

TRUE METRIX® Blood Glucose Monitoring System Troubleshooting Steps

Meter to Meter Comparison

Meter to meter comparisons should not be done due to differences in product manufacturing processes. Test results from your meter should only be compared to a laboratory instrument and not to another meter. This recommendation is in alignment with information on the FDA website regarding checking blood glucose meter performance.

- If you are concerned, you should confirm that your meter and test strips are working properly by performing a control solution test with TRUE METRIX control solution. Other control solutions will not work with the system.
- Have your doctor check your blood glucose levels using laboratory equipment and compare results to your meter results. This comparison should be performed within 30 minutes of the laboratory test.
- The FDA defines what is accurate for any blood glucose meter. A meter is considered accurate if it is within 15mg/dL +/- of the value that a lab would provide if the result is 100mg/dL or lower. If the result is above 100mg/dL, the allowance is 15% of the true result. Home meters may be calibrated slightly low or high, depending on the manufacturer, to ensure consistent results. That means that if your blood glucose is really 100mg/dl, a meter result that is between 85 and 115 is considered accurate per the FDA (Refer to Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Guidance Document <https://www.fda.gov/media/87721/download> Page 12)
- The potential differences get larger as your glucose goes higher. For example, if your blood glucose is 300mg/dL, as confirmed by a lab test, your meter results could be between 255 and 345 and be considered accurate, because you are still within 15% +/- of the 300mg/dL result. While this can be a bit confusing, you should consider an average of these two extremes, which will likely be very close to what your actual blood glucose is.
- As a comparison, consider weighing yourself on two different scales. To have a fair comparison, you should weigh yourself at the same time, wearing the same clothing when you use each scale. There will most likely be a slight difference between the two results. Consider the difference between your bathroom scale and the one at your doctor's office or the gym where you work out.

Proper Storage and Handling of Test Strip

Verify the following:

- Test strips are not expired (if expired, immediately discard product).
- Test strips have not been opened past 4 months (discard test strips past the open vial dating).

- Test strips have not been stored improperly (e.g., not in car, hot places, cold places, the kitchen, the bathroom, etc.).
- Test strips have not been subjected to flooded areas, direct sunlight, or extended power outage.
- Test strip vial cap is always replaced immediately after each test strip is removed.
- Test strips have not been transferred from their original vial into another vial, zip-sealed bag or in the meter carrying case pouch.
- If you feel you stored or handled test strips incorrectly, test with a new unopened test strip vial handled and stored correctly.

Testing Technique

1. Gather all testing supplies: meter, test strips, lancing device, lancet, and control solution.
2. Wash hands with soap and warm water, dry thoroughly, and remove a test strip from the vial.

Obtaining Blood Sample

3. Perform a control test if control solution is available, otherwise perform a blood test.
4. Set up the lancing device and select the appropriate depth.
5. Insert a test strip in the meter's test port with the contact blocks facing up and wait for the blood drop icon to appear on the screen.
6. Use alcohol pad/swabs to clean the area puncturing the finger to obtain a blood sample to prevent infection.
7. Dry thoroughly before lancing.
8. Lance the finger and wait for a sufficient blood drop to form on the finger. **Warning:** if unable to get enough blood, hold hands below the waist level and rub hands briskly together to promote blood flow prior to the fingerstick.
9. With the test strip still in the meter, touch sample tip of test strip to the top of the blood drop and allow blood to be drawn up into the test strip. **Warning:** make sure the tip of the test strip does not touch the skin, make sure not to sweep the blood drop off the finger.
10. Remove test strip from blood drop immediately after the meter beeps and dashes appear across the display.
11. After 4 seconds, the meter will display a result or trigger an error.
12. If an error occurs, discard the test strip, and repeat the blood test with a new test strip and a different finger.
13. If an error occurs again on the second test of the same test strip vial, use a new vial of test strips (if available) to perform another blood test. If a result is obtained, the issue is resolved. If you have questions, call customer care at 1-800-803-6025.