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TECHNOLOGY REPORT

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 ≤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.

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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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Introduction

Global prevalence of diabetes in adults is predicted to rise from 6.6% in 2010 to 7.8% in 2030, and affect 285 million and 438 million people, respectively.[1] Diabetes accounts for an estimated 6.8% of global all-cause mortality among adults.[2]

In Asia, prevalence of type 2 diabetes mellitus (T2DM) has increased rapidly over a relatively short time period:[3,4] from 2.5% in 1994 to 9.7% in 2010[5,6] in China, and from 13.9% in 2000 to 18.6% in 2006 in Chennai, India (an urban area).[7] The International Diabetes Federation predicts that the number of adults with diabetes in Southeast Asia will rise from 58.7 million in 2010 to 101 million in 2030, with the estimated prevalence climbing from 7.0% to 8.4%.[8] Perhaps not surprisingly, diabetes-related mortality is high in Southeast Asia. Diabetes is estimated to have accounted for 14.3% of deaths among adults in 2010—more than double the proportion of mortality attributed to diabetes worldwide.[2,8]

Several authorities acknowledge the benefit of self-monitoring of blood glucose (SMBG) by patients with diabetes. Glucose meters should not be used to diagnose diabetes, and may have limited values for screening purposes.[9–12] Self-monitoring of blood glucose is recommended in patients with type 1 diabetes and in those with insulin-treated T2DM.[11] Evidence regarding the value of SMBG in noninsulin-treated T2DM patients is mixed,[11,13] but guidelines support its value under certain circumstances.[9–12] There are accepted international standards for assessing BG meter accuracy; these standards are currently under review, and narrower performance criteria are anticipated.[14,15]

The OneTouch® SelectSimple™ BG monitoring system (BGMS) (**Figure 1**) has no coding steps or buttons because it is designed for ease of use. The meter turns on when a test strip is inserted. It has an alarm alerting patients 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)] BG readings.

Present studies have evaluated the performance of the One-Touch SelectSimple BGMS according to criteria published by the International Organization for Standardization (ISO).[14] Specifically, studies assessed repeatability and intermediate precision in laboratory settings as well as accuracy and ease of use in a clinical setting.

ISO 15197 defines repeatability as "precision under repeatability conditions," i.e., precision under essentially unchanged conditions. Precision is the "closeness of agreement between independent test results obtained under stipulated conditions." Intermediate precision is "intended to measure precision in conditions leading to variability representative of actual use." Accuracy is "closeness of agreement between a test result and the accepted reference value."

Methods

Repeatability and Intermediate Precision Studies

Repeatability and intermediate precision studies were performed in compliance with ISO 15197.[14] For repeatability testing, blood samples from one donor were adjusted to five different glucose concentrations [40, 100, 130, 200, and 300 mg/dl (2.2, 5.6, 7.2, 11.1, and 16.7 mmol/liter)], and tested on 10 OneTouch SelectSimple meters (10 times per meter) for a total of 100 repetitions per glucose level. All evaluations used test strips from the same lot number. Mean, standard deviation (SD), and coefficient of variation (CV) were calculated at each glucose concentration.

