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ORIGINAL ARTICLES

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

Anna Chang, M.D.,[1] Alice Orth, R.N., C.D.E.,[2] Bryan Le, C.R.A.,[3] Perla Menchavez, C.C.R.A., C.L.S., M.T.(A.S.C.P.),[3] and Lupe Miller, C.C.R.A.[3]

## 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.

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**Author Affiliations:** [1]John Muir Physician Network Clinical Research Center, Concord, California; [2]Diabetes Society, San Jose, California; and [3]Clinical Research Department, LifeScan, Inc., Milpitas, California

**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

**Corresponding Author:** Anna Chang, M.D., John Muir Physician Network Clinical Research Center, 2700 Grant St. #200, Concord, CA 94520; email address *Anna.Chang_MD@johnmuirhealth.com*

## Introduction

The worldwide prevalence of diabetes is expected to rise from 2.8% in 2000 to 4.4% in 2030, with a corresponding increase in the number of people with this disorder from 171 million to 366 million.[1] Developed and developing countries are expected to have an even higher diabetes prevalence by 2030. In Japan, for example, diabetes is expected to affect 8.9 million people by 2030, representing an increase in prevalence of nearly 25% from 2000.[1] Notably, the largest increase in diabetes prevalence is expected among the elderly. By 2030, it is estimated that there will be more than 48 million diabetes patients in developed countries and more than 82 million patients in developing countries who are aged ≥65 years.[1]

Self-monitoring of blood glucose (SMBG) is a valuable tool for helping patients to achieve and then maintain target blood glucose levels to reduce risk of diabetes-related complications.[2–5] Modern handheld blood glucose meters are small, easy to handle, simple to use, and require very little blood. In analytical and clinical studies, these meters provide clinically acceptable accuracy at rates ≥95%, thereby allowing patients and clinicians to monitor glycemic control and then modify treatment as needed.[6] However, elderly patients with diabetes may have trouble holding or viewing some smaller devices, and consequently require a device that is easier to handle and use.

OneTouch® UltraVue™ is a new meter for SMBG designed for the Japanese diabetes population, particularly elderly patients with poor eyesight, a weak grip, or shaky hands. The meter includes a color liquid crystal display capable of displaying characters from Chinese and Japanese languages, a no-contact used-strip ejector, and a no-button interface (**Figure 1**). The system utilizes OneTouch Ultra Test Strips that are compatible with all OneTouch Ultra Meters.[7] These test strips use an electrochemical biosensor technology based on glucose oxidase chemistry. This highly specific enzyme, glucose oxidase, oxidizes glucose to gluconic acid, thereby transferring electrons from the glucose molecule to a chemical mediator (ferricyanide) that in turn delivers the electrons to a carbon-based electrode. The resulting electrochemical current is converted into a plasma-equivalent glucose concentration that is displayed on the meter. Each test takes 5 s and requires a small drop of blood (a minimum of 1 μl). The meter contains two working electrodes to double-check each test result for accuracy, provides visual confirmation for each appropriate end-filled blood application, and automatically detects when the blood application is insufficient. OneTouch UltraVue has lower and upper limits for detecting glucose of 20 and 600 mg/dl (1.1 and 33.3 mmol/liter), respectively.


**Figure 1.** The OneTouch UltraVue blood glucose meter.

The present studies were conducted to evaluate the performance of the OneTouch UltraVue meter according to criteria published by the International Organization for Standardization (ISO).[8] Two studies evaluated the accuracy of the blood glucose meter when used by diabetes patients and/or health care providers (HCPs), whereas the other two studies evaluated the same-day and day-to-day reproducibility of the meter, respectively.

## Methods

### *Accuracy Studies*

Two accuracy studies were conducted at two study sites in California using an open-label, nonrandomized study design. The protocol and informed consent form were approved by the local Institutional Review Board. In each study, subjects were briefed on the study procedures and requirements, and they were then provided with a

written informed consent form to sign before any study procedure was performed.

