SELF MONITORING BLOOD GLUCOSE SYSTEM

MĚTRIX

AIR

8:30eM

Owner's Booklet

Use only with TRUE METRIX[®] Self Monitoring Blood Glucose Test Strips

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

TRUE



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

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Fast Test Guide 2 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.

Expected Results for people without diabetes: <u>Plasma Blood Glucose Result</u>¹ Before eating < 100 mg/dL 2 hours after a meal < 140 mg/dL

<u>INTRODUCTION:</u> TRUE METRIX[®] AIR Self Monitoring Blood Glucose System

TRUE METRIX AIR is a simple, accurate way to test your whole blood glucose (sugar) level, anytime, anywhere. Our goal is to provide quality healthcare products and dedicated customer service. For questions about TRUE METRIX products, visit our web site at: www.niprodiagnostics.com.

The TRUE METRIX AIR Self Monitoring Blood Glucose System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm. The TRUE METRIX AIR Self Monitoring Blood Glucose System is intended to be used by a single person and not to be shared.

The TRUE METRIX AIR Self Monitoring Blood Glucose System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The TRUE METRIX AIR Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). The TRUE METRIX Self Monitoring Test Strips are for use with the TRUE METRIX AIR Self Monitoring Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip or forearm.

The TRUE METRIX AIR Self Monitoring Meter measures the current, detects, analyzes and corrects for hematocrit and temperature, and calculates the glucose result.

The TRUE METRIX Control Solution is for use with the TRUE METRIX AIR Self Monitoring Meter and TRUE METRIX Self Monitoring Test Strips to check that the meter and the test strip are working together properly and the test is being performed correctly.

The TRUE METRIX AIR Self Monitoring Meter can send results both to an application (App) you have on your smartphone or via docking station/ USB Smart data cable to a PC.

Importance of Blood Glucose Monitoring

The more you know about diabetes, the better you will be able to care for yourself. A Doctor or Healthcare Professional determines 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 your 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 Healthcare Professional.

IMPORTANT INFORMATION:

For the most accurate results using TRUE METRIX AIR:

- Read <u>all</u> product instructions for use before testing.
- Use of TRUE METRIX AIR in a manner not specified in this Owner's Booklet is not recommended and may affect ability to determine true blood glucose levels.
- TRUE METRIX AIR is a quantitative system for selftesting outside the body (*in vitro* diagnostic use) of human whole blood only.
- Alternate site (forearm) testing should not be used to calibrate continuous glucose monitors (CGMs).
- Alternate site (forearm) testing should not be used for insulin dose calculations.
- Use only TRUE METRIX Self Monitoring Test Strips and TRUE METRIX Control Solution with the TRUE METRIX AIR Self Monitoring Meter.
- Remove only one test strip at a time from test strip vial. Recap vial immediately.
- NEVER reuse test strips. NEVER wipe test strips with water, alcohol or any cleaner. DO NOT attempt to remove blood or control solution 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 test strip. Adding more sample gives an error message.
- Perform Control Tests *before* performing a blood glucose test for the first time.

IMPORTANT INFORMATION (cont.):

- Perform Control Tests with more than one level of control solution. Three levels of TRUE METRIX Control Solution are available for Control Tests. Call 1-800-803-6025, available 24 hours a day, 7 days a week, for assistance in obtaining control solution.
- The TRUE METRIX AIR Self Monitoring Blood Glucose System is for one person use **ONLY. DO NOT** share your meter or lancing device with anyone, including family members. Do not use on multiple patients!
- ALL parts of your blood glucose monitoring system could carry blood-borne pathogens after use, even after cleaning and disinfecting.^{2,3}
- Cleaning and disinfecting the lancing device and the meter destroys most, but not necessarily all, blood-borne pathogens.
- Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips, as contact with blood presents an infection risk.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- It is important to keep the meter and the lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see *Meter Cleaning and Disinfecting* and *Lancing Device Cleaning and Disinfecting*.

IMPORTANT INFORMATION (cont.):

- 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, dry mouth, vomiting, and headache.
- Do not use for diagnosis or screening of diabetes or for neonatal use.
- Inaccurate results may occur in severely hypotensive individuals or in dehydrated patients or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.

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Know Your System

Meter

Top of Meter



① " **◄** " Button

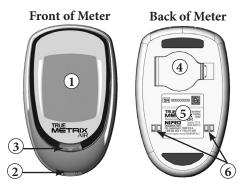
Decrease numbers in Meter Set Up; add ALT Symbol; move backward by date/time when viewing results and Averages in Memory; scroll through Event Tags to mark results (if feature on).

2 "•" Button

Turn meter on to view Average values, to view results in Memory, to access Meter Set Up, to turn on Event Tags in Meter Set Up, turn on/off Bluetooth Smart.

