

Questions and Answers

About Standard Glucose Meters and Glucose Sensors

FACT SHEET

Q: What is the accuracy standard for meters and sensors?

A: The medical community considers meters and sensors to be clinically accurate if the measurements fall within ± 20 percent of an accepted laboratory test. The Medtronic Diabetes sensor values, on average, fall well within this acceptable guideline.

Q: How much do meter readings vary?

A: When patients use glucose meters, they will seldom get exactly the same results from one meter sample to the next, even when using the same meter and the same blood draw. A study that compared glucose meter results with laboratory measurements over a ten-year period found that meters varied an average of 13.8 percent. Meter accuracy can depend on a number of variables.

Since meter measurements can vary, it is only natural that meter and sensor values will vary too; however, this does not affect clinical decisions made by patients and healthcare professionals.

Q: Will a meter reading match a sensor reading?

A: It is difficult to compare a "single moment-in-time" measurement from a meter with continuous glucose monitoring. While a meter reading may not exactly match a sensor value, sensor devices provide 864 glucose measurements over a 3-day period, providing valuable trend information and alerting patients to take action – something a meter is not designed to do. Sensors, however, are highly correlated with meter measurements and laboratory tests. Both sensor and meter measurements help patients make clinically accurate decisions.

Q: When might meter and sensor measurements vary?

A: Glucose sensor and meter results are similar when blood glucose is not changing rapidly. When blood glucose is quickly rising or falling, the difference between glucose in interstitial fluid and blood glucose readings usually last about 10 minutes. Overall, the variation between blood and interstitial fluid glucose levels do not affect the clinical utility of the continuous glucose sensor data.

Q: Why do CGM devices require calibration using a standard meter?

A: At this point in time, CGM systems must be calibrated using a fingerstick measurement obtained by a standard meter. This gives the sensor a "starting point" for continuous glucose tracings. In addition, a confirmatory fingerstick is required prior to making a self-management adjustment.

Q: How accurate are sensors?

A: When comparing sensor measurements to each other, glucose readings are highly accurate. A study¹ using CGMS[®] System Gold™ (a device that uses a historical algorithm) that compared sensor-to-sensor measurements found that sensor readings were on average within 12.3 percent of each other. Moreover the same study found that when comparing sensors to meters, the sensors accuracy averaged 13.8 percent.

Subcutaneous glucose sensors have been used by clinicians for more than six years, and have been studied extensively with more than 200 clinical references (abstracts and papers) supporting the use of CGM devices.

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Q: How do algorithms differ in historical and continuous display CGM devices?

A: Medtronic Diabetes has developed two distinct technologies for diabetes management: a historical system and a continuous display system. Each of these technologies uses the same subcutaneous glucose sensor, yet different algorithms are applied. An algorithm is a logical sequence of calculations used in medical device software.

Historical Devices

(e.g., CGMS[®] System Gold™)

- A historical algorithm is used in blinded devices that generate reports for trend analysis used by healthcare professionals.
- Since this device is used to evaluate patients' diabetes control from a historical point of view, the algorithm software is not designed for users to respond to glucose fluctuations.

Continuous display Devices

(e.g., MiniMed Paradigm[®] REAL-Time Insulin Pump and Continuous Glucose Monitoring System and Guardian[®] REAL-Time Continuous Glucose Monitoring System)

- A prospective algorithm is used in devices that allow patients to make continuous self-management decisions.
- A confirmatory fingerstick measurement is required prior to making a self-management decision.

Q: How has Medtronic Diabetes improved its CGM technologies?

A: With more than 10 years of CGM experience, Medtronic Diabetes has continually improved the accuracy of its glucose sensors by refining sensor chemistry, extending sensor longevity, enhancing algorithms, and advancing its manufacturing practices. The table below lists accuracy improvements for historical and continuous display CGM devices developed by Medtronic Diabetes. Future studies are expected to add to the growing body of evidence in support of CGM devices.

Historical Devices

(e.g., CGMS[®] System Gold™)

- The accuracy of devices using historical readings compared to meter readings has improved significantly.
- A study³ published in *Diabetes Technology and Therapeutics* reported an 11 percent median relative absolute difference between a modified CGM sensor and a home blood glucose meter. This compares with results from an earlier CGM sensor where the median relative absolute difference was reported to be 19 percent.

Continuous display Devices

(e.g., MiniMed Paradigm[®] REAL-Time Insulin Pump and Continuous Glucose Monitoring System and Guardian[®] REAL-Time Continuous Glucose Monitoring System)

- The accuracy of new devices that display continuous glucose readings compared to meter readings continues to improve.
- An abstract⁴ presented at the American Diabetes Association, reported a 12 percent median absolute difference between a prototype sensor-augmented insulin pump and a home blood glucose meter. This can be compared to an earlier study⁵ appearing in *Diabetes Technology and Therapeutics*, where the median absolute difference was reported to be 17 percent for a first generation Guardian[®] Continuous Glucose Monitoring System.

Historical and continuous display devices are not meant to be compared to each other due to algorithm differences.