The accuracy of the OneTouch UltraVue system was measured by HCPs in accuracy study 1. Subjects with or without diabetes were evaluated for eligibility by measuring their plasma glucose on a YSI 2300 STAT PLUS Select Biochemistry Analyzer (YSI Inc., Yellow Springs, OH) and hematocrit on a STAT-CRIT® instrument (Inverness Medical Innovations, Inc., Waltham, MA). The YSI 2300 uses enzyme-based biosensor technology to measure glucose concentrations in a 25–µl sample (plasma or whole blood) diluted with 600 µl of buffer. Within-run and between-run coefficients of ≤3.5% have been reported using protein-based quality control solutions.[9] Subjects were enrolled to cover a series of plasma glucose concentration ranges (i.e., <50, 50–80, >80–120, >120–200, >200–300, >300–400, and >400 mg/dl, corresponding to <2.8, 2.8–4.4, >4.4–6.7, >6.7–11.1, >11.1–16.7, >16.7–22.2, and >22.2 mmol/liter). Patients with glucose values in a range that was already adequately covered were excluded, as were those whose hematocrit fell outside the OneTouch UltraVue specific range of 30% to 55%. For accuracy testing, the HCP performed a capillary finger stick and then applied the blood directly to test strips inserted into six different meters. Three different test strip lots were used (two meters per lot). Blood from the same finger puncture (or from another finger puncture, if necessary) was then collected in a tube and analyzed by the YSI reference method.

In accuracy study 2, the clinical accuracy of the OneTouch UltraVue system was measured by diabetes patients and HCPs. Each subject was trained by a HCP on the use of the meter during a structured familiarization period. During this period, the subject performed two self-tests and recorded the test results as well as any error messages and problems. For accuracy testing, subjects performed three self-tests and HCPs performed three additional tests on the subject using six OneTouch UltraVue meters, which were rotated systematically from subject to subject. Each subject tested three different test strip lots that were randomized across subjects. The subject performed a fingertip lancing for each of the three pairs of tests (self-test and HCP test) using a different finger for each lancing, and after each test, the HCP recorded the glucose values on the case report form. A separate blood sample was drawn by the HCP immediately after the meter testing was completed. This sample was used for duplicate measurements of plasma glucose concentration on a YSI 2300 analyzer and for hematocrit testing.

Blood glucose test results obtained using the OneTouch UltraVue were compared with values obtained by the YSI reference method. Bias plots were constructed to determine the percentage of test results that met acceptability criteria for system accuracy published by the ISO and the Japanese Ministry of Health, Labour and Welfare.[8,10] Both organizations state that 95% of individual glucose test results should fall within ±15 mg/dl (±0.8 mmol/liter) of the reference value at glucose concentrations <75 mg/dl (<4.2 mmol/liter) and within ±20% at glucose concentrations ≥75 mg/dl (≥4.2 mmol/liter).[8,10] In addition, consensus type 1 error grids were constructed, which divided the plot of UltraVue values versus YSI values into five zones signifying the degree of clinical risk posed by an incorrect measurement.[11]

### *Reproducibility Studies*

Same-day and day-to-day reproducibility studies were conducted at LifeScan Laboratories in Inverness, Scotland. For the same-day reproducibility assessment, the glucose concentration in blood from one donor was measured on a calibrated YSI analyzer and was then adjusted to seven different target levels (±4 mg/dl [±0.2 mmol/liter]): 25, 40, 100, 130, 200, 300, and 500 mg/dl, corresponding to 1.4, 2.2, 5.6, 7.2, 11.1, 16.7, and 27.8 mmol/liter, respectively. Samples with high glucose concentrations were prepared by adding aqueous glucose solution (0.9%) to the blood. Samples with a low glucose concentration were prepared by placing the blood specimen in a water bath until the required blood glucose concentration was obtained. Ten tests were performed on 10 meters using two lots of tests per glucose level. The mean, standard deviation (SD), and coefficient of variation (CV) were determined for glucose measurements on each meter, as well as for the 10 meters combined.

In the day-to-day reproducibility study, aqueous control solutions at five different glucose concentrations (25, 40, 120, 350, and 550 mg/dl, corresponding to 1.4, 2.2, 6.7, 19.4, and 30.6 mmol/liter, respectively) were tested daily over a 10-day period. On each day, each glucose control solution was tested on 20 meters using two test strip lots with 10 meters used per test strip lot. The mean, SD, and CV were calculated at each glucose concentration for each of the 10 meters across the 10-day testing period. The results of both reproducibility studies were evaluated based on acceptability criteria that the meter should have a within-meter CV <5% at glucose levels >100 mg/dl (>5.6 mmol/liter) and a SD <5 mg/dl (<0.3 mmol/liter) at glucose levels <100 mg/dl (<5.6 mmol/liter).

