iGlucose Touch Blood Glucose Meter GETTING STARTED GUIDE (For self-testing use)

Intended Use

The iGlucose Touch Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is intended to be used by a single person and should not be shared.

The iGlucose Touch Blood Glucose Monitoring System is intended for self- testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

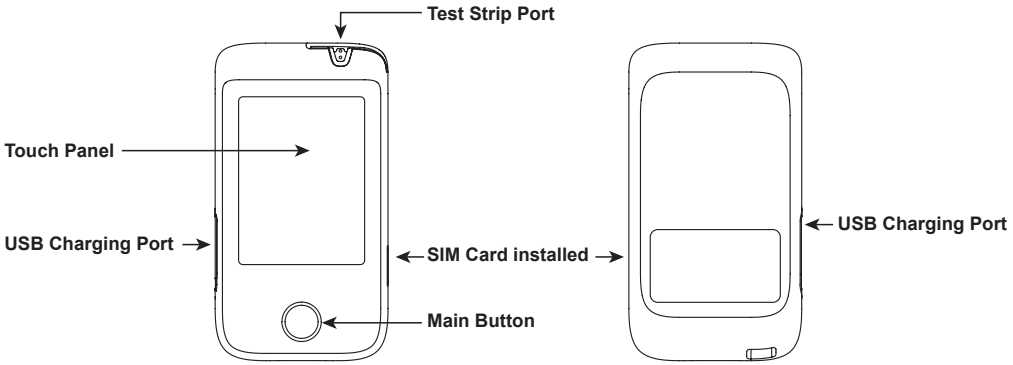
The iGlucose Touch Blood Glucose Monitoring System is comprised of the iGlucose Touch Meter and the iGlucose Touch Blood Glucose Test Strip.

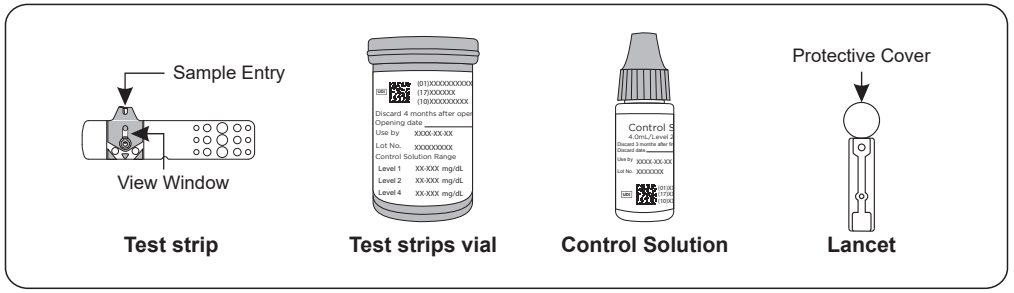
Limitations

- The iGlucose Touch Blood Glucose Monitoring System can only be used with capillary whole blood samples.
- The iGlucose Touch Blood Glucose Monitoring System is for single-patient use only.
- Not for use on neonates.
- Not for screening or diagnosis of diabetes mellitus.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Hematocrit range is 10 - 70%. Check with your healthcare provider if you do not know your hematocrit level.
- Not for use on critically ill patients, severely hypotensive individuals, patients in shock, dehydrated patients, or in a hyperglycemic-hyperosmolar state with or without ketosis.
- 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 bloodborne pathogens.
- Alternative site sample results may be different from fingertip sample results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise).
- Do not rely on test results at an alternative sampling site, but use samples taken from the fingertip, if any of the following applies:
  - you think your blood sugar is low.
  - you are not aware of symptoms when you become hypoglycemic.
  - the results do not agree with the way you feel.
  - after a meal.
  - after exercise.
  - during illness.
  - during times of stress.
- DO NOT use the results from alternative sites (palm, forearm) for insulin dose calculations.
- DO NOT use the results from alternative site testing (palm, forearm) to calibrate Continuous Glucose-Monitoring (CGM) devices.
- 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.
- LTE network is set on by default when the meter is on. Data transmission via LTE network is not suggested during flights at any time. This is because the meter, when turning on, will emit electronic signals, which should be restricted at all times aboard aircraft. Please turn on flight mode to avoid the auto-enabling of LTE network.