Q: What do leading experts think about CGM?

A: Experts believe that CGM will become the next gold standard of diabetes care. "In the 1920s home urine tests were used to measure blood sugar. In the 1970s glucose meters arrived. Today the most advanced technology for treating diabetes is available – continuous glucose monitoring. It allows patients and clinicians to manage diabetes more effectively than ever before," said William Tamborlane, M.D., professor and chief of Pediatric Endocrinology, Yale School of Medicine.

"Traditionally, capillary glucose has been used as a reference value because intermittent fingerstick measurements have been the standard for testing glucose levels. But a lot of people believe that interstitial fluid is the one we want to measure. That's what the cells see, that's what the brain sees, so that should be a better measure of glycemia than blood glucose," states Samir Mitragotri, Ph.D., assistant professor of engineering at the University of California, Santa Barbara, as published in *Countdown* magazine published by the Juvenile Diabetes Research Foundation International (Winter 2005).

References

¹ Armstrong D, King A. *Diabetes* 2003; 52 (Suppl. 1):384(P).

³ The Diabetes Research in Children Network (DirecNet) Study Group. *Diabetes Technology & Therapeutics* 2005; 7:109-114.

⁴ Bode et al., *Diabetes Technology & Therapeutics* 2004; 6:105-113.

⁵ Halvorson et al., *Diabetes* 2004; 53 (Suppl. 2):3-LB.

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Distinctions between Standard Glucose Meters and Glucose Sensors



FACT SHEET

Glucose meters are considered today's standard for measuring blood sugar levels in diabetes patients. Glucose meters allow patients to see their glucose value at a single moment in time. Tomorrow's standards take this several steps further. Continuous glucose monitoring (CGM) allows patients to see more information than ever before, such as how fast and in what direction their glucose levels are trending. Since both of these technologies are in use today, it is important to understand the distinctions between standard glucose meters and glucose sensors.

Description

Glucose Meters

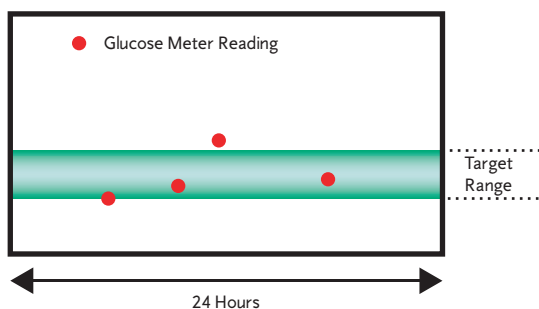
- Glucose meters are portable devices that read glucose levels from a blood sample that is placed on a tiny test strip. Test strips are discarded after a single use.
- Some meters store a limited number of glucose results in memory. The results can be downloaded into a computer.

Glucose Sensors

- A glucose sensor is a tiny flexible electrode that is inserted under a patient's skin (subcutaneous tissue) and continuously records glucose levels around the clock. The sensor is worn for up to three days before it is discarded and replaced by the patient.
- Glucose readings are transmitted to a monitor or insulin pump where updated values are displayed every 5 minutes. Trend reports and charts can be viewed after data is downloaded to a computer.

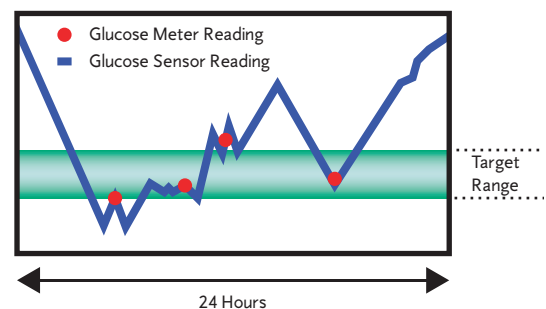
Information Provided by Glucose Meters and Sensors

Glucose Meters



- Glucose meters only reveal a glucose value at a single moment in time – much like a snapshot using a digital camera.
- Information gaps can be misleading. They suggest that blood glucose levels are normal when, in fact, they may not be.
- Diabetes patients base management decisions upon random meter measurements.

Glucose Sensors



- Continuous Glucose Monitoring (CGM) is like watching a movie – anyone can follow the storyline and anticipate what's going to occur next.
- CGM allows patients and their clinicians to discover how diet, exercise, medication and lifestyle affect their glucose levels.
- CGM devices that display continuous readings allow patients to see how fast, and in which direction, their glucose levels are heading, allowing them to intervene earlier to reduce the frequency and severity of high and low glucose episodes.

How and Where Do Meters and Sensors Measure Glucose?

Glucose Meters

- Measure glucose in the blood.
- Glucose results can be obtained from the fingertip or the arm using a lancet and test strip.

Glucose Sensors

- Measure glucose in the interstitial fluid, which is found under the skin between the cells. In this fluid, cells receive oxygen and nutrients, including glucose.
- Convert glucose values from interstitial fluid into an electrical signal, which represents the amount of glucose. Values are displayed every 5 minutes.
- Sensors are typically inserted in the abdominal area.