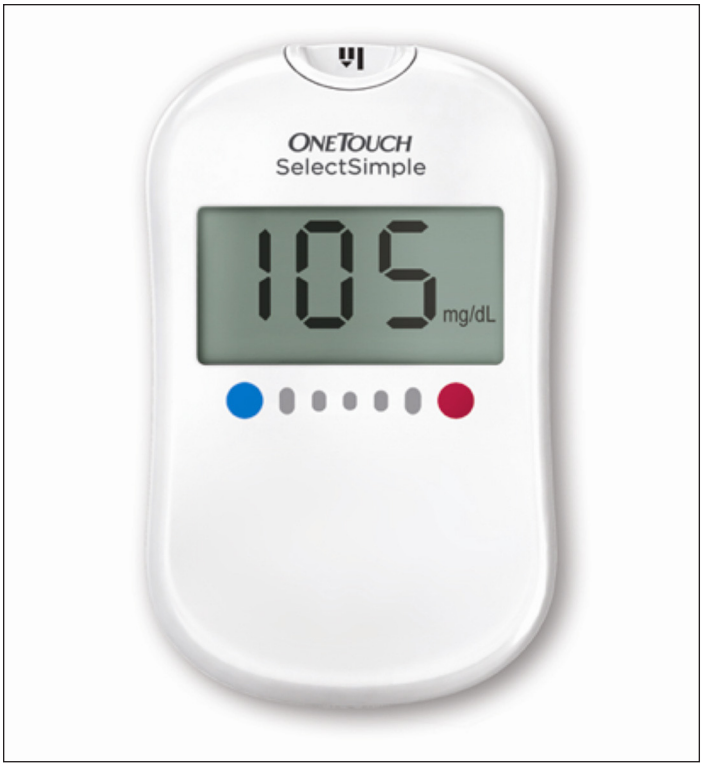

Figure 1. OneTouch SelectSimple BGMS.

To evaluate intermediate precision by a user across multiple days with the same meter and reagent system lot, 10 OneTouch SelectSimple meters measured aqueous control solutions at low [30–50 mg/dl (1.7–2.8 mmol/liter)], medium [96–144 mg/dl (5.3–8.0 mmol/liter)], and high [280–420 mg/dl (15.5–23.3 mmol/liter)] glucose levels. Each meter measured each of the three control solutions twice daily for 10 days, for a total of 200 measurements per glucose level. Test strips for OneTouch SelectSimple were taken from the same lots as in the repeatability study.

Acceptability criteria for the repeatability and intermediate precision studies were within-lot precision ≤5.0% CV at BG levels ≥100 mg/dl (5.6 mmol/liter) or ≤5.0 mg/dl (0.3 mmol/liter) SD at glucose levels <100 mg/dl (5.6 mmol/liter).

System Accuracy

Both system and clinical accuracy were defined as the extent to which the OneTouch SelectSimple meter measurements agree with those of the reference method, the YSI 2300 STAT analyzer. To assess system accuracy, data from fresh capillary blood samples from 100 patients at a diabetes outpatient clinic at Birmingham Heartland Hospital, United Kingdom, were collected and analyzed. The glucose concentration range of the blood samples was required to be distributed roughly in a bell curve fashion from <50 mg/dl (2.8 mmol/liter) to >400 mg/dl (22.2 mmol/liter), per ISO requirements.

Ten BG meter readings were taken from 10 capillary blood samples from each patient. All blood samples were taken from a single finger stick whenever possible. A health care professional (HCP) performed the finger stick lancing and obtained a blood sample, which was tested on: the reference method (YSI 2300 STAT; two plasma glucose readings); the OneTouch SelectSimple BGMS (three lots of test strips, two readings per lot); and a control meter [OneTouch Select BGMS; one control test-strip lot (3022345); two readings]. One sample was used to test hematocrit.

Acceptable system accuracy was defined as 95% of individual glucose test results falling within ±15 mg/dl (0.83 mmol/liter) of the YSI results at glucose concentrations <75 mg/dl (<4.2 mmol/liter), and within ±20% at glucose concentrations ≥75 mg/dl (≥4.2 mmol/liter) over the glucose range 20–600 mg/dl (1.1–33.1 mmol/liter). Additionally, consensus error grids were constructed.[16] The goal was that all data points fall within zones A and B, i.e., no effect on clinical action or altered clinical action—little or no effect on outcome, respectively.

User Accuracy in a Clinical Setting

An open, nonrandomized study evaluating user accuracy in a clinical setting was conducted at two sites in concord and La Jolla, California, using a protocol and informed consent forms approved by a centralized institutional review board. All participating subjects (all had diabetes) provided informed consent. Subjects were required to complete two site visits of roughly 1–1.5 hours each, with a home-testing period of 3–5 days between visits. At visit 1, each subject took an oral reading test (Slosson Oral Reading Revised Test)[17] and received a home-testing kit. A HCP directed the subjects to use the OneTouch SelectSimple BGMS, including performing skin punctures, in addition to his or her usual SMBG regimen during the home-testing period. Subjects received no training on the OneTouch SelectSimple BGMS, and were instructed to use the findings of their regular SMBG regimen to make any treatment decisions.

