TRUENESS™ AIR
Blood Glucose Monitoring System

Owner's Booklet

Use only with TRUENESS™ Blood Glucose Test Strips

Customer Consultation • Monday - Friday, 8AM-8PM Eastern Standard Time
English or Spanish
1-800-803-6025
www.trividiahealth.com

Bluetooth®

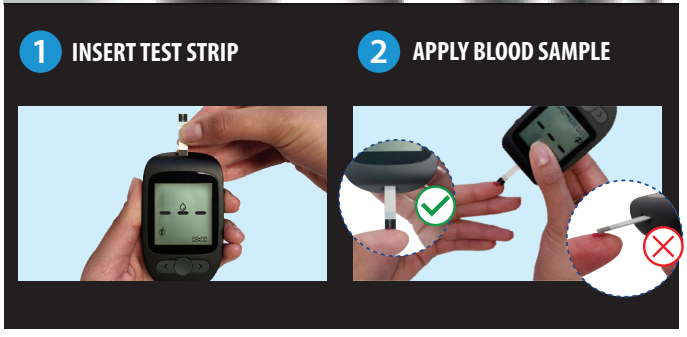
Manufactured for:
TRIVIDIA HEALTH™
Fort Lauderdale, FL 33309 U.S.A.

P/N: 36301324-B.1
Release date: 2024/03/18
ZEA4TVH35 Rev. 1

TRUENESS™ AIR
Blood Glucose Monitoring System

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:

Plasma glucose for people without diabetes[1]	
Before eating	**< 100 mg/dL**
2 hours after a meal	**< 140 mg/dL**

Table Of Contents

INTRODUCTION:

TRUENESS™ AIR Blood Glucose Monitoring System

Dear **TRUENESS™ AIR** Blood Glucose Monitoring System Owner:

Thank you for choosing the **TRUENESS™ AIR** Blood Glucose Monitoring System. This Owner's Booklet contains important information about the System and how it operates. Please read it carefully before using your new System.

The **TRUENESS™ AIR** Blood Glucose Monitoring System is designed for easy, user-friendly and convenient operation. It only needs a small volume of sample (1μL). The **TRUENESS™** blood glucose test strip does not require coding. This feature saves time and avoids errors due to improper coding. The memory allows you to save up to 600 test results. All these advantages make the **TRUENESS™ AIR** Blood Glucose Monitoring System an excellent blood glucose monitoring tool.

The **TRUENESS™ AIR** Blood Glucose Monitoring System is designed to help you and your healthcare professional monitor your blood glucose levels. This Owner's Booklet provides the instructions for the correct use of your system. Please read it carefully before use.

If you need assistance, please call Customer Care at 1-800-803-6025, Monday-Friday 8AM-8PM EST. Please call your healthcare professional when Customer Care is closed, or visit our website at www.trividiahealth.com.

Intended Use

The **TRUENESS™ AIR** Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended to be used by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program.

The **TRUENESS™ AIR** Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is for *in vitro* diagnostic use only.

The **TRUENESS™ AIR** Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.

The **TRUENESS™ AIR** Blood Glucose Monitoring System is comprised of the **TRUENESS™ AIR** blood glucose meter and the **TRUENESS™** blood glucose test strip.

Description

The **TRUENESS™ AIR** Blood Glucose Monitoring System is for self-testing outside the body (*in vitro* diagnostic use). The meter package contains 1 **TRUENESS™ AIR** blood glucose meter and 2 AAA alkaline batteries.

Note: **TRUEdraw** Lancing Device, **TRUEplus** Lancets, **TRUENESS™** Blood Glucose Control Solutions, **TRUENESS™ AIR** Blood Glucose Meter, and **TRUENESS™** Blood Glucose Test Strips are sold separately.

The lancing device and lancets are manufactured for Trividia Health, Inc. They may be used with the **TRUENESS™ AIR** Blood Glucose Monitoring System.

Other lancets and lancing devices that are cleared can be used with **TRUENESS™ AIR** Blood Glucose Monitoring System.

Use only SUPER SANI-CLOTH ® Germicidal Disposable Wipes (EPA Reg. No. 9480-4) for cleaning and disinfecting the meter and **TRUEdraw** lancing device. The wipes can be purchased at: Amazon.com, Officedepot.com or Walmart.com.

Test Principle

A glucose test is based on the measurement of electrical current caused by the reaction of glucose with the FAD glucose dehydrogenase enzyme on the electrode of the test strip. The blood or control solution sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with the FAD glucose dehydrogenase enzyme and generates electrons, which produce an electrical current.

The **TRUENESS™ AIR** blood glucose meter measures the electrical current and calculates the glucose result. The glucose result is displayed by the meter in mg/dL units.

Limitations

►For *in vitro* diagnostic use only.
►For self-testing.
►Not for use on the critically ill.
►Not for neonatal use.
►Not for screening or diagnosis of diabetes mellitus.
►Not for alternative site testing (AST) use.
►Xylose: Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.
►Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
►Inaccurate results may occur in severely hypotensive individuals or patients in shock.
►Inaccurate results may also occur in individuals experiencing a hyperosmolar-hyperglycemic-state (HHS).
►For single patient use only and should not be shared.
►NOT intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities, including for routine assisted testing or as part of glycemic control procedures.
►The meter and lancing device are for single patient use! DO NOT share them with anyone including other family members! DO NOT use on multiple patients. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.

Important Safety Instructions

Read this section before using your **TRUENESS™AIR** Blood Glucose Monitoring System.

Always take the following basic safety precautions:

►Insufficient sample may cause inaccurate test results.
►If you have symptoms that do not reflect your blood glucose test results, and you have followed all instructions described in this booklet, call your healthcare professional.
►DO NOT change your treatment based on a single result that does not match how you feel.
►DO NOT use other brands of blood glucose test strips and control solutions with the **TRUENESS™AIR** blood glucose meter.
► Before using any product to test your blood glucose level, read all instructions and practice a test. Do all quality control checks as directed and consult your diabetes healthcare professional.
► Keep the test strip vial and control solution bottle away from children. The test strip vial, test strip, and control solution bottles can be choking hazards. Do not drink the control solution.
► All parts of this package are considered biohazardous once they have been used for a blood test. They can potentially transmit infectious diseases, even after cleaning and disinfection.
► If your blood glucose result is below 70 mg/dL (or a low glucose level per your healthcare professional's instruction), or the meter displays "LO" (less than 40 mg/dL), retest with a new test strip. If you get a similar result, call your healthcare professional immediately.
► If your blood glucose result is above 200 mg/dL (or a high glucose level per your healthcare professional's instruction), or the meter displays "HI" (greater than 600 mg/dL), retest with a new test strip. If you get a similar result call your healthcare professional immediately.
► Close supervision is necessary when the device is used by, on, or near children or people with physical limitations that may impair correct use of the system.
► Use the **TRUENESS™AIR** Blood Glucose Monitoring System only for the intended use as described in this Owner's Booklet.
► DO NOT use the **TRUENESS™AIR** Blood Glucose Monitoring System if it is not working properly, or if it has suffered any damage.

For further information, please refer to:

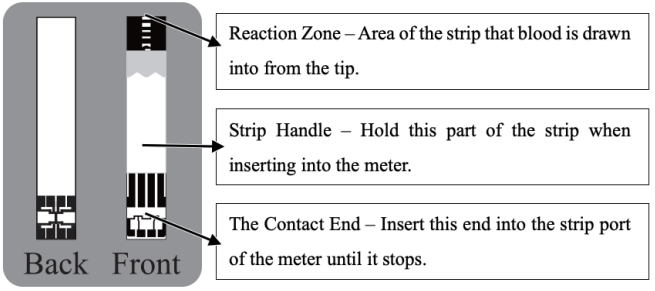
"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens: Initial Communication", at https://wayback.archive-it.org/7993/20170111013014/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

CDC website on "Infection Prevention during Blood Glucose Monitoring and Insulin Administration", at http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

About the TRUENESS™ Blood Glucose Test Strip

The **TRUENESS™** blood glucose test strip is intended to be used with the **TRUENESS™ AIR** blood glucose meter to measure the amount of blood glucose in fresh capillary whole blood. The **TRUENESS™** blood glucose test strip used with the **TRUENESS™ AIR** blood glucose meter provides a complete test system that is intended for *in vitro* diagnostic use by people with diabetes. The **TRUENESS™** blood glucose test strips do not require coding. Please refer to the "Performing a Blood Glucose Test" section for complete instructions.

The **TRUENESS™** blood glucose test strip consists of the following parts:



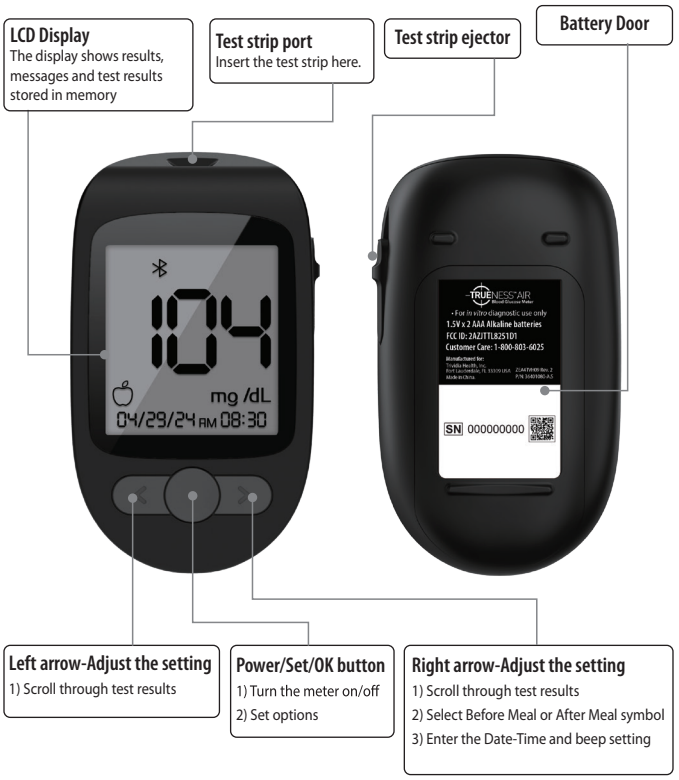
Important TRUENESS™ Blood Glucose Test Strip Information

- Store the test strip in a cool dry place between 41°F-86°F (5°C-30°C), and 10% - 85% relative humidity. Keep away from direct sunlight and heat. DO NOT FREEZE.
- Keep your test strips in the original vial. Do not transfer them to any other vial or container.
- Before handling the test strip, wash your hands with soap and water and dry them. Hold the sides of the test strip when removing it from the vial or inserting it into the meter.
- Only remove the test strip from the vial when you are ready to perform a test. Firmly recap the vial immediately after removing a test strip.
- Only apply blood or control solution to the tip of the test strip. Ensure that the reaction zone is completely filled. Do not place blood on any other part of the test strip. This may cause an inaccurate result.
- When using a new vial of test strips, write the date opened on the vial label. Discard any test strips 6 months after the written date or once the printed expiration date has passed, whichever comes first.
- Do not use the test strips beyond the expiration date printed on the vial.

WARNING: *Keep the test strip vial away from children. The vial and the test strip can be a choking hazard.*

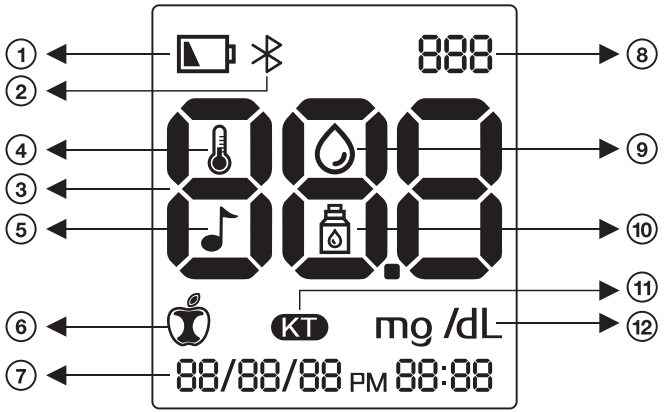
Knowing Your TRUENESS™ AIR Blood Glucose Meter

Key Functions of the **TRUENESS™ AIR** Blood Glucose Meter



For assistance obtaining other components, please call 1-800-803-6025.

TRUENESS™ AIR Blood Glucose Meter Display



1. Battery symbol
2. Bluetooth symbol
3. Test result or error message
4. Temperature symbol
5. Audio symbol
6. Meal Symbol-Unmarked / Before Meal / After Meal
7. Date and time
8. Sequence number of test result
9. Drop Symbol-Apply blood or control solution
10. Control Symbol-Result is from control solution
11. Ketone test alert symbol
12. Unit of measure (Factory set to mg/dL; cannot be changed by user)

Setting Up Your TRUENESS™AIR Blood Glucose Meter

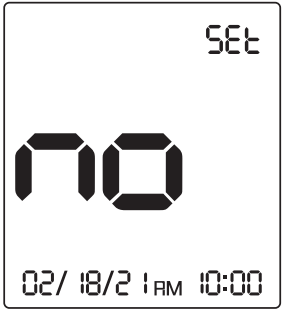
The meter is preset with the date and time. You may need to adjust it to your local time zone. Check the date and time each time the batteries are replaced. Reset the date and time if they are not correct.

STEP 1: Insert the Batteries

Refer to "Battery" section for instructions.
Open the Battery Cover on the back of the meter. Insert two AAA alkaline batteries as indicated by the "+" and "-" symbols. Meter automatically enters into set up mode.

STEP 2: How to Enter the Setup Mode

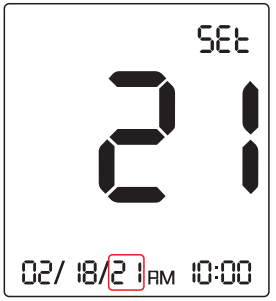
Starting with the meter turned off, press and hold the ">" button until the Display shows "no" and "SEt". The meter enters into the setup mode. Press ">" or "<" to choose "yES" to set time or date. Press ">" or "<" to choose "no" to enter into Sound setting mode.



STEP 3: How to Set the Year

Press the "OK" button when the LCD displays "yES', the last two digits of the year flashes. Press ">" or "<" to change the year.

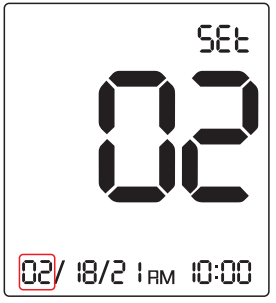
Year:



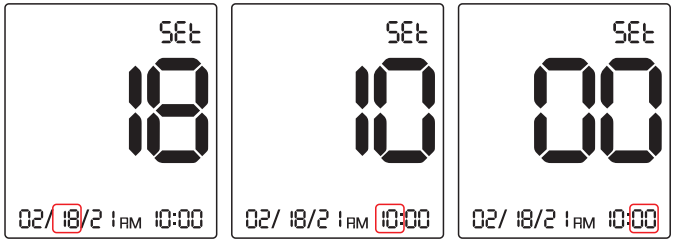
STEP 4: How to Set the Month

Press the "OK" button after selecting the Year. The meter enters into the month setup mode and the month number flashes. Press ">" or "<" to adjust the month. Press "OK" to confirm and enter day setup mode.

Month:



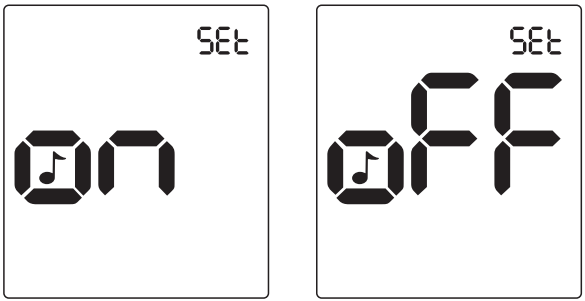
STEP 5: Repeat steps 3-4 to set up day, hour and minutes



Day Hour Minute

STEP 6: How to Set Sound

After finished setting the minutes, the Meter automatically enters beeper setting mode. The display shows "On" and "♪". Press ">" or "<" to choose "On" or "Off". Press "OK" to confirm your selection. The meter turns off automatically.



Note: If the batteries are replaced, it may cause the date and time to reset. Resetting the date and time does not change the time stamps of previous test results.

Power Saving

- ▸ Meter automatically turns off after 3 minutes if no blood or control sample is applied while in test mode.
- ▸ After testing blood or control sample, the result is displayed for one **(1)** minute if the test strip remains in the meter. If the test strip is removed, the meter immediately turns off.
- ▸ Meter automatically turns off if there is no activity within one minute while in setup mode, test results review mode, and control solution test review mode.

Control Solution Testing

There are two levels of control solution with different concentrations of glucose: Level 1 and Level 2. Each test strip lot has its own control ranges for Levels 1 and 2 printed on the test strip vial.

The control solution helps determine if the meter and test strip are working properly. A control test also helps you practice proper testing technique. The control solution is a water-based solution containing a certain amount of glucose. It reacts with the test strip when used in place of blood. The control solution gives results within the corresponding range for its level printed on the test strip vial label. You can use Level 1 or Level 2 **TRUENESS™** control solution with your **TRUENESS™ AIR** blood glucose meter and **TRUENESS™** blood glucose test strips.

Caution: The control solution ranges printed on the test strip vial are not recommended ranges for your blood glucose.

If there is a large difference between the storage temperature and the ambient temperature for the test, wait at least 30 minutes before testing to allow the meter, control solution and test strips to adjust to the ambient temperature.

Important Information

- Use only **TRUENESS™** control solution and test strips with your **TRUENESS™ AIR** blood glucose meter.
- Check the expiration date on the control solution bottle. Do not use if expired.
- When using a new bottle of control solution, write the date opened on the control solution bottle. Discard the bottle 3 months after the date written or once the printed expiration date has passed, whichever comes first.
- Control solution is for *in vitro* diagnostic use only.

Why Perform a Control Solution Test?

- Ensures your meter and test strip are working properly.
- Allows practice testing without using blood.

When Should You Perform a Control Solution Test?

- When you begin using a new vial of test strips.
- When the test strip has been exposed to extreme environmental conditions.
- If you drop the meter.
- If you suspect your results.
- After cleaning and disinfection of your meter.
- It is recommended to perform a Control Solution Test once a week.

Storage and Handling

- Close the control solution bottle cap tightly after each use.
- Store the control solution at temperatures between 34°F-86°F (1°C-30°C).
- DO NOT FREEZE.

WARNING! *If there is a large difference between the storage temperature and the ambient temperature for the test, wait at least 30 minutes before testing to allow the meter and test strips to adjust to the ambient temperature.*

Performing a Control Solution Test

Check the expiration and written opened dates on your control solution bottle and blood glucose test strip vial. Discard any expired test strip vial or control solution bottles. DO NOT apply blood while in Control Solution Testing Mode, it will cause an E-8 Error message.

STEP 1: Wash your hands

Wash your hands with soap and water. Be sure to dry your hands before performing a test.

STEP 2: Insert a test strip into the meter

Start with the blood glucose meter off. Insert a test strip with the printed side facing up and contact end toward the meter. Push the test strip into the meter Test Strip Port until it stops.

STEP 3: Enter Control Solution Testing Mode

IMPORTANT: **Press "<", the meter will enter into control solution testing mode and display the control symbol .**

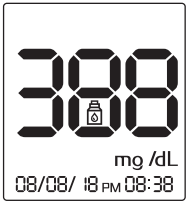
Caution: DO NOT smear or scrape the control solution onto the test strip. DO NOT apply control solution to the test strip when the test strip is out of the meter. DO NOT move meter or test strip during test countdown. DO NOT apply control solution while in Blood Testing Mode, it will cause an E-8 Error message.

STEP 4: Apply the control solution

1. Gently swirl and invert the control solution bottle to mix and remove the cap. DO NOT shake the control solution.
2. Squeeze the bottle and discard the first drop. Wipe the bottle tip with a clean tissue.
3. Squeeze one drop of control solution onto a clean piece of aluminum foil or plastic wrap.
4. With the test strip still in the meter, touch the tip of the test strip to the control solution drop until the meter beeps. Make sure the reaction zone is completely filled.

