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# Performance Evaluation of a New Blood Glucose Monitor That Requires No Coding: The OneTouch® Vita™ System

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## Abstract

***Background:***

Improvements to blood glucose monitoring systems aim to simplify the testing process, reduce or eliminate errors, and provide additional information for patients with diabetes. New systems must continue to demonstrate high-quality analytical performance. The new OneTouch® Vita™ System (LifeScan, Inc., Milpitas, CA) offers a no-code testing process and proven technology found in the OneTouch® Ultra® System. Comparative studies were conducted with the new and established systems to evaluate their precision and accuracy.

***Methods:***

Within-run precision in blood, total precision with controls, and system accuracy were evaluated using three lots of OneTouch Vita Test Strips and one lot of OneTouch Ultra Test Strips. Accuracy was tested across a wide glucose range (38–520 mg/dl, 2.1–28.9 mmol/liter) using fingertip blood samples from 139 subjects. Reference plasma glucose values were obtained using the YSI 2300 STAT Plus Glucose & Lactate Analyzer (YSI Inc., Yellow Springs, OH). All studies were designed in accordance with requirements published by the International Organization for Standardization (ISO 15197).

***Results:***

Precision testing (within-run and total) with both systems produced coefficients of variation (CVs) of <5% for all sample types and glucose levels. Within-run precision testing with blood showed CVs of <3.1% and <4.7% for the OneTouch Vita and OneTouch Ultra Systems respectively. Total precision with control samples gave CVs of <3.0% and <3.6% for the two systems. Consensus error grid analysis showed equivalent clinical accuracy with 98.4% (821/834) and 98.2% (273/278) of results within zone A. Both systems met the ISO acceptability requirements for system accuracy.

***Conclusion:***

The OneTouch Vita System provides a simple no-code testing process with performance comparable to the OneTouch Ultra and OneTouch Ultra2 Systems.

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**Abbreviations:** (CV) coefficient of variation, (ISO) International Organization for Standardization

**Keywords:** accuracy, calibration, glucose monitoring, precision

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## Introduction

Systems for self-monitoring of blood glucose are evolving to meet the needs of a larger and more diverse patient population. Removing steps in the testing process can make self-monitoring more convenient and help minimize sources of error. However, simplifying the testing process must not sacrifice system performance and accuracy. The new OneTouch® Vita™ Blood Glucose Monitoring System (LifeScan, Inc., Milpitas, CA) uses the same proven technology found in the OneTouch® Ultra® System but has eliminated the need for the user to review and, if necessary, change the calibration code of the meter with each test.

Clinical studies focusing on the precision and accuracy of the OneTouch Vita System have recently been completed. Precision testing was performed by trained research personnel at LifeScan laboratories in Inverness, Scotland. Accuracy evaluations were performed at one clinical site in the United Kingdom and one site in the United States. Both studies were designed in accordance with the system performance requirements published by the International Organization for Standardization (ISO).[1] This report presents the results from testing conducted with the OneTouch Vita System in which the OneTouch Ultra or Ultra2 System was included as a control.

## Materials and Methods

### *OneTouch Ultra System*

The OneTouch Ultra System (LifeScan, Inc., Milpitas, CA) was introduced in 2000 and has established a record of excellent performance and a high level of user acceptability.[2-4] A key component of the system is the OneTouch Ultra Test Strip which is used across the family of OneTouch Ultra Meters. The test strip utilizes a highly specific enzyme, glucose oxidase, to oxidize glucose to gluconolactone. Electrons from the glucose molecule are transferred to a chemical mediator (ferricyanide) which then delivers the electrons to a carbon-based electrode where they are measured electrochemically. The resulting current is converted into a blood glucose result and displayed on the meter (test time = 5 seconds). The strip uses an end-fill design with hydrophilic layers to quickly draw in a small blood sample (minimum 1µl) and enable testing at fingertip and alternative sites. To ensure accurate results, the meter carries out six checks, including short-sample detection, during every test.