③ **" ▶** " Button

Increase numbers in Meter Set Up; remove ALT Symbol; move forward by date/time when viewing results and view Averages in Memory; scroll through Event Tags to mark results (if feature on).



1 Display Screen

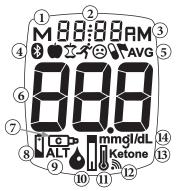
Shows results, messages, user prompts, information.

- ② Test Port Insert TRUE METRIX Test Strip here, contact blocks facing up.
- ③ Strip Release Button Releases test strip after testing for disposal.
- **④ Battery Door**

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

- ⑤ Meter Labels Contain serial number of meter.
- (6) Docking Station Contacts Contacts used for uploading meter results to a computer using a Docking Station (Please call 1-800-803-6025, available 24 hours a day, 7 days a week, for assistance).

Full Display Screen



- 1. Result is from Memory
- 2. Time, Date
- 3. Time is AM/PM
- 4. Bluetooth Symbol and Event Tag Symbols
- 5. Result is 7, 14, 30, 60 or 90 day Average
- 6. Test Result
- 7. Control Symbol
- 8. Battery Symbol
- 9. Alternate Site (ALT) Symbol
- 10. Drop Symbol Apply blood or control solution
- 11. Temperature Symbol
- 12. Test Reminder Symbol
- 13. Ketone Test Alert Symbol
- **14.** Unit of Measure (*Note: Factory set to mg/dL*, *cannot be changed by user.*)

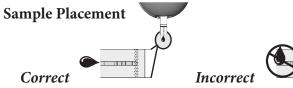
Test Strip

Top of Test Strip

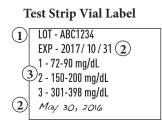


- ① **Contact End** Insert into Test Port with contact blocks facing up.
- ② Sample Tip Bring Tip of test strip to top of sample drop (blood or control solution) <u>after</u> Drop Symbol appears in the Display.

Note: Insert test strip into meter <u>before</u> touching Sample Tip to blood or control solution drop.



- Allow sample drop to be drawn into Sample Tip until testing begins (meter beeps and dashes move across Display).
- Do not smear or scrape drop with test strip.
- Do not apply more sample to test strip after testing begins.
- Do not apply blood or control solution to top of test strip.
- Do not insert Sample Tip with sample into Test Port. May damage meter.



- 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 if either 4 months after first opening or date printed next to EXP on vial label has passed, whichever comes first.

| Caution! | Use of test strips or control solution past the |
|----------|---|
| | Expiration Dates may give incorrect test |
| | results. Discard out-of-date products and test |
| | with new products. |

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

Note: Examples only. Do not represent actual Control Test ranges.

Control Solution (Control)

Control Solution 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 first opening or date printed next to EXP on bottle label has passed, whichever comes first.
- ③ Control Solution Level (1, 2, or 3) Testing with at least 2 levels of control solution is recommended. Contact 1-800-803-6025, available 24 hours a day, 7 days a week, for assistance with obtaining different levels of control solution.

Getting Started

Meter comes with pre-set time and date, and Bluetooth Smart feature on. The Event Tag feature, Ketone Test Alert, and all Test Reminders are off. Before using the meter for the first time or after a battery change, check the time, date, Bluetooth Smart, Event Tags, Alert and Reminders, and update as needed (see *Meter Set Up*).

The meter turns on when a test strip is inserted into the Test Port or when "•" Button is pressed (see *Memory* and *Meter Set Up*).

Meter turns off when the test strip is released or removed from the meter, "•" Button is pressed, or after 2 minutes of non-use.

The Bluetooth Smart feature turns off when a test strip is inserted into the Test Port or when meter is placed into docking station.

Turning the Ketone Test Alert on sets a reminder to check your ketones per your treatment plan when a blood glucose result is over 240 mg/dL.

Test Reminders are set like an alarm clock to sound a tone for 10 seconds to remind you to test. Up to four Test Reminders per day may be set.

Getting Started (cont.)

Event Tags allow you to tag your blood glucose results to link to the following events:

- Before meal –test was taken just before a meal,
- ☆ After meal –test was taken 2 hours after the start of a meal,
- * Exercise test was taken during or after exercise,
- Medications medication taken may have affected test result,
- ☺ Sick test was taken when sick,
- Other any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with this Event Tag in the meter Memory reminds you that there is more about this test result in your log book.

Tagging results helps track the effect specific events may have on your blood glucose test results. Event Tagging may assist you and your doctor or healthcare provider with managing your diabetes.

Quality Control Testing

To assure you are getting accurate and reliable results, TRUE METRIX AIR offers two kinds of quality

Control Tests. These tests let you know that your 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 test strip is inserted correctly into the Test Port.

Insert a test strip into the Test Port.

The meter is working properly if:

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

If an error message appears in the Display, the meter will not perform a test.

See *Troubleshooting* or call 1-800-803-6025, available 24 hours a day, 7 days a week.