## Results

### *Accuracy Studies*

A total of 145 subjects were enrolled in accuracy study 1, but 23 subjects (16.0%) were withdrawn before meter testing began because the initial YSI 2300 measurement placed the subject into a glucose concentration bin that was already filled. In addition, one subject (0.7%) was excluded from the accuracy analysis because the hematocrit reading was an out-of-range reading (<30%), and eight subjects (5.5%) were excluded because their YSI 2300 results did not meet protocol-defined run-to-run criteria. The remaining 113 subjects (77.9%) were included in the accuracy analysis. The mean age of this cohort was 58.7 years. The majority of subjects were male (51.3%) and white (79.6%), and most had either type 1 (23.0%) or type 2 (69.0%) diabetes (**Table 1**). The reference plasma glucose measured by the YSI analyzer ranged from 33.0 to 531.5 mg/dl (1.8 to 29.5 mmol/liter), and the hematocrit ranged from 30.1% to 48.2%.

Using the OneTouch UltraVue, 6 subjects (5.3%) had glucose concentrations <50 mg/dl (<2.8 mmol/liter), 18 (15.9%) had concentrations 50 to 80 mg/dl (2.8 to 4.4 mmol/liter), 25 (22.1%) had concentrations >80 to 120 mg/dl (>4.4 to 6.7 mmol/liter), 31 (27.4%) had concentrations >120 to 200 mg/dl (>6.7 to 11.1 mmol/liter), 17 (15.0%) had concentrations >200 to 300 mg/dl (>11.1 to 16.7 mmol/liter), 11 (9.7%) had concentrations >300 to 400 mg/dl (>16.7 to 22.2 mmol/liter), and 5 (4.4%) had concentrations >400 mg/dl (>22.2 mmol/liter). The glucose concentrations measured using the OneTouch UltraVue were strongly correlated with the plasma YSI reference values over the wide range of concentrations tested. For the 678 tests (each patient's sample was tested on six meters), the relationship was defined by UltraVue = 0.972*YSI +1.15 mg/dl ($S_{y,x}$ = 13.8 mg/dl, $r$ = 0.99) (**Figure 2**). Consensus error grids showed that 676 of the 678 tests (99.7%) fell within zone A (has no effect on clinical action). The other two test results (0.3%) fell within zone B (altered clinical action has little or no effect on outcome).

The bias analysis showed that the OneTouch UltraVue measured glucose concentrations fell within acceptable accuracy boundaries in 676 of the 678 tests (99.7%). All 114 samples (100%) with glucose concentrations <75 mg/dl (<4.2 mmol/liter) were within ±15 mg/dl (±0.8 mmol/liter) of the YSI reference value, and 562 of 564 samples (99.6%) with glucose concentrations ≥75 mg/dl (≥4.2 mmol/liter) were within ±20% of the YSI reference

**Table 1.**
**Demographics of Subjects in the System Accuracy and Clinical Accuracy Studies**

| | Accuracy study 1 ($n$ = 113) | Accuracy study 2 ($n$ = 79) |
|---|---|---|
| Age, mean (range), *y* | 58.7 (23–83) | 55.2 (18–84) |
| Gender, *n* (%) | | |
| Female | 55 (48.7) | 50 (63.3) |
| Male | 58 (51.3) | 29 (36.7) |
| Ethnicity, *n* (%) | | |
| White | 90 (79.6) | 54 (68.4) |
| Hispanic/Latino | 8 (7.1) | 9 (11.4) |
| Black/African American | 5 (4.4) | 7 (8.9) |
| Asian/Pacific Islander | 8 (7.1) | 7 (8.9) |
| American Indian/Native Alaskan | 1 (0.9) | 1 (1.3) |
| Other or unknown | 1 (0.9) | 1 (1.2) |
| Type of diabetes, *n* (%) | | |
| Type 1 | 26 (23.0) | 29 (36.7) |
| Type 2 | 78 (69.0) | 50 (63.3) |
| None | 9 (8.0) | 0 (0) |
| YSI-measured plasma glucose | | |
| Median (range), mg/dl | 131.3 (33.0–531.5) | 169.5 (66.8–356.3) |
| Hematocrit (%) | | |
| Median (range) | 40.0 (30.1–48.2) | 38.9 (30.3–49.2) |

