TRUEbalance®

Owner's Booklet

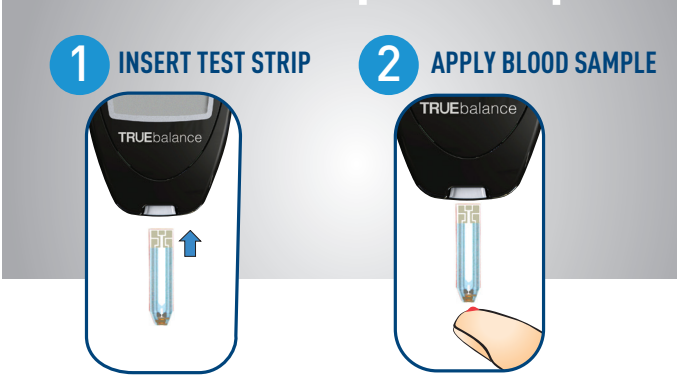
24/7 Customer Consultation
English or Spanish **1-800-803-6025**
www.niprodiagnostics.com

Manufactured by:
NIPRO DIAGNOSTICS™
Fort Lauderdale, FL 33309 U.S.A.

H4NPD03 Rev. 26

TRUEbalance®

Two simple steps



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.

Welcome to the TRUEbalance® Blood Glucose Monitoring System

Congratulations on your purchase of the TRUEbalance Blood Glucose Monitoring System. You now have a very simple and accurate way to test your blood glucose (sugar) level, anytime, anywhere. TRUEbalance is a no-coding system, which means the Meter does not have to be coded to each lot of Test Strips.

Our Commitment to You

Our goal is to provide you with quality healthcare products and dedicated customer service. If you have questions about using TRUEbalance products, visit our web site at: **www.niprodiagnostics.com**.

Instructions for use of the System for more than one person may be found in the Quality Assurance/ Quality Control Manual. The QA/QC Manual is available on our website www.niprodiagnostics.com or call 1-800-803-6025 or 1-954-677-4599.

CAUTION! Please read complete Owner's Booklet and all product Instructions for Use.

Expected Results for people without diabetes[1]:

	Plasma Blood Glucose Result
Before eating	< 100 mg/dL

Importance of Blood Glucose Monitoring

The more you know about diabetes, the better you will be able to take care of yourself. A Doctor or Diabetes Healthcare Professional will determine your target range for your blood glucose results and how often to test. Having the majority of your results within your target range helps slow or stop complications of diabetes.

Having most blood glucose results within your target range shows how well a treatment plan is working to control glucose levels. NEVER change your treatment plan without consulting with your Doctor or Diabetes Healthcare Professional.

Use of the TRUEbalance in a manner not specified in this Owner's Booklet is not recommended and may affect your ability to determine your blood glucose.

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 sample from Test Strips or clean Test Strips and re-use. Reuse of Test Strips will cause inaccurate results.

DO NOT add a second drop of sample to the Strip. Adding more sample gives an error message.

The TRUEbalance Blood Glucose Monitoring System is for one person use **ONLY. DO NOT** share your Meter or your Lancing Device with anyone, including family members. **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 and disinfecting 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.*

IMPORTANT INFORMATION:

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):[4]

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

If you have any of these symptoms, check your blood glucose. 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.

Important Information

For the most accurate results using TRUEbalance:

- **Read all instructions** before testing.
- **Meter displays results as plasma values**.
- TRUEbalance 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.
- **Use only TRUEbalance** Test Strips and TRUEcontrol Glucose Control with TRUEbalance Meter.
- **Do not use for diagnosis of diabetes or for testing blood glucose in newborns.**
- **The TRUEbalance is recommended for testing of human capillary whole blood only.** TRUEbalance is not recommended for use with venous samples.
- **Perform Quality Control Testing *before*** performing a blood test for the first time.

Note: *Three levels of TRUEcontrol Glucose Control Solution are available for Quality Control Testing. We recommend testing at least 2 levels of Control. Contact place of purchase or call for assistance to obtain Control.*

- **Set date and time** for correct Morning Average values.
- 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.

Health Related Information

For Healthcare Professionals:

If comparing results between TRUEbalance and a lab system, perform a TRUEbalance blood test within 30 minutes of lab test. Results from TRUEbalance are considered accurate if within +/– 20% of lab results.[5] If patient has recently eaten, fingerstick results from TRUEbalance can be up to 70 mg/dL higher than venous lab results.[6] Do not use venous blood with TRUEbalance.

Instructions for use of the System for more than one person may be found in the Quality Assurance/ Quality Control Manual. The QA/QC Manual is available on our website www.niprodiagnostics.com or call 1-800-803-6025 or 1-954-677-4599.