Caution! If any segments are missing in the Display when meter is first turned on, do not use the meter for testing. Call 1-800-803-6025, available 24 hours a day, 7 days a week.

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 a vial of test strips,
- When opening a new vial of test strips,
- If results seem unusually high or low,
- If a vial has been left opened or exposed to humidity or to extreme heat or cold,
- Whenever a check on performance of the system is needed,
- If meter damage is suspected (meter was dropped, crushed, wet, etc.)

Note: It is important to perform Control Tests with more than one level of control solution. Three levels of TRUE METRIX Control Solution are available for Control Tests. Call 1-800-803-6025, available 24 hours a day, 7 days a week, for assistance in obtaining different levels of control solution.

Caution! 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 control solution.

How to Test Control Solution

Use **ONLY** TRUE METRIX Control Solution with the TRUE METRIX AIR Self Monitoring Meter and TRUE METRIX Self Monitoring Test Strips.

 Check dates on control solution label and test strip vial label. Do not use control solution or test strips if expiration dates have passed. (Control solution - 3 months after first opening or date next to EXP on label; test strips - 4 months after first opening or date next to EXP on labels.) Discard expired products and use new products.



- 2. Allow control solution, vial of test strips and meter to adjust to room temperature. Write date first opened on both control solution bottle label and test strip vial label when using for the first time.
- Gently swirl or invert control solution bottle to mix.
 DO NOT SHAKE!
- **4.** Remove one test strip from vial. Close test strip vial immediately. Use test strip quickly after removal from vial.

- **5.** Insert test strip into Test Port. Meter turns on.
- Note: If test strip has been out of the vial too long before testing, an error message appears upon insertion of the test strip into the meter. Release and discard old test strip. Use new test strip for testing.
- 6. Wait until Drop Symbol appears in Display. Keep test strip in meter until testing is finished.
- *Note:* If test strip is removed before testing is finished, an error message appears. Release and discard old test strip. Use new test strip for testing.
- With cap removed, turn control solution bottle upside down. Squeeze one drop of control solution onto a clean tissue. Wipe off bottle tip and discard tissue.
- 8. Gently squeeze a drop of control solution onto a small piece of unused aluminum foil or clear plastic wrap. Dispose after use.

Discard Control Solution Drop on Tissue







- **9.** With test strip still in meter, touch Sample Tip of test strip to top of drop of control solution. Allow drop to be drawn into test strip. Remove test strip from drop when meter beeps.
- **10.** Dashes appear across the Display to show meter is testing.



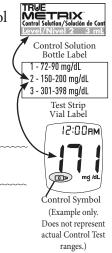


Meter testing

Note: If meter does not beep and begin testing soon after drawing up sample, release and discard test strip. Repeat test with new test strip. If problem persists, see Troubleshooting.

11. Compare meter result to Control Test range printed on test strip vial label for level of control solution you are using. If result is in range, System can be used for testing blood. If result does not fall within range, repeat test using a new test strip.

Note: Control Test result shows the Control Symbol in the Display.



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 1-800-803-6025, available 24 hours a day, 7 days a week.

12. After result is shown, Strip Release Button flashes. Hold meter with test strip pointing down. Press Strip Release Button to release and discard test strip into appropriate container. Meter turns off.

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

Obtaining a Blood Sample WARNING!

- The TRUE METRIX AIR Self Monitoring Blood Glucose System is for one person use **ONLY. DO NOT** share your meter or lancing device with anyone, including family members. Do not use on multiple patients!
- ALL parts of your blood glucose monitoring system could carry blood-borne pathogens after use, even after cleaning and disinfecting.²
- Cleaning and disinfecting the lancing device and the meter destroys most, but not necessarily all, blood-borne pathogens.
- Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips as contact with blood presents an infection risk.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be disinfected prior to use by the second person.
- It is important to keep the meter and the lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see *Meter Cleaning and Disinfecting* and *Lancing Device Cleaning and Disinfecting*.

Obtaining a Blood Sample (cont.)

Refer to lancing device Instructions for Use for detailed instructions.

- Never share lancets or lancing device. Lancets are for single use only. Do not re-use.
- Do not use venous blood for testing.
- To help prevent false high results, wash hands before using the system to test blood, especially after fruit has been handled.

From Fingertip

- 1. Prepare fingertip by washing hands in warm, soapy water. Rinse well. Dry thoroughly.
- 2. Place end of lancing device equipped with a lancet 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 the test strip. Apply sample to test strip Sample Tip.
- **4.** Recap and remove used lancet from lancing device. The used lancet may be biohazardous. Please discard it carefully according to your healthcare provider's instructions.

