

TRUE METRIX AIR

BLOOD GLUCOSE MONITORING SYSTEM

**NO
CODING**

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TRUE METRIX AIR

BLOOD GLUCOSE MONITORING SYSTEM

Owner's Booklet

Bluetooth
SMART



TRIVIDIA
HEALTH



BLOOD GLUCOSE MONITORING SYSTEM

Fast Test Guide

Two simple steps

1 INSERT TEST STRIP **2** APPLY BLOOD SAMPLE



For quick reference only, not intended as a substitute for complete instructions. Please read entire Owner's Booklet and product Instructions for Use before testing.

Expected Results for people without diabetes:¹

Before breakfast

Two hours after meals

Plasma Blood Glucose Result

$< 5.6 \text{ mmol/L}$

< 7.8 mmol/l

The TRUE METRIX AIR Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh, human whole blood taken from the fingertip or forearm (capillary) and from the vein (venous). The System is intended for at-home use (self-testing by a single person and not shared) and for use by Healthcare Professionals for multiple patient use in professional healthcare settings. The system is not to be used on neonates or for the diagnosis or screening of diabetes mellitus. Alternate site testing can only be performed during steady-state blood glucose conditions. Testing is performed outside the body (*in vitro*) as an aid for monitoring the effectiveness of diabetes control.

Notes:

INTRODUCTION:

TRUE METRIX AIR

Blood Glucose Monitoring System

TRUE METRIX AIR is a simple, accurate way to test whole blood glucose (sugar) level, anytime, anywhere. Our goal is to provide quality healthcare products and dedicated customer service.

Importance of Blood Glucose Monitoring

A Doctor or Healthcare Professional determines how often to test and what the target ranges are for blood glucose results. Having most blood glucose results within target range shows how well a treatment plan is working to control glucose levels. Keeping results within target range helps slow or stop complications from diabetes. **NEVER** change a treatment plan without consulting a Doctor or Healthcare Professional.

SYMBOLS:



Biological Risks

STERILE [R] Sterilized using irradiation



Do Not Resterilize



Single Use

CONTROL Control

① ② ③ Control Level



Serial Number



Caution



Use-by Date



Keep Dry



Single patient use only



Consult instructions for use



Temperature Limit



Humidity Limitation



Lot Number



In vitro
Diagnostic Medical Device



Authorized representative in the
European Community



Manufacturer



Date of Manufacture



Waste Electrical and Electronic
Equipment

IMPORTANT INFORMATION:

For the most accurate results using TRUE METRIX AIR:

- Read all 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 an *in vitro* (outside body) **IVD** quantitative system that is used for self-testing of human whole blood only.
- Do not use TRUE METRIX AIR System during a xylose absorption test. This may falsely raise glucose results. Please check with your Doctor before using TRUE METRIX AIR.
- 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 Test Strips and TRUE METRIX Control Solution with the TRUE METRIX AIR 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 TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Contact place of purchase or contact for assistance to obtain control solution.
- Do not use for the diagnosis of or screening for diabetes mellitus or for measuring blood glucose in newborns.

FOR PATIENTS:

- DO NOT use on more than one person. **ALL** parts of the TRUE METRIX AIR Blood Glucose Monitoring System could carry blood-borne pathogens after use, even after cleaning and disinfecting.²
- The TRUE METRIX Blood Glucose Monitoring System is for one person use ONLY. DO NOT share your Meter or your Lancing Device with anyone, including family members.
- Wash 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. For instructions on how to clean the meter and lancing device, see *Meter Care, Cleaning/Disinfecting* and *Lancing Device Care and Cleaning*.

- If there are symptoms of low or high blood glucose, check blood glucose immediately. If the result does not match the way you feel, repeat the test. If the results still do not match the way you feel, contact a Doctor or Healthcare Professional immediately.
 - ~ Low blood glucose (hypoglycaemia) symptoms may be trembling, sweating, intense hunger, nervousness, weakness, and trouble speaking.
 - ~ High blood glucose (hyperglycaemia) symptoms may be intense thirst, a need to urinate often, dry mouth, vomiting, and headache.

WARNING! Upon opening the test strip carton, examine the product for missing, damaged or broken parts. Ensure the test strip vial cap is securely closed. If the product is damaged or the vial cap is not closed, DO NOT use the test strips for testing; product may give inaccurate results. Contact Trividia Health Customer Care for replacement and assistance.

IMPORTANT INFORMATION (cont.): **FOR HEALTHCARE PROFESSIONALS:**

- The TRUE METRIX AIR Blood Glucose Meter can be used on multiple patients. Healthcare Professionals always need to wear gloves and follow Cleaning/Disinfecting section and/or adhere to the infection control policies and procedures approved by their facility. The test strips and lancets are for single-use. Lancing device is restricted to be used on one patient only.
- Venous whole blood drawn into only sodium heparin blood collection tubes must be used for testing. Mix well before use.
- DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause inaccurate results.
- Reuse of devices labeled for single-use may result in product contamination and patient infection.
- 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 perform capillary blood glucose testing on the critically ill.** Capillary blood glucose levels when critically ill with reduced peripheral blood flow may not reflect the true physiological state. Reduced peripheral blood flow may result from the following conditions (for example):³
 - ~ shock • severe hypotension • severe dehydration
 - ~ hyperglycaemia with hyperosmolarity, with or without ketosis.

