TRUEresult®

Owner's Booklet

**Use only with TRUEtest®
Blood Glucose Test Strips**

24/7 Customer Consultation
English or Spanish
**1-800-803-6025
1-954-677-9201**
www.niprodiagnostics.com

Manufactured by:

**NIPRO
DIAGNOSTICS**™

Fort Lauderdale, FL 33309 U.S.A.

TRUEresult®
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:

	Plasma Blood Glucose Result[1]
Before eating	**< 100 mg/dL**

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, visit our web site at: **www.niprodiagnostics.com**.

> *Caution! Please read complete Owner's Booklet and all product Instructions for Use.*

Additional instructions for use of the System in a professional multi-patient setting are included in the Quality Assurance/Quality Control Manual. The QA/QC Manual is available on our website www.niprodiagnostics.com, or call 1-800-803-6049 or 1-954-677-4599.

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 blood glucose results within your target range shows how well a treatment plan is working to control glucose levels. Keeping results within your target range 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.

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 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 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 diseases 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.

Caution!   *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:

- **DO NOT** use the TRUEresult System to test your blood glucose if you are undergoing peritoneal dialysis (dialysis through the abdomen/stomach area).

- **DO NOT** use the TRUEresult System to test your blood glucose if you are receiving medical treatment that contains sugars such as maltose or xylose (Extraneal˚, Icodial˚, immunoglobulins such as Octagam˚, or Orencia˚).

The treatments listed above may cause false high glucose results when testing with the TRUEresult System.[4]

Before using the TRUEresult System, check with your Doctor or Healthcare Professional if you think you may be receiving any of these treatments.

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 (hypoglycemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and trouble speaking.

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

FOR HEALTHCARE PROFESSIONALS IMPORTANT HEALTH and SAFETY INFORMATION:

DO NOT use the TRUEresult System for patients receiving the following treatments:

- Peritoneal dialysis using solutions containing icodextrin (Extraneal®, Icodial®) that is metabolized to maltose,
- Injections or infusions of solutions containing galactose or maltose, including some human immunoglobulin preparations (Octagam®, WinRho®, SDF Liquid, HepaGam B™),
- Xylose absorption testing,
- Intravenous solutions containing maltose,
- Any drugs that contain or metabolize to maltose, galactose, or xylose (Orencia®, Adept®, Bexxar®).

Using the TRUEresult System when receiving the above treatments may cause false high glucose results. False high results may lead to inappropriate therapy, which may result in coma or death.

Additional instructions for use of the System in a professional multi-patient setting are included in the Quality Assurance/Quality Control Manual. The QA/QC Manual is available on our website www.niprodiagnostics.com, or call 1-800-803-6049 or 1-954-677-4599.

Safe Practices Recommendations for Healthcare Professionals:

- At patient admission/presentation and periodically throughout the patient's stay at the facility, assess the presence and use of therapies containing interfering drugs (see previous page).

- Use only laboratory methods for monitoring blood glucose levels in patients receiving interfering drugs.

- If there are pre-print order sets for patients receiving interfering drugs, include a prescription to test blood glucose using only laboratory methods.

- Establish facility protocols to verify point-of-care (bedside) blood glucose results with laboratory results for patients who are unresponsive or unable to communicate.

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 drawn into EDTA (purple top tube) or heparin (green top tube) may be used. 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.[5] If the patient has recently eaten, fingerstick results from the TRUEresult System can be up to 70 mg/dL higher than venous laboratory results.[6]

Health Related Information 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):[7]

- shock
- severe hypotension
- severe dehydration
- hyperglycemia with hyperosmolarity, with or without ketosis.

IMPORTANT INFORMATION:

For the most accurate results using TRUEresult:

- **Read <u>all instructions</u>** before testing.
- TRUEresult is an in vitro (outside body) quantitative system that is used for self-testing and point-of-care testing of human whole blood only.
- **Meter displays results as *plasma* values.**
- **Use only TRUEtest** Test Strips and TRUEtest 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: Three levels of TRUEtest Glucose Control Solution are available for Quality Control Testing. It is important to perform Control Tests with more than one level of Control to assure your System is working properly and your testing technique is good. Contact place of purchase or call for assistance to obtain Control.*
- **Remove only one Strip at a time from vial when testing. Recap vial immediately after removing Strip.**
- When using the meter for the first time, check the unit of measure in the meter Display after performing a control or blood test. Result must display in the correct unit of measure (mg/dL).
- If the result does not display in the correct unit of measure, **DO NOT** use the meter and **DO NOT** use the meter result to determine treatment.

