Journal of Diabetes Science and Technology
Volume 3, Issue 5, September 2009

ORIGINAL ARTICLES

Performance Analysis of the OneTouch® UltraVue™ Blood Glucose Monitoring System

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Abstract

Background:

OneTouch® UltraVue™ is a new meter for self-monitoring of blood glucose that includes a color display, used-strip ejector, and no-button interface. The system uses an electrochemical biosensor technology based on glucose oxidase chemistry to detect glucose concentrations from 20 to 600 mg/dl (1.1 to 33.3 mmol/liter).

Methods:

Accuracy and reproducibility were evaluated over a wide range of glucose concentrations according to standard criteria. Clinical accuracy was assessed by health care providers (HCPs) in two studies and by diabetes patients in the second study. Reference glucose levels were determined by a YSI 2300 analyzer. Same-day reproducibility and day-to-day reproducibility were also evaluated.

Results:

In the accuracy studies, 99.7% and 98.7% of tests by HCPs and 97.0% of tests by patients were within ±15 mg/dl (±0.8 mmol/liter) of the YSI reference for blood glucose <75 mg/dl (<4.2 mmol/liter), and within ±20% for blood glucose ≥75 mg/dl (≥4.2 mmol/liter), respectively. Consensus error grid analysis showed that 99.7% and 95.3% of tests by HCPs and 97.0% of tests by patients fell within zone A (i.e., has no effect on clinical action); all other results were in zone B (i.e., altered clinical action, little or no effect on clinical outcome). In the reproducibility studies, the standard deviation was <1.5 mg/dl (<0.1 mmol/liter) for glucose concentrations <100 mg/dl (<5.6 mmol/liter), and the coefficient of variation was <2% for concentrations ≥100 mg/dl (≥5.6 mmol/liter).

Conclusions:

OneTouch UltraVue meets standard acceptability criteria for accuracy and reproducibility across a wide range of glucose concentrations. Its simple interface and lack of contact with used strips make it a viable option for older patients and their caregivers.

J Diabetes Sci Technol 2009;3(5):1158-1165

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Abbreviations: (CV) coefficient of variation, (HCPs) health care providers, (ISO) International Organization for Standardization, (SD) standard deviation, (SMBG) self-monitoring of blood glucose

Keywords: accuracy, blood glucose meter, OneTouch UltraVue, reproducibility

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