Visit 2 occurred after the home-testing period. A HCP observed and evaluated the subject's technique in using the OneTouch SelectSimple BGMS. Specifically, the HCP observed and recorded an assessment of the subject's performance of self-testing with fingertip samples, attempting to obtain a BG result using a sample from the palm and/or forearm, and his or her use of the BGMS features and functions.

Each subject then performed two BG tests and underwent an additional two BG tests conducted by a HCP. Each test was performed using a different OneTouch SelectSimple meter. Each subject and HCP used two test strips from each of two different lots. Additionally, the HCP obtained from the subject two separate blood samples for reference testing by a LifeScan technician. Hematocrit was measured in one of the blood samples used for reference testing.

As with laboratory accuracy, clinical accuracy was defined as the extent to which the meter measurements using the OneTouch SelectSimple BGMS agreed with plasma glucose values acquired by the YSI 2300 STAT analyzer. Specifically, acceptance criterion was defined as at least 95% of the individual patient and HCP results (evaluated separately) obtained with the OneTouch SelectSimple BGMS falling within ±15 mg/dl (±0.83 mmol/liter) of the corresponding YSI results at glucose concentrations <75 mg/dl (<4.2 mmol/liter) and within ±20% of the corresponding YSI results at glucose concentrations ≥75 mg/dl (≥4.2 mmol/liter), consistent with ISO criteria for laboratory accuracy.[14]

Consensus error grids were constructed, dividing the plot of OneTouch SelectSimple BGMS values compared with YSI 2300 values into five zones, according to the degree of clinical risk posed by an incorrect measurement.[16] As for laboratory accuracy, the goal was that all data points fall within zones A and B, i.e., no effect on clinical action or altered clinical action—little or no effect on outcome, respectively.

Accuracy of Subject Technique, User Understanding, and User Acceptance

Data describing accuracy of subject technique, understanding of OneTouch SelectSimple BGMS instructions, and user acceptance of the OneTouch SelectSimple BGMS were also collected. Each subject completed two self-administered questionnaires. The instructions for use questionnaire evaluated user understanding of cautions, warnings, and the functionality of the OneTouch SelectSimple BGMS meter. An acceptable correct response rate was risk dependent. For example, a correct response rate with a 90% confidence interval lower limit (CI LL) of ≥90% was regarded as acceptable for medium-risk test areas. The OneTouch SelectSimple BGMS user acceptance questionnaire included questions regarding ease of use, preference, maintenance, size and shape of the meter, and readability of the meter display. It was analyzed for the proportion of neutral or better responses. A neutral or better response rate with a 90% CI LL of ≥70% was regarded as acceptable.

Results

Repeatability and Intermediate Precision Studies

The OneTouch SelectSimple BGMS met the criteria of ≤5.0% CV at BG levels ≥100 mg/dl (5.6 mmol/liter) or ≤5.0 mg/dl (0.3 mmol/liter) SD at BG levels <100 mg/dl (5.6 mmol/liter). In the repeatability study, CV for BG ≥100 mg/dl (5.6 mmol/liter) ranged from 1.40% to 2.38%; SD for BG level <100 mg/dl (5.6 mmol/liter) was 1.64 mg/dl (0.09 mmol/liter) (**Table 1**). For intermediate precision of day-to-day measurements, CV for BG ≥100 mg/dl (5.6 mmol/liter) was 2.23%; SD for BG <100 mg/dl (5.6 mmol/liter) was 1.35 mg/dl (0.07 mmol/liter) (**Table 2**).