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.
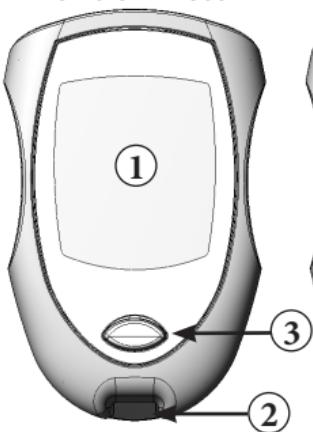
Front of Meter   **Back of Meter**
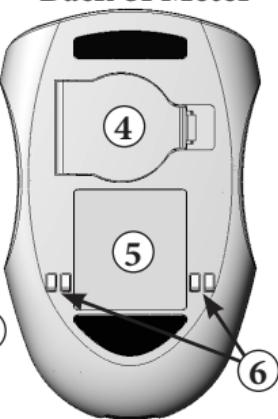
① **Display Screen**
Shows results, messages, user prompts, information.

② **Test Port**
Insert TRUEtest 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 and phone
number to call for assistance.

⑥ **Data Contacts**
Connects cradle to meter for data upload to a
computer.

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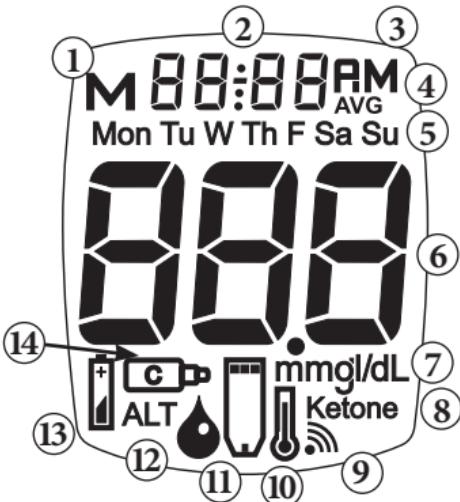
1. Result is from Memory
2. Time, Date
3. Time is AM/PM
4. Result is from 7, 14, or 30 day Average
5. Day of Week
6. Test Result
7. Units of Measure *(Note: Factory set, cannot be changed by user.)*
8. Ketone Test Alert
9. Testing Reminder
10. Temperature Symbol
11. Drop Symbol - Apply blood or Glucose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

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Test Strip

Top of 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 <u>before</u> touching Sample Tip to blood or Control drop.*

Sample Placement
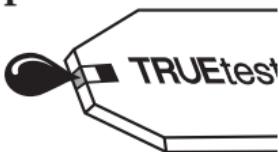
Correct Placement   *Incorrect Placement*

- Allow sample (blood or Glucose Control drop) to be drawn into Sample Tip until testing begins (Meter beeps and dashes move across Display).

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

Test Strip Vial Label

① **LOT**	L-003	
EXP	2017/10/31 ②	
③ 1	31-61	mg/dL
2	87-117	mg/dL
3	247-335	mg/dL
② *May 30, 2017*		

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

② **Expiration Dates (EXP)** - Write date first opened on vial label. Discard vial and unused Strips if either 4 months after opening or date printed next to **EXP** on vial label has passed, whichever comes first..

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

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

Glucose Control

Glucose Control Bottle Label

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

② **Expiration Dates (EXP)** - Write date first opened on bottle label. Discard bottle if either 3 months after opening or date printed next to **EXP** on bottle label has passed, whichever comes first.

③ **Control Level (1, 2, or 3)** - Three levels of TRUEtest 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*).

Quality Control Testing

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

Contacts Facing Up
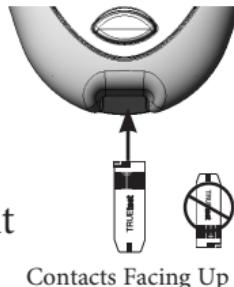
Automatic Self-Test

An Automatic Self-Test is performed by the Meter each time a TRUEtest 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,

Full Display

- the Drop Symbol begins to blink.
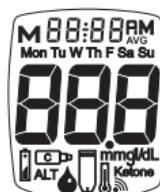
If an error message appears in the Display, the Meter will not perform a test. See *Troubleshooting* or call for assistance *(see cover for phone number)*.

> *Caution!* *If any segments are missing in the Display when Meter is first turned on, do not use the Meter for testing. Call for assistance.*

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Control Test

We recommend performing Control Tests for practice before using your Meter for the first time to test your blood.

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

Note: *Three levels of TRUEtest Glucose Control Solution are available for Quality Control Testing. It is important to perform Control Tests with more than one level of Control to assure your System is working properly and your testing technique is good. Contact place of purchase or call for assistance to obtain Control.*

Caution! *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

Use **ONLY** TRUEtest Glucose Control Solution with the TRUEresult Meter.

