mmol/L (HCP finger vs. YSI)

±0.3 mmol/L	25/35 = 71%
±0.6 mmol/L	33/35 = 94%
±0.8 mmol/L	35/35 = 100%

Fingertip Capillary Blood
≥ 4.2 mmol/L (HCP finger vs. YSI)

±5%	76/165 = 46%
±10%	122/165 = 74%
±15%	154/165 = 93%
±20%	165/165 = 100%

98.5% of Health-care Professional (HCP) TRUEresult mini forearm values fell within 0.83 mmol/L of the fingertip results at glucose levels < 4.2 mmol/L and within 20% at glucose levels ≥ 4.2 mmol/L when users' glucose values are not fluctuating.

Forearm Capillary Blood
< 4.2 mmol/L
(HCP forearm vs. HCP finger)

±0.3 mmol/L	12/16 = 75%
±0.6 mmol/L	16/16 = 100%
±0.8 mmol/L	16/16 = 100%

Forearm Capillary Blood
≥ 4.2 mmol/L
(HCP forearm vs. HCP finger)

±5%	173/324 = 53%
±10%	260/324 = 80%
±15%	304/324 = 94%
±20%	319/324 = 98%

Precision (Repeatability): Precision describes the variation between results. Precision results were performed in a laboratory.

Within Lot Precision (n=100)

Mean (mmol/L)	2.3	4.2	6.8	9.8	16.5
SD (mmol/L)	0.10	0.13	0.15	0.41	0.66
%CV	4.3	3.2	2.2	4.1	4.0

Within-Vial Precision (n=10)

Mean (mmol/L)	2.3	4.2	6.8	9.8	16.5
SD (mmol/L)	0.08	0.11	0.14	0.31	0.56
%CV	3.6	2.5	2.1	3.1	3.4

Control Solution Precision (n=100)

Mean (mmol/L)	2.5	6.2	17.2
SD (mmol/L)	0.06	0.21	0.74
%CV	2.6	3.4	4.3

System Specifications

Result Range: 1.1 - 33.3 mmol/L
Sample Size: Minimum 0.5 microlitre (0.5 µL)
Sample: Fresh capillary whole blood, venous blood drawn in sodium or lithium heparin tubes, or TRUEresult Control Solution
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 = 8.6mW
Battery Life: Approximately 2146 tests or 1.5 years
Automatic shut-off: After two minutes of non-use
Weight: 25.5 g w/out battery; 28.3 g with battery
Size: 8.4 cm x 3 cm x 15.2 cm
Memory Size: 500 blood glucose results, 1 Control Test result

Operating Range (Meter & Test Strips):
Relative Humidity: 10-90% (Non-condensing)
Temperature: 10°C - 40°C
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 Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

System Safety Information

Electromagnetic Compatibility

This meter meets the electromagnetic immunity requirements as per ISO 15197 Annex A. 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.

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Notes: