Clinical Accuracy and User Performance of the TRUE METRIX® GO Self-Monitoring Blood Glucose System

TRIVIDIA HEALTH™

Summary

Objective:

To demonstrate that the TRUE METRIX® GO Self-Monitoring Blood Glucose System, from Trividia Health, Inc., meets the International Organization for Standardization (ISO) 15197:2013 standard for accuracy requirements.

Methods:

The TRUE METRIX® GO System is designed to provide diabetic patients with an accurate, but small and conveniently portable meter for self-monitoring of blood glucose. To evaluate the clinical accuracy of the TRUE METRIX® GO System, trained healthcare professionals obtained fingerstick blood samples from patients with type 1 or type 2 diabetes, and then used the samples to perform blood glucose tests. Patients also performed blood glucose tests with the TRUE METRIX® GO System and evaluated the ease of use of the system. Clinical accuracy was determined by comparing blood sample results obtained with the TRUE METRIX® GO System versus the standard Yellow Springs Instruments (YSI) laboratory reference instrument.

Results:

Healthcare professionals obtained and tested fingerstick blood samples from 103 adult diabetes patients. The TRUE METRIX® GO System exceeded the minimum ISO 15197:2013 requirements for accuracy, with ≥99% of both healthcare professional and patient results <100 mg/dL and ≥100 mg/dL falling within the ISO bias limits, and 100% of results within Zone A of a Parkes Error Grid analysis. Healthcare professionals also indicated that patients demonstrated good testing performance following review of the TRUE METRIX® GO instructions for use (ratings of ≥4.80 out of a maximum of 5 for all procedural questions). In addition, patients indicated that the instructions for use are clear and that TRUE METRIX® GO is easy to use, with maximal rating scores (5.00) for all questions.

Conclusion:

The TRUE METRIX® GO Self-Monitoring Blood Glucose System meets the ISO 15197:2013 standard for clinical accuracy and is considered easy to use by untrained diabetic patients.

INTRODUCTION

Self-monitoring of blood glucose (SMBG) is a valuable tool for helping patients with diabetes to achieve and maintain target blood glucose levels, thereby reducing the risk of diabetes-related complications.[1] The American Diabetes Association (ADA) recommends SMBG as an integral part of diabetes management for patients who are treated with insulin and as a useful component for achieving glycemic goals for patients on oral medications or medical nutrition therapy.[2] Therefore, it is important that SMBG results be accurate and reliable. The International Organization for Standardization (ISO) has published standards for the acceptable performance of blood glucose monitoring systems. The ISO 15197 *In Vitro Diagnostic Test Systems–Requirements for Blood-Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus*, was updated in 2013 to include guidance on accuracy limits, procedures for design verification, and validation of performance by the intended users.[3]

The TRUE METRIX® GO Self-Monitoring Blood Glucose System, developed by Trividia Health, Inc., comprises a portable blood glucose meter, test strips with glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) chemistry, and control solution. The TRUE METRIX® GO System is intended to help diabetes patients and their physicians monitor the effectiveness of their diabetes control through in vitro home self-testing of glucose levels in fresh capillary whole blood. A summary of performance criteria for the TRUE METRIX® GO System is provided in **Table 1**. The TRUE METRIX® GO Meter is small, twisting onto a vial of test strips for maximum portability and convenience, and it offers full data management features (**Figure 1**).

Table 1. Summary of TRUE METRIX® GO Performance Criteria

Features	Performance
Coding	No coding
Blood volume	0.5 µL
Testing time	As little as 4 seconds
Sample type	Capillary
Enzyme	GDH-FAD
Control detection	Automatic detection
Blood glucose range	20-600 mg/dL
Maltose interference	No
Hematocrit range	20%-70%
Altitude range	Up to 10,200 ft
Temperature range	41°F-104°F
Test memory	500 tests
Test averaging	7-, 14-, and 30-day
Time/date tracking	Both time and date
Data management capability	Yes

GDH-FAD, glucose dehydrogenase flavin-adenine dinucleotide.

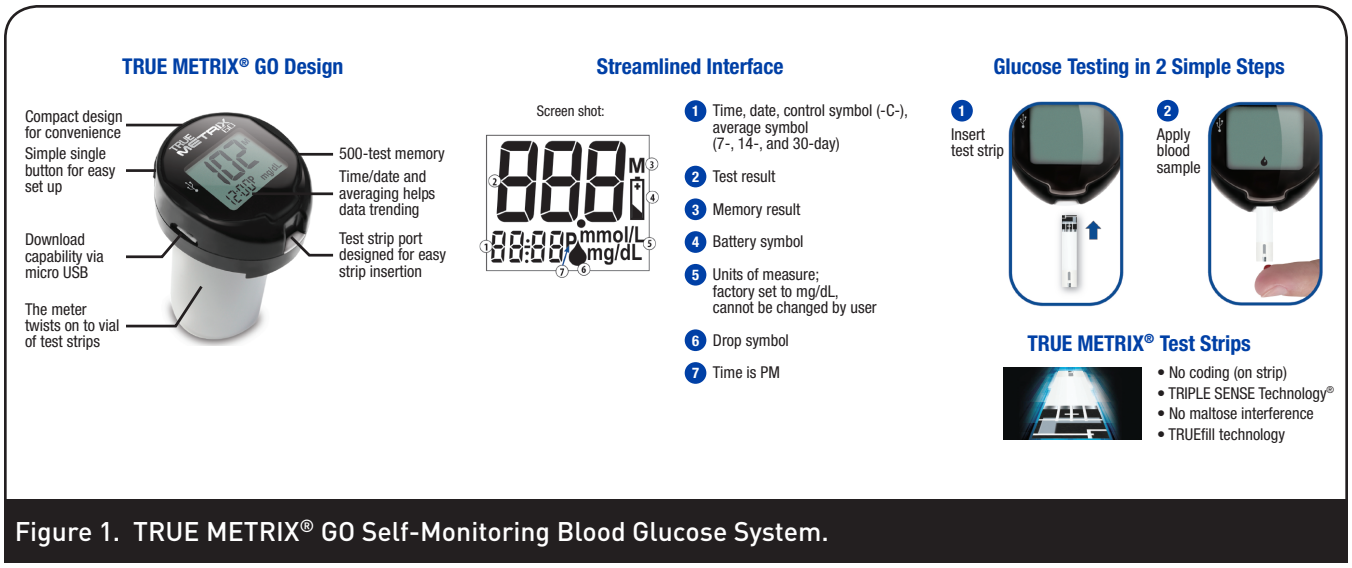


Figure 1. TRUE METRIX® GO Self-Monitoring Blood Glucose System.

Featuring TRIPLE SENSE Technology®, the TRUE METRIX® GO System's chemistry, trio of test strip electrodes, and built-in algorithm work together to detect, analyze, and correct for environmental variables (hematocrit, temperature, and sample size) that can adversely impact the accuracy of test results. Use of the TRUE METRIX® GO is simple: The no-coding meter powers on upon insertion of a test strip; sample is then applied to the test strip by touching the edge of the test strip to the sample. The meter will detect when the sample chamber is full and initiate testing in as little as 4 seconds, and display the glucose result when testing is complete. Additional features of the TRUE METRIX® GO include time and date; 7-, 14-, and 30-day data averaging; and the ability to store up to 500 results in memory, along with a micro USB port for result downloading. Together, these features provide patients with confidence and convenience when monitoring and identifying trends in their blood glucose levels.

OBJECTIVE

The objective of the study was to demonstrate that the TRUE METRIX® GO Self-Monitoring Blood Glucose System from Trividia Health, Inc., meets the ISO 15197:2013 standard for clinical accuracy.

METHODOLOGY

Research Design

To evaluate the accuracy of new SMBG devices, the ISO 15197:2013 standard[3] require clinical evaluation of blood samples by healthcare professionals and patients using the test system compared with a reference method. In this study, clinical accuracy of the TRUE METRIX® GO System was determined by comparing capillary (fingerstick) blood glucose results against those obtained with the Yellow Springs Instruments (YSI) Blood Glucose Analyzer, which is a recognized reference standard for the measurement of blood glucose.