1. Allow Control, vial of Strips and Meter to adjust to 68°-77°F (room temperature). Write date first opened on both 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 Expiration Dates have passed. (Control - 3 months after opening or date next to EXP on label, whichever comes first; Strips - 4 months after opening or date next to EXP on labels, whichever comes first.) Discard expired products and use new products.

LOT 8LOA18
EXP 2017/10/31

LOT L-003
EXP 2017/10/31

1	31-61	mg/dL
2	87-117	mg/dL
3	247-335	mg/dL

May 30, 2017

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.

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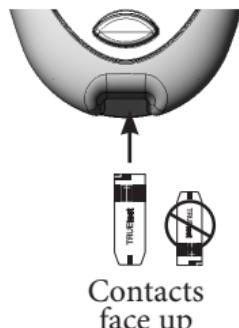
6. Wait until Drop Symbol appears in Display. Keep Strip in Meter until testing is finished.

12:00AM

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

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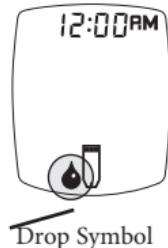
7. Turn Control bottle upside down. Squeeze one drop of Control onto a clean tissue. Wipe off bottle tip.

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.

TRUEtest

10. Dashes appear across the Display to show Meter is testing.
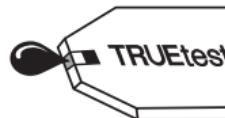
Note: *If Meter does not beep and begin testing soon after drawing up sample, release and discard Strip. Repeat test with new Strip. If problem persists, see* Troubleshooting.
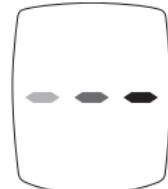
Meter testing

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.*

Note: *When using the meter for the first time, check the unit of measure in the meter Display after performing a control or blood test. Result must display in the correct unit of measure (mg/dL). If the result does not display in the correct unit of measure, **DO NOT** use the meter and **DO NOT** use the meter result to determine treatment.*

TRUEtest™
Glucose Control/Control de Gluco
Level/Nivel 2   3 mL

Glucose Control
Bottle Label

| 1 | 31-61 | mg/dL |
| 2 | 87-117 | mg/dL |
| 3 | 247-335 | mg/dL |

Test Strip
Vial Label

12:00PM

110 mg/dL

Control Symbol
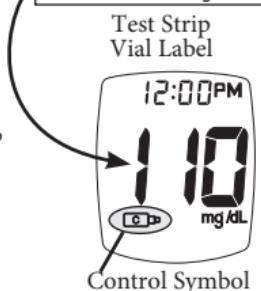
Caution! *If Control Test result is outside range, test again. If result is still outside range, System should not be used for testing blood. Call for assistance (see cover for phone number).*

12. After result is shown, Strip Release Button flashes. 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.*
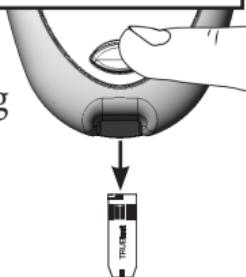
Obtaining a Blood Sample

Refer to Lancing Device "Instructions for Use" for detailed instructions.

Caution!	*The Lancing Device is for single patient use ONLY. For cleaning/disinfecting your Lancing Device see Lancing Device Care in the Lancing Device Instructions for Use. Wash your hands thoroughly with soap and warm water after handling the Meter, Lancing Device, or Test Strips. Contact with blood presents an infection risk.*

• Never share lancets or lancing device.

• Lancets are for single use only. Do not re-use.

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 massaging finger from palm to fingertip. Allow blood drop to form before attempting to apply to Test Strip.

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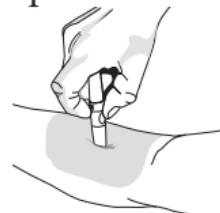
Note: *Some lancing devices include a special end cap for alternate site testing. Check lancing device Instructions for Use.*

Important Notes Regarding Forearm Testing[8]

- 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 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.

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 **EXP** on label, whichever comes first.

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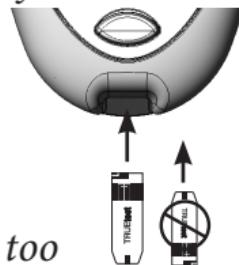
Note: *If Strip has been out of the vial too long before testing, an error message appears upon insertion of the Strip into the Meter. Release and discard old Strip. Use new Strip for testing.*

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).*

Drop Symbol

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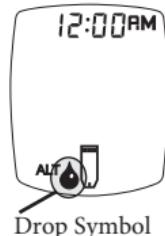
7. With Test Strip still in Meter, touch edge of Sample tip to blood drop and allow blood to be drawn into Strip. Remove Test Strip Sample Tip from sample drop immediately after the Meter beeps and dashes appear across the Meter Display.