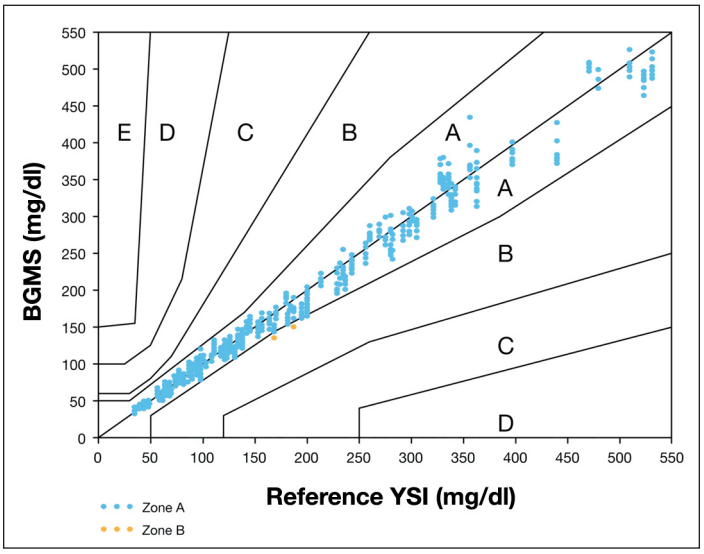


**Figure 2.** Regression plot with consensus error grid showing accuracy of the OneTouch UltraVue compared with the YSI reference values ($r$ = 0.99). Of the 678 tests, 676 (99.7%) fell within zone A (no effect on clinical action) and 2 (0.3%) fell within zone B (altered clinical action, little or no effect on clinical outcome). None of the test results fell within zone C (altered clinical action; likely to affect clinical outcome), zone D (altered clinical action; could have significant medical risk), or zone E (altered clinical action; could have dangerous consequences). BGMS, blood glucose monitoring system.

value (**Figure 3**). Three error messages were obtained during accuracy testing, which indicated double application of the blood sample to the test strip, sample application before the meter was ready, and insufficient blood sample, respectively. In each case, the HCPs performed a successful test on the second attempt using the same meter and test strip lot.

In accuracy study 2, 81 diabetes patients were enrolled, and 79 (97.5%) were evaluable. Two subjects were excluded because the timing between specific tests exceeded protocol-defined limits. In addition, numerical results were not available for the second lancing in one subject. Thus evaluable results were available for 236 test sets (self-test and HCP test). The study cohort had a mean age of 55.2 years, and the majority of subjects were female (63.3%) and white (68.4%) (**Table 1**). Most had type 2 diabetes rather than type 1 (63.3% versus 36.7%). The study cohort had been performing SMBG for a median of 11 years (0.3 to 31 years) and was testing at a median frequency of three times per day (range 1 to 10). Forty-five patients (57.0%) had difficulty reading without wearing corrective lenses, and seven subjects (8.9%) had difficulty handling small objects. Most patients (72.2%) were using a OneTouch meter (Ultra, Ultra2, UltraSmart, or UltraMini). Plasma glucose measured by the YSI analyzer ranged from 66.8 to 356.3 mg/dl (3.7 to 19.8 mmol/liter), and hematocrit ranged from 30.3% to 49.2%.