Both healthcare professionals and adult diabetes patients participated in the study. Healthcare professionals were trained on how to use the device prior to obtaining patient blood samples and performing testing. Patients with type 1 or type 2 diabetes were included; however, patients with gestational diabetes were not enrolled. Within the patient pool, efforts were made to equally include both sexes, as well as a range of ages and ethnic groups.

Blood glucose results were obtained by a healthcare professional using the YSI instrument before and after TRUE METRIX® GO System testing for each patient; samples for patients who demonstrated significant drift in their blood glucose values during testing (ie, their ending YSI glucose value was not within 4 mg/dL for glucose values ≤100 mg/dL, or within 4% for glucose values >100 mg/dL of their beginning YSI value) were excluded from the analysis. In addition, because data were collected in accordance with the ISO 15197:2013 glucose distribution for accuracy testing (**Table 2**), only the first 100 patients with glucose concentrations meeting the distribution were included in the analysis; after the needed samples for a given glucose range had been obtained, no further samples were added for that range.

Table 2. ISO 15197:2013 Glucose Distribution for Blood Glucose System Accuracy[3]

ISO category	Glucose concentration	Proportion of samples for clinical evaluation
	mg/dL	%
1	≤50	5
2	>50-80	15
3	>80-120	20
4	>120-200	30
5	>200-300	15
6	>300-400	10
7	>400	5

Data Collection

All testing and data collection were consistent with the ISO 15197:2013 standard.[3] Patients fasted for at least 2 hours prior to providing blood samples. A healthcare professional first obtained a reference blood glucose measurement for each patient using the YSI reference instrument. Hematocrit target levels were to be in the range of 24% to 51%, and temperature exposure ranged from 70°C to 77°C.

Patients were then given the TRUE METRIX® GO instructions for use and asked to perform a self-test with the TRUE METRIX® GO System using a fingerstick whole blood sample and 1 lot of test strips. The observing healthcare professional or other study investigator was not allowed to intervene or answer questions from the patients during testing. Healthcare professionals monitored the patients to evaluate how compliant each user was with following the instructions, and then rated the patient's performance using a scale of 1 to 5 (1 = non-compliance; 5 = full compliance). Patient performance was considered acceptable if the average score for all patients was ≥3.0.

Patients were also asked questions about the quality of the TRUE METRIX® GO instructions for use and about ease of use of the TRUE METRIX® GO System, ranking specified aspects on a scale of 1 to 5 (1 = strongly disagree, 5 = total agreement). The instructions for use were considered acceptable if the average score for all patients was ≥3.0.

Once patient testing was completed, a healthcare professional obtained fingerstick samples from the patients for accuracy testing using the same TRUE METRIX® GO Meter. Three test strip lots, with 2 replicates per test strip lot, were used for each sample, resulting in 6 data points per sample and a total of 600 data points for the analysis.

The majority of testing and data collection was performed at Medical Research South in Charleston, SC. However, some samples with very low glucose concentration (ie, <80 mg/dL) or very high glucose concentration (>300 mg/dL) were prepared in the laboratory by Trividia Health, Inc., in Fort Lauderdale, FL to complete the number of results required for those 2 glucose ranges. For the altered samples, fingerstick blood was collected in heparinized tubes and pooled. Low glucose concentrations were obtained by incubating the blood at 98.6°C until achieving glucose <80 mg/dL or <50 mg/dL (about 2-4 hours), while high glucose concentrations were obtained by adding glucose to the pooled blood to achieve concentrations >300 mg/dL or >400 mg/dL. The samples were then tested by healthcare professionals using the TRUE METRIX® GO and YSI reference instrument, as performed for fresh blood samples.

Data Analysis

Per the ISO 15197:2013 standard, acceptable system accuracy is met when 95% of individual TRUE METRIX® GO glucose test results fall within ±15 mg/dL of the YSI reference results at glucose concentrations <100 mg/dL, and within ±15% at glucose concentrations ≥100 mg/dL (**Table 3**).[3] System accuracy is also shown graphically on a bias plot, visually showing how individual values obtained with the TRUE METRIX® GO System differ from average YSI reference values across glucose concentration intervals.

The Parkes Error Grid (a consensus error grid)[4] was also used to assess the potential clinical significance of the bias between TRUE METRIX® GO results versus the YSI reference instrument. The Parkes Error Grid is divided into 5 Zones (A-E), which represent increasing risk levels related to potential clinical outcomes. The ISO 15197:2013 standard requires that 99% of test results fall within Zones A and B (**Table 3**), which are associated with no or little effect on clinical action; in contrast, glucose results within Zones C, D, and E represent altered clinical action with increasing negative effect on clinical outcome.

Table 3. ISO 15197:2013 Defined Limits for Blood Glucose System Accuracy[3]

Glucose concentration	ISO limits	Criteria for accuracy
<100 mg/dL	±15 mg/dL	95% of all results must be within ISO limits[a]
≥100 mg/dL	±15%	
99% of measured glucose values shall fall within Zones A and B of the Parkes Error Grid.		

[a]ISO 15197:2013 standard requires that all 3 lots tested should pass these criteria.

RESULTS

Patient Participants

A total of 103 patients with type 1 or type 2 diabetes were enrolled in the study, and 100 of these were included in the patient evaluations (**Table 4**). Capillary blood samples from 87 patients whose blood glucose level met the ISO 15197:2013 glucose distribution for accuracy evaluation were included in the healthcare provider analysis, along with 17 samples prepared in the Trividia Health laboratory to meet the glucose distribution needs.

Table 4. Patient Demographics

	Patient testing (n = 100)	HCP testing (n = 83)
Mean (range) age	58 (27-94) years	53 (25-94) years
Gender		
Male	37%	39%
Female	63%	61%
Ethnicity		
African-American	65%	57%
White	29%	29%
Hispanic	2%	5%
Other	4%	9%
Years of education		
<12 years	12%	10%
12 years	49%	40%
>12 years	35%	49%

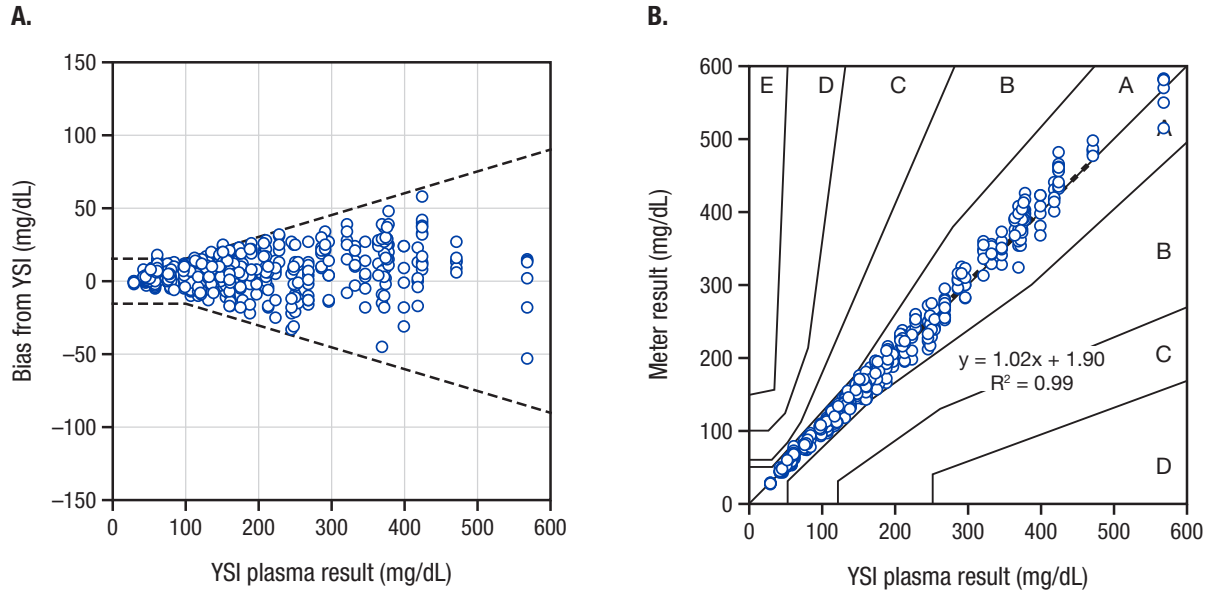
HCP, healthcare professional.

Device Accuracy

Healthcare professional results using the TRUE METRIX® GO System exceeded the ISO 15197:2013 accuracy criteria, with 99.5% of all measurements within the required bias limits (**Table 5** and **Figure 2A**). The Parkes Error Grid analysis for TRUE METRIX® GO versus the YSI reference instrument for fingerstick samples tested by healthcare professionals is presented in **Figure 2B**; 100% of the data points fell within Zone A. The slope of the regression line was 1.02 (standard error [SE] ±0.00), and the intercept was 1.90 (SE ±0.87) mg/dL. The results demonstrated that the TRUE METRIX® GO System accurately detects glucose in whole capillary blood when operated by healthcare professionals.

Table 5. ISO 15197:2013 Accuracy Results for Healthcare Professionals Using TRUE METRIX® GO Versus YSI Reference Instrument

	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Results <100 mg/dL	94/156 (60%)	146/156 (94%)	155/156 (>99%)
	Within ±5%	**Within ±10%**	**Within ±15%**
Results ≥100 mg/dL	227/444 (51%)	383/444 (86%)	442/444 (>99%)



A, Bias plot of all TRUE METRIX® GO results versus YSI reference instrument results analyzed per the ISO 15197:2013 accuracy standard.
B, Parkes Error Grid of TRUE METRIX® GO results versus YSI reference instrument results.

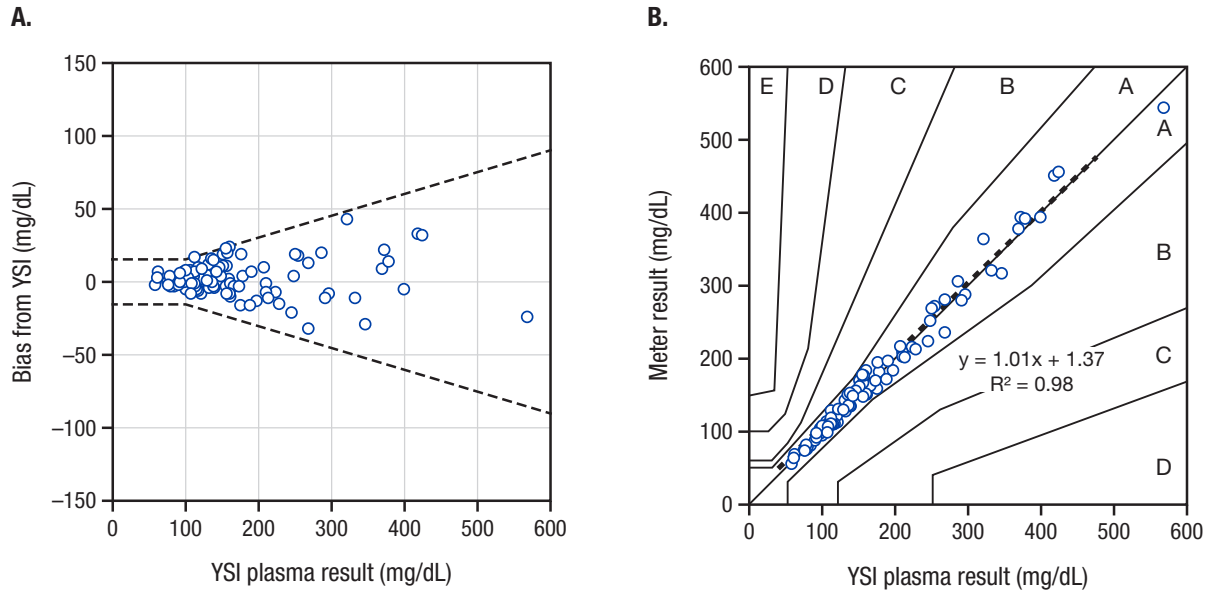
Figure 2. ISO 15197:2013 Accuracy Results for Healthcare Professionals Using TRUE METRIX® GO Versus YSI Reference Instrument

