

## Precision, Accuracy, and User Acceptance of the OneTouch SelectSimple Blood Glucose Monitoring System

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### Abstract

#### *Background:*

The OneTouch® SelectSimple™ blood glucose monitoring system (BGMS) is a device for self-monitoring of blood glucose designed for ease of use. Alarms alert subjects to low [20–69 mg/dl (1.1–3.8 mmol/liter)], high [180–239 mg/dl (9.9–13.2 mmol/liter)], and very high [240–600 mg/dl (13.3–33.1 mmol/liter)] blood glucose readings.

#### *Methods:*

Repeatability in blood and intermediate precision with aqueous controls were examined using blood from one donor adjusted to different glucose concentrations, and tested with 10 meters and 1 test-strip lot. System accuracy was evaluated with blood samples from 100 diabetes patients tested on 3 test-strip lots, compared with a reference system (YSI 2300 STAT). To test user accuracy, patients ( $n = 156$ ) and health care professionals (HCPs) tested subject blood with the SelectSimple twice. Health care professionals evaluated subject BGMS technique after a 3–5 day home-testing period. Users evaluated the instructions for use and responded to a user acceptance questionnaire.

#### *Results:*

In repeatability and intermediate precision testing, the SelectSimple BGMS had a coefficient of variation of  $\leq 5\%$  or standard deviation of  $\leq 5$  mg/dl. In the clinical accuracy study, 100% of measurements  $< 75$  mg/dl (4.2 mmol/liter) were within  $\pm 15$  mg/dl (0.8 mmol/liter) of reference value, and 99.6% of measurements  $\geq 75$  mg/dl (4.2 mmol/liter) were within  $\pm 20\%$ . Patients were able to use the BGMS appropriately and evaluated it as easy to use. Acceptance of the SelectSimple BGMS was within predefined limits.

#### *Conclusions:*

In these studies, the SelectSimple BGMS met all criteria for precision, system, and user accuracy, was easy to use, and was well accepted by patients.

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**Abbreviations:** (BG) blood glucose, (BGMS) blood glucose monitoring system, (CV) coefficient of variation, (CI LL) confidence interval lower limit, (HCP) health care professional, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose, (SD) standard deviation, (T2DM) type 2 diabetes mellitus

**Keywords:** accuracy, blood glucose meter, intermediate precision, OneTouch SelectSimple, repeatability

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