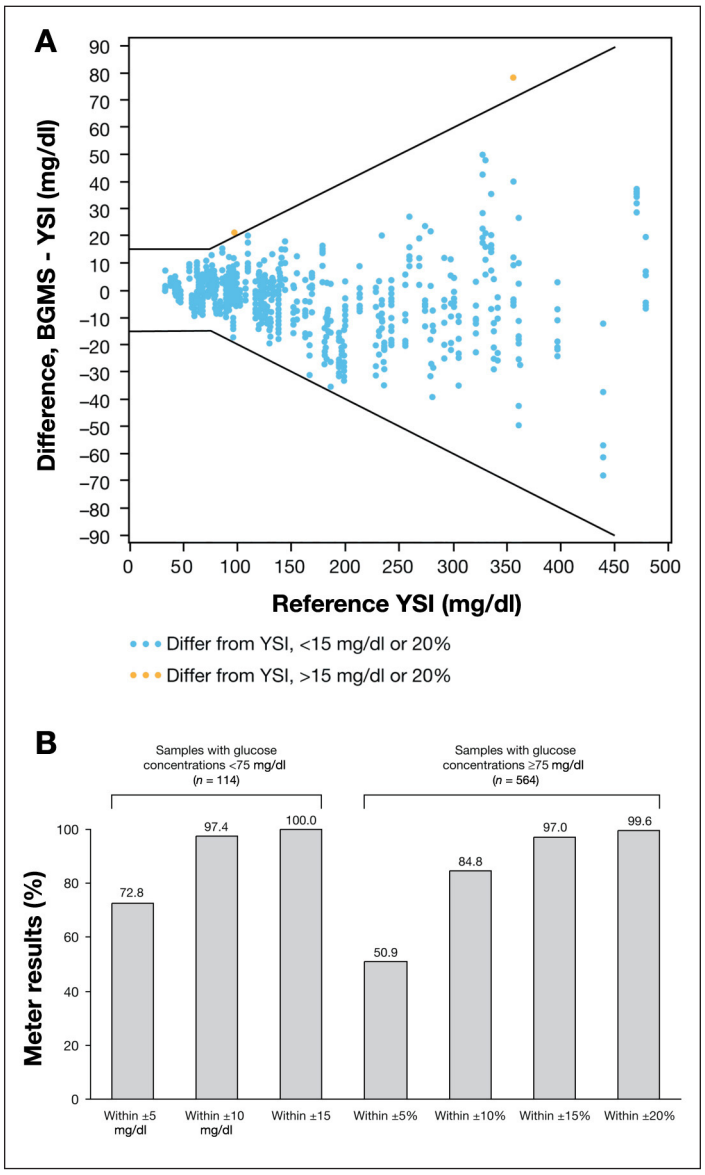


**Figure 3.** Accuracy of the OneTouch UltraVue. **Figure 3A** shows the bias plot with error tolerances for the OneTouch UltraVue compared with the YSI reference method. **Figure 3B** shows the percentage of samples falling within the indicated ranges relative to the YSI reference method. BGMS, blood glucose monitoring system.

The glucose concentrations in the self-tests performed by subjects and in the tests performed by HCPs using the OneTouch UltraVue were strongly correlated with the plasma glucose levels measured by the YSI reference method (**Figure 4**). For the 236 self-tests (each subject tested three samples except for one subject who tested only two), the relationship was defined by UltraVue = 0.994*YSI -1.86 mg/dl ($S_{y,x}$ = 15.5 mg/dl, $r$ = 0.976). For the 236 tests conducted by HCPs, the relationship was defined by UltraVue = 0.993*YSI -4.97 mg/dl ($S_{y,x}$ = 14.8 mg/dl, $r$ = 0.977). The linear relationship between OneTouch UltraVue test results and YSI reference values was overlaid with consensus type 1 error grids to estimate the degree of clinical risk posed by an incorrect measurement (see **Figure 4**). Overall, 229 of the 236 self-tests performed by patients (97.0%) and 225 of the 236 tests performed by HCPs (95.3%) fell within zone A, signifying that any error in measurement compared with the reference value would have no effect on clinical action (**Table 2**). All other tests, including 7 self-tests (3.0%) and 11 HCP tests (4.7%) fell within zone B.

Bias plots were used to show the percentage of subject self-tests and HCP tests that fell within the boundary limits specified in ISO criteria (**Figure 5**). Overall, 229 of the 236 self-tests (97.0%) and 233 of the 236 HCP tests (98.7%) fell within the accuracy boundaries specified in ISO criteria. Error messages indicating sensor damage or an incompletely filled confirmation window were obtained in six self-tests. In five of the six cases, the second attempt resulted in a successful measurement that was included in the accuracy analysis. Error messages for not enough blood were obtained in six HCP tests, and again, in five cases, a successful test was obtained on retesting.

