



FACT SHEET

Clinically Accurate and Reliable Glucose Sensor Readings

Background

The evidence supporting the value of continuous glucose monitoring has been gaining widespread acceptance throughout the medical community.

- This technology is a prominent feature in several Medtronic Diabetes products approved by the FDA in the last eight years: CGMS[®], CGMS[®] System Gold, and most recently, the MiniMed Paradigm[®] REAL-Time System.

Clinical study protocol

- 16 patients wore two devices simultaneously
- 3,941 sensor values were compared to YSI reference* values
- 3 day timeframe
- 2 blood glucose calibrations daily

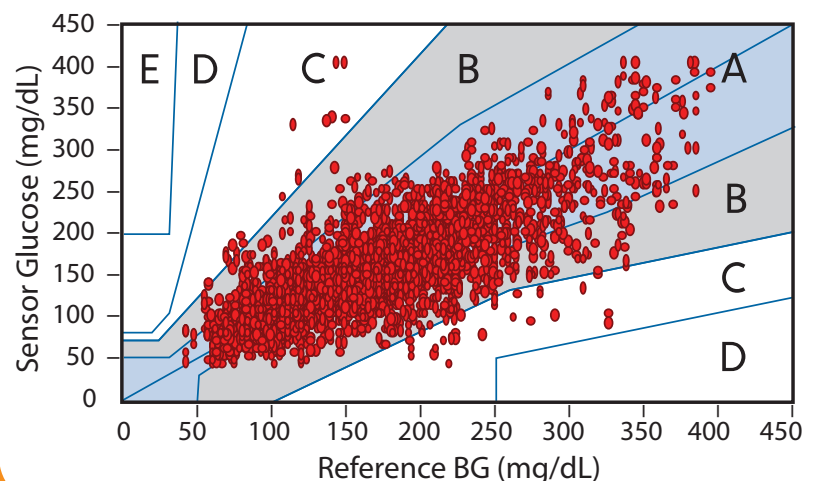
Summary of Findings

- 98.9% of interstitial glucose sensor readings fell within the clinically acceptable range indicated on the Consensus Error Grid (Zones A and B).
 - Zone A is clinically accurate with no risk
 - Zone B is benign with slight risk
- 0% of sensor readings fell in undesirable zones D and E.
 - Zone D is failure to detect
 - Zone E is dangerous
- The glucose sensor mean and median absolute difference are **19.7%** and **15.6%** respectively.
- These findings led to the recent FDA approval of the MiniMed Paradigm REAL-Time System, the world's first insulin pump with continuous glucose monitoring.

Trusted Reliability

- While interstitial fluid and blood glucose readings seldom display an identical match, they do correlate well with each other.
- Differences may be attributed to:
 - Variation in the glucose sensor or blood glucose meter
 - Physiological delay in glucose transport
 - Human Error

Consensus Error Grid



Conversion Chart (mg/dL to mmol/L)	
mg/dL	mmol/L
50	2.7
100	5.5
150	8.3
200	11.1
250	13.8
300	16.6
350	19.4
400	22.2
450	25





Glucose Sensor Readings: Clinically Accurate and Reliable

Differences between Glucose Sensor and Blood Glucose Meter Readings (BGM)

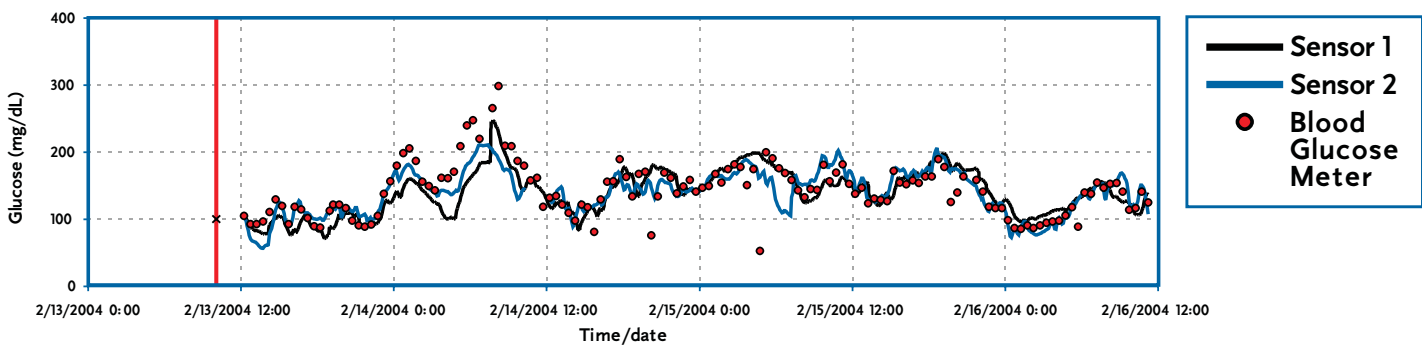
- Variation:** Just as meter readings vary, glucose sensor readings vary.
 - **Blood glucose meter readings are rarely identical** — Two consecutive meter readings will rarely yield the same result. However, such variation is rarely large enough to lead to a different clinical action.
 - Similarly, glucose sensors have variation with a median absolute difference of 15.6%.
 - This compares well with the FDA minimum acceptable standard of accuracy which allows for a +/–20% variation between blood glucose meter readings and a laboratory value (ISO Standard 15197).¹
- Physiological Delay:** During rapid glucose changes there can be a short time gap between blood and interstitial glucose equivalence.

Event	Interstitial Fluid Sensor Reading
Blood glucose rising rapidly	Interstitial fluid glucose may lag by about 4 minutes. ² Hence, a sensor reading may lag 10 minutes behind a BGM reading.
Blood glucose falling	Glucose sensor reading may either trail or lead BGM readings by about 4 minutes. (Current data inconclusive.)

- Human Error**
 - Blood glucose meter readings can be compromised by these user errors:
 - Improper technique
 - Unclean meter
 - Inappropriate site
 - Blood incorrectly applied
 - Incorrect control test
 - Unclean fingers
 - Inadequate sample size
 - Sensor performance may be temporarily affected by these user errors:
 - Calibrating during an episode of rapidly changing glucose
 - Entering an incorrect meter reading
 - Waiting to enter a meter reading

Strong Correlation and Similar Trend

- Based on three days of FDA trial data, the simultaneous readings of two glucose sensors correlate well when compared with frequent blood glucose measurements (YSI).



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1. "Evolution of Analytical Performance in Portable Glucose Meters in the Last Decade"; Bohme P, Floriot M, Sirveaux M, Durain D, Ziefler O, Drouin P, Guerci B. *Diabetes Care*, Vol. 26(4), April 2003.

2. "Determination of Plasma Glucose During Rapid Glucose Excursions with Subcutaneous Glucose Sensor." Steil G, Rebrin K, Mastrototaro J, Barnaba B, Saad M. *Diabetes Technology & Therapeutics*, 2003, Vol. 5(1): 27-31.

* (YSI) Yellow Springs Instrument is considered the gold standard in laboratory blood glucose measurement.