### *OneTouch Vita System*

The new OneTouch Vita System was designed to simplify the testing procedure for people with diabetes by eliminating the meter coding process. The OneTouch Vita Test Strip uses the same chemistry found in OneTouch Ultra Test Strips and is produced using manufacturing parameters that eliminate the need for a calibration code. As a result, the OneTouch Vita System has the same technical specifications and error-trapping technology found in OneTouch Ultra Systems.

### *Within-run Precision*

For within-run precision (repeatability) testing, blood from a single donor was adjusted to five blood glucose concentrations spanning the hypo- and hyperglycemic ranges. Testing was performed using 10 OneTouch Vita Meters and 10 OneTouch Ultra Meters. Three lots of OneTouch Vita Test Strips and one lot OneTouch Ultra Test Strips were tested at each blood glucose level ($n$ = 100 tests per glucose level). Results were evaluated by calculating the coefficient of variation (CV) at each blood glucose level. For the OneTouch Vita System, the CV values of the three strip lots were averaged.

### *Total Precision*

Control solutions having three glucose concentrations (low, normal, high) were tested over a 10-day period. On each day, two tests were performed using 20 OneTouch Vita Meters and 20 OneTouch Ultra Meters. Three lots of OneTouch Vita Test Strips and one lot of OneTouch Ultra Test Strips were tested at each glucose level ($n$ = 200 tests per glucose level). As with within-run precision testing, results were evaluated by calculating the CV at each glucose level and results for the OneTouch Vita System were averaged across strip lots.

### *System Accuracy*

The OneTouch Vita and OneTouch Ultra2 Systems were tested side by side during two clinical studies designed in accordance with the system accuracy requirements published in the ISO standard. Studies in the United Kingdom and United States were conducted according to protocols that were reviewed and approved by local ethics and Institutional Review Board committees. All testing was conducted by trained study personnel using capillary blood samples obtained directly from the finger of each subject.

Eighteen OneTouch Vita Meters and four OneTouch Ultra2 Meters were included in the clinical testing along with three lots of OneTouch Vita Test Strips and one lot of OneTouch Ultra Test Strips. At the clinical sites, subjects also provided a fingertip blood sample for hematocrit measurement, and duplicate reference glucose tests were performed using the YSI 2300 STAT Plus Glucose & Lactate Analyzer (YSI Inc., Yellow Springs, OH). All glucose meter and reference measurements were performed according to manufacturer's instructions.

Individual results from each meter system were plotted against the mean of duplicate YSI plasma reference measurements. The correlation between meter results and YSI reference values was analyzed using linear regression analysis. Clinical accuracy was evaluated using consensus error grid analysis, which categorizes meter results according to the degree of clinical risk posed by an inaccurate measurement.[5] The number and percentage of accurate meter results were determined according to the ISO standard, which states that the minimum acceptable accuracy for a meter system is demonstrated if at least 95% of the individual glucose meter results fall within ±15 mg/dl (±0.83 mmol/liter) of the reference method at glucose concentrations <75 mg/dl (4.2 mmol/liter) and within ±20% at glucose concentrations >75 mg/dl (4.2 mmol/liter).[1]

## Results and Discussion

### *Within-run Precision*

Within-run precision (repeatability) testing with blood samples showed similar performance for the two meter systems, with CVs for both systems falling below 5% at all glucose levels (**Table 1**). Averaged over three test strip lots, the no-code OneTouch Vita System produced slightly lower CVs in four of the five samples when compared to results from a single lot tested with the OneTouch Ultra System. For the OneTouch Vita System, this testing shows a strip-to-strip variability of <3.1%.

**Table 1.**
**Summary of Within-run Precision Data for OneTouch Vita and OneTouch Ultra Systems**

| | | OneTouch Vita | OneTouch Ultra |
|---|---|---|---|
| Blood sample | Target blood glucose, mg/dl (mmol/liter) | Coefficient of variation (%) | Coefficient of variation (%) |
| 1 | 40 ± 4 (2.2 ± 0.2) | 3.1 | 4.7 |
| 2 | 100 ± 4 (5.6 ± 0.2) | 2.5 | 2.5 |
| 3 | 130 ± 6 (7.2 ± 0.3) | 1.7 | 2.3 |
| 4 | 200 ± 8 (11.1 ± 0.4) | 1.5 | 3.3 |
| 5 | 300 ± 12 (16.7 ± 0.7) | 1.6 | 1.8 |

### *Total Precision*

Total precision testing conducted over a 10-day period with control samples also showed similar performance for the two meter systems (**Table 2**). Coefficients of variation for both systems were well below 5%, with CVs of <3.0% and <3.6% for the OneTouch Vita and OneTouch Ultra Systems respectively.