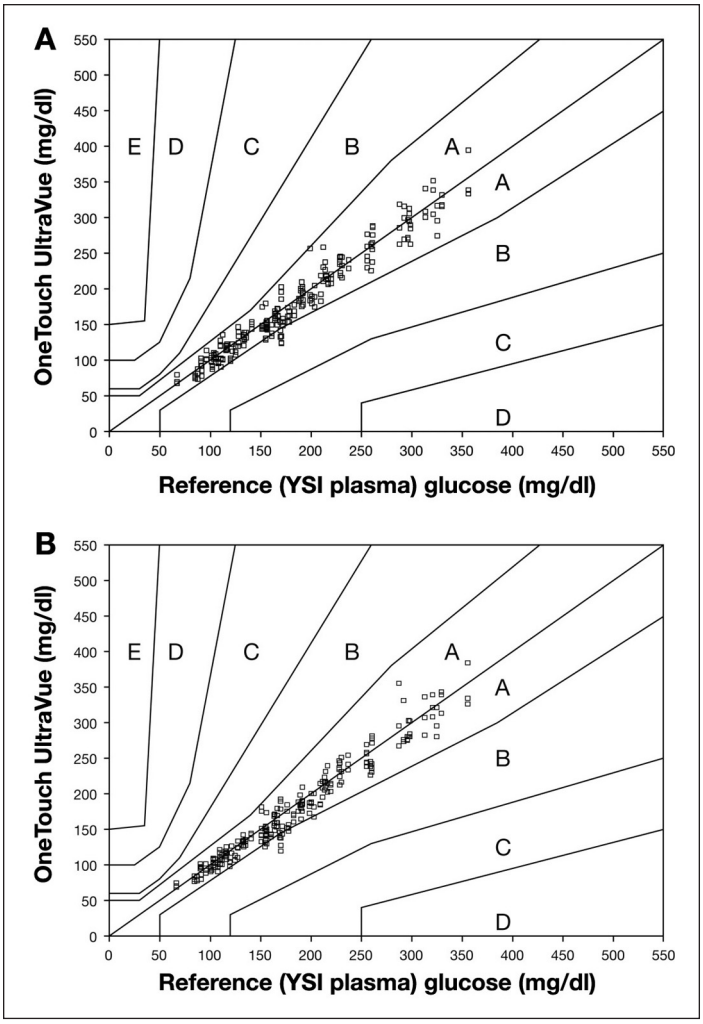


**Figure 4.** Regression plot with consensus error grid showing accuracy of the OneTouch UltraVue test results compared with the YSI reference values for 236 self-tests performed by subjects (**Figure 4A**) and by HCPs (**Figure 4B**).

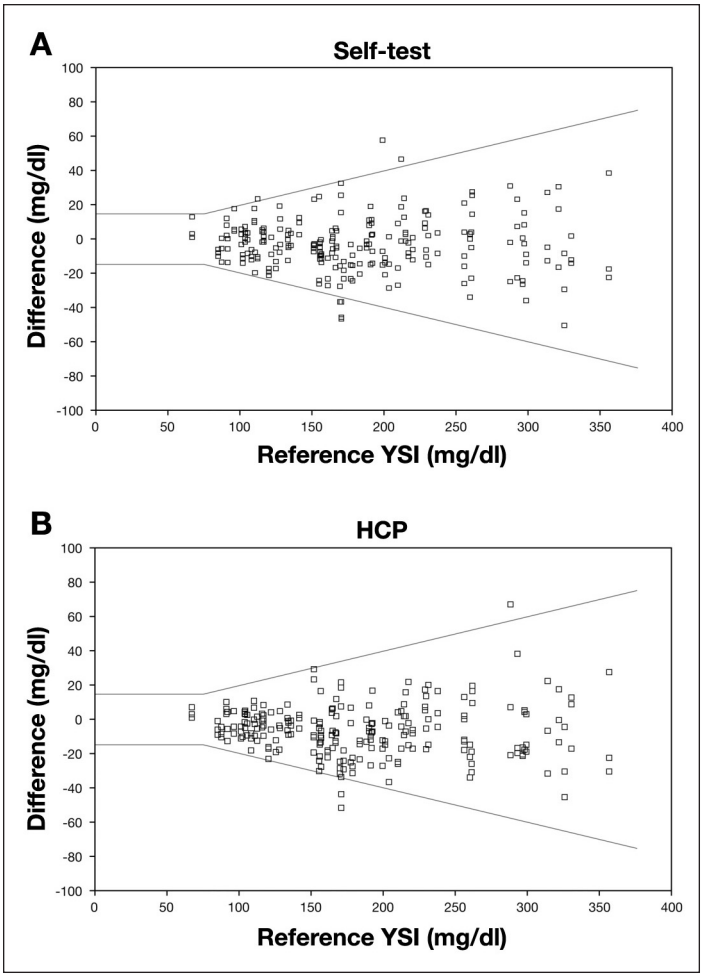


**Figure 5.** Bias plot with error to tolerances for the OneTouch UltraVue test results compared with YSI reference values for 236 self-tests performed by subjects (**Figure 5A**) and by HCPs (**Figure 5B**).