TABLE OF CONTENTS

| | |
|---|-----------|
| Contact Information, Fast Test Guide, Expected Results.... | |
| See Cover | |
| Introduction and Important Information | 1 |
| Know Your System | |
| Meter | 8 |
| Test Strip | 11 |
| Control Solution | 13 |
| Getting Started | 14 |
| Quality Control Testing | 16 |
| Automatic Self Test | 16 |
| Control Test | 17 |
| How to Test Control Solution | 18 |
| Testing Blood | |
| Obtaining a Blood Sample..... | 22 |
| How to Test Blood | 25 |
| System and Laboratory Testing..... | 29 |
| System Out of Range Warning Messages..... | 30 |
| Meter Set Up | |
| Set Time / Date | 31 |
| Set Bluetooth® Smart, Event Tags, Ketone Test Alert and Test Reminders | 33 |

Meter Memory

| | |
|---|----|
| View Averages | 37 |
| View Memory..... | 38 |
| Pairing (Connecting) Meter with Mobile Device | 39 |

System Care

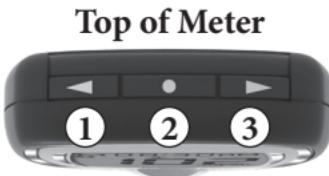
| | |
|---|----|
| Meter Care, Cleaning and Disinfecting | 43 |
| Control Solution Care | 45 |
| Test Strip Care | 45 |
| Lancing Device Cleaning and Disinfecting..... | 46 |
| Changing Battery | 48 |
| Troubleshooting..... | 50 |
| Messages..... | 52 |

Performance Characteristics

| | |
|--|----|
| System Specifications/Chemical Composition | 59 |
| Electromagnetic Compatibility..... | 60 |
| References..... | 62 |
| Notes | 63 |

Know Your System

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, view results in Memory, access Meter Set Up, turn on Event Tags in Meter Set Up, and 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).

Front of Meter



Back of Meter



① Display Screen

Shows results, messages, user prompts, information.

② Test Port

Insert 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*).

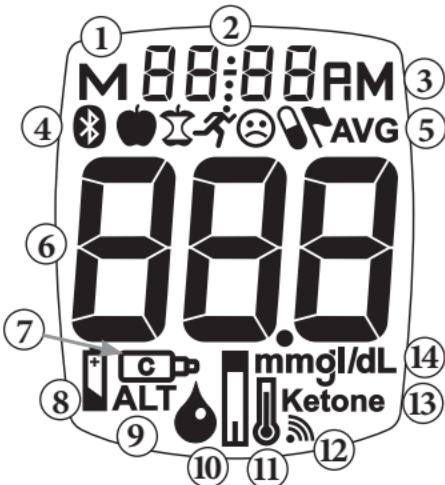
⑤ Meter Labels

Contains serial number of meter.

⑥ Docking Station Contacts

Connects meter with docking station for data upload to a computer.

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, cannot be changed by user.)

Test Strip

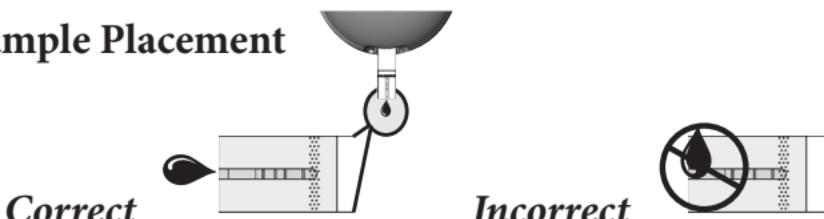
Top of Test Strip



- 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) after Drop Symbol appears in the Display.

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

Sample Placement



- 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.

Test Strip Vial Label

| | | |
|---|--------------|------------------|
| ① | LOT | L-003 |
| | ⌚ | 2024/10/31 ② |
| ③ | 1 | 1.7-3.4 mmol/L |
| | 2 | 4.8-6.5 mmol/L |
| | 3 | 13.7-18.6 mmol/L |
| ② | May 30, 2024 | |

- ① **Lot Number (LOT)** - Used for identification when calling for assistance.
- ② **Use By Dates (⌚)** - Write date first opened on vial label. Discard vial and unused test strips if either the open vial Use By date or the date printed next to ⌚ on vial label has passed, whichever comes first. See the test strip Instructions for Use for open vial Use By date.