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Know Your System

Meter

Top of Meter

Front of Meter

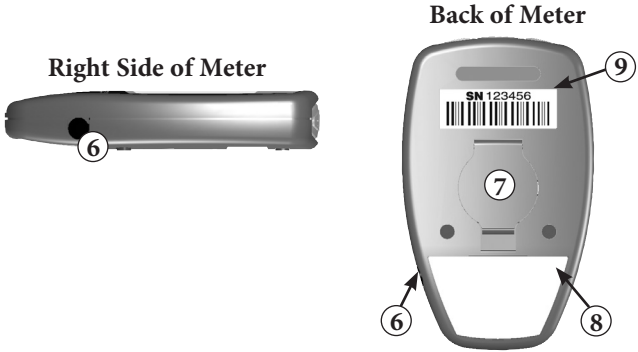
① **Button** - Decrease numbers in Set Up; remove Control Symbol; move backward by time/date when viewing results in Memory.

② **Button** - Select settings; view Morning Average values; view results in Memory.

③ **Button** - Increase numbers in Set Up; add Control Symbol; move forward by time/date when viewing results in Memory.

④ **Display** - Shows test results, messages, user prompts, and other information.

⑤ **Test Port** - Insert TRUEbalance Test Strip here.



⑥ **Data Port** - For data download to a computer using the usb cable. Contact Customer Care at the number located on cover for more information.

Caution! *Do not try to recharge battery by plugging usb cable into a power outlet. Meter will be destroyed.*

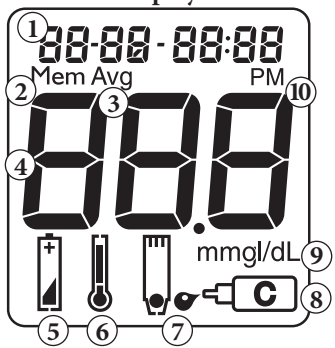
⑦ **Battery Compartment** - Use one non-rechargeable 3V lithium battery (#CR2032), positive ("+") side up.

Note: *See* Changing Battery *for details.*

⑧ **Meter Label** - Contains telephone number for assistance.

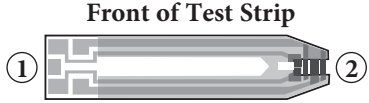
⑨ **Serial Number Label** - Identifies Meter when calling for assistance.

Display



1. Time, Date, 14/30 Day Average.
2. Result in Memory.
3. 14- or 30-Day Morning Average.
4. Test result.
5. Battery Symbol (see *Display Messages*).
6. Temperature Symbol (see *Display Messages*).
7. Drop Symbol - Apply blood or Glucose Control.
8. Control Symbol (see *Control Test*).
9. Unit of Measure.
   Note: *Factory Set. Cannot be changed by user.*
10. Time is P.M.
    Note: *"AM" does not appear. "PM" is not an option if factory set for 24-hour clock.*

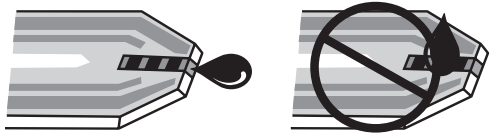
Test Strip



① **Contact End** - Insert into Meter with Contacts (metallic blocks) facing up ***before*** adding sample.

② **Sample Tip** - Touch sample (blood or Glucose Control) to edge of Tip.

Placement of Sample to Test Strip



Correct ***Incorrect***

- Allow sample (blood or Glucose Control drop) to be drawn into Sample Tip.

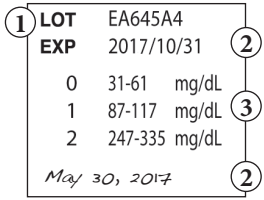
Caution! *Holding the Test Strip Sample Tip to the blood sample too long after the Meter begins testing may cause inaccurate results.*

- Do not smear or scrape drop with Strip.
- Do not apply more sample to Strip after removing from drop.

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

② **Expiration Dates (EXP)** - Write date first opened on vial label. Discard vial and unused Test Strips 120 days after written date or date printed next to EXP, whichever comes first.

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

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.*

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 (0, 1, or 2)** - Three levels of TRUEcontrol Control are available. We recommend testing at least 2 levels of Control. Contact place of purchase or call for assistance to obtain Control.

Getting Started

The Meter turns on automatically when a Test Strip Contact End is inserted into the Test Port or when S is pressed (*see* Set Up *and* Memory).