From Forearm

Important Notes Regarding Forearm Testing⁴

- Check with your Doctor or Healthcare Professional to see if forearm testing is right for you.
- Results from forearm are not always the same as results from fingertip.
- Always perform testing using fingertip samples under the following conditions:
 - ~ 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.
- 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 equipped with a lancet firmly against forearm. Press Trigger Button. Apply firm pressure on lancing device for 10 seconds. Apply sample to test strip Sample Tip.

4. Recap and remove lancet from lancing device.

Caution! The used lancet may be biohazardous. Please discard it carefully according to your healthcare provider's instructions.

How to Test Blood

- 1. Check dates on test strip vial being used. Do not use if either 4 months after first opening or after date printed next to **EXP** on label, whichever comes first.
- 2. Wash hands (and forearm for alternative site testing). Rinse well and dry thoroughly.
- 3. Remove one test strip from vial. Close vial immediately. Use test 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 test strip in meter until testing is finished.

To mark test as alternate site (forearm) result, press " ► " Button. ALT Symbol appears in Display. Press " ◄ " Button to remove ALT Symbol.Wait until Drop Symbol appears in Display.



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

- 5. Lance fingertip or forearm. Allow drop to form (see Obtaining a Blood Sample).
- 6. With test strip still in meter, touch Sample Tip of test strip to top of blood drop and allow blood to be drawn into test strip. Remove test strip from blood drop immediately after the meter beeps and dashes appear across the Display.
- *Note:* If meter does not begin testing soon after touching Sample Tip to drop, discard test strip. Repeat test with new test strip and new blood drop. If problem persists, see Troubleshooting.
- 7. Dashes appear across Display to show meter is testing.
- - 12:00em





8. After the test is finished, result is displayed. The Strip Release Button flashes.

To mark the result with an Event Tag, make sure that Event Tags are turned on (see Set Event Tags, Ketone Alert and Test Reminders). The Event Tag icons flash. Press "▶" or "◄" Button to go to the correct Event Tag. Press "•" Button to mark the test result with an event (icon stops flashing).

Event Tags are as follows:

 Before meal –test was taken just before a meal,





(Before Meal Icon - shown)



Top of Meter

- ☆ After meal -test was taken 2 hours after the start of a meal,
- A Exercise test was taken during or after exercise,
- Medications medication taken may have affected test result,
- ⊗ Sick test was taken when sick,
- Other any other reason that the test is unique or different in some way (example: stress, drinking alcohol). In your logbook, note the reason that the test result was tagged. Seeing a result with this Event Tag in the meter Memory reminds you that there is more about this test result in the log book.

Record result in log book.

9. Hold meter with test strip pointing down. Press test strip Release Button to discard test strip in the appropriate container. Meter turns off. Result is stored in Memory with date and time.



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

Caution! The used lancet and test strip may be biohazardous. Please discard them carefully according to your healthcare provider's instructions.

TRUE METRIX AIR Self Monitoring Blood Glucose System and Laboratory Testing

When comparing results between TRUE METRIX AIR Self Monitoring Blood Glucose System and a laboratory system, TRUE METRIX AIR Self Monitoring Blood Glucose System blood tests should be performed within 30 minutes of a laboratory test. If you have recently eaten, fingerstick results from the TRUE METRIX AIR Self Monitoring Blood Glucose System can be up to 70 mg/dL higher than venous laboratory results.⁵

Results Out of System Range Warning Messages WARNING!

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

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

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

ALWAYS repeat blood tests to confirm Low ("Lo") and High ("Hi") results. If blood results still display "Lo" or "Hi", call your Doctor or 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 Test Alert is turned on, "Ketone" appears in Display with glucose result (see *Ketone Test Alert*).



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

Note: Ketone Test 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.
- With meter off, press and hold

 "Button until the full Display is shown and a series of beeps sound (after about 10 seconds). Release "•" Button. Meter goes into Set Up.

Set Time/Date

- 2. The hour flashes. To change, press
 " ▶ " or " ◄ " Button 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 " " Button to set.
- The minutes flash. To change, press
 " ▶ " or " ◄ " Button to select the minutes. Press " " Button to set.









- 4. The month (number) flashes. To change, press " ▶ " or " ◄ " Button to select the month. Press " • " Button to set.
- 5. The day (number) flashes. To change, press " ▶ " or " ◄ " Button to select the day. Press " • " Button to set.
- 6. The year flashes. To change, press " ▶ " or " ◄ " Button to select the year. Press " • " Button to set.

Note: Meter beeps every time a setting is confirmed ("•" Button is pressed).



Set Bluetooth Smart, Event Tags, Ketone Alert and Test Reminders

Meter comes with Bluetooth Smart feature turned on. Event Tags, Ketone Test Alert and all Test Reminders are turned off.

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

Bluetooth Smart

Uploading results using the Bluetooth Smart feature allows your meter to send results to an application (App) on a paired smartphone. See Pairing (Syncing) Meter with Your Smartphone on page 40 for more information.

