Evaluation of the CGMS Gold® Using a Standardized Test

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Objective
We investigated the accuracy of the Medtronic CGMS Gold® under a standardized glycemic pattern.

Methods
Paired reference/sensor data were collected in twelve subjects. In each subject, the blood glucose was manipulated in a predefined manner using intravenous infusions of insulin and dextrose. Each reference value was the average of two plasma glucose concentrations measured simultaneously on both channels of the YSI 2300 Stat Plus (Yellow Springs, OH) using a single venous blood sample. Blood samples were obtained at alternating intervals of two and five minutes. The sensor’s output current from the CGMS Gold (Medtronic Diabetes, Northridge, CA) was recorded every five minutes. Spline interpolation was used to pair each reference value in time to a corresponding sensor value using Matlab (Mathworks, Natick, MA). Any data pairs recorded in the 60 minutes after sensor insertion were not analyzed. The correlation coefficient was computed for each subject.

Results
The minimum, maximum, and mean number of paired values per subject were 86, 131, and 108. The average maximum and minimum blood glucose concentrations were 183 ± 24 and 41 ± 4 mg/dL and the average range was 142 ± 21 mg/dL. The minimum, maximum, median, mean and standard deviation of the correlation coefficients are 0.3251, 0.9597, 0.7422, 0.7386 and 0.1831.

Conclusions
The correlation coefficient has not been widely used as a measure to assess the CGM accuracy because it is sensitive to the glycemic range under which the CGM is evaluated. However, if the test is standardized, any CGM can be evaluated and compared.

Further Discussion
The standardized test described here was used to evaluate accuracy of continuous glucose monitors. It has been reported that continuous interstitial glucose monitoring is inaccurate when the change in blood glucose is greater than 1.5 mg/dL/min (1) or glycemic levels are below 70 mg/dL (2). As such, this standardized test includes two periods of controlled glucose change and two periods of hypoglycemia.

References