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

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

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

Control Solution Bottle Label



- ① **Lot Number (LOT)** - Used for identification when calling for assistance.
- ② **Use By Dates (⌚)** - Write date first opened on bottle label. Discard bottle if either 3 months after first opening or date printed next to ⌚ on bottle label has passed, whichever comes first.
- ③ **Control Solution Level (1, 2, or 3)** - We recommend testing at least 2 levels of control solution. Contact the number on the cover of this Booklet for information on how to obtain 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 13.3 mmol/L.

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 after 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 Professional with managing your diabetes.

Quality Control Testing

To assure you are getting accurate and reliable results, the System 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

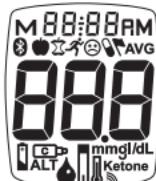
An Automatic Self-Test is performed by the meter each time a test strip is inserted correctly into the Test Port.

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 contact for assistance (see Booklet cover for contact information).



Full Display



Drop Symbol



Error Message



If any segments are missing in the Display when meter is first turned on, do not use the meter for testing. Contact for assistance.

Control Test

We recommend performing Control Tests to check the performance of the system.

Control Tests should be performed:

- To practice before using the system for the first time,
- For practice to ensure testing technique is good,
- Occasionally when using 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 extreme heat or cold, or humidity,
- 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 TRUE METRIX Control Solution. Three levels of control solution are available for Control Tests. Use contact on the cover for more information on how to obtain control solution.

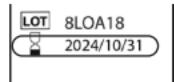


Ranges printed on test strip vial label are for Control Test results only and are not suggested levels for blood glucose. Do not drink control solution.

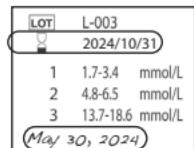
How to Test Control Solution

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

1. Check dates on control solution label and test strip vial label. Do not use control solution or test strips if either Use By Dates have passed. (control solution - 3 months after first opening or date next to ☰ on bottle label; test strips - after open vial Use By date (see test strip Instructions for Use) or date next to ☰ on vial label.) 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.
3. 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.

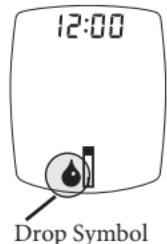


5. Insert test strip into Test Port.
Meter turns on.



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.

Contact Blocks
Face Up



6. Wait until Drop Symbol appears in Display. Keep test strip in meter until testing is finished.

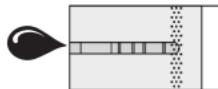
Note: If test strip is removed before testing is finished, an error message appears. Release and discard old test strip. Use new test strip for testing.

7. 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

- 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 and begins testing.
- 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.

- 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.



Control Solution Bottle Label

| | | |
|---|-----------|--------|
| ① | 1.7-3.4 | mmol/L |
| ② | 4.8-6.5 | mmol/L |
| ③ | 13.7-18.6 | mmol/L |

Test Strip Vial Label



Control Symbol (Example only. Does not represent actual Control Test ranges)

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



If Control Test result is outside range, test again. If result is still outside range, system should not be used for testing blood. Call for assistance (see Booklet cover for phone number).

12. After result is shown, Strip Release Button flashes. Hold meter with test strip pointing down. Press Strip Release Button to release and discard 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.*

TESTING BLOOD

Obtaining a Blood Sample

Refer to lancing device Instructions for Use for detailed instructions.



The lancing device is for single patient use ONLY. For cleaning your lancing device see lancing device's 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.
- 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 with soap and warm water. Rinse and dry thoroughly. Disinfect the clean skin with an antiseptic (e.g., 70% alcohol). 
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 for testing. Apply sample to test strip Sample Tip.
4. After testing, recap and remove used lancet from lancing device. Discard used lancet into appropriate container.



Treat used lancets as a biological risk. Dispose used lancets in approved container.

Tips for Forearm Sampling

Important Notes Regarding Forearm Testing⁴

- Check with the Doctor or Diabetes Healthcare Professional to see if forearm testing is appropriate.
- Results from the forearm are not always the same as results from the finger.
- Use finger for testing instead of forearm for more accurate results under the following conditions:
 - ~ Within 2 hours of eating, exercise, or taking insulin,
 - ~ If blood glucose may be rising or falling rapidly or their results often fluctuate,
 - ~ If the patient is ill or under stress,
 - ~ If your forearm test results do not match how you feel,
 - ~ If the glucose result may be low or high,
 - ~ If symptoms of low or high glucose levels are not evident.

1. Select area to be lanced. Wash with soap and warm water, rinse and dry thoroughly. Disinfect the clean skin with an antiseptic (e.g., 70% alcohol).
2. Rub area vigorously or apply a warm, dry compress to increase blood flow.
3. Lance forearm. Apply sample to Sample Tip of test strip.
4. After testing, recap and remove used lancet from lancing device. Discard all biohazard materials into appropriate container.



Used test strips and lancets are considered biohazardous. Dispose used test strips and lancets into approved biohazard container.

From Vein

Venous whole blood drawn into only sodium heparin blood collection tubes must be used for testing. Mix well before use.