Table 1.
Repeatability

N	Target glucose, mg/dl (mmol/liter)	Mean glucose, mg/dl (mmol/liter)	SD, mg/dl (mmol/liter)	CV, %
100	40 (2.2)	39.0 (2.2)	1.64 (0.09)	4.20
100	100 (5.6)	102.2 (5.7)	2.26 (0.13)	2.21
100	130 (7.2)	122.9 (6.8)	2.92 (0.16)	2.38
100	200 (11.1)	205.6 (11.4)	3.65 (0.20)	1.77
100	300 (16.7)	312.2 (17.3)	4.36 (0.24)	1.40

Table 2.
Intermediate Precision

N	Glucose levels	Mean glucose, mg/dl (mmol/liter)	SD, mg/dl (mmol/liter)	CV, %
200	Low 30–50 mg/dl (1.7–2.8 mmol/liter)	45.4 (2.5)	1.35 (0.07)	2.96
200	Medium 96–144 mg/dl (5.3–8.0 mmol/liter)	117.1 (6.5)	2.52 (0.14)	2.15
200	High 280–420 mg/dl (15.5–23.3 mmol/liter)	343.0 (19.0)	7.64 (0.42)	2.23

System Accuracy

Blood sample glucose concentrations were distributed in the range required by the ISO standard (data not shown). One thousand blood samples were tested (10 samples each from 100 patients); 200 samples with each of three test-strip lots using the OneTouch SelectSimple meter, for a total of 600 samples; 200 using a control OneTouch Select meter; and 200 samples using the reference method. Another 100 samples were analyzed to measure hematocrit.

All BG concentration test results with the OneTouch SelectSimple meter were within ±15 mg/dl (0.83 mmol/liter) of results obtained with the reference method at glucose concentrations <75 mg/dl (4.2 mmol/liter); therefore, meeting ISO criteria of ≥95% (**Figure 2**). All but two test results (598 of 600; 99.7%) with the OneTouch SelectSimple meter were within ±20% of results obtained with the reference method at glucose concentrations ≥75 mg/dl (4.2 mmol/liter) (**Figure 2**). Again, this result met ISO criteria of ≥95%. Consensus error grid analysis demonstrated that all glucose concentration results obtained with the OneTouch SelectSimple and the control meter fell within zones A or B, consistent with ISO criteria; all but two readings fell in zone A (598 of 600; 99.7%).

User Accuracy in a Clinical Setting

The study population comprised 160 subjects, with 80 subjects at each of the two sites. Four subjects withdrew voluntarily prior to visit 2; therefore, 156 subjects completed the study at two clinical sites. Of the 156 subjects in the study, 47 subjects were relatively new to SMBG testing (defined as ≤8 months of self-

