

## Performance Variability of Seven Commonly Used Self-Monitoring of Blood Glucose Systems: Clinical Considerations for Patients and Providers

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### Abstract

#### **Background:**

Blood glucose data are frequently used in clinical decision making, thus it is critical that self-monitoring of blood glucose (SMBG) systems consistently provide accurate results. Concerns about SMBG accuracy have prompted the development of newly proposed International Organization for Standardization (ISO) standards:  $\geq 95\%$  of individual glucose results shall fall within  $\pm 15$  mg/dl of the results of the manufacturer's reference procedure at glucose concentrations  $< 100$  mg/dl and within  $\pm 15\%$  for values  $\geq 100$  mg/dl. We evaluated seven marketed systems against the current and proposed ISO criteria (criterion A).

#### **Method:**

Capillary blood samples were collected from 100 subjects and tested on seven systems: Accu-Chek Aviva Plus, Advocate Redi-Code, Element, Embrace, Prodigy Voice, TRUEbalance, and WaveSense Presto. Results were compared with manufacturer's documented reference system, YSI or perchloric acid hexokinase; three different strip lots from each system were tested on each subject, in duplicate.

#### **Results:**

Compared against current ISO criteria ( $\geq 95\%$  within  $\pm 15$  mg/dl for values  $< 75$  mg/dl and  $\pm 20\%$  for values  $\geq 75$  mg/dl) the Accu-Chek Aviva Plus, Element, and WaveSense Presto systems met accuracy criteria. However, only the Accu-Chek Aviva Plus met the proposed ISO criteria (criterion A) in all three lots. The other six systems failed to meet the criteria in at least two of the three lots, showing lot-to-lot variability, high/low bias, and variations due to hematocrit.

#### **Conclusions:**

Inaccurate SMBG readings can potentially adversely impact clinical decision making and outcomes. Clinicians can reduce controllable variables by prescribing accurate SMBG systems. Adherence to the proposed ISO criteria should enhance patient safety by improving the accuracy of SMBG systems.

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**Abbreviations:** (BG) blood glucose, (FDA) Food and Drug Administration, (ISO) International Organization for Standardization, (PCA-HK) perchloric acid hexokinase, (SMBG) self-monitoring of blood glucose, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

**Keywords:** accuracy, hematocrit, International Organization for Standardization, self-monitoring of blood glucose, variability

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