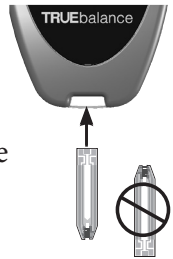
The Meter turns off automatically after the Test Strip is removed from the Test Port or after 2 minutes of non-use.

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 and update as needed (*see* Set Up).

The TRUEbalance is a no-coding system, which means that the Meter does not have to be coded to each lot of Test Strips.

Quality Control Testing

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

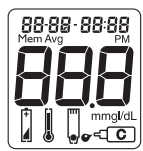


Automatic Self-Test

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

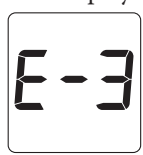
Insert a Strip into the Test Port. The Meter is working properly if:

- the full Display appears, then
- the time appears in the upper part of the Display, and then,
- the Drop Symbol begins to blink.



Full 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).



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.*

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.*

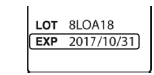
Caution! *Control ranges printed on Test Strip vial label are for Control Test results only and* ***<u>are not</u>*** *suggested levels for your blood glucose.* ***Do not drink Glucose Control.***

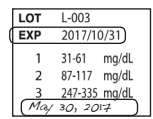
Only the most current Control Test result is stored in Memory.

How to Test Glucose Control

Use **ONLY** TRUEcontrol Glucose Control Solution with the TRUEbalance Meter.

1. Wash hands with soap and water, dry thoroughly. Allow Control, vial of Strips and Meter to adjust to room temperature (68-77°F). Write date first opened on Control Label and/or Strip vial label.
2. Check dates on Control label and Strip vial label. Do not use Control if 3 months past written opened date *or* past date printed next to EXP, whichever comes first. Do not use Strips 120 days past written opened date *or* past date printed next to EXP, whichever comes first. Discard out-of-date products and use new products if either date has passed.
3. Swirl or invert bottle gently to mix Control. **DO NOT SHAKE**!
4. Remove Strip from vial. Recap vial immediately.

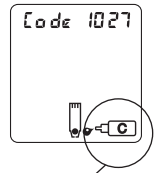




Note: *Use Strip quickly after removal from vial. Strips that have been left out of vial too long will give an error message. If error message appears in Display, discard old Strip and test with new Strip.*

5. Insert Test Strip Contact End (Contacts facing up) into Test Port. Meter turns on. Keep Strip in Meter until testing is finished.

6. Press + . Control Symbol appears in Meter Display.

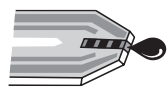


Note: *If you decide not to perform a Control Test, press − to remove Control Symbol.*

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

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

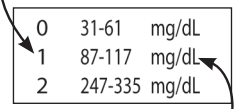
9. With Strip still in Meter, touch edge of Sample Tip to drop of Control and allow drop to be drawn into Strip. Remove Strip from drop when Meter beeps.

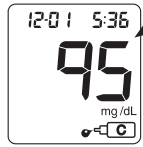


Note: *If Meter does not beep and begin countdown soon after placing Sample Tip to Control drop, discard Strip. Repeat test with new Strip. If problem persists, see* Troubleshooting.

10. Compare result to Control range printed on Strip vial label.

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.*

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).*

11. Remove Strip from Meter and discard. Meter turns off. Recap Control bottle tightly.

How to Obtain 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.

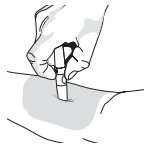
3. Set Lancing Device aside. To help blood drop form, lower hand to waist level, gently massaging finger from palm to fingertip. Allow blood drop to form before attempting to apply to Test Strip.

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.*

For Forearm Testing

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[7]

- 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

Always check your supplies before using. Check Meter for damage (damaged or cracked Display, missing or damaged buttons). If any damage is seen, do not use Meter. Call for assistance. Check Strip vials for damage. Discard any vials that appear cracked or broken.

1. Check dates on Strip vial being used. Do not use if 120 days past written date or date printed next to EXP, whichever comes first.
2. Wash hands (and forearm for alternate site testing). Rinse well and dry thoroughly.
3. Remove Strip from vial. Recap vial immediately.

Note: *Use Strip quickly after removal from vial. Strips that have been left out of vial too long will give an error message when used. Discard old Strip and use new Strip for testing.*

4. With Meter off, insert Test Strip Contact End (Contacts facing up) into Test Port. Meter turns on. Keep Strip in Meter until testing is finished.

5. Wait until Drop Symbol appears in Display.
6. Lance fingertip or forearm. Allow drop to form.
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 starts to countdown on Meter Display.

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

Note: *If Meter did not beep and begin countdown 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. After countdown, result is displayed with date and time. Remove Strip and discard. Result is stored in Memory. Meter turns off.