After setting the year, press " ▶ " or " ◀ " Button to turn on or off the Bluetooth Smart feature. Press " • " Button to set. Meter goes to set Event Tags.



Bluetooth Smart Enabled



Bluetooth Smart Disabled

Event Tags

Event Tags are used to mark a test result that was taken during a specific event.

 After turning on or off the Bluetooth Smart feature, press " ▶ " or " ◄ " Button to turn Event Tags on or off. Press " • " Button to set, then the Meter goes to set Ketone Test Alert.

Ketone Test Alert

When a blood glucose result is over 240 mg/dL, the Ketone Test Alert is a reminder to check your ketones per your treatment plan.

 Press " ► " or " ◄ " Button to turn Alert on or off. Press " • " Button to set, then the Meter goes to set Test Reminder.



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

Test Reminder

Up to four Test Reminders per day may be set. Reminder sounds at set time for 10 seconds. Meter comes with all Test Reminders off. To set the Test Reminders:

- After pressing "•" Button to set Ketone Test Alert, Display shows first Reminder setting (A-1). To turn Reminder on, press "►" Button. Press "◄" Button to turn Reminder back to off. Press "•" Button to set.
- When "on" is chosen, press "•" Button. The hour flashes. Press "▶" or "◄" Button to set the hour. To set AM/PM, scroll (press "▶" or "◄" Button) until "AM" or "PM" is next to correct time. Press "•" Button to set.
- The minutes flash. Press " ▶" or " ◄" Button to set the minutes. Press " •" Button to set. Meter goes to the next Test Reminder.



Test Reminder





Πn

4. Turn Reminders on and repeat setting the time for next 3 Reminders (if needed).



Exit Set-Up

Press and hold "•" Button until meter turns off. Meter also turns off after 2 minutes of non use. Set Up choices are saved.

Note: If Test Reminders are set, the Alert Symbol appears in all Displays. If battery dies or is replaced, Ketone test alert and test reminders may have to be reset.



Meter Memory

View Averages

The Averages feature allows you to view the average of all your blood glucose results within a 7-, 14-, 30-, 60-, or 90-day period. Control Test results are not included in the Averages.

You can review the average of your glucose results from the last 7-, 14-, 30-, 60-, or 90-days.

- With meter off press and release "•" Button. Display scrolls through 7-, 14-, 30-, 60-, and 90-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-, 30-, 60-, and 90-day Averages.



No Average



7-Day Average

View Memory

Meter Memory stores 1000 results. When Memory is full, the oldest result is replaced with the newest result.

- 1. Press and release "•" Button. Meter displays 7-, 14-, 30-, 60-, and 90-day Averages. Press and release
 - "•" Button again to view most recent test result in Memory. If there are no results in Memory, dashes appear with the Memory Symbol.
- Press " ► " Button to scroll forward through results or " ◄ " Button to scroll backwards through results.

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

Control Test results display the Control Symbol.

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

Tests marked with an Event Tag shows the Event Tag icon in the Display.



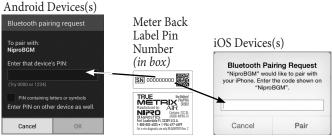
Event Tag (Before Meal Icon - shown)

<u>Pairing (Connecting) Meter with Your</u> <u>Smartphone</u>

Pairing enables your meter to upload your results when requested by an App (application) on your smartphone. The meter must have the Bluetooth Smart feature turned on and your smartphone must have an App that is able to receive the results. The meter and the smartphone must be within 10 feet of each other for the results to upload. The meter can be paired with up to four (4) smartphones.



- 1. Make sure that the Bluetooth Smart feature is turned on in the meter (see Bluetooth Smart on page 34).
- 2. Press "•" Button on the meter.
- 3. Follow your smartphone instructions in order to locate TRUE METRIX AIR Self Monitoring meter (look for a device named NiproBGM). Enter the last 6 digits of the meter serial number (found on meter back label) into the smartphone. This is the meter's PIN number. Wait for smartphone(s) to confirm connectivity. Once both devices are paired, you can have the App on your smartphone upload test results from the meter memory



(Example only. Does not represent meter actual serial number.)

Caution

• If you make any changes through the meter set up, turn the meter off and start at Step #2 in order to be able to pair.

• Look for the Bluetooth icon 😵 on your meter display to confirm it is turned on. You must first pair your smartphone(s) with your meter for test results to be uploaded.

• This meter operates with Bluetooth Smart. Make sure that your smartphone can work with Bluetooth Smart.

• Don't pair more than one smartphone to the meter at a time. If your meter has already paired with four (4) smartphones and is attempting to be paired with new smartphone, the smartphone paired first is replaced with the new smartphone.

• If a test strip is inserted into the meter during the uploading of the results to the App, the results stop uploading. You must re-start the upload from the App in your smartphone.