**Table 2.**
**OneTouch UltraVue Test Results Falling within Each Zone of the Consensus Type 1 Error Grid in Clinical Accuracy Study 2**

| Zone[a] | Subject self-test ($n$ = 236) | HCP test ($n$ = 236) |
|---|---|---|
| A | 229 (97.0%) | 225 (95.3%) |
| B | 7 (3.0%) | 11 (4.7) |
| 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 action; zone D, altered clinical action—could have a significant medical risk; and zone E, altered clinical action—could have dangerous consequences.

### *Reproducibility Studies*

The performance criteria for same-day reproducibility were met for all seven blood glucose concentrations tested (i.e., 25, 40, 100, 130, 200, 300, and 500 mg/dl) (**Table 3**). The two concentrations <100 mg/dl (<5.6 mmol/liter) had pooled SDs <1.5 mg/dl (<0.1 mmol/liter), which were well within the acceptability criteria of <5 mg/dl (<0.3 mmol/liter). The five concentrations >100 mg/dl (>5.6 mmol/liter) had CVs <2%, which were well within the acceptability criteria of <5%. Similarly, the performance criteria for day-to-day reproducibility were met for all 5 control glucose concentrations tested (**Table 4**). The two concentrations <100 mg/dl (<5.6 mmol/liter) had SDs ≤1.51 mg/dl (<0.1 mmol/liter), which were well within the acceptability criteria of <5 mg/dl (<0.3 mmol/liter). Three concentrations >100 mg/dl (>5.6 mmol/liter) had CVs <2%, which were well within the acceptability criteria of <5%.

**Table 3.**
**Day-to-Day Reproducibility**

| | Test strip lot 1[a] | | | Test strip lot 2[a] | | |
|---|---|---|---|---|---|---|
| Sample | Mean glucose (mg/dl) | SD (mg/dl) | CV (%)[b] | Mean glucose (mg/dl) | SD (mg/dl) | CV (%)[b] |
| 1 | 34.69 | 1.46 | — | 28.91 | 0.87 | — |
| 2 | 50.60 | 1.34 | — | 44.42 | 1.02 | — |
| 3 | 103.77 | 1.89 | 1.82 | 99.87 | 1.74 | 1.74 |
| 4 | 132.97 | 2.05 | 1.54 | 120.34 | 1.84 | 1.53 |
| 5 | 201.14 | 2.72 | 1.35 | 214.28 | 2.97 | 1.39 |
| 6 | 322.55 | 3.76 | 1.17 | 320.01 | 4.45 | 1.39 |
| 7 | 543.91 | 10.20 | 1.88 | 527.23 | 6.44 | 1.22 |

[a] Test strip lots 1 and 2 were lot numbers 26458182 and 27091712, respectively.
[b] Criteria does not apply to concentrations <100 mg/dl.

**Table 4.**
**Same-Day Reproducibility**

| | Test strip lot 1[a] | | | Test strip lot 2[a] | | |
|---|---|---|---|---|---|---|
| Sample | Mean glucose (mg/dl) | SD (mg/dl) | CV (%)[b] | Mean glucose (mg/dl) | SD (mg/dl) | CV (%)[b] |
| 1 | 28.60 | 1.07 | — | 23.89 | 0.99 | — |
| 2 | 47.42 | 1.30 | — | 41.91 | 1.51 | — |
| 3 | 120.93 | 2.25 | 1.86 | 114.65 | 2.12 | 1.85 |
| 4 | 348.02 | 4.57 | 1.31 | 336.80 | 6.37 | 1.89 |
| 5 | 535.59 | 10.55 | 1.97 | 515.28 | 9.66 | 1.88 |

[a] Test strip lots 1 and 2 were lot numbers 26458182 and 27091712, respectively.
[b] Criteria does not apply to concentrations <100 mg/dl.