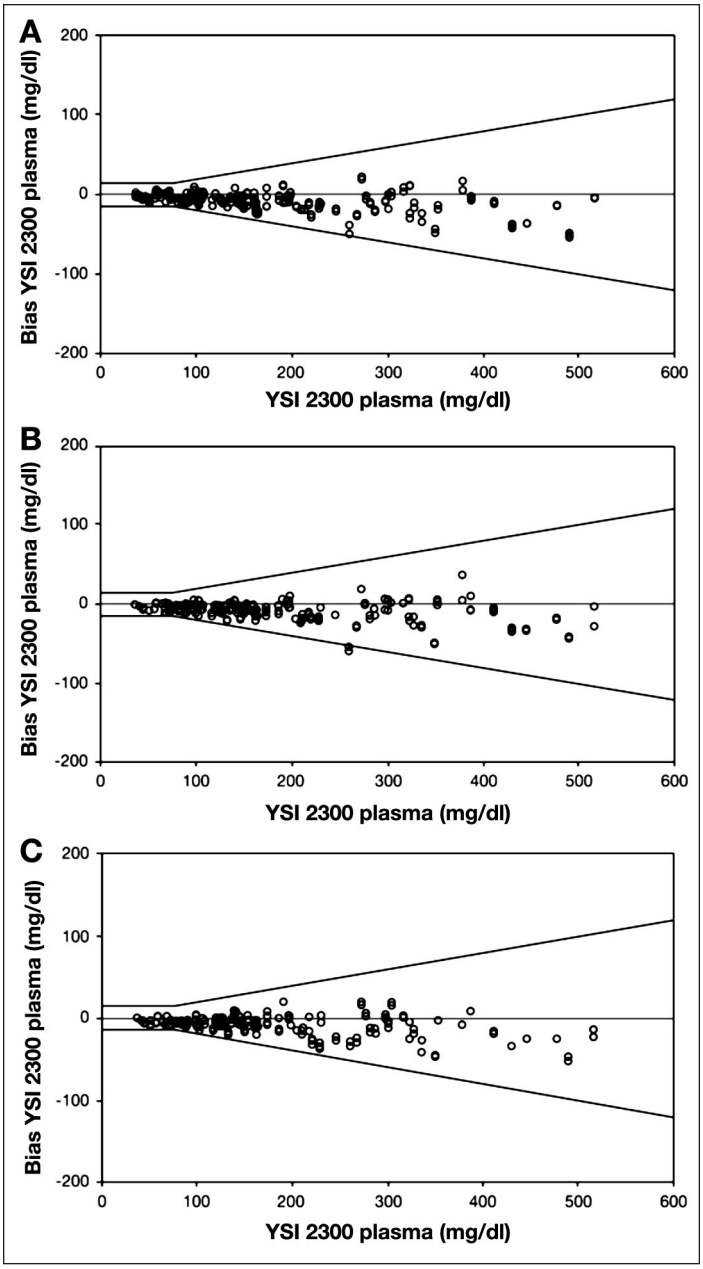

Figure 2. System accuracy of OneTouch SelectSimple using three different test-strip batches: **(A)** lot 3022344; **(B)** lot 3022345; and **(C)** lot 3043510.

monitoring). **Table 3** summarizes the demographic and baseline characteristics of subjects.

A total of 147 subjects were included in this analysis, as 9 subjects did not meet YSI 2300 STAT run-to-run criteria. Each subject self-tested twice and underwent two tests conducted by a HCP, generating 294 subject test results and 294 HCP-performed test results. Retests were performed if insufficient blood or an error message was obtained during the first test, yielding a total of 300 subject test results. All subject self-test results, including results

Table 3.
Demographics of All Evaluable Subjects

	Clinical accuracy study (n = 156)
Gender, *n* (%)	
Female	84 (53.8)
Male	72 (46.2)
Age, *y*	
Mean	57.4
Median	58.5
Range	20.5–84.8
Ethnicity, *n* (%)	
American Indian/Native Alaskan	1 (0.6)
Asian/Pacific Islander	14 (9.0)
Black/African American	5 (3.2)
Hispanic/Latino	22 (14.1)
White	109 (69.9)
Other	5 (3.2)
Education completed, *n* (%)	
Did not complete high school	2 (1.3)
Completed high school with or without additional education	154 (98.7)
Type of diabetes, *n* (%)	
Type 1	32 (20.5)
Type 2	124 (79.5)
Frequency of self-monitoring per day	
Mean	2.6
Median	2
Range	0.03–18

from the group that was relatively new to SMBG testing, and all HCP results fell within the ISO system accuracy boundaries when compared with the YSI results (**Figures 3 and 4**).

Consensus error grids showed that 299 of the 300 self-test (99.7%) and 290 of the 294 HCP tests (98.6%) fell within zone A (no effect on clinical action). The other five test results fell within zone B (altered clinical action—little or no effect on outcome) (**Table 4 and Figure 5**).

Accuracy of Subject Technique, User Understanding, and User Acceptance

Health care professionals rated subjects on 16 parameters related to technique of using the OneTouch SelectSimple BGMS. These parameters included the ability to perform (1) basic maintenance tasks, (2) control solutions tests, and (3) alternate-site testing. At least 94% of subjects completed each task after one or two unassisted attempts, with the exception of reading whether the test strip conformation window was full after sample application from the forearm (86.8%). The risk associated with this particular assessment was low.