• *Go to*

www.niprodiagnostics.com/truemanagerair for a list of compatible mobile devices and applications.

WARNING! • To prevent other people's results from being sent, do not let anyone else use your meter to test their blood glucose. This meter is for single patient use only. • To make sure that your results are secure, only let trusted people (doctor, family, etc.) download your results to a computer

• *Keep your meter serial number private.*

program or connect to a mobile App.

• Allowing other people to download your meter to a computer or mobile Apps that is not yours could result in a loss of privacy of your data.

Care, Cleaning/Disinfecting and Troubleshooting

- Store System (meter, control solution, test strips) in Carrying Case to protect from liquids, dust and dirt.
- Store in a dry place at temperatures between 40°F-86°F. **DO NOT FREEZE.**
- Do not keep meter in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).
- Do not share your meter with anyone, including family members.
- Allow system to sit at room temperature for 10 minutes before testing.

Meter Care, Cleaning and Disinfecting

Cleaning removes blood and soil from the meter.

- **Disinfecting** removes most, but not all possible infectious agents (bacteria or virus) from the meter, including blood-borne pathogens.
 - Clean and disinfect immediately after getting any blood on the meter or if meter is dirty.
 - Clean and disinfect meter at least once a week. Meter may be cleaned and disinfected once a week for up to 5 years.
 - If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be disinfected prior to use by the second person. Do not clean the meter during a test.
 - Cleaning step #2 must occur before disinfecting steps #3 and #4.

To Clean and Disinfect the Meter:

- 1. Wash hands thoroughly with soap and water.
- 2. To Clean: Make sure meter is off and a test strip is not inserted. With <u>ONLY</u> PDI Super Sani Cloth Wipes (EPA* reg. no. 9480-4), rub the entire outside of the meter using 3 circular wiping motions with moderate pressure on the front, back, left side, right side, top and bottom of the meter. Discard used wipes. (*Environmental Protection Agency.)
- 3. To Disinfect: Using fresh wipes, make sure that all outside surfaces of the meter remain wet for 2 minutes. Make sure no liquids enter the Test Port or an other opening in the meter.



Super Sani-Cloths may be purchased at the following places:

- <u>Amazon.com</u>,
- <u>Officedepot.com</u> or visit your local Office Depot store,
- <u>Walmart.com</u>
- **4.** Let meter air dry thoroughly before using to test.

- 5. Wash hands thoroughly again after handling meter.
- 6. Verify that the System is working properly by performing an Automatic Self-Test (see *Getting Started*).



Stop using the meter and call Customer Care for assistance at 1-800-803-6025, available 24 hours a day, 7 days a week, if:

- Meter display appears cloudy or any display segments are missing,
- Markings on meter, including back meter label, are coming off or are missing,
- Buttons on the meter are hard to push or do not work,
- Unable to insert test strip into Test Port,
- Automatic Self-Test gives an error message.

Note: Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the meter. Use of disinfectants other than Super Sani Cloth Wipes may damage meter.

Note: Super Sani Cloth Wipes have been tested on the meter for a total of 260 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the meter once a week for a 5 year period. The use life of the meter is 5 years.

Lancing Device Care, Cleaning and Disinfecting

Cleaning removes blood and soil from the lancing device.

- **Disinfecting** removes most, but not all possible infectious agents (bacteria or virus) from the lancing device, including blood-borne pathogens.
 - Clean and disinfect immediately after getting any blood on the lancing device or if lancing device is dirty.
 - Clean and disinfect the lancing device at least once a week. Lancing device may be cleaned and disinfected once a day for a 3 year period.
 - If the lancing device is being operated by a second person who provides testing assistance, the lancing device should be disinfected prior to use by the second person.
 - Do not clean lancing device if there is a lancet inside. Remove lancet from lancing device before cleaning.
 - Cleaning step #2 must occur before disinfecting steps #3 and #4.

To clean and disinfect the lancing device:

- 1. Wash hands thoroughly with soap and water.
- To Clean: With <u>ONLY</u> PDI Super Sani Cloth Wipes (EPA* reg. no. 9480-4), rub the entire outside of the lancing device using 3 circular wiping motions with moderate pressure. Discard used wipes. (*Environmental Protection Agency.)





3. To Disinfect: Using fresh wipes, make sure that all outside surfaces of the lancing device remain wet for 2 minutes.

Super Sani-Cloths may be purchased at the following places:

- <u>Amazon.com</u>,
- Officedepot.com or visit your local store,
- Walmart.com
- Let lancing device air dry thoroughly before using to test. Replace End Cap. Gently pull back and release Arming Barrel and press the Trigger Button. A click will be heard if the lancing device is functioning properly.
- 5. Wash hands thoroughly again after handling the lancing device.