## Discussion

These studies demonstrate that the OneTouch UltraVue blood glucose system provides accurate and reproducible results across a wide range of blood glucose concentrations. The accuracy and reproducibility of the system meet the performance criteria established by the ISO and Japanese Ministry of Health, Labour and Welfare. The clinical accuracy of the meter was assessed by HCPs in both accuracy studies and by intended users (i.e., patients with type 1 or type 2 diabetes) in accuracy study 2. In both accuracy studies for both sets of users, the blood glucose concentrations measured by the OneTouch UltraVue meter were highly correlated with the values obtained by the YSI reference method, with $r$ values exceeding 0.97. Error grid analyses showed that 97.0% of the self-tests performed by subjects in accuracy study 2 and 99.7% and 95.3% of those performed by HCPs in accuracy studies 1 and 2, respectively, fell within zone A, signifying that any error in measurement compared with the reference value would have had no effect on clinical action. The remaining tests fell within zone B, signifying that the error in test results may have altered the clinical action but would have had little or no effect on clinical outcome. None of the test values in either study—whether measured by patients or HCPs—fell within zones C, D, or E, signifying that the errors would not have affected clinical outcome, placed the subject at significant medical risk, or had dangerous consequences.

Bias analysis showed that the vast majority of test results fell within the boundary for clinical accuracy established by the ISO and Japanese Ministry of Health, Labour and Welfare. Specifically, 99.7% of HCP test results in accuracy study 1 and 97.0% of self-test results and 98.7% of HCP test results in accuracy study 2 fell within ±15 mg/dl (±0.8 mmol/liter) of the YSI reference value for samples with glucose concentrations <75 mg/dl

(<4.2 mmol/liter) or within ±20% of the YSI reference value for samples with glucose concentrations ≥75 mg/dl (≥4.2 mmol/liter).[8] Further analysis showed that a vast majority of the tests fell within ±10 mg/dl (±0.6 mmol/liter) when glucose concentrations were <75 mg/dl (<4.2 mmol/liter) and within ±15% when glucose concentrations were ≥75 mg/dl (≥4.2 mmol/liter).

The reproducibility studies showed that the OneTouch UltraVue system provides reproducible same-day and day-to-day test results. In the same-day tests, seven different blood glucose concentrations were measured on 10 different OneTouch UltraVue meters using two different test strip lots, whereas in the day-to-day tests, five different glucose concentrations in solution were measured by 20 different meters using two different test strip lots. All seven glucose concentrations measured in the same-day reproducibility study and all five glucose concentrations measured in the day-to-day reproducibility study were well within the criteria for reproducibility established by the ISO and Japanese Ministry of Health, Labour and Welfare. The SD was <1.5 mg/dl (<0.1 mmol/liter) at glucose concentrations <100 mg/dl (<5.6 mmol/liter; ISO criteria require an SD of <5 mg/dl [<0.3 mmol/liter]), and the CV was <2% at concentrations >100 mg/dl (>5.6 mmol/liter; ISO criteria require a CV <5%).[8]

The accuracy and reproducibility of the OneTouch UltraVue system determined in these studies are consistent with the performance of other blood glucose meters. In a recent report, the system accuracy of the OneTouch Vita and OneTouch Ultra2 blood glucose meters was compared in two studies involving a total of 834 blood samples from 139 subjects; consensus error grid analyses showed that 98.4% and 98.2% of the test results were in zone A, with all remaining values falling in zone B.[7] The CVs for OneTouch Vita and OneTouch Ultra2 were ≤3.1% and ≤4.7%, respectively, when same-day reproducibility was assessed and ≤3.0% and ≤3.4%, respectively, on day-to-day reproducibility. The accuracy and reproducibility obtained with the OneTouch UltraVue in the present studies compare favorably with those obtained for these other OneTouch systems.

## Conclusions

OneTouch UltraVue provides accurate and reproducible blood glucose testing results across a wide range of blood glucose concentrations. Its accuracy and reproducibility meet established performance criteria—consistent with the performance of other OneTouch meters. The simple interface and lack of contact with used strips make the OneTouch UltraVue a viable option for older patients and their caregivers in monitoring glycemic control and for using test results to make treatment modifications as needed.

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