Table 4.
Number and Percentage of OneTouch SelectSimple BGMS Finger Stick Results Falling Within Each Zone of the Consensus Grid

	Subject self-test (*n* = 300)		HCP test (*n* = 294)	
Zone[a]	*n*	%	*n*	%
A	299	99.7	290	98.6
B	1	0.3	4	1.4
C	0	—	0	—
D	0	—	0	—
E	0	—	0	—

[a] Zone A: no effect on clinical action.
Zone B: altered clinical action—little or no effect on clinical outcome.
Zone C: altered clinical action—likely to affect clinical outcome.
Zone D: altered clinical action—could have significant medical risk.
Zone E: altered clinical action—could have dangerous consequences.

On the only assessment for which risk of consequences due to error was high (ability to read the display correctly), all but two subjects (154 of 156; 98.7%) succeeded on their first attempt. One subject once misread a display of 171 mg/dl as 111 mg/dl, but read the result correctly when asked to reread it. The other subject twice misread a value of 161 mg/dl as 191 mg/dl, but read it correctly a third time. Each time this subject read the result, the meter was in the correct orientation. In all cases, when subjects were asked to recall and reread a display, it was done at a point later in the testing process and in a neutral tone, as if the patient were presented with another task; this was done to avoid signaling that an error had occurred. Investigators considered these as misreadings; not indicative of a meter design issue.

Patient comprehension of the instructions for use as well as patient responses to the user acceptance questionnaire fell within acceptable limits for all parameters. Several questions in the instructions for use questionnaire inquired

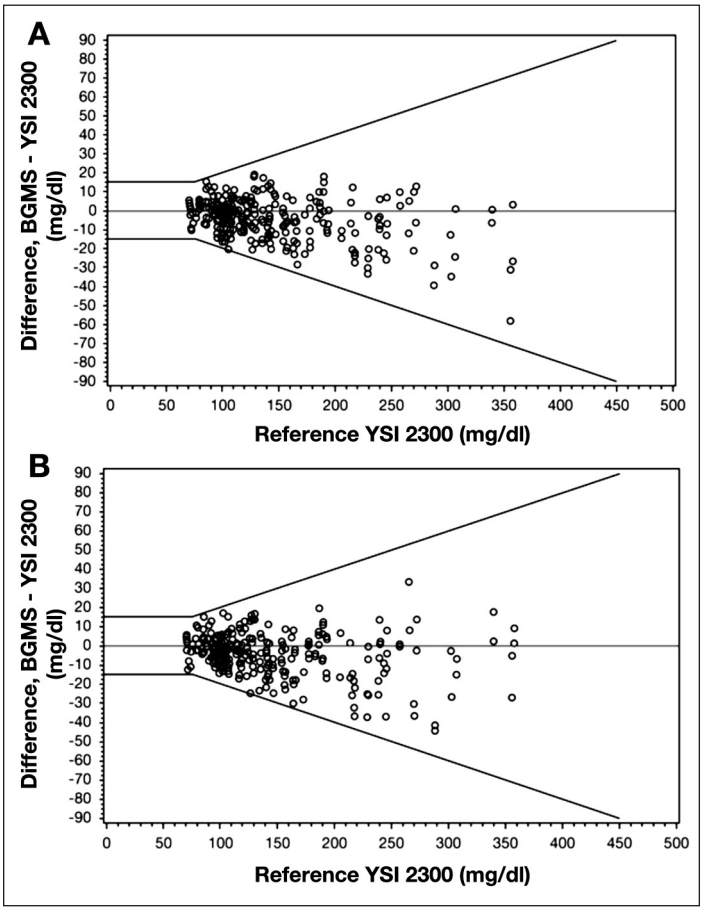

Figure 3. Bias plots for: **(A)** subject self-test and **(B)** HCP test data. Solid lines represent the boundaries of ISO accuracy criteria; specifically, ±15 mg/dl for glucose values <75 mg/dl (4.2 mmol/liter), and within ±20% for glucose values ≥75 mg/dl (4.2 mmol/liter) of the laboratory reference YSI 2300.