Note: **If sample is not applied within 3 minutes of inserting a test strip, the meter turns off. Reinsert test strip and retest.**

5. The meter counts down for 5 seconds, then displays the control solution test result with the control symbol . If the meter does not display the control symbol, re-do the test.
6. Check if the test result is in range. Compare the test result with the corresponding level's control range printed on the test strip vial you are using.



Note: **If the test results in an E-8 error, repeat test with new test strip making sure that the meter is set to control mode by pressing the "<" button.**

7. Press Eject button and eject the test strip into a trash container. Discard the used test strip carefully as medical waste.

Unexpected Results:

If the test result falls outside the control range that is printed on the test strip vial for the control level you are using, check the Troubleshooting Guide located in the System Troubleshooting section of this booklet and repeat the test. Results that fall outside the control range may indicate:

- ► Error in performing the test
- ► Control solution has not been mixed well
- ► Expired or contaminated control solution
- ► Control solution that is too warm or too cold
- ► Expired or deteriorated test strip
- ► Meter malfunction

Caution: *Do not use test strips or control solution that are past the discard date, expired, or have been damaged, as your results may be inaccurate.*

Contact Customer Care:

If your test strip has been damaged or if you continue to get out-of-range results, it means that the **TRUENESS™AIR** blood glucose monitoring system or the control solution may not be working as they should.

DO NOT use the meter or test strips to test your blood glucose level. If you are unable to resolve the problem, contact Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST. Please call your healthcare professional when Customer Care is closed.

Performing a Blood Glucose Test

WARNING!

If there is a large difference between the storage temperature and the ambient temperature for the test, wait at least 30 minutes before testing to allow the meter and test strips to adjust to the ambient temperature.

Obtaining a Blood Sample

- Lancing device and meter are intended only for a single user and should not be shared with anyone, including your family members.
- Check the expiration date of the sterile lancet before testing. Do not use if expired.
- Sterile 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 in warm, soapy water. Rinse well. Dry thoroughly. Refer to lancing device Instructions for Use for detailed instructions on cleaning and disinfecting the fingertip.
2. Place end of lancing device equipment 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 palms 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

Caution! The used lancet is biohazardous. Please discard it carefully according to your Healthcare Professional's instructions.

How to Test Blood

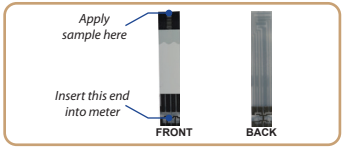
STEP 1:

Take a test strip out of the test strip vial. Immediately close the vial lid.

STEP 2:

Fully insert the test strip into the meter Test Strip Port until it stops.

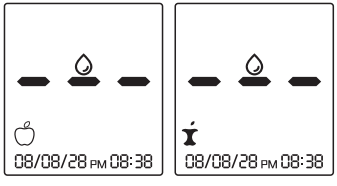
Tip: Insert **TRUENESS™** blood glucose test strip with the printed side facing up and contact end toward the meter. Caution: DO NOT insert and remove the test strip repeatedly.



STEP 3:

When the blood glucose meter screen displays a flashing blood drop symbol, press " >"to mark the test as Before Meal or After Meal.

Tip: If you do not choose Before Meal or After Meal, you will have 1 minute to set it again after the meter displays the test result.



STEP 4:

Make sure the lancing device is pressed firmly to your finger. Lance finger and allow a blood drop to form. Images for lancing device are for illustration purposes only. Your lancing device may look different. Refer to lancing device Instructions for Use for detailed instructions on using the lancing device to obtain a blood drop.

Attention:

- **The cap of the lancet is a single sterile barrier system. Do not use the lancet if the cap has been previously removed from the device.**
- **Used or contaminated lancets present a serious infection hazard that can lead to dangerous infections if not properly stored or disposed. Please discard them carefully according to your healthcare professional's instructions or dispose them in an appropriate trash container.**
- **If you did not produce a large enough blood sample, gently massage your finger. DO NOT SQUEEZE YOUR FINGER. Refer to Lancing Device Instructions for Use to adjust the puncture depth and lance again.**

STEP 5:
While the meter screen displays the flashing blood drop symbol, apply the blood sample to the **tip** of the Test Strip Reaction Zone.

Allow the blood to be drawn into the test strip filling the entire Reaction Zone.

Attention: Hold the tip of the test strip to the blood drop until the meter beeps.
Visually confirm that the blood sample fills the entire Test Strip Reaction Zone at the end of the test strip. If blood is not applied within 3 minutes of inserting a test strip, the meter turns off. Reinsert the test strip and start test as in Step 5.

Caution:

DO NOT smear or scrape the blood onto the test strip.
DO NOT apply blood to the test strip when the test strip is out of the meter.
DO NOT move meter or test strip during test countdown.
DO NOT expose the blood drop to the air for a long time.
DO NOT apply blood sample before a blood drop symbol flashes on the display.

STEP 6:
After a 5-second count down, the meter displays the test result.

Caution
If a test result exceeds 250 mg/dL, "KT" symbol will be displayed on the screen to remind you to perform a ketone test.

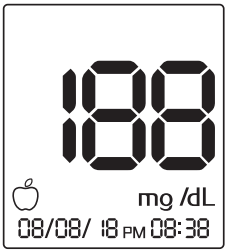
STEP 7:
Eject the test strip into a trash container. Discard the used test strip carefully to avoid contamination.

Caution: Used lancets and test strips are biohazardous. Please discard them carefully according to your healthcare professional's instructions or dispose them in an appropriate trash container.

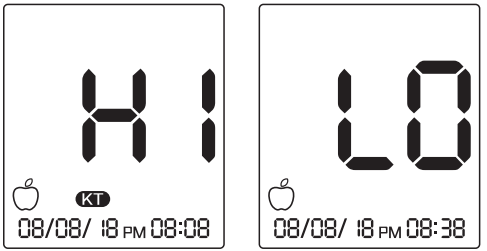
Note: Wash hands thoroughly with soap and water after handling the meter, lancing device, or the test strip.

Understanding Your Result

After the meter counts down from 5, your blood glucose result appears along with the unit of measure, date, and time.
This blood glucose result is stored in the meter memory.



If your test result is above 600 mg/dL, the screen displays “HI”.
If your test result is below 40 mg/dL, the screen displays “LO”.



Caution: If a test result exceeds 250 mg/dL, "KT" symbol will be displayed on the screen to remind you to perform a ketone test.