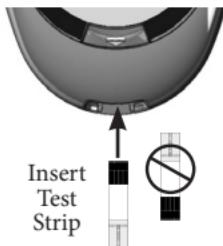
DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing. This may cause inaccurate results.



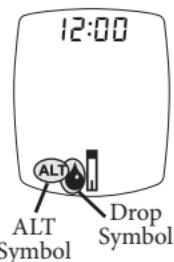
*Used lancets and test strips are considered biohazardous.
Please discard them according to the healthcare professional's instructions.*

How to Test Blood

1. Check Meter time and date before each glucose test. With meter off, press and hold the “•” Button until the full Display is shown and a series of beeps sound. Release “•” Button. If time and date are incorrect, see Meter Set Up to set the correct time and date.
2. Check dates on test strip vial being used. Do not use if either open vial Use By date (see test strip Instructions for Use) or date printed next to  on vial label has passed, whichever comes first.
3. Clean and disinfect fingertip (or forearm for alternative site testing) (see *Obtaining a Blood Sample*).
4. Remove one test strip from vial. Close vial immediately. Use test strips quickly after removal from vial.
5. 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.

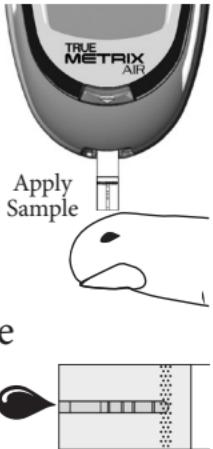


To mark test as alternate site (forearm) result, press “►” Button. ALT Symbol appears in Display. Press “◀” Button to remove ALT Symbol. Wait until Drop Symbol appears in Display.



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.

6. Lance fingertip or forearm.
Allow drop to form
(see *Obtaining a Blood Sample*).



7. 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 Sample Tip 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.

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



9. 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 Bluetooth Smart, Event Tags, Ketone Alert and Test Reminders*). The Event Tag icons flash.

Note: Event Tag must be marked prior to the removal of test strip from meter.

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,
- 🍏 After meal – test was taken after 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 the log book.

Record result in log book.



Test Result



Event Tag
(Before Meal Icon - shown)



Top of Meter

10. 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.*



Used lancets and test strips are considered biohazardous. Please discard them according to the Doctor or Healthcare Professional's instructions.

System and Laboratory Testing

The most accurate glucose results come from using fresh, capillary whole blood from the fingertip. Capillary whole blood taken from the forearm or venous whole blood drawn into only sodium heparin blood collection tubes must be used for testing.

DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause inaccurate results.

When comparing results between TRUE METRIX AIR and a laboratory system, TRUE METRIX AIR blood tests should be performed within 30 minutes of a laboratory test. If you have recently eaten, fingerstick results from the TRUE METRIX AIR System can be up to 3.9 mmol/L higher than venous laboratory results.⁵ Diabetes experts have suggested that 95% of glucose meter results agree within 0.83 mmol/L of a laboratory system when the glucose concentration is less than 5.55 mmol/L, and within 15% of a laboratory system when the glucose concentration is 5.55 mmol/L or higher.⁶

System Out of Range Warning Messages



Meter reads blood glucose levels from 1.1 - 33.3 mmol/L.

If blood test result is less than 1.1 mmol/L, “Lo” appears in meter Display.

If blood test result is greater than 33.3 mmol/L, “Hi” appears in meter Display.



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

Note: “Lo” results are included in the Average as 1.1 mmol/L.
“Hi” results are included as 33.3 mmol/L.

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



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

Note: Ketone Test Alert can be turned on or off during Meter Set Up.

Meter Set Up

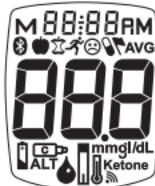
Note: If the meter turns off at any time during Set Up, go back to Step #1 under Meter Set Up and begin again.



1. 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. Press “•” Button to set.
3. The minutes flash. To change, press “▶” or “◀” Button to select the minutes. Press “•” Button to set.



Full Display



Set Hour



Set Minutes

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 meter to send results to an application (App) on a paired mobile device. See *Pairing (Connecting) Meter with Mobile Device* on page 39 for more information.

After setting the year, press “▶” or “◀” Button to turn the Bluetooth Smart feature on or off. 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.

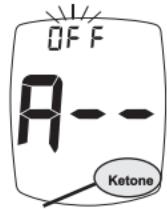
1. After turning the Bluetooth Smart feature on or off, press “▶” or “◀” Button to turn Event Tags on or off. Press “•” Button to set, then the Meter goes to set Ketone Test Alert.



Top of Meter



Event Tags



Ketone Test Alert

Ketone Test Alert

When a blood glucose result is over 13.3 mmol/L, the Ketone Test Alert is a reminder to check your ketones per your treatment plan.

2. Press “▶” or “◀” Button to turn Alert on or off. Press “•” Button to set, then the Meter goes to set Test Reminder.



When a Ketone Test Alert sounds, 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

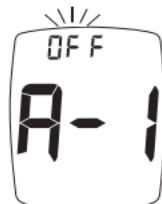
Up to four Test Reminders per day may be set.