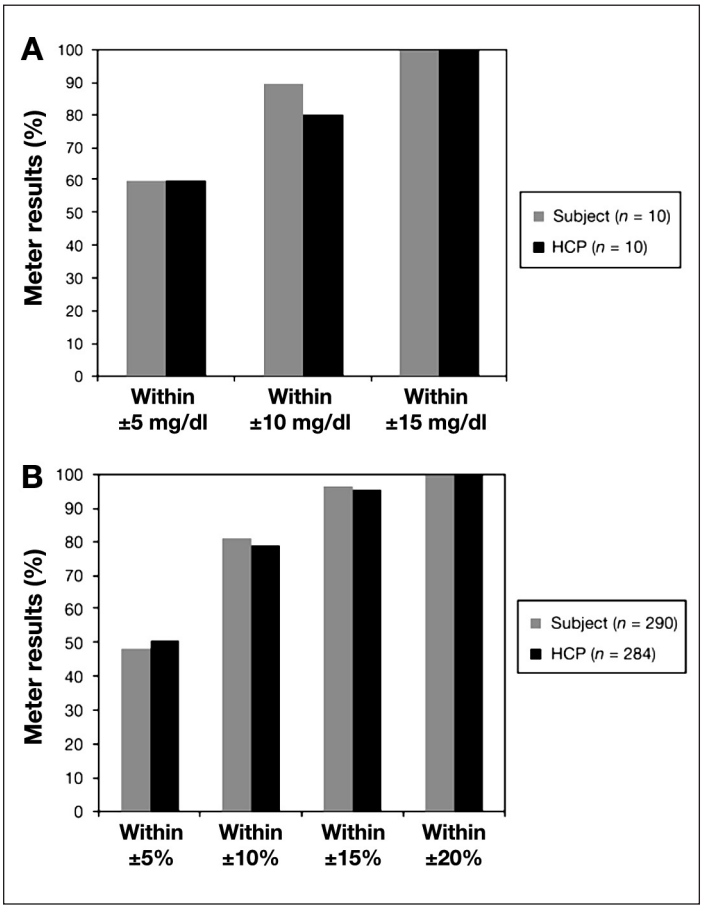

Figure 4. Percentage difference between OneTouch SelectSimple BGMS and YSI 2300 reference values when measured by subjects and HCPs for reference values: **(A)** <75 mg/dl (4.2 mmol/liter) and **(B)** ≥75 mg/dl (4.2 mmol/liter). *Y*-axis shows the proportion of BGMS results falling within the range denoted by the *x*-axis.

about subject understanding of the alerts to low, high, and very high BG levels. Nearly all subjects (155 of 156; 99.4%) correctly recognized the low BG level alarm signal and most correctly identified the signal of a very high BG level (152 of 156; 97.4%). Regarding recognition of the alarm for a high BG level, 140 of 156 subjects (89.7%) correctly identified this signal; most of those who misidentified this signal classified it as a very high BG level alert (14 of 16).

Discussion

Accuracy of BGMS is crucial, as inaccurate readings could form the basis of incorrect treatment decisions, which could lead to serious consequences. The ISO has established accepted criteria for evaluating accuracy, intermediate precision, and repeatability of BGMS performance.[14] These criteria are under review and expected to tighten. The OneTouch SelectSimple BGMS met these ISO criteria, with 100% of findings within current ISO standards.

The OneTouch SelectSimple BGMS is indicated for use on blood from alternate testing sites, specifically the forearm or palm, as well as on blood from the fingertip. The system employs glucose oxidase technology, which means that results from this meter are not affected by the presence of nonglucose sugars (e.g., due to maltose-containing medication).[18]

User skill is one of the factors that can contribute to erroneous readings in SMBG. Patient education has the potential to improve accuracy.[19,20] In our study, subjects were able to correctly use the system, even without any further training than the user manual. Nearly all responses to the user acceptance questionnaire indicated that the meter was easy to learn and easy to use (98.7% neutral or better response; 96.6% CI LL).