Interference

- If you have a condition, such as kidney disease or gout, that may cause your blood levels of uric acid to rise to more than 12 mg/dL, the results from your meter may not be correct.
- If you are taking a high level of vitamin C (ascorbic acid level in your blood > 3 mg/dL), your blood glucose results may not be reliable. If you are unsure, ask your doctor.
- If you have a condition, such as jaundice, that may cause your blood levels of Conjugated Bilirubin to rise to more than 30 mg/dL, the results from your meter may not be correct.
- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.



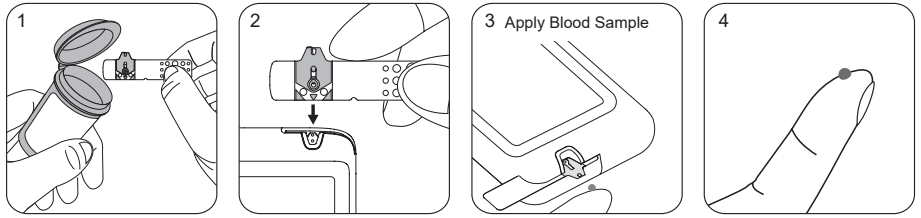


1 Preparing the Lancing Device

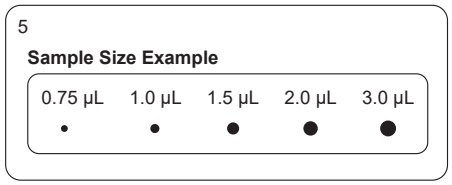
1) Wash and dry your hands. Users should wash their hands with soap and warm water and dry thoroughly before touching the meter, lancing device or test strips.
2) Please check the sampling step on the lancing device insert carefully.

2 Performing a Test

1) Take one Test Strip from the vial then immediately close the vial.
2) Insert the strip into the Test Strip Port of the iGlucose Touch Meter with the View Window face up.
3) "Apply Blood Sample" will display on the screen, please apply the sample within 2 minutes after you see it.
4) Using the lancing device for pricking the finger.

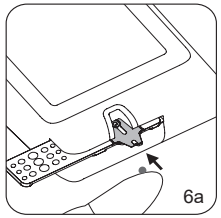


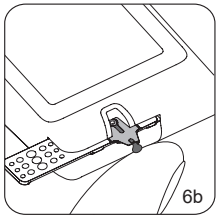
5) Blood samples must be between 0.75 - 3.0 µL for testing. See the Sample Size Example Chart. Blood sample sizes greater than 3.0 µL may contaminate the test strip port and the meter. Samples smaller than 0.75 µL will cause Er4. If this occurs, repeat the test with a new test strip.

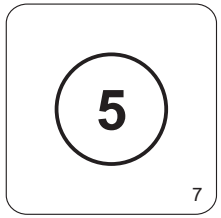


6) Touch the blood drop to the edge of the sample port until the View Window is filled with blood. If the View Window is not filled, the test will not start. In this case, discard the test strip and repeat the test procedure with a new Test Strip.

7) The screen will display a countdown timer. Your test result will be displayed after 5 seconds.

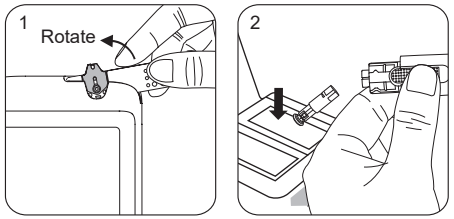






3 Lancet and Test Strip Disposal

1) Remove the test strip and discard it in accordance with local regulations.
2) Discard the used disposable lancet into an appropriate puncture-proof or bioharzard container.



NOTE
- For more information, please see the Owner's Manual.

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Please contact your healthcare provider for assistance after normal business hours.

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