Reminder sounds at set time for 10 seconds.

Meter comes with all Test Reminders off.

To set the Test Reminders:

1. 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.
2. When “on” is chosen, press “•” Button. The hour flashes. Press “▶” or “◀” Button to set the hour. Press “•” Button to set.
3. The minutes flash. Press “▶” or “◀” Button to set the minutes. Press “•” Button to set. Meter goes to the next Test Reminder.



Test Reminder



Set Hour



Set Minutes

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.



Test Reminder Symbol

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.

1. 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.



7-Day Average



No 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.

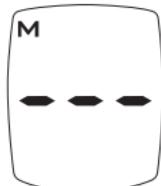
2. Press “▶” Button to scroll forward through results or “◀” Button to scroll backwards through results.

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

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

Test results above 13.3 mmol/L 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.



Memory Symbol



Alternate Site Symbol



Control Symbol



Ketone Test Alert Symbol



Event Tag
(Before Meal Icon - shown)

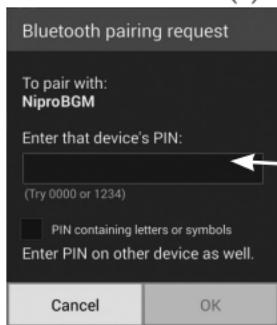
Pairing (Connecting) Meter with Mobile Device

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



1. Make sure that the Bluetooth Smart feature is turned on in the meter (see *Bluetooth Smart* on page 33).
2. Press “•” Button on the meter.
3. Follow mobile device instructions in order to locate TRUE METRIX AIR meter (look for a device named NiproBGM or TRUEAIR). Enter the last 6 digits of the meter serial number (found on meter back label) into the mobile device. This is the meter's PIN number. Wait for mobile device(s) to confirm connectivity. Once both devices are paired, you can have the App on the mobile device upload test results stored in the meter memory.

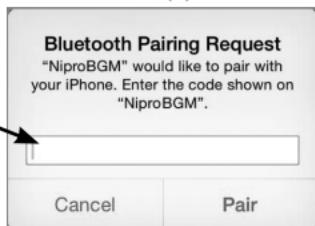
Android Devices(s)



Meter Back
Label Pin
Number
(in box)



iOS Devices(s)



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



- 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 meter display to confirm it is turned on. You must first pair mobile device(s) with meter for test results to be uploaded.
- This meter operates with Bluetooth Smart. Make sure that mobile device to be paired can work with Bluetooth Smart.
- Don't pair more than one mobile device to the meter at a time. If your meter has already paired with four (4) and is attempting to be paired with a new mobile device, the mobile device paired first is replaced with the new mobile device.
- 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 installed on the mobile device.

WARNING!

- *To make sure that test results are secure, only let trusted people (doctor, family, etc.) download results to a computer program or connect to a mobile App.*
- *Keep meter serial number private.*
- *Allowing other people to download meter results to a computer or mobile App that is not yours could result in a loss of privacy of your data.*

System Care

- Store system (meter, control solution, test strips) in carrying case to protect from liquids, dust and dirt. Do not keep system in an area where it may be crushed (i.e. back pocket, drawer, bottom of bag, etc.).
- Store in a dry place at room temperature (4°C - 30°C) at 10%-80% relative humidity (Non-condensing).
DO NOT FREEZE.
- Allow system to sit at room temperature for 10 minutes before testing.



Meter Care, Cleaning/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 immediately after getting any blood on the meter or if meter is dirty. Repeat if needed until all meter surfaces are visibly clean.
- Clean and disinfect the meter before allowing anyone else to handle it.
- 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 cleaned and 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 the Meter:

1. Wash hands thoroughly with soap and water.
2. Make sure meter is off and a test strip is not inserted. Rub the entire outside of the meter with a cleaning/disinfecting agent wipe with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%). Do not use bleach. 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. Make sure no liquids enter the Test Port or any other opening in the meter. Discard used wipes.



To Disinfect the Meter:

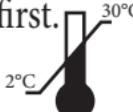
3. Using fresh wipes, make sure that all outside surfaces of the meter remain wet for 2 minutes.
4. Let meter air dry thoroughly before using to test.
5. Wash hands thoroughly again after handling meter.
6. Verify that the meter is working properly by performing an Automatic Self-Test. See *Automatic Self-Test* on how to perform.



Stop using the Meter and use the contact information on the front cover for assistance 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 are hard to push on the meter or do not work,
- Unable to insert test strip into Test Port,
- Automatic Self-Test gives an error message.

Control Solution Care

- Write date opened on control solution bottle label. Discard if either 3 months after first opening or date printed next to  on bottle label has passed, whichever comes first.
- Store at room temperature (2°C-30°C).  **DO NOT FREEZE.**
- After each use, wipe bottle tip clean and recap tightly.
- Discard any control solution bottles that appear cracked or leaking.