User Analyses

Patient results for the TRUE METRIX® GO System also exceeded the minimum ISO 15197:2013 accuracy criteria, with 99% of all results within the specified bias limits (**Table 6** and **Figure 3A**). The Parkes Error Grid, shown in **Figure 3B**, shows that 100% of fingerstick samples test by patients fell within Zone A, indicating that any observed difference between the TRUE METRIX® GO System and the YSI reference method is expected to have no clinical impact. The slope of the regression line was 1.01 (SE ±0.01), and the y-intercept was 1.37 (SE ±2.53) mg/dL. Together, these analyses demonstrated that testing fingerstick capillary whole blood results obtained by patients using the TRUE METRIX® GO System are similar to those obtained with the YSI reference glucose analyzer.

Table 6 ISO 15197:2013 Accuracy Results for Patients Using the TRUE METRIX® GO Versus YSI Reference Instrument

	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Results <100 mg/dL	13/17 (77%)	17/17 (100%)	17/17 (100%)
	Within ±5%	**Within ±10%**	**Within ±15%**
Results ≥100 mg/dL	46/83 (55%)	73/83 (88%)	82/83 (99%)



A, Bias plot of all TRUE METRIX® GO results versus YSI reference instrument results analyzed per the ISO 15197:2013 accuracy standard.
B, Parkes Error Grid of TRUE METRIX® GO results versus YSI reference instrument results.

Figure 3. ISO 15197:2013 Accuracy Results for Patients Using TRUE METRIX® GO Versus YSI Reference Instrument

Trained healthcare professionals observed each patient during blood glucose testing with the TRUE METRIX® GO System and rated the patients' testing performance. The healthcare professionals' evaluations indicated that patients did a good job following the TRUE METRIX® GO instructions for use, with average ratings of ≥4.80 out of a maximum score of 5 for all questions (**Table 7**).

Table 7. Healthcare Professional Evaluation of Patient Performance Using the TRUE METRIX® GO System

Questions asked of healthcare professionals	Average response
Was the patient able to insert the strip correctly?	4.80
Was the patient able to apply blood correctly?	4.90
Was the patient able to read the result?	5.00
Did the patient correctly follow the written instructions?	4.90

Responses rated on a scale of 1 to 5, with 1 = non-compliance and 5 = full compliance.

Following blood glucose testing with the TRUE METRIX® GO System, patients rated their testing experience. Patients' responses indicated that the TRUE METRIX® GO instructions for use are clear and easily understood and that the System is easy to use, with ratings of 5.00 for all questions (**Table 8**).

Table 8. Patient Evaluation of the TRUE METRIX® GO System Instructions and Ease-of-Use

Questions asked of patients	Average response
Are the instructions for use generally easy to understand?	5.00
Did the instructions clearly state how to apply blood to the test strip?	5.00
Did the instructions clearly state how to read the result?	5.00
Was the display easy to read?	5.00
Was the system easy to use?	5.00

Responses rated on a scale of 1 to 5, with 1 = strongly disagree and 5 = total agreement.

CONCLUSIONS

The TRUE METRIX® GO Self-Monitoring Blood Glucose System, from Trividia Health, Inc., meets the accuracy requirements of the ISO 15197:2013 standard for SMBG systems when tested by trained healthcare professionals and first-time patient users, with results equivalent to the reference method. A Parkes Error Grid analysis showed that any variation or differences in measurement, as compared with reference instrument values, would have had no effect on clinical action. Patients were able to correctly follow testing instructions without training or help from observing healthcare professionals. Additionally, patients reported that the TRUE METRIX® GO System was easy to use and the instructions for use were clear and easy to understand. The TRUE METRIX® GO System is an accurate and easily portable blood glucose monitoring system with a full array of data management features, providing diabetes patients with confidence and convenience when monitoring their blood glucose levels.

REFERENCES

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