**Table 2.**
**Summary of Total Precision Data for OneTouch Vita and OneTouch Ultra Systems**

| | OneTouch Vita | | OneTouch Ultra | |
|---|---|---|---|---|
| Control sample | Mean glucose, mg/dl (mmol/liter) | Coefficient of variation (%) | Mean glucose, mg/dl (mmol/liter) | Coefficient of variation (%) |
| 1 | 37 (2.1) | 3.0 | 41 (2.3) | 3.4 |
| 2 | 111 (6.2) | 2.3 | 118 (6.6) | 2.2 |
| 3 | 351 (19.5) | 1.7 | 349 (19.4) | 2.1 |

### *System Accuracy*

A total of 834 capillary blood samples from 139 subjects were analyzed. The samples presented a wide range of blood glucose concentrations (38–520 mg/dl, 2.1–28.9 mmol/liter). Linear regression analyses for paired meter and YSI results showed high correlations with similar regression statistics for each meter system (**Table 3**).

**Table 3.**
**Regression Statistics: OneTouch Vita and OneTouch Ultra2 Systems vs YSI Plasma Reference**

| Meter System | No. of samples | Regression equation | Correlation coefficient (*r*) | Standard error ($S_{y.x}$) |
|---|---|---|---|---|
| OneTouch Vita | 834 | Y = 1.01x – 9.6 mg/dl (0.53 mmol/liter) | 0.991 | 15.4 mg/dl (0.85 mmol/liter) |
| OneTouch Ultra2 | 278 | Y = 0.974x – 4.7 mg/dl (0.26 mmol/liter) | 0.992 | 14.0 mg/dl (0.78 mmol/liter) |

Consensus error grid analyses indicated that 98.4% (821/834) and 98.2% (273/278) of meter results were in zone A for the OneTouch Vita and OneTouch Ultra2 Systems respectively. For both systems, all remaining meter results fell within zone B (**Figures 1 and 2, Table 4**). At blood glucose levels below 75 mg/dl (4.2 mmol/liter), 96.7% of OneTouch Vita and 100% of OneTouch Ultra2 Meter results were within ±15 mg/dl (±0.83 mmol/liter) of the reference method (**Table 5**). Based on ISO system accuracy requirements, 98.3% (820/834) of the individual