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 vial and unused test strips if either open vial Use By date or date printed next to  on vial label has passed, whichever comes first.
- Discard any test strip vials that appear cracked or broken.
- Close vial immediately after removing test strip.
- Store in a dry place at room temperature (4°C-30°C) at 10%-80% relative humidity (Non-condensing).  **DO NOT FREEZE.**
- Do not reuse test strip.
- Do not bend, cut or alter test strips in any way.

Lancing Device Cleaning and Disinfecting

Cleaning and disinfecting the lancing device is a two-step process. The first step is Cleaning. Cleaning removes any blood, liquids, dust or dirt. The second step is Disinfecting. Disinfecting removes most, but not all possible infectious agents (bacteria or viruses), including blood-borne pathogens. Cleaning must be done before Disinfecting.



Clean and disinfect the lancing device at least once a week.

Lancing device may be cleaned and disinfected once a day for up to 3 years. If blood gets on the lancing device, clean and disinfect it before anyone else touches it. If someone is helping you test your blood or performs a test on you, do the cleaning and disinfecting before allowing anyone else to handle it.

1. Wash hands thoroughly with soap and water or wear disposable gloves.
2. **To Clean:** Using a cleaning/disinfecting agent wipe with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%), thoroughly wipe the entire outside surface of the lancing device with one cloth by wiping in circles 3 times.
Discard the used cloth.
3. Repeat step 2 if the lancing device is not visually clean, or safely dispose of it according to your state/local regulations.
4. **To Disinfect:** Remove a fresh cleaning/disinfecting agent wipe with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%), thoroughly wipe the entire outside surface of the lancing device by wiping in circles 3 times. Make sure that you go over the entire lancing device.



5. Using fresh cloths, if needed, make sure that all outside surfaces of the lancing device stay wet for 2 minutes by patting with the cloth. Discard used cloth. Let lancing device air dry completely before using.
6. Gently pull back Arming Barrel and press the Trigger Button. You will hear a click if the lancing device is working properly.
7. Wash hands thoroughly again.

 *Other disinfectants have not been tested. The effect of other disinfectants used interchangeably has not been tested with the lancing device. Use of disinfectants other than cleaning/disinfecting agent wipe with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%) may damage lancing device.*

Do not use lancing device and use the contact information on the cover for assistance, if:

- ~ Markings on lancing device are coming off,
- ~ Trigger Button is hard to push,
- ~ End Cap does not go back on,
- ~ Arming Barrel does not click when gently pulled back.

Cleaning/disinfecting agent wipes with the active ingredients ammonium chloride with up to 0.25% of each quaternary ammonium compound and isopropyl alcohol (up to 55%) 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 a day for a 3-year period. Lancing device may be cleaned and disinfected up to 7 cycles per week for 3 years.

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:



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

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.
5. Press “•” Button to turn meter on. Check time, date, 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. Contact for assistance if problem persists.



Note: If battery is out of meter or dead too long, meter may reset to original factory settings. Verify settings are correct after replacing battery by going into Meter Set Up and checking time, date, Ketone Testing Alert, and Testing Reminders. Change if needed. Results in Memory are not deleted and time and date on the results does not change if battery is dead or removed for any length of time.



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 adaptor for an electrical outlet or use any other type of charger. Trying to recharge the battery or power the meter by plugging into an adaptor for an electrical outlet may cause meter to catch on fire and/or battery may explode.

Battery might explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local 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 | Contact for assistance. |

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

| Reason | Action |
|--|---|
| Sample drop too small | Repeat test with new 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 | Contact for assistance. |

Use contact information on cover for assistance.

Troubleshooting (cont.)

3. *Meter Bluetooth Smart feature is enabled but test result was not received by mobile device.*

| Reason | Action |
|---|---|
| Mobile Device containing App linked to the meter not turned on. | Turn on the mobile device. |
| Bluetooth Smart on the mobile device is turned off. | Turn on Bluetooth Smart on the mobile device. |
| Meter not linked with specific mobile device. | Link (pair) meter with mobile device. |
| Meter and mobile device are too far apart. | Bring mobile device and meter within 10 feet of each other. |
| Mobile device does not support Bluetooth Smart | Unable to use with mobile device. |
| App not compatible with Bluetooth Glucose profile ⁷ | Download compatible mobile App. |

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

Use contact information on cover for assistance.