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. Remove Strip from drop.

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

Note: *When using the meter for the first time, check the unit of measure in the meter Display after performing a control or blood test. Result must display in the correct unit of measure (mg/dL). If the result does not display in the correct unit of measure, **DO NOT** use the meter and **DO NOT** use the meter result to determine treatment.*

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.*
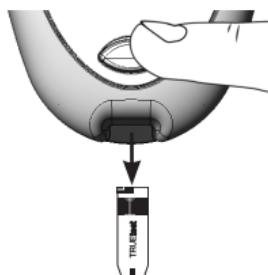
System Out of Range Warning Messages

WARNING!

Meter reads blood glucose levels from 20-600 mg/dL.

If blood test result is less than 20 mg/dL, "**Lo**" appears in Meter Display.

If blood test result is greater than 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 20 mg/dL. "**Hi**" results are included as 600 mg/dL.*

If blood glucose test result is greater than 240 mg/dL, and Ketone Testing Alert is turned on, "Ketone" appears in Display with glucose result (see *Ketone Testing Alert*).

Ketone 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.*
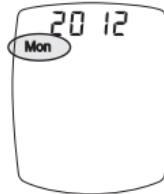
Note: *Meter beeps every time a setting is confirmed (" S " is pressed).*

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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 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.

Caution! *When a Ketone Testing Alert is shown in the Display, 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.

Ketone Testing Alert

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).

OFF
A-2

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

OFF
A-3

OFF
A-4

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

08:30AM
120
mg/dL

Alert Symbol

Note: *If battery dies or is replaced, Alert 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.
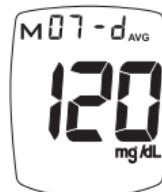
7-Day Average

14-Day Average
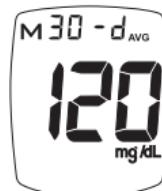
30-Day Average

No Average

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 Control Test 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 blood test. Press " + " to scroll forward through results or " - " to scroll backwards through results.

Alternate Site Symbol

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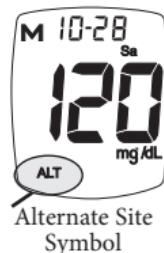
Control Symbol

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

Ketone Testing Alert
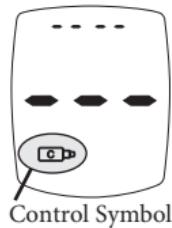
Test results above 240 mg/dL display Alert Symbol, when Ketone Testing Alert is turned on during user Meter Set Up.

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 room temperature (36-86°F). **DO NOT REFRIGERATE OR FREEZE.**
- Do not keep meter in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.)

Meter Care, Cleaning/Disinfection
Cleaning removes blood and soil, disinfecting removes infectious agents.

To Clean the Meter (removing blood or soil):

- We suggest cleaning the 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.

For assistance contact Customer Care using the phone number on the cover of the Owner's Booklet.

For Healthcare Professionals, please refer to the Quality Assurance/Quality Control Manual for instructions on Meter care, cleaning and disinfection.

The QA/QC Manual is available on our website www.niprodiagnostics.com, or call 1-800-803-6049 or 1-954-677-4599.

TRUEtest Glucose Control Care

- Write date opened on Control label. Discard if either 3 months after opening or after date printed next to **EXP** on label has passed, whichever comes first.
- After use, wipe bottle tip clean and recap tightly.
- Store at room temperature (36-86°F).
  DO NOT REFRIGERATE OR FREEZE.

TRUEtest 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 from vial if either 4 months after opening or after date printed next to **EXP** on label has passed, whichever comes first. Use of Strips past either date may give incorrect results.
- Close vial immediately after removing Strip. Store in a dry place at room temperature below 86°F.
  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, beeps, and then turns off.

Low

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.

Tab

Battery Door

3. Discard old battery into appropriate container.
4. Insert new battery, positive ("+") facing up. Close Battery Door.
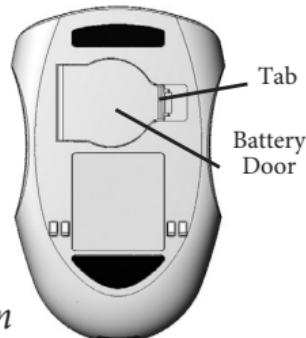
Note: *Use non-rechargeable 3V lithium battery (#CR2032).*

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.