The OneTouch SelectSimple BGMS includes warnings (colored dots, blinking or steady arrow, meter beeps) to alert the patient 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)] glucose readings. Use of two visual cues and an auditory cue to signal this is intended to draw patient attention to hyper- or hypoglycemic episodes. The alarm system was well understood by the test subjects, who indicated in responses to the user acceptance questionnaire that it helped them interpret the meter results (97.2% neutral or better response; 94.9% CI LL). Specifically, more than 95% of subjects answered affirmatively when asked if the alarm "made it easy to know if my result is low or high." Literacy and numeracy rates vary greatly around the world. For example, among people aged 15–24 years in South Asia, literacy has been reported as less than 75%, with older adult literacy rates lower.[21] Poor numeracy skills are omnipresent, and can impair risk communication, which limits prevention efforts.[22] The benefit of having a BGMS with warning signals for low, high, and very high readings in addition to a numeric value may be significant in this setting, as well as being convenient for more literate subjects by alerting them to the need to take action to prevent hypo- or hyperglycemia.

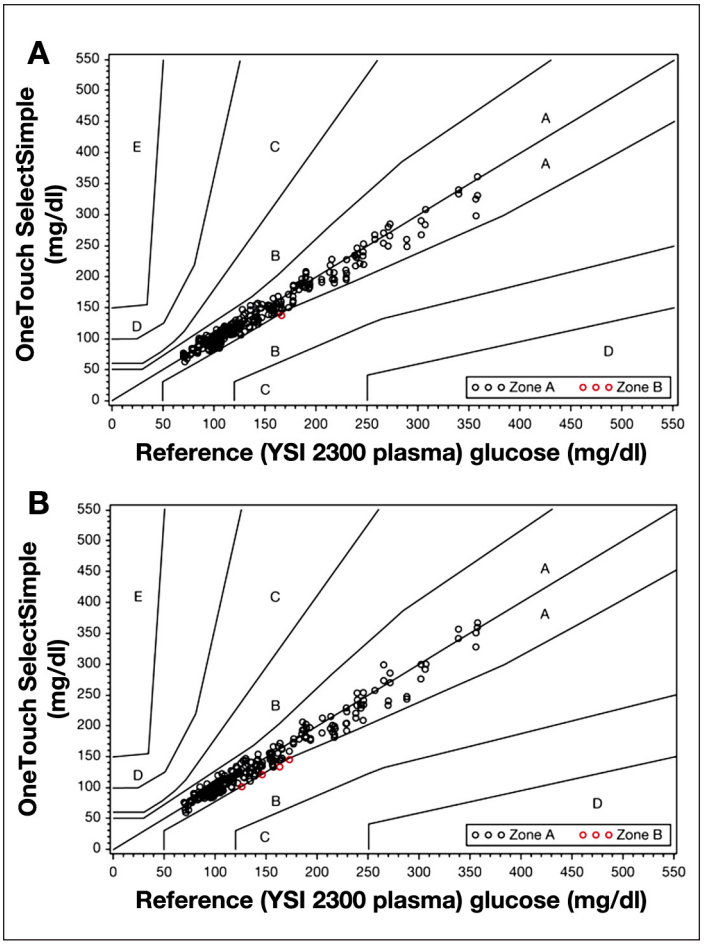

Figure 5. Consensus error grid showing accuracy of OneTouch SelectSimple test results compared with YSI 2300 reference values for: (A) 300 self-tests performed by subjects and (B) 294 tests performed by HCPs.

Conclusion

The OneTouch SelectSimple BGMS met all requirements of ISO 15197 regarding accuracy, intermediate precision, and repeatability of performance. In addition, test subjects highly appreciated the ease of use of the system. With its on-meter application that alerts subjects to

hyper- and hypoglycemia, this system could be used effectively by individuals with varying degrees of literacy and numeracy.

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