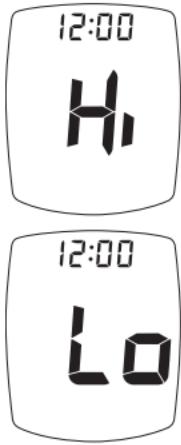
Messages

| Display | Reason | Action |
|---|--|---|
|  | Invalid Haematocrit | Repeat with new test strip, using capillary whole blood from the finger, forearm or venous whole blood collected only in a sodium heparin blood collection tube. If error persists, contact for assistance. |
|  | Temperature error • Too cold/ Too hot | Move meter and test strips to area between 5°C-40°C; wait 10 minutes for system to reach room temperature before testing. |
|  | Sample not detected or using wrong test strip | Retest with new test strip and larger sample. |
|  | 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, contact for assistance. |

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

| Display | Reason | Action |
|--|--|---|
|  | Meter error | Contact for assistance. |
|  | Test strip error or very high blood glucose result (higher than 33.3 mmol/L) | Retest with new test strip. If error persists, contact for assistance. If symptoms such as fatigue, excess urination, thirst, or blurry vision are found, follow Doctor or Healthcare Professional's advice for high blood glucose. |
|  | Test strip removed during test | Retest with new test strip. Make sure result is displayed <u>before</u> removing test strip. |
|  | Communication error | Contact for assistance. |
|  | 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, contact for assistance.

| Display | Reason | Action |
|--|--|--|
|  | Broken Display | Do not use meter for testing. Contact for assistance. |
|  |  Out of range - High results $> 33.3 \text{ mmol/L}$ - Low results $< 1.1 \text{ mmol/L}$ |  Retest with new test strip. If result is still “Hi” (High) or “Lo” (Low) contact Doctor or Healthcare Professional <i>immediately.</i> |

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

Performance Characteristics⁸

Precision: Precision describes the variation between results. There are two types of precision results measured, repeatability (using blood) and intermediate precision (using control solution).

Repeatability: N=100

| | | | | | |
|---------------|------|------|------|------|------|
| Mean (mmol/L) | 2.4 | 4.8 | 8.0 | 11.3 | 17.8 |
| SD (mmol/L) | 0.09 | 0.16 | 0.24 | 0.39 | 0.49 |
| %CV | 3.9 | 3.3 | 3.0 | 3.4 | 2.7 |

Intermediate Precision: N=100

| | | | |
|---------------|-----|-----|------|
| Mean (mmol/L) | 2.1 | 6.4 | 18.4 |
| SD (mmol/L) | 0.1 | 0.2 | 0.6 |
| %CV | 4.3 | 3.2 | 3.4 |

System Accuracy: Diabetes experts have suggested that 95% of glucose meter results should agree within \pm 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and within \pm 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L. The tables below show how often healthcare professionals (HCP) and users achieve these goals using capillary fingertip and forearm blood samples when glucose results are not fluctuating. The laboratory reference instrument is the Yellow Springs Instrument (YSI).

For Healthcare Professionals

99.3% of TRUE METRIX AIR fingertip values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels \geq 5.55 mmol/L.

Fingertip Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

| Within ± 0.28 mmol/L | Within ± 0.56 mmol/L | Within ± 0.83 mmol/L |
|-----------------------------|-----------------------------|-----------------------------|
| 99/156 (63.5%) | 135/156 (86.5%) | 155/156 (99.4%) |

Fingertip Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ |
|------------------|-------------------|-------------------|
| 207/444 (46.6%) | 364/444 (82%) | 441/444 (99.3%) |

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

| Within ± 0.83 mmol/L and $\pm 15\%$ |
|---|
| 596/600 (99.3%) |

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

100% of TRUE METRIX AIR forearm values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels \geq 5.55 mmol/L.

Forearm Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

| Within ± 0.28 mmol/L | Within ± 0.56 mmol/L | Within ± 0.83 mmol/L |
|-----------------------------|-----------------------------|-----------------------------|
| 13/41 (31.7%) | 26/41 (63.4%) | 41/41 (100%) |

Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ |
|------------------|-------------------|-------------------|
| 17/59 (28.8%) | 38/59 (64.4%) | 59/59 (100%) |

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

| Within ± 0.83 mmol/L and $\pm 15\%$ |
|---|
| 100/100 (100%) |

Parkes Error Grid: 100% of individual forearm glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

Venous Blood

96.4% of TRUE METRIX AIR venous values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels \geq 5.55 mmol/L.

Venous Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

| Within ± 0.28 mmol/L | Within ± 0.56 mmol/L | Within ± 0.83 mmol/L |
|--------------------------|--------------------------|--------------------------|
| 16/50 (32%) | 39/50 (78%) | 50/50 (100%) |

Venous Samples (HCP vs. YSI) for glucose concentrations \geq 5.55 mmol/L

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ |
|------------------|-------------------|-------------------|
| 33/174 (19%) | 100/174 (57.5%) | 166/174 (95.4%) |

Venous Samples for glucose concentrations between 1.1-33.3 mmol/L

| Within ± 0.83 mmol/L and $\pm 15\%$ |
|---|
| 216/224 (96.4%) |

Parkes Error Grid: 100% of individual venous glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

For Consumers

99% of TRUE METRIX AIR fingertip values performed by users fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels \geq 5.55 mmol/L.

