

# Clinical accuracy and user acceptance of the Smartest Blood Glucose Monitoring System

## Abstract

The clinical accuracy and use of the Smartest Blood Glucose Monitoring System when used by 154 patients with diabetes were determined at three clinical sites. At each site, patients performed self-monitoring tests using capillary blood samples and results were compared to those obtained by a healthcare professional (HCP). Clinical accuracy was assessed for patients and HCP's by comparing meter values to plasma glucose results obtained from the same sample using a Yellow Springs Instruments blood glucose analyzer (YSI). Patient results were equivalent to those obtained by the HCP. Using Clarke Error Grid Analysis, results for the clinical accuracy of the patient tests gave 98% of the results within Zone A (clinically accurate) and in Zone B (benign or no treatment). System equivalence testing demonstrated that the Smartest system gives equivalent glucose results on finger stick capillary blood obtained from patients with diabetes. All patients were asked to evaluate the Smartest system by completing a user acceptance questionnaire regarding the ease of use and value of the system features. The average ratings ranged from 3.6 to 5.0 out of a possible 5.0. Patients gave the system high marks for blood application, ease of detecting adequate sample size, volume required, and testing time.

## Objective

The purpose of this clinical study was: 1) to assess the clinical accuracy of the new system and its equivalence to the YSI. 2) To estimate the user error of the new blood glucose monitoring system; and 3) to obtain patient feedback on the ease of use of the new system.

## Method

### Study Design

During a single visit to one of the three clinical sites, patients with diabetes and healthcare professionals evaluated the performance and ease of use of the Smartest System.

### Clinical Sited POC Facilities

1. Endocrinology Consultants  
Virginia Beach, VA
2. Dr. Jenkins  
Wheatridge, CO
3. Drs. Deputron & Geiger  
Sebastian, FL

### Materials

Three lots of Smartest Test strips were used for the studies. Smartest meters were used for the study. Bayer Elite meters were used for the studies.

## Participants

All study participants patients had experience performing routine self-monitoring of blood glucose (SMBG). Patients represented a wide range of age, education, and frequency of SMBG. All patients who participated in the clinical studies were asked to complete a questionnaire about their experience with the Smartest Blood Glucose Monitoring System

## Procedure

One hundred fifty-four (154) subjects at three sites, including three point-of-care sites, physicians offices tested their own glucose and were tested by a professional using the Smartest Glucose Test System and the Bayer Elite (predicate). Finger-stick capillary blood was the sample. The Smartest was calibrated using 10 levels of whole blood glucose and fitted to a straight line. The correlation data is listed in the table that follows. The graphs of each of the Smartest run by laboratory professionals vs. the predicate Bayer Elite and the Smartest run by consumers vs. the predicate also follow in this section. Graphs of the Clarke Error Grid Analysis demonstrate clinical accuracy.

**Table 2. Clinical Accuracy**

## Analysis

Clinical accuracy for HCP and patient testing was assessed using linear regression analysis and error grid analysis. User error was evaluated using partitioned bias analysis.

## Results

### Clinical Accuracy

Linear regression analysis indicated acceptable agreement between the Smartest and the YSI reference method

### Smartest Linearity Results

The slope of the regression is statistically indistinguishable from the ideal slope of 1.0. The y-intercept is insignificant the correlation is 0.9992. This confirms that the Smartest system is linear from 20 to 600 mg/dL

Range of Samples	20-600 mg/dL
N	60
Slope	1.0241
y-intercept	-4.8
Correlation	0.9992
Coefficient	

## User Error

All 95% confidence levels of bias estimated using the partitioned bias calculations include 0,0 indicating that the mean bias between patient tests and HCP tests is not significantly different from zero throughout the range of glucose concentrations tested.

## System Equivalence

The 95% confidence intervals if systematic differences at each medical decision level bracket 0,0, indicating a lack of statistically significant systematic differences at each glucose concentration tested.

## Patient Acceptance Evaluation

Each patient answered a questionnaire about the experience with the Smartest System. Questions were selected to highlight keys functions of the system such as blood testing procedure, handling, and overall ease of use. Patients were asked to rate these functions on a scale of one to five.

Ease of Use: Average 4.8  
Easy to Read: Yes  
Easy to follow Instructions: Yes

## Conclusions

The Smartest Blood Glucose Monitoring System produced clinically accurate results in the hands of patients with diabetes and healthcare professionals when compared to plasma glucose reference values. Based on the questionnaire results, patients described the system easy to use and gave the system high ratings for ease of blood application, ease of detecting adequate blood volume, and test time.

	Smartest Professional vs. Bayer Elite	Smartest Consumer vs. Bayer Elite
Number of Patients(n)	154	154
Number of sites	3	3
Slope	0.9565	0.9601
Upper 95% CI for slope	1.0000	1.0048
Lower 95% CI for slope	0.9123	0.9154
Intercept	7.375	5.882
Upper 95% CI for intercept	0.960	-0.710
Lower 95% CI for intercept	13.79	12.474
Correlation Coefficient(r)	0.9620	0.9603
Range of Glucose Values (mg/dL)	58-447	43-462
Mean of Elite method(mg/dL)	132	132
Mean of Smartest method (mg/dL)	134	133
Bias (measurement error) at 126 mg/dL	1.89	0.85
Average bias(mg/dL)	1.63	0.61