Stop using the lancing device and call Customer Care for assistance at 1-800-803-6025, available 24 hours a day, 7 days a week, if:

- Markings on lancing device are coming off,
- Trigger Button hard to push,
- End Cap does not go back on,
- Arming Barrel does not click when gently pulled back.
- **Note:** Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the meter. Use of disinfectants other than Super Sani Cloth Wipes may damage meter.

Note: Super Sani Cloth Wipes have been tested on the lancing device for a total of 1,095 cleaning and disinfecting cycles, which is equal to cleaning and disinfecting the lancing device once per day for a 3 year period. Lancing device may be cleaned and disinfected up to 7 cycles per week for 3 years.

TRUE METRIX Control Solution Care

- Write date opened on control solution bottle label. Discard if either 3 months after first opening or after date printed next to **EXP** on label has passed, whichever comes first.
- After each use, wipe bottle tip clean and recap tightly.
- Store at temperatures between 36°F-86°F. DO NOT FREEZE.

TRUE METRIX Self Monitoring Test Strip Care

- Store test strips in original vial only. Do not transfer test strips to new vial or store test strips outside of vial.
- Write date first opened on test strip vial label. Discard unused test strips from vial if either 4 months after first opening or after date printed next to **EXP** on label has passed, whichever comes first. Use of test strips past expiration dates may give incorrect results.
- Close vial immediately after removing test strip. Store in a dry place at temperatures between 40°F-86°F. DO NOT FREEZE.
- Do not reuse test strip.
- Do not bend, cut or alter test strips in any way.

Changing Battery

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

- 1. Lift tab on Battery Door.
- 2. Turn meter over. While holding meter in one hand with Battery Door facing down, tap meter gently on the palm of your other hand to loosen and remove battery.
- **3.** Discard old battery into appropriate container.
- 4. Insert new battery, positive ("+") side facing up. Close Battery Door.

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

 Press "•" Button to turn meter on. Check time, date, Ketone Test Alert and Test Reminders (see *Meter Set Up*). If meter does not turn on, check that battery was installed properly. If not, remove and reinsert battery. Turn meter on by pressing "• " Button. Call 1-800-803-6025, available 24 hours a day, 7 days a week, 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! 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 regulations.





Troubleshooting

1. After inserting test strip, meter does not turn on.

| Reason | Action |
|--|--|
| Test strip inserted upside down or backwards | Remove test strip. Re-insert correctly. |
| Test strip not fully inserted | Remove test strip. Re-insert test strip fully into meter. |
| Test strip error | Repeat with new test strip. |
| Dead or no battery | Replace battery. |
| Battery in backwards | Battery positive ("+") side must face up. |
| Meter Error | Call 1-800-803-6025, available 24 hours a day, 7 days a week. |

2. After applying sample, test does not start (meter does not beep or begin testing).

| Reason | Action |
|---|--|
| Sample drop too small | Repeat test with new test strip and larger drop. |
| Sample applied after two minute shut-off | Repeat test with new test strip. Apply sample within 2 minutes of inserting test strip. |
| Problem with test strip | Repeat with new test strip. |
| Problem with meter | Call 1-800-803-6025, available 24 hours a day, 7 days a week. |

For assistance, call 1-800-803-6025, available 24 hours a day, 7 days a week.

Troubleshooting (cont.)

3. Meter Bluetooth Smart feature is enabled but test result was not received by your smartphone.

| Reason | Action |
|--|--|
| Smartphone containing App linked to your meter not turned on. | Turn on your smartphone. |
| Bluetooth Smart on your smartphone is turned off. | Turn on Bluetooth Smart your smartphone. |
| Meter not linked with specific smartphone. | Link (pair) meter with your smartphone. |
| Meter and smartphone are too far apart. | Bring smartphone and meter within 10 feet of each other. |
| Your smartphone does not support Bluetooth Smart | Unable to use with your smartphone. |
| App not compatible with Bluetooth Glucose profile ⁶ | Download compatible mobile App. |

Note: Any interruption in transmission may cancel the transfer of test results from your meter to your smartphone. Results are re-transmitted the next time a data transfer is started.

For assistance, call 1-800-803-6025, available 24 hours a day, 7 days a week. 52

Messages

| Display | Reason | Action |
|--------------|--|--|
| E-0 | Invalid Hematocrit | Repeat with new test strip, using capillary whole blood from the finger or forearm. If error persists, call 1-800-803-6025, available 24 hours a day, 7 days a week. |
| E - 1 | Temperature Error Too Cold/ Too Hot | Move meter and test strips to area between 41°F-104°F; wait 10 minutes for system to reach room temperature before testing. |
| 8-3 | Sample Not Detected or Using Wrong Test Strip | Retest with new test strip and larger sample. |
| E-3 | Used Test Strip, Test Strip outside of vial too long, Sample on top of Test Strip. | Repeat with new test strip. Make sure Sample Tip of test strip touched top of sample drop. If error persists, call 1-800-803-6025, available 24 hours a day, 7 days a week. |
| E-4 | Meter Error | Call 1-800-803-6025, available 24 hours a day, 7 days a week. |