Fingertip Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L

| Within ± 0.28 mmol/L | Within ± 0.56 mmol/L | Within ± 0.83 mmol/L |
|--------------------------|--------------------------|--------------------------|
| 9/18 (50%) | 17/18 (94.4%) | 18/18 (100%) |

Fingertip Samples (User vs. YSI) for glucose concentrations \geq 5.55 mmol/L

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ |
|------------------|-------------------|-------------------|
| 39/82 (47.6%) | 65/82 (79.3%) | 81/82 (98.8%) |

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

| Within ± 0.83 mmol/L and $\pm 15\%$ |
|---|
| 99/100 (99%) |

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

98% of TRUE METRIX AIR forearm values performed by users fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels \geq 5.55 mmol/L.

Forearm Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L

| Within ± 0.28 mmol/L | Within ± 0.56 mmol/L | Within ± 0.83 mmol/L |
|--------------------------|--------------------------|--------------------------|
| 21/41 (51.2%) | 32/41 (78%) | 41/41 (100%) |

Forearm Samples (User vs. YSI) for glucose concentrations \geq 5.55 mmol/L

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ |
|------------------|-------------------|-------------------|
| 21/59 (35.6%) | 39/59 (66.1%) | 57/59 (96.6%) |

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

| Within ± 0.83 mmol/L and $\pm 15\%$ |
|---|
| 98/100 (98%) |

Parkes Error Grid: 100% of individual forearm glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

User Performance Evaluation: A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.8% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

System Specifications

Result Range: 1.1 - 33.3 mmol/L

Sample Size: 0.5 microlitre (0.5 µL)

Sample: Fresh capillary whole blood, venous whole blood collected in sodium heparin blood collection tubes, 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

Weight: 47 grams

Size: 8.7 x 5.5 x 1.7 cm

Memory Size: 1000 glucose results and 1 control result

Operating Range (Meter & Test Strips For Blood Testing):

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

Temperature: 5°C - 40°C

Haematocrit: 20%-70%

Altitude: Up to and including 3109 metres

Note: Use within specified environmental conditions only.

Wireless Frequency: 2.4 GHz Band

Max Radio-Frequency Power Transmitted: 4dBm (2.5 mW)

Device Compatibility: Mobile devices running applications compatible with Bluetooth Glucose Profile⁷

Chemical Composition

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

Control Solution: Water, d-glucose, buffers, viscosity enhancing agent, salts, dye and preservatives.

System Safety Information

Electromagnetic Compatibility

The TRUE METRIX AIR meter was tested and found to comply with the electromagnetic emission and immunity requirements as specified in IEC 60601-1-2 Edition 4.0. The meter's electromagnetic emission is low. The TRUE METRIX AIR has met the following requirements of 60601-1-2, Edition 4:

| EMC Test | Compliance Information |
|---|---|
| Radiated Emissions | CISPR 11 Class B limits |
| Conducted Emissions Voltage | Not applicable |
| Radiated RF EM Fields | 10v/m, 80 MHz – 2.7 GHz, 80% AM at 1 kHz |
| Proximity fields from RF wireless communications equipment | Per table 8.10 |
| Power Frequency Magnetic Fields | 30 A/m, 50 Hz and 60 Hz |
| Electrical Fast Transients / Bursts | Not applicable |
| Surges | Not applicable |
| Conducted Disturbances induced by RF fields | Not applicable |
| Voltage Dips and Voltage Interrup- tions | Not applicable |
| Electrostatic Discharge | +/-8kV contact ; +/-15kV air discharges. |

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 TRUE METRIX AIR meter close to sources of strong electromagnetic radiation, as these may interfere with the proper operation of the meter.

Do not use electrical equipment, including antennas, closer than 12 inches to any part of the TRUE METRIX AIR meter, including cables specified by the manufacturer.

Blood Glucose Monitoring System Components

- TRUE METRIX AIR Blood Glucose Monitoring Meter
- TRUE METRIX Blood Glucose Test Strips
- TRUE METRIX Control Solution
- Lancing Device
- Sterile Lancet

Kit may contain one or more of the components above.

Other accessories may negatively affect EMC performance. No adverse events to the Patient and Operator are anticipated due to electromagnetic disturbances because all electrical components of the TRUE METRIX AIR meter are fully enclosed.

References

1. Joslin Diabetes Center. *Goals for Blood Glucose Control* [Electronic Version]. Retrieved June 8, 2015 from <http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html>.
2. FDA Public Health Notification: *Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens: Initial Communication Update 11/29/2010* [Electronic Version]. Retrieved February 22, 2012 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
3. Atkin, 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.
4. U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter*. [Electronic Version]. Retrieved July 6, 2009: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm.
5. Larsson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests*. Scand J Clin Lab Invest 36:805-808, 1976.
6. European Committee for Standardization. *In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus*. Reference number EN ISO 15197:2015 (E). Brussels: European Committee for Standardization; 2015.
7. Bluetooth Special Interest Group, Adopted Bluetooth Profiles, Glucose Profile <https://www.bluetooth.org/en-us/specification/adopted-specifications>.
8. Data on file.

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