New Generation Blood Glucose Monitoring System Exceeds International Accuracy Standards

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Keywords

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Blood glucose data are frequently used in clinical decision-making. Therefore, it is critical that self-monitoring of blood glucose (SMBG) systems consistently provide accurate results. The new generation Accu-Chek® Guide blood glucose monitoring system (Roche Diabetes Care, Indianapolis, IN, USA) (system) utilizes innovative electrochemistry technologies that reduce the influence of environmental and endogenous factors on accuracy. When blood is applied to the test strip, several multi-frequency impedance measurements are taken in the first 2 seconds followed by fast-pulsed direct current (DC) amperometric measurements. Utilizing advanced algorithms, the information is analyzed to yield an estimate of the glucose concentration in less than 4 seconds.

We utilized the testing protocol defined in the ISO 15197:2013 criteria¹ to evaluate the accuracy and lot-to-lot variability in the system. The accuracy of the system against more stringent accuracy measures was also evaluated.

In comparison against current ISO criteria (DIN EN ISO 15197:2013), the system met the requirements in all 3 test strip lots (Table 1), and all test values (n = 600) were within Zone A of the Parke's consensus error analysis² demonstrating consistent performance with negligible bias. The system also met tightened accuracy criteria of ≥95% of blood glucose (BG) values within ±10 mg/dl of laboratory reference value at glucose levels < 100 mg/dl and within ±10% of laboratory reference value at BG levels ≥ 100 mg/dl (Table 1). No discernable hematocrit effect was observed.

The enhanced accuracy demonstrated in our study is largely achieved by reducing the influence on the BG result of factors such as temperature, ambient humidity, hematocrit, and endogenous interferences present in the blood. A notable improvement in the system is a novel, spill-resistant container, which presents and retains the individual strips in an easy-to-handle manner, which may significantly reduce contamination and wastage of test strips due to accidental spillage. Other improvements, which are less visible to the user, are embodied in the technology of the test strip. For example, the proprietary flavin adenine dinucleotide (FAD)-dependent glucose dehydrogenase enzyme used in the chemistry eliminates any effects from maltose, maltose derivatives

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Table 1. System Accuracy Versus ISO 15197 2013 Requirements and Tightened Accuracy Targets.

All Lots N = 600

All Lots Within ±15 mg/dl (±0.83 mmol/l) or 15%			
All lots	Lot EI5040	Lot EI5042	Lot EI5044
600/600 (100%)	200/200 (100%)	200/200 (100%)	200/200 (100%)

All lots within ±10 mg/dl (±0.56 mmol/l) or 10%			
All lots	Lot EI5040	Lot EI5042	Lot EI5044
598/600 (99.7%)	200/200 (100%)	199/200 (99.5%)	199/200 (99.5%)

Accuracy results for glucose concentrations <100 mg/dl (5.55 mmol/l)

Within ±15 mg/dl (±0.83 mmol/l)	Within ±10 mg/dl (±0.56 mmol/l)
180/180 (100%)	178/180 (98.9%)

Accuracy results for glucose concentrations ≥100 mg/dl (5.55 mmol/l)

Within ±15%	Within ±10%
420/420 (100%)	420/420 (100%)

Lot EI5040 N = 200

Accuracy results for glucose concentrations <100 mg/dl (5.55 mmol/l)

Within ±15 mg/dl (±0.83 mmol/l)	Within ±10 mg/dl (±0.56 mmol/l)
60/60 (100%)	60/60 (100%)

Accuracy results for glucose concentrations ≥100 mg/dl (5.55 mmol/l)

Within ±15%	Within ±10%
140/140 (100%)	140/140 (100%)

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Lot E15042 N = 200

Accuracy results for glucose concentrations <100 mg/dl (5.55 mmol/l)	
Within ± 15 mg/dl (± 0.83 mmol/l)	Within ± 10 mg/dl (± 0.56 mmol/l)
60/60 (100%)	59/60 (98.3%)
Accuracy results for glucose concentrations ≥ 100 mg/dl (5.55 mmol/l)	
Within $\pm 15\%$	Within $\pm 10\%$
140/140 (100%)	140/140 (100%)

Lot E15044 N = 200

Accuracy results for glucose concentrations <100 mg/dl (5.55 mmol/l)	
Within ± 15 mg/dl (± 0.83 mmol/l)	Within ± 10 mg/dl (± 0.56 mmol/l)
60/60 (100%)	59/60 (98.3%)
Accuracy results for glucose concentrations ≥ 100 mg/dl (5.55 mmol/l)	
Within $\pm 15\%$	Within $\pm 10\%$
140/140 (100%)	140/140 (100%)

or excess galactose. The reagent formulation also significantly reduces inaccuracy when a patient fails to close the container for extended periods in high humidity.

The complex measurements are made possible by a new generation, complete, battery-powered, high-precision “meter-on-chip” based on the ADuCM350 part from Analog Devices Inc (Waltham, MA, USA). This technology was recently developed for portable device applications such as body-worn devices for monitoring vital signs and chemical sensors, and is designed for high precision potentiostatic, current, voltage and impedance measurement capabilities. Through an advanced and proprietary encoding system, information for every lot manufactured is communicated to the meter whenever the user inserts a test strip without requiring any additional action.

The system was developed on a foundation of electrochemical technology that provides notably improved

accuracy over previous Accu-Chek product generations.³ Our study demonstrated that the system met and exceeded current ISO accuracy requirements.

Abbreviations

BG, blood glucose; DC, direct current; SMBG, self-monitoring of blood glucose.

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Declaration of Conflicting Interests

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