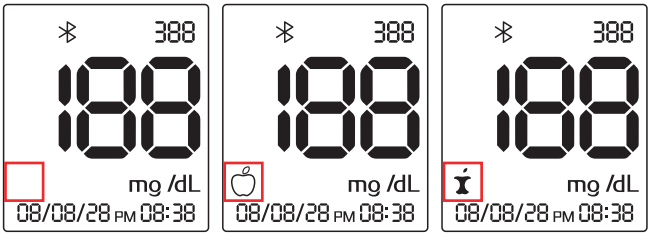
If you cannot test due to a problem with your testing supplies, contact Customer Care at 1-800-803-6025, Monday-Friday 8AM-8PM EST. Please call your healthcare professional when Customer Care is closed. Failure to test could delay treatment and/or lead to serious medical conditions.

Using the TRUENESS™ AIR Blood Glucose Meter Memory

The meter can store 600 test results including blood glucose test results and control solution test results with the date and time in its memory. You can review the individual results by entering the memory mode.

STEP 1: Enter the Memory Mode

While the meter is turned off, **press and hold the “OK” button to turn on the meter.** The most recent blood glucose test result is displayed.

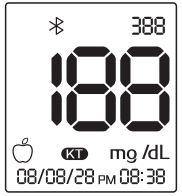


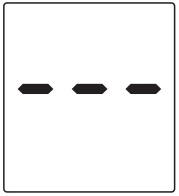
Unmarked | Before meal | After meal

STEP 2: Reviewing the Blood Glucose Test Results

Press the "<" button to view all the blood glucose results in memory. The number of the test result that you are viewing is displayed in the upper right hand corner of the screen. Press the ">" button to view all/before meal/after meal test result averages for the past 7, 14, 30, and 90 days. The Average of days that you are viewing is displayed in the upper right hand corner of the screen. If no blood glucose test results have been stored, the meter displays "– – –".

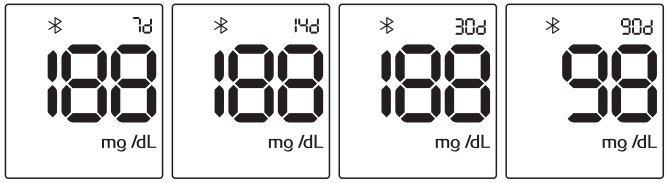
Blood Glucose Test Result





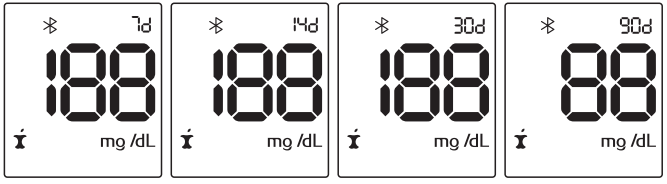
No Blood Glucose Test Result

Averages of All Results



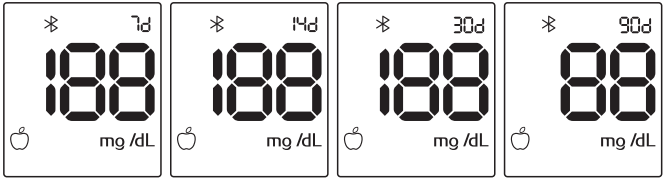
7 day average | 14 day average | 30 day average | 90 day average

After Meal Averages



7 day average | 14 day average | 30 day average | 90 day average

Before Meal Averages:



7 day average | 14 day average | 30 day average | 90 day average

Note: *"LO" results are included in the Average as 40 mg/dL.*

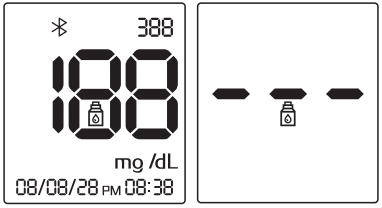
"HI" results are included as 600 mg/dL

STEP 3: ***Reviewing the Control Solution Test Results***

Press the "OK" button to view your control solution test results after entering the Memory Mode. The most recent control solution test results appear along with the control symbol. Press "<" or ">" button to view all the control solution results in memory. The number of the test result that you are viewing is displayed in the upper right hand corner of the screen. If no control solution test results been stored, the meter displays "– – –".

To view the blood glucose results again, press the "OK" button. After viewing your blood glucose results or control solution results, press and hold the "OK" button until the meter turns off.

Control Solution Result



No Control Solution Result

The meter can store 600 test results including blood glucose test results and control solution test results. If these numbers are exceeded, any new result causes the oldest result in memory to be deleted.

TRUE MANAGER AIR APP

Receives blood glucose test data and control solution data from the Meter.
Only displays data and trends.
No two-way communications (from App to the Meter).

CAUTION: The TRUENESS AIR Meter has not been tested for use with any other App other than compatible TRUE MANAGER AIR APP.
The manufacturer is not responsible for any erroneous results from the use of other APPs.

Download the TRUE MANAGER AIR APP

Step 1: On your compatible smartphone or tablet, go to the App Store or the Google Play store.
Step 2: Search for the TRUE MANAGER AIR APP.
Step 3: Install the TRUE MANAGER AIR APP.

How to use the TRUE MANAGER AIR APP

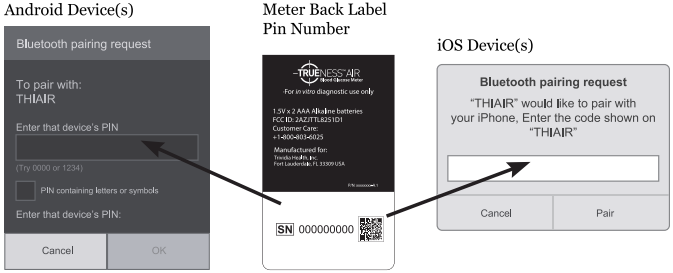
Step 1: Open the APP.
Step 2: Click the Sync icon " " to pair your meter with your smartphone or tablet (see Pairing (Connecting) Meter with Mobile Device section below).
Step 3: The test results will be uploaded automatically.

Pairing (Connecting) Meter with Mobile Device

Pairing enables the meter to upload test results from the meter's memory when requested by an App (application) on a mobile device. The meter must be 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.

1. Press and hold the "OK" button until the meter turns on.
2. Follow your mobile device's App instructions in order to locate the **TRUENESS™AIR** meter (look for a device named THIAIR). **Enter the last 6 digits of the meter serial number** (found on the meter back label) into the mobile device. This is the meter's PIN number. Wait for mobile device 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.

3. If Bluetooth cannot connect to the App, please check whether the mobile device's Bluetooth is on. If yes, please turn off the meter, press and hold the "OK" button to restart the meter to reconnect Bluetooth. If it remains unconnected after 3 attempts, please call Customer Care at 1-800-803-6025, Monday-Friday 8AM-8PM EST or visit our website at www.trividiahealth.com.



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

Attention:

- This meter operates with Bluetooth. Make sure that device to be paired can work with Bluetooth.
- Keep the meter powered on in Memory mode when uploading data.
- If a test strip is inserted into the meter during the uploading of results to the App, the results stop uploading. You must re-start the upload from the App installed on the mobile device.
- To make sure that test results are secure, only let trusted people (doctor, family, etc.) connect your meter to a mobile App.
- Keep meter serial number private.
- Allowing other people to upload results to a mobile App that is not yours could result in a loss of privacy of your data.

