

## Numerical Simulation of the Effect of Rate of Change of Glucose on Measurement Error of Continuous Glucose Monitors

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### Abstract

#### **Background:**

A 5-day in-patient study designed to assess the accuracy of the FreeStyle Navigator® Continuous Glucose Monitoring System revealed that the level of accuracy of the continuous sensor measurements was dependent on the rate of glucose change. When the absolute rate of change was less than  $1 \text{ mg}\cdot\text{dl}^{-1}\cdot\text{min}^{-1}$  (75% of the time), the median absolute relative difference (ARD) was 8.5%, with 85% of all points falling within the A zone of the Clarke error grid. When the absolute rate of change was greater than  $2 \text{ mg}\cdot\text{dl}^{-1}\cdot\text{min}^{-1}$  (8% of the time), the median ARD was 17.5%, with 59% of all points falling within the Clarke A zone.

#### **Method:**

Numerical simulations were performed to investigate effects of the rate of change of glucose on sensor measurement error. This approach enabled physiologically relevant distributions of glucose values to be reordered to explore the effect of different glucose rate-of-change distributions on apparent sensor accuracy.

#### **Results:**

The physiological lag between blood and interstitial fluid glucose levels is sufficient to account for the observed difference in sensor accuracy between periods of stable glucose and periods of rapidly changing glucose.

#### **Conclusions:**

The role of physiological lag on the apparent decrease in sensor accuracy at high glucose rates of change has implications for clinical study design, regulatory review of continuous glucose sensors, and development of performance standards for this new technology. This work demonstrates the difficulty in comparing accuracy measures between different clinical studies and highlights the need for studies to include both relevant glucose distributions and relevant glucose rate-of-change distributions.

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**Abbreviations:** (ARD) absolute relative difference, (CGMetric) Continuous Glucose Metric, (CV) coefficient of variation, (FDA) Food and Drug Administration, (ISF) interstitial fluid

**Keywords:** continuous glucose monitoring system, glucose, glucose monitoring, glucose sensors, Navigator

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