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.*

9. Record result in log book.

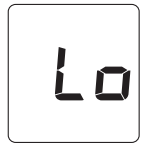
Note: *Used Strips and lancets are considered biohazardous. Dispose of used Strips and lancets in approved biohazard container.*

System Out of Range Warning Messages

CAUTION!

TRUEbalance measures blood glucose results from 20-600 mg/dL.

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



If blood glucose result is greater than 600 mg/dL, "**Hi**" appears in Meter Display.

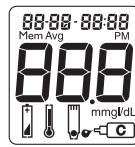
Always repeat test to confirm Low ("**Lo**") and High ("**Hi**") results. If results still display "**Lo**" or "**Hi**", call your Doctor or Diabetes Healthcare Professional ***immediately***.

Note: *"**Lo**" results are included in the Morning Average as 20 mg/dL. "**Hi**" results are included as 600 mg/dL.*

Set Up (Time/Date)

1. Start with Meter off. Do not insert Test Strip.

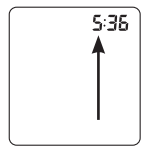
Press and hold S. Date/Time appears in display. Release **after** full Display appears and Meter beeps.



Full Display

Set Time

2. The hour flashes.
To change, press + or − on top of Meter to select the hour. Like many alarm clocks, to set "PM", scroll through hours until "PM" appears in Display.



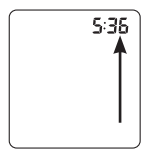
Hour

Note: "PM" does not display if Meter is factory set to 24-hour clock.

Press S to set.

PM

3. The minutes flash.
To change, press + or − to select the minutes. Press S to set.



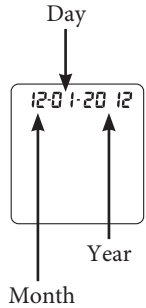
Minutes

Set Date

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.



Exit Set-up

To review settings, press S. Make changes as needed, per instructions above.

Press and hold S until Display goes blank. Options are saved. Meter turns off.

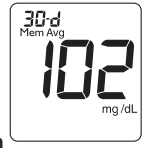
Memory

Morning Averages (14 and 30 Day)

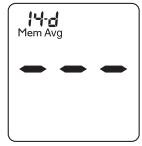
For Morning Average values, only the earliest blood test result performed between 4:00 am - 9:59 am (according to Meter clock) is used. Meter clock must be set correctly (see *Set Up*) for accurate Morning Average values.

1. Start with Meter off. Press and release S. Display shows 14 day Morning Average value and then 30 day Morning Average value.
2. Meter switches between 14 and 30 day Morning Average values for 2 minutes before turning off.
3. If there are no Morning Average values, 3 dashes are displayed.
4. Press and release S to view results in Memory. Press and hold S to turn Meter off, or Meter turns off after 2 minutes of inactivity.

14 Day Average



30 Day Average

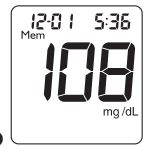


No Averages

Viewing Results in Memory

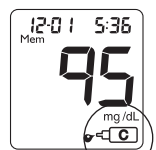
Memory stores 365 results, which are displayed from most recent to oldest. The oldest result is removed from Memory when Memory is full and a new result is added.

1. Start with Meter off. Press and release S. Meter displays date and time followed by 14 and 30 Day Morning Averages. Press S again to view most recent result in Memory.



Memory

2. Press + and release to advance to the first blood glucose result in Memory.
3. Press + and release again to view the latest Control Test result. The control test result shows the Control Symbol in Display. Only one Control Test result is stored in Memory.



Control Symbol

4. Continue to press and release + to advance through the blood glucose results. Holding + scrolls through the results quickly. Press and release the − to reverse through the results.
5. Press and hold S to turn Meter off. Meter also turns off automatically after 2 minutes of inactivity.

Caring for TRUEbalance

- Store System (Meter, Glucose Control, Test Strips) in Carrying Case to protect from liquids, dust and dirt.
- Store System 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 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.

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/Disinfection.

The QA/QC Manual is available on our website www.niprodiagnostics.com or call 1-800-803-6025 or 1-954-677-4599.

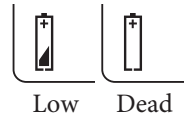
Glucose Control Care

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

Test Strip Care

- Store Strips in original vial only. Do not transfer old Strips to new vial.
- Write date opened on vial. Discard unused Strips from vial 120 days after opening or after date printed next to EXP, whichever comes first. Use of Strips past either date may give incorrect results.
- Close vial immediately after removing Strip. Use Strip quickly after removal from vial. Never store Strips outside of vial. 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



Replace battery when Low or Dead Battery Symbol appears in Display or Meter does not turn on.

