

## Performance of a New Meter Designed for Assisted Monitoring of Blood Glucose and Point-of-Care Testing

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### Abstract

#### **Background:**

Blood glucose (BG) meters used for assisted monitoring of blood glucose (AMBG) require different attributes compared with meters designed for home use. These include safety considerations (i.e., minimized risk of blood-borne pathogen transmission), capability for testing multiple blood sample types, and enhanced performance specifications. The OneTouch® Verio™Pro+ BG meter is designed to incorporate all of these attributes.

#### **Methods:**

Meter accuracy was assessed in clinical studies with arterial, venous, and capillary blood samples with a hematocrit range of 22.9–59.8%. The effect of interferents, including anticoagulants, on accuracy was evaluated. The meter disinfection protocol was validated, and instructions for use and user acceptance of the system were assessed.

#### **Results:**

A total of 97% (549/566) of BG measures from all blood sample types and 95.5% (191/200) of arterial blood samples were within  $\pm 12$  mg/dl or 12.5% of reference measurements. The system was unaffected by 4 anticoagulants and 57 of 59 endogenous and exogenous compounds; it was affected by 2 compounds: pralidoxime iodide and xylose. Bleach wipes were sufficient to disinfect the meter. Users felt that the meter's quality control (QC) prompts would help them to comply with regulatory requirements.

#### **Conclusion:**

The meter provided accurate measurements of different blood samples over a wide hematocrit range and was not affected by 57 physiologic and therapeutic compounds. The QC prompts and specific infection-mitigating design further aid to make this meter system practical for AMBG in care facilities.

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**Abbreviations:** (AMBG) assisted monitoring of blood glucose, (BG) blood glucose, (CLSI) Clinical and Laboratory Standards Institute, (EDTA) ethylenediamine tetra-acetic acid, (FDA) Food and Drug Administration, (HBV) hepatitis B virus, (HCP) health care professional, (PAM) pralidoxime iodide, (POCT) point-of-care testing, (QC) quality control, (SMBG) self-monitoring of blood glucose

**Keywords:** assisted monitoring of blood glucose, bloodborne infection, diabetes, glucose, hepatitis, monitor, self-monitoring of blood glucose

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