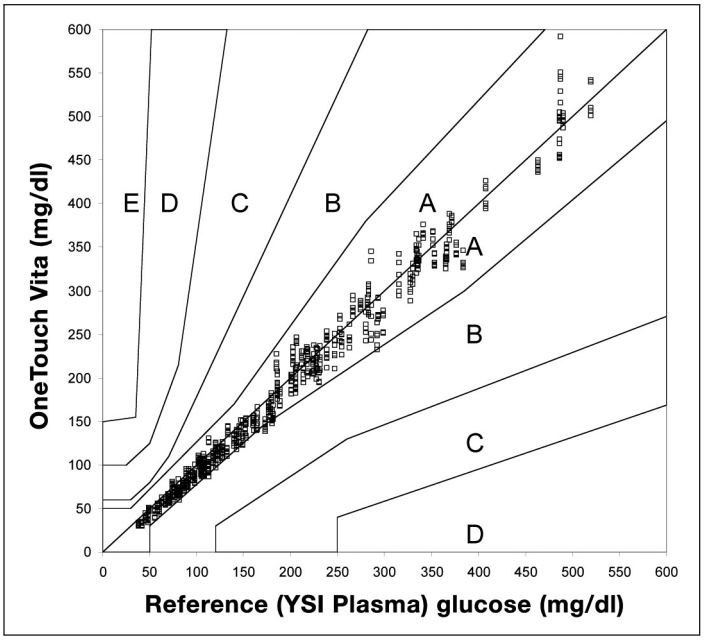


**Figure 1.** Regression plot with consensus error grid for OneTouch Vita System.

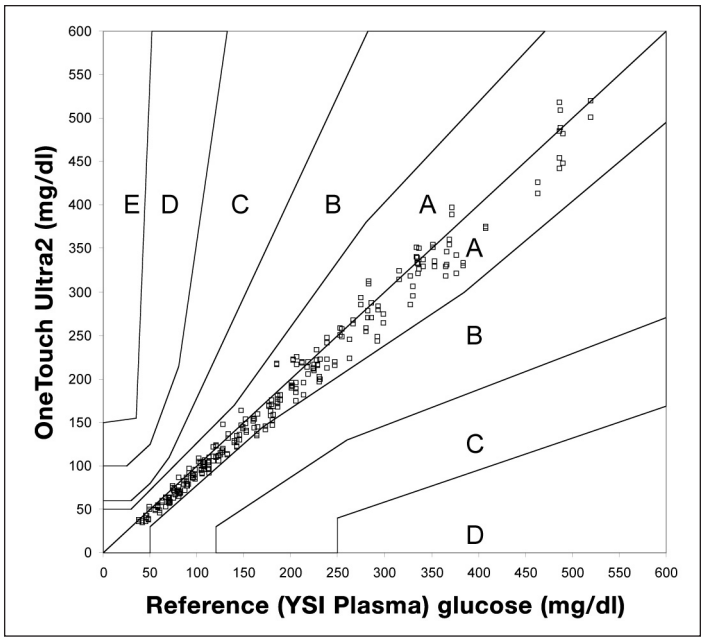


**Figure 2.** Regression plot with consensus error grid for OneTouch Ultra2 System.

OneTouch Vita System results were within the published criteria, as were 100% (278/278) of the OneTouch Ultra2 System results.

## Conclusions

Data collected on the new OneTouch Vita System indicate that the meter provides precise and accurate blood glucose readings across a wide range of blood glucose concentrations. Based on standard criteria, the analytical performance of the OneTouch Vita System was found to be comparable to that of the OneTouch Ultra and Ultra2 Systems. By combining no-coding technology with proven test strip design and error detection capabilities, the OneTouch Vita System provides accurate and reliable blood glucose results with greater simplicity of use.

**Table 4.**
**Number and Percentage of Meter Results within Zones of the Consensus Error Grid.**

| Meter System | Zone A | Zone B | Zones C, D & E |
|---|---|---|---|
| OneTouch Vita | 821/834 (98.4%) | 13/834 (1.6%) | 0/834 (0.0%) |
| OneTouch Ultra2 | 273/278 (98.2%) | 5/278 (1.8%) | 0/278 (0.0%) |

Zone A = no effect on clinical action (clinically accurate);
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 effect;
Zone E = altered clinical action – could have dangerous consequences.

**Table 5.**
**Summary of Accuracy Data for OneTouch Vita and OneTouch Ultra2 Systems Using Error Intervals Published by the International Organization for Standardization (ISO)**

| Glucose results <75 mg/dl (4.2 mmol/liter) | Within 5 mg/dl (0.3 mmol/liter) | Within 10 mg/dl (0.6 mmol/liter) | Within 15 mg/dl (0.8 mmol/liter)[a] |
|---|---|---|---|
| OneTouch Vita system | 26/120 (21.7%) | 78/120 (65.0%) | 116/120 (96.7%) |
| OneTouch Ultra2 system | 15/40 (37.5%) | 30/40 (75.0%) | 40/40 (100.0%) |

| Glucose results >75 mg/dl (4.2 mmol/liter) | Within 5% | Within 10% | Within 15% | Within 20%[a] |
|---|---|---|---|---|
| OneTouch Vita system | 268/714 (37.5%) | 500/714 (70.0%) | 628/714 (88.0%) | 704/714 (98.6%) |
| OneTouch Ultra2 system | 85/238 (35.7%) | 169/238 (71.0%) | 220/238 (92.4%) | 238/238 (100.0%) |

[a] ISO acceptability criteria for system accuracy

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