Cleaning and Disinfection of Your System:

The **TRUENESS™AIR** blood glucose meter has been tested and proven robust to the recommended cleaning and disinfection procedures. If meter deterioration occurs (e.g., foggy LCD screen, failure to detect inserted test strip, faded or missing LCD screen segments, false high or false low results for blood glucose test or control solution test), stop using the meter and contact Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST. Please call your healthcare professional when Customer Care is closed.

Clean the meter and lancing device to remove blood, skin oils, dirt, and dust after each use. Clean and disinfect the meter and lancing device at least once per week to eliminate infectious agents.

The wipes below have been shown to be safe and effective for use with the **TRUENESS™AIR** blood glucose meter: SUPER SANI-CLOTH ® Germicidal Disposable Wipes (EPA Reg. No. 9480-4). They can be purchased at: Amazon.com, Officedepot.com, Walmart.com.

Attention: Used wipes should be disposed of according to local regulations for infectious waste disposal.

Meter Cleaning Procedure

Step 1: Use one area of a new wipe to wipe 3 times horizontally with moderate pressure on the entire meter surface. Then, using another unused area of the same wipe, wipe 3 times vertically on the entire meter surface again. One time is counted as one back and forth action (for example, left to right to left).

Step 2: Allow the meter to air dry at room temperature. We recommend cleaning the meter at least once per week.

Meter Disinfection Procedure

The disinfection procedure helps to eliminate infectious agents. Meter disinfection should be performed at least once per week.

Step 1: After cleaning the meter, use an unused wipe to cover the entire meter surface for 2 minutes. Make sure all external surfaces of the meter remain wet for 2 minutes.

Step 2: Allow the meter to air dry at room temperature.
The meter can be cleaned and disinfected up to 520 times, with cleaning and disinfection at least for 5 years.

NOTE:

To clean and disinfect the lancing device, refer to the Lancing Device Instructions for Use for detailed instructions.

Please contact Customer Care if you have any questions at 1-800-803-6025, Monday – Friday 8AM-8PM EST.

- ► If the lancing device button fails to work, stop using the device and contact Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.
- ► Clean and disinfect the meter and lancing device prior to handling if a second person assists you with testing.
- ► Wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Performance Characteristics

Accuracy for Home Use by Lay-Users

Your **TRUENESS™AIR** meter results may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.

The table below shows the results where typical users enrolled in a clinical study used the **TRUENESS™AIR** meter to measure their blood glucose levels. For example, in this study, the **TRUENESS™AIR** meter displayed results within 15% of their actual blood glucose level in 345 out of 354 measurements as compared to an approved lab instrument.

Difference range between the actual blood glucose level and the TRUENESS AIR meter result	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Percent (and number) of samples within specified range	52.3% (185/354)	82.2% (291/354)	97.5% (345/354)	99.7% (353/354)

Precision:

Within Run Precision (300 Venous Blood Tests per glucose level)

Mean, mg/dL	*Pooled Standard Deviation, mg/dL*	*Pooled Coefficient of Variation, %*
43.4	1.8	4.0%
102.3	3.5	3.5%
132.1	4.2	3.3%
212.5	6.3	3.0%
339.8	9.7	2.9%

Intermediate Precision (300 Control Solution Tests per Glucose Level)

Control Level	*Mean, mg/dL*	*Pooled Standard Deviation, mg/dL*	*Pooled Coefficient of Variation, %*
1	45.0	1.9	4.3%
2	98.2	2.5	2.6%
3	137.8	3.3	2.4%
4	204.1	4.2	2.1%
5	381.7	9.2	2.4%

System Specifications:

Sample Volume	1 µL
Sample Type	Fresh capillary whole blood
Results Value	Plasma equivalent values
Assay Method	Electrochemical
Meter Storage Conditions	-4°F-131°F (-20°C-55°C) (RH≤95%)
Dimensions	3.65 in. (L) x 2.11 in. (W) x 0.89 in. (H) (92.8 mm (L) x 53.5 mm (W) x 22.5 mm (H))
Weight	1.89 oz (53.5 g) with batteries
Power Source	2 AAA alkaline batteries
Battery Life	Approximately 1,000 tests
Display	LCD
Memory	600 test results including blood glucose test results and control solution test results
Operating Range	**Temperature:** 50°F-104°F (10°C-40°C) **Relative Humidity:** 10%-90% RH (non-condensing) **Hematocrit:**15%-60% **Altitude:** Up to 10,100 feet (3,078 meters) ***Note: Use within specified environmental conditions only.*** **Results Range:** 40-600 mg/dL

Caring for Your TRUENESS™ AIR Blood Glucose Meter

The **TRUENESS™AIR** blood glucose meter does not require professional maintenance services.

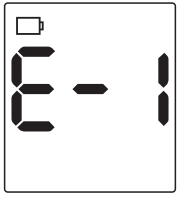
- Avoid getting dirt, dust, blood, control solution, foods, or liquids inside the meter.
- After each use, store the meter, test strips, and control solution in the carrying case at room temperature in a dry place.
- DO NOT FREEZE.
- Do not store in the bathroom or kitchen.
- Your **TRUENESS™AIR** blood glucose meter is a precision instrument. Handle with care.

Battery

Your **TRUENESS™ AIR** blood glucose meter is powered by 2 AAA alkaline batteries. You can find replacement batteries in most stores. The meter shows a battery symbol only when the batteries are low.

Low Battery

The meter shows a battery symbol and E-1 in the display to indicate the condition of the meter batteries. When these messages appear, there is not enough power to perform a test. Replace the batteries as soon as possible.



Changing the Batteries

To replace the batteries, make sure the meter is turned off.

Step 1: With the meter turned off, push down on the Battery Door and slide to open.

Step 2: Remove the used batteries from the meter and replace them with 2 new AAA alkaline batteries. Install the batteries according to the "+" and "–" symbols in the battery compartment. Check that you have placed the batteries correctly and close the Battery Door.

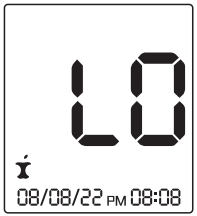
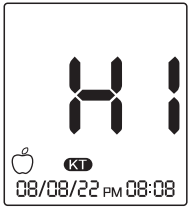
Step 3: Check the date and time. The date and time settings may need to be reset. Replacing the batteries does not affect the meter's test result memory. The unit of measure remains as mg/dL.