| Display | Reason | Action |
|------------|--|---|
| E-5 | Test Strip Error, or very high blood glucose result (higher than 600 mg/dL) | Retest with new test strip. If error persists, call 1-800-803-6025, available 24 hours a day, 7 days a week. If you have symptoms such as fatigue, excess urination, thirst, or blurry vision follow your healthcare professional's advice for high blood glucose. |
| E-6 | Test Strip Removed During Test | Retest with new test strip. Make sure result is displayed <u>before</u> removing test strip. |
| E-9 | Communication Error | Call 1-800-803-6025, available 24 hours a day, 7 days a week. |
| | Low or Dead Battery | Low: About 50 tests can be done before battery dies. Dead: Battery Symbol appears and beeps before meter turns off. |

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call 1-800-803-6025, available 24 hours a day, 7 days a week.

| Display | Reason | Action |
|--|---|---|
| | Broken Display | Do not use meter for testing. Call 1-800-803-6025, available 24 hours a day, 7 days a week. |
| I2:00RM MJ I2:00RM L0 mg /dL | WARNING!! Out of Range - High Results > 600 mg/dL - Low Results < 20 mg/dL | WARNING!! Retest with new test strip. If result is still "Hi" (High) or "Lo" (Low) contact Doctor <i>immediately</i> . |

If error message still appears, any other error message appears, or troubleshooting does not solve the problem, call 1-800-803-6025, available 24 hours a day, 7 days a week. System Specifications Result Range: 20-600 mg/dL **Sample Size:** 0.5 microliter (0.5 µL) Sample: Fresh capillary whole blood from the finger and forearm, or control solution Test Time: Results in as little as 4 seconds **Result Value:** Plasma values Assay Method: Amperometric **Power Supply:** One 3V lithium battery #CR2032 (non-rechargeable) Battery Life: Approximately 1000 tests or 1 year Automatic shut-off: After two minutes of non-use Size: 3.44" x 2.16" x 0.69" Weight: 1.66 ounces Memory Size: 1000 glucose results **Operating Range (meter & test strips): Relative Humidity:** 10-90% (Non-condensing) Temperature: 41-104°F Hematocrit: 20-70% Altitude: Up to and including 10,200 feet *Note:* Use within specified environmental conditions only. Wireless Frequency: 2.4 GHz Band Contains FCC ID: 2ADDB-NIPRO-01 Device Compatibility: Smartphones running applications compatible with Bluetooth Glucose Profile6 **Chemical Composition** TRUE METRIX Test Strips: Glucose dehydrogenase-FAD (Aspergillus species), mediators, buffers and stabilizers. TRUE METRIX Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

ABOUT BLUETOOTH SMART

The TRUE METRIX AIR Self Monitoring Blood Glucose Meter uses Bluetooth Smart to connect wirelessly (pair) with applications (Apps) found on your smartphone that can work with Bluetooth Glucose Profile⁶ in order to transmit test results from your meter's memory.

TRUE METRIX AIR Self Monitoring Blood Glucose Meter contains FCC ID: 2ADDB-NIPRO-01 This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions. (1) This device may not cause harmful

interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

- **Note:** This meter containing the Bluetooth Smart feature has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This meter generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this meter does cause harmful interference to radio or television reception, which can be determined by turning the meter off and on, try to correct the interference by one or more of the following measures:
 - Move the meter away from the radio or television antenna.
 - Move the radio or television antenna away from the meter.

If you continue to have problems, contact Customer Care at 1-800-803-6025 available 24 hours a day, 7 days a week.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The Bluetooth Smart feature on your meter sends test results to your paired device. To prevent other people's results from being sent and keep your data consistent, **Do Not** let anyone else use your meter to test their blood glucose.

TRUE METRIX AIR Self Monitoring Limited Lifetime Warranty

Nipro Diagnostics, Inc. provides the following Warranty to the original purchaser of the TRUE METRIX AIR Self Monitoring 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.

System Safety Information Electromagnetic Compatibility

Meter EMC testing was performed and was adequate. 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.

Blood Glucose Monitoring System Components

- TRUE METRIX AIR Blood Glucose Meter
- TRUE METRIX Self Monitoring Blood Glucose Test Strips
- TRUE METRIX Control Solution
- Lancing Device
- Single Use Lancet

Kit may contain one or more of the components above. To obtain components, contact place of purchase of original kit. For assistance call 1-800-803-6025, available 24 hours a day, 7 days a week.

<u>References</u>

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- 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.
- 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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- 6. Bluetooth Special Interest Group, *Adopted Bluetooth Profiles*, *Glucose Profile* https://www.bluetooth.org/en-us/specification/ adopted-specifications.