*Warning! Battery is not rechargeable. If you have a cable or a cradle for downloading results to a computer, **DO NOT** plug the usb cable end into an electrical outlet. Trying to recharge the battery or power the meter by plugging into an electrical outlet will cause meter to catch on fire or melt.*

Caution! *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.*

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 beep or 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
$E - 1$	**Temperature Error** • **Too Cold/ Too Hot**	Move Meter and Strips to area between 50-104ºF; wait 10 minutes for System to reach room temperature before testing.
$E - 2$	**Sample Not Detected or Using Wrong Test Strip**	Retest with new TRUEtest Test Strip and larger sample.
$E - 3$	**Used Strip, Strip outside of vial too long, Sample on top of Strip.**	Repeat with new Strip. Make sure sample is touched to edge of Strip (not top). If error persists, call for assistance.
$E - 4$	**Meter Error**	Call for assistance.
$E - 5$	**Test Strip Error, Very high blood glucose result (higher than 600 mg/dL)**	Retest with new Strip. If error persists, call for assistance. If you have symptoms such as fatigue, excess urination, thirst, or blurry vision, follow your healthcare professional's advice for high blood glucose.

Display	Reason	Action
E-6	**Strip Removed During Test**	Retest with new Strip. Make sure result is displayed <u>before</u> removing Strip.
E-8	**Meter Error**	Call for assistance.
E-9	**Communication Error**	Call for assistance.
(battery symbol)	**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.
12:00 **Hi** / 12:00 **Lo**	**WARNING!! Out of Range - High Results** > 600 mg/dL **Out of Range - Low Results** < 20 mg/dL	**WARNING!!** 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.

<u>System Specifications</u>
Result Range: 20-600 mg/dL
Sample Size: Minimum 0.5 microliter (0.5 μL)
Sample: Fresh capillary whole blood, venous blood drawn
       in EDTA or 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)
Battery Life: Approximately 2146 tests or 1.5 years
Automatic shut-off: After two minutes of non-use
Weight: 1.66 ounces
Size: 3.44" x 2.16" x 0.69"
Memory Size: 500 glucose results

Operating Range (Meter & Test Strips):
       Relative Humidity: 10-90% (Non-condensing)
       Temperature: 50-104°F
       Hematocrit: 20-60%
Note: *Use within specified environmental*
        conditions only.

Chemical Composition
TRUEtest Test Strips: Glucose dehydrogenase-PQQ
(Acinetobacter calcoaceticus), mediators, buffers and
stabilizers.
TRUEtest Glucose Control: Contents: Water,
d-glucose, buffers, viscosity enhancing agent, salts,
dye and preservatives.

TRUEresult Limited Lifetime Warranty

Nipro Diagnostics, Inc. provides the following Warranty to the original purchaser of the TRUEresult Blood Glucose Meter:

1) Nipro Diagnostics Inc. warrants this Meter to be free of defects in materials and workmanship at the time of purchase. If the meter is ever inoperative, Nipro Diagnostics, Inc will replace the Meter with an equivalent Meter, at its option, at no cost to the purchaser. Failure of the meter due to abuse or use not in accordance with the instructions for use is not covered by this Warranty.

2) This Warranty does not include the battery supplied with the Meter.

3) Do not take the Meter apart. This action will void the Warranty and cause the Meter to display false results.

4) The duration of any implied Warranty, including any implied Warranty of merchantability or fitness for a particular purpose shall be limited to the lifetime in use with the original user in accordance with any state law to the contrary.

5) Nipro Diagnostics, Inc. disclaims liability for incidental or consequential damages for breach of any expressed or implied Warranty, including any implied Warranty of merchantability or fitness for a particular use with respect to the Meter. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusion may not apply.

6) This Warranty gives the user specific legal rights, and the user may also have other rights which vary state to state.

Your Nipro Diagnostics, Inc. Customer Care Representative will be able to provide detailed information regarding procedures for returning your Meter, if necessary.

References
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2. FDA Public Health Notification: *Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication (2010)* http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices.
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4. U.S. Food and Drug Administration, Center for Biologics Evaluation and Research. *Important Safety Information on Interference With Blood Glucose Measurement Following Use of Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products.* [Electronic Version]. Retrieved June 30, 2009. www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm.
5. Data on file.
6. Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests.* Scand J Clin Lab Invest 36:805-808, 1976.
7. Atkins, S. H., Dasmahapatra, A., Jaker, M.A., Chorost, M. I., Redd, S., *Fingerstick Glucose Determination in Shock.* Annals of Internal Medicine, 114:1020-1024, 1991.
8. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter.* [Electronic Version]. Retrieved December 22, 2009 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.html.

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