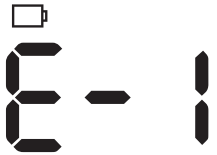
WARNING! *As with all small objects, keep batteries away from small children. If a battery is swallowed, seek medical help right away.*

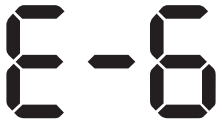
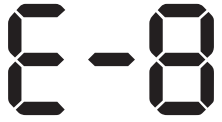
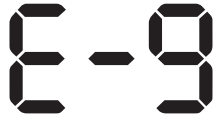
System Troubleshooting

Special Messages

Special messages and error messages help to identify certain problems. However, improper use may cause an inaccurate result without showing an error message. In the event of a problem, refer to the Troubleshooting Guide below. If you follow the actions recommended but the problem persists, please contact Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST for assistance. Please call your healthcare professional when Customer Care is closed. Never change your treatment plan without consulting your healthcare professional.

Message	Description
	**What it means:** The blood glucose test result is less than 40 mg/dL. **Action:** *Retest with new test strip. If result is still "LO" contact your healthcare professional immediately.*
	**What it means:** The blood glucose test result is greater than 600 mg/dL. **Action:** *Retest with new test strip. If result is still "HI" contact your healthcare professional immediately.*

	**What it means:** Low battery. A test cannot be performed. **Action:** *Replace the batteries.*
	**What it means:** Meter outside of operating temperature range. **Action:** *Move the meter and test strip vial to an appropriate location between 50°F-104°F (10°C-40°C).* *Wait at least 30 minutes and test again.*
	**What it means:** Operation error or test strip may be wet. E.g., re-used a test strip. **Action:** *Use a new test strip and test again.*
	**What it means:** Wrong use of test strip. E.g., test strip inserted backwards. **Action:** *Check the test strip vial and use a new* **TRUENESS™** *test strip.*
	**What it means:** Operation error. E.g., the test strip was ejected during the test. **Action:** *Use a new test strip and test again.*

	**What it means:** Meter internal error. **Action:** *Call Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.*
	**What it means:** Insufficient sample size. **Action:** *Use a new test strip and test again with enough sample.*
	**What it means:** Test process error or testing in the wrong mode (control testing in blood testing mode or blood testing in control testing mode). **Action:** *Use a new strip and test again.*
	**What it means:** Abnormal Hematocrit. The Hematocrit is outside of the range 15% to 60%. **Action:** *Use a new strip and test again. If the meter still displays E-9, please contact your healthcare professional.*
	**What it means:** Meter memory error or Meter communication error. For example, the meter is disturbed by environment. **Action:** *Reinstall the batteries in the meter. If the meter still displays E-0, Call Customer Care at 1-800-803-6025, Monday–Friday 8AM-8PM EST.*

Troubleshooting Guide

- 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 test with new test strip.
Dead or no batteries	Replace batteries.
Batteries installed incorrectly	Check that the batteries are correctly installed in the proper orientation of "+" and "-".
Meter error	Call Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.

- 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 sample drop.
Sample is applied to wrong area of test strip	Repeat test with new test strip and apply the sample to the tip of the Reaction Zone.

Test strip inserted incorrectly	Remove test strip. Insert the contact end of the test strip into the meter until it stops. Printed side of test strip must face up. Reapply the blood sample.
Sample applied after 3 minute shut-off	Repeat test with new test strip. Apply sample within 3 minutes of inserting test strip into the meter.
Problem with test strip	Repeat test with new test strip. If meter still does not begin testing, call Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.
Problem with meter	Call Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.

- Control test result is out of range

Reason	*Action*
Testing error	Read the instructions for use thoroughly and repeat test.
Control solution bottle is not mixed well	Gently swirl the control solution bottle and repeat test.
The first drop of control solution is used to test	Repeat test with new test strip.
Expired or contaminated control solution	Check the printed expiration and written open dates of the control solution. Use control solution that is within the expiration and discard dates.
Control solution temperature exceeds 50°F-104°F (10°C-40°C).	Place control solution at room temperature between 50°F-104°F (10°C-40°C) for 30 minutes and test again.
Test strip error	Repeat the test with new test strip. If meter still does not begin testing, call Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.
Meter error	Call Customer Care at 1-800-803-6025, Monday – Friday 8AM-8PM EST.

Important Information about TRUENESS™ AIR Blood Glucose Meter

Comparing TRUENESS™ AIR Blood Glucose Meter and Laboratory Results

The test results obtained from your **TRUENESS™ AIR** blood glucose meter may differ from laboratory results due to normal variation. **TRUENESS™ AIR** blood glucose meter results can be affected by factors and conditions that do not affect laboratory results in the same way. See **TRUENESS™** Blood Glucose Test Strip Instructions for Use for important information on its limitations. To make an accurate comparison between **TRUENESS™ AIR** blood glucose meter and laboratory results, follow the guidelines below.

Before you go to the laboratory:

Perform a control solution test to make sure that the meter and test strips are working properly. If your doctor requested you to fast, it would be a good time to do a comparison test. Take your meter and test strips with you to the laboratory. You may still have a variation in the results because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medications, or experienced stress. If you have eaten recently, the blood glucose level from a fingerstick can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.[2]

Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of bodily fluids (severe dehydration) may also cause the **TRUENESS™ AIR** blood glucose meter result to be different from a laboratory result.

While at the laboratory:

- Make sure that the fingertip blood sample for the **TRUENESS™ AIR** blood glucose meter and the venous blood sample for the laboratory analyzer are drawn within 15 minutes of each other.
- Wash and dry your hands before drawing a blood sample.
- Only use fresh capillary whole blood with the **TRUENESS™ AIR** blood glucose monitoring system.

Expected Test Results

Consult your healthcare professional for your ideal glucose ranges. The American Diabetes Association (ADA) suggests the following expected glucose range for people without diabetes. More or less strict goals may be appropriate for each person.

Time	Plasma glucose for people without diabetes[1]
Before eating	< 100 mg/dL
2 hours after a meal	< 140 mg/dL

Your **TRUENESS™ AIR** blood glucose meter is designed to help you and your healthcare professional manage your diabetes. You must always rely on your healthcare professional to interpret your test results and to decide how to treat your diabetes.

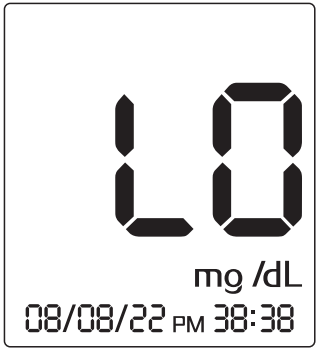
Unexpected Test Results

Unexpected test results can occur. If this happens, please refer to the cautions below.

CAUTION: Low Blood Glucose Test Results

False low results may occur if you are severely dehydrated. If you think that you are severely dehydrated, contact your healthcare professional right away.