1. Lift tab on Battery Cover.
2. Turn Meter over, tap gently to loosen and remove battery.
3. Insert new battery, positive ("+") side up. Close cover.

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

4. Discard old battery in appropriate container.
5. Turn Meter on. If Meter will not turn on, check that battery was installed properly. If not, reinsert battery and try again. 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 is not rechargeable. Battery might explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not disassemble or attempt to recharge battery. Dispose according to local/country specific regulations.***

Note: *Replacing battery may affect date and time settings. Check date and time by going to* Set Up *and scrolling through the time/date settings by pressing* S .

Troubleshooting

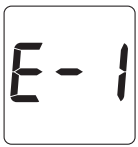
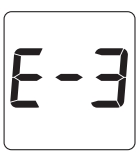
1) After inserting Test Strip, Meter does not turn on.

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.

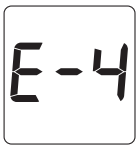
2) After applying sample, test does not start/ Meter does not beep or begin countdown.

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 and apply drop after Meter beeps.
Problem with Test Strip	Repeat with new Strip.
Problem with Meter	Call for assistance.

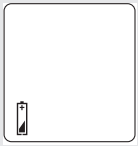
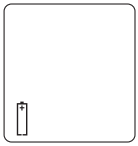
Messages

Display	Reason	Action
	**Temperature Error** Temperature change too quick	Wait 10 minutes for Meter and Test Strips to reach room temperature before testing.
	**Temperature Too Cold** Meter temperature less than 50°F	Move Meter and Test Strips to area between 50°-104°F before testing.
	**Temperature Too Hot** Meter temperature greater than 104°F	Move Meter and Test Strips to area between 50°-104°F before testing.
	**Sample Not Detected or Using Wrong Test Strip**	Retest with new or correct Strip and larger sample.
	**Used Test Strip or Test Strip outside of vial too long.**	Repeat with new Strip. If error persists, call for assistance.

Messages *(continued)*

Display	Reason	Action
	**Meter Error**	Call for assistance.
	**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.
	**Test Strip Removed During Test**	Retest with new Strip. If error persists, call for assistance.
	**Meter Error**	Call for assistance.
	**Meter Error**	Call for assistance.

Messages *(continued)*

Display	Reason	Action
	**Communication Error**	Turn Meter off and on again. If error persists, call for assistance.
	**Low Battery**	About 50 tests can be done before battery must be replaced.
	**Dead Battery**	Replace battery.
 	**WARNING!!** **Out of range - Hi** Result > 600 mg/dL **Out of range - Lo** Result < 20 mg/dL	**WARNING!!** Retest with new Strip. If result is still "Hi" or "Lo" contact Doctor ***immediately***.

System Specifications

Result Range: 20-600 mg/dL

Sample Size: Minimum 1 microliter (1 µL)

Sample: Fresh capillary whole blood or Glucose Control

Test Time: 10 seconds

Result Value: Plasma values

Assay Method: Electrochemical

Reference Method: Yellow Springs Instrument (YSI)

Power Supply: One 3V lithium battery
#CR2032 (non-rechargable)

Battery Life: Approximately 1,100 tests or 1 year

Automatic shut-off: After two minutes of non-use

Weight: 1.66 ounces

Size: 3.52" x 2.15" x 0.67"

Memory Size: 365 blood glucose results,
1 Control Test result

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

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

Temperature: 50°F-104°F

Hematocrit: 30-55%

Note: *Use within specified environmental conditions only.*

Chemical Composition

TRUEbalance Test Strips: Glucose Oxidase *(Aspergillus sp.)* 2.5 Units, Mediators, Buffers and Stabilizers.

TRUEcontrol Glucose Control: Contents: Volume: 3 mL. Water - 73%, D-glucose - 0.09 - 0.20%, Viscosity Enhancing Agent - 25%, Inorganic Salts - 1.8%, Amaranth - 0.08%, and Preservatives - 0.03%.

TRUEbalance Limited Lifetime Warranty

Nipro Diagnostics, Inc. provides the following Warranty to the original retail purchaser of the TRUEbalance 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

1. American Diabetes Association. *Diagnosis and Classification of Diabetes Mellitus.* Diabetes Care, Volume 36, Supplement 1, January 2013.

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.

3. CDC Clinical Reminder: *Use of Fingerstick Devices on More than one Person Poses Risk for Transmitting Bloodborne Pathogens* (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

4. 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.

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. U.S. 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.htm.

Notes: