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 ≤5% or standard deviation of ≤5 mg/dl. In the clinical accuracy study, 100% of measurements <75 mg/dl (4.2 mmol/liter) were within ±15 mg/dl (0.8 mmol/liter) of reference value, and 99.6% of measurements ≥75 mg/dl (4.2 mmol/liter) were within ±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.