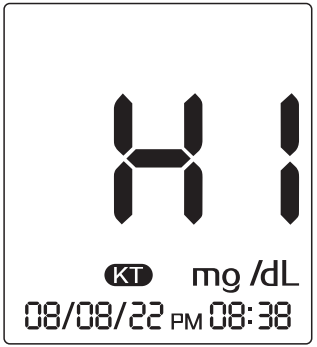
If your test result is lower than expected or "LO" appears on your meter display, retest with a new test strip. If the result continues to be lower than expected, contact your healthcare professional right away.



Caution: High Blood Glucose Test Results

If your test result is higher than expected, retest with a new test strip. If the result continues to be higher than expected, contact your healthcare professional right away.

If "HI" appears on your meter screen, (result higher than 600 mg/dL) retest with a new test strip. If you continue to get "HI" contact your healthcare professional right away.



If you continue to get unexpected test results, check the performance of your **TRUENESS™ AIR** blood glucose monitoring system by performing a control solution test. Refer to the "**Performing a Control Solution Test**" section in this booklet.

Caution: Unusual Red Blood Cell Count

A hematocrit (percentage of red blood cells in the blood) that is extremely high (above 60%) or low (below 15%) can also cause inaccurate results.

Cybersecurity/Electromagnetic Compatibility/Wireless

Caution:

•Keep your Bluetooth pairing code from other people.
•TRUENESS™ AIR meter cannot be updated or patched by user, so DO NOT accept any change or update to the Meter.
•Any cybersecurity information will be published on the website www.trividiahealth.com.
•If any other suspected cybersecurity event occurs, please exit the memory mode to allow the Meter automatically turn off the Bluetooth, but the meter can test blood glucose still, and call Customer Care at 1-800-803-6025 Monday-Friday 8AM-8PM EST. or visit our website at www.trividiahealth.com.

Software bill of materials		
Asset(s) where the software component resides	Blood Glucose Meter	Bluetooth Module
Software component name	TRUENESS™ AIR Meter writing program bin	TL8251-BGM(GLS_GLP) Meter writing program bin
Software component version	(V01)	v1.4.1
Software component manufacturer	Sinocare	Sinocare
Software level	Moderate	Minor
Software component's end-of-support date	N/A	N/A
Known vulnerabilities	None	None
Relationship between software components	Independent	Independent

Cybersecurity/Electromagnetic Compatibility/Wireless

The meter complies with the electromagnetic requirements of IEC 60601-1-2:2014+A1:2020.

- Essential Performance (accuracy of measurement value):
  ± 10 mg/dL for glucose levels 40 mg/dL - 74 mg/dL
  ± 10% for glucose levels 75 mg/dL - 600 mg/dL

This equipment is designed for use at home. If you suspect that performance is affected by electromagnetic interference, please increase the distance between the equipment and the interference source.

Guidance and manufacturer's declaration – Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1 Class B	The TRUENESS™ AIR Blood Glucose meter uses electromagnetic energy only to perform its intended function. Nearby electronic equipment may be affected.

Guidance and manufacturer's declaration- Electromagnetic Immunity

Immunity Test	Test Level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Air discharge: ±2kV, ±4kV, ±8kV, ±15kV Contact discharge: ±8kV	Air discharge: ±2kV, ±4kV, ±8kV, ±15kV Contact discharge: ±8kV	Wrong conclusions may occur when TRUENESS™ AIR Blood Glucose meter is used in a dry environment, especially with man-made materials. It may cause damaging electrostatic discharge
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80%AM,1	10 V/m 80 MHz to 2.7 GHz 80%AM,1kHz	The TRUENESS™ AIR Blood Glucose meter complies with all applicable EMC standards, for residential, commercial and light industry environments. Portable and mobile RF communications equipment should be used no closer to any part of the machine, including cables, than the recommended 30 cm separation distance.

Recommended Separation Distance:
$d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.7\sqrt{p}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity Test	Test Level	Compliance Level	Electromagnetic environment – guidance
Power frequency magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical residential environment.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the meter is used exceeds the applicable RF compliance level above, the Model 006 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 006.

Recommended isolation distance between portable and mobile radio frequency communication equipment and equipment or system

This instrument is expected to be used in electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication equipment (transmitter) and this instrument as recommended below

Maximum rated output power of transmitter (W)	Isolation distance corresponding to different frequencies of transmitter/m	
	80MH - 800MHz $d = 0.35\sqrt{p}$	80MHz - 2.7GHz $d = 0.7\sqrt{p}$
0.01	0.04	0.07
0.1	0.11	0.22
1	0.35	0.7
10	1.11	2.21
100	3.5	7

For transmitter maximum rated output power not listed in the above table, the recommended isolation distance D in meters (m) can be determined by the formula in the corresponding transmitter frequency column where P is the transmitter maximum rated output power provided by the transmitter manufacturer in watts (w) Note 1: At the frequency points of 80MHz and 800MHz, the formula of higher frequency range is adopted Note 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection of building objects and human body.

Federal Communications Commission Interference Statement

The TRUENESS™ AIR Blood Glucose meter complies with Part 15 of the FCC Rules.

FCC ID: 2AZJTTL8251D1.These limits are designed to provide reasonable protection against harmful interference in residential installation. However, there is no guarantee that interference will not occur in anyway. If this equipment does cause harmful interference to radio or television reception. which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by increasing the separation between the equipment and receiver.

Operation is subject to the following two conditions: This machine may not cause harmful interference, and this machine must accept any interference received, including interference that may cause undesired operation.

Wireless specifications

Frequency: 2.402GHz-2.480GHz

Power: 0dbm

Operating distance ≤10m

Quality of Service

TRUENESS™ AIR blood glucose Meter can transmit blood glucose data in an open environment within 10 meters through BLE. After Meter successfully pairs with APP, APP reads the storage data on the Meter. If reading fails, it allows repeated readings. After successful reading, the Meter transmits blood glucose data in a timely manner. Data integrity is ensured through verification during transmission.

Limited Warranty

Trividia Health Inc. provides the following Limited Warranty to the original purchaser of the **TRUENESS™AIR** blood glucose monitoring system:

1. Trividia Health Inc. warrants this meter to be free of defects in materials and workmanship for 5 years from the date of purchase. If during this 5 year period, the meter does not work properly, Trividia Health will replace it with a new **TRUENESS™AIR** blood glucose meter or equivalent product free of charge. 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 batteries 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. Trividia Health Inc. disclaims liability for incidental, consequential, indirect, special, or punitive 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 limitations of incidental or consequential damages, so the above limitations may not apply to you.
5. This warranty gives you specific legal rights which vary from state to state.

References

1. American Diabetes Association. Standards of Medical Care in Diabetes January 2023 Volume 46, Supplement 1: S19-S40
2. Larsson-Cohn U: Difference between capillary and venous blood glucose during oral glucose tolerance tests. Scand J Clin Lab Invest 36:805-808, 1976. 45.

Manufactured For:
Trividia Health, Inc.
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Notes: