# Clinical Accuracy and User Performance of the TRUE METRIX GO Blood Glucose Monitoring System

TRIVIDIA HEALTH

# Summary

## Objective:

To demonstrate that the TRUE METRIX GO Blood Glucose Monitoring System, from Trividia Health, Inc., meets the International Organization for Standardization EN ISO 15197:2015 standard for accuracy requirements.

## Methods:

The TRUE METRIX GO System is designed to provide diabetic patients and healthcare professionals with an accurate, but small and conveniently portable meter for monitoring of blood glucose levels. 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 EN ISO 15197:2015 standard for accuracy, with ≥99% of both healthcare professional and patient results <5.55 mmol/L and ≥5.55 mmol/L 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 ≥4.8 out of a maximum of 5 for all procedural questions). In addition, patients indicated that the instructions for use are clear and that the TRUE METRIX GO is easy to use, with maximal rating scores (5.0) for all questions.

## Conclusion:

The TRUE METRIX GO Blood Glucose Monitoring System met current EN ISO 15197:2015 standard for clinical accuracy and is considered easy to use by healthcare professionals and 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*, which was updated in 2013 (EN ISO 15197:2003), and in 2015 (EN ISO 15197:2015), includes guidance on accuracy limits, procedures for design verification, and validation of performance by the intended users.[5]

The TRUE METRIX GO Blood Glucose Monitoring 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 is intended for the quantitative determination of glucose in human whole blood taken from the fingertip or forearm (capillary) or from the vein (venous) during either at-home use (self testing) by diabetes patients or use by healthcare professionals in physicians' offices and in acute and convalescent care bedside testing facilities, in order to assist in the management of diabetes. The system may not be used for neonates. 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 | 1.1-33.3 mmol/L |
| Maltose interference | No |
| Hematocrit range | 20%-70% |
| Altitude range | Up to 3,060 m |
| Temperature range | 5°C-40°C |
| 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.

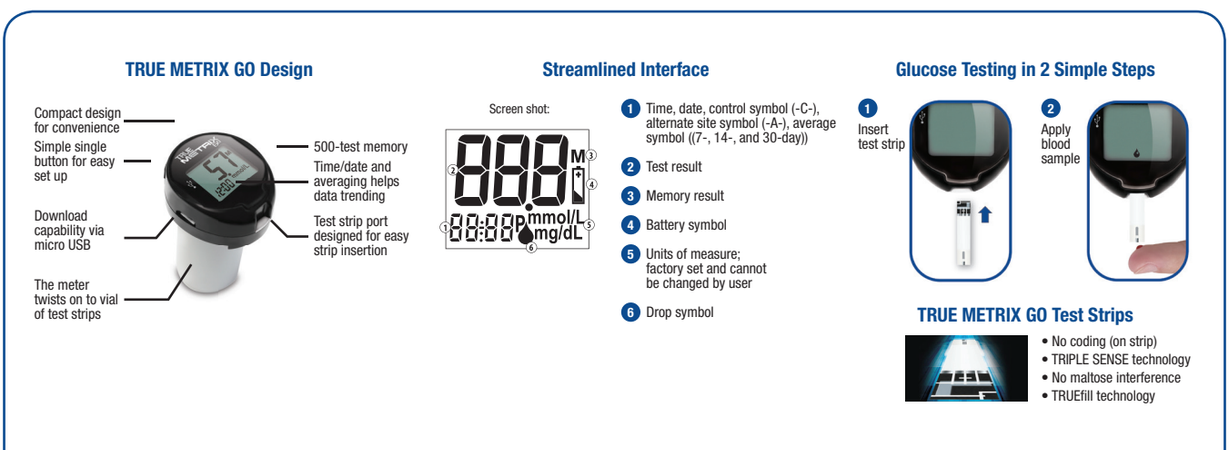



Figure 1. TRUE METRIX GO Blood Glucose Monitoring System.

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 Blood Glucose Monitoring System from Trividia Health, Inc., meets the EN ISO 15197:2015 standard for clinical accuracy.

# METHODOLOGY

## Research Design

To evaluate the accuracy of new SMBG devices, EN ISO 15197:2015 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 0.22 mmol/L for glucose values ≤5.55 mmol/L, or within 4% for glucose values >5.55 mmol/L 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. EN ISO 15197:2015 Glucose Distribution for Blood Glucose System Accuracy[3]**

| ISO category | Glucose concentration | Proportion of samples for clinical evaluation |
|---|---|---|
| | mmol/L | % |
| 1 | ≤2.77 | 5 |
| 2 | >2.77-4.44 | 15 |
| 3 | >4.44-6.66 | 20 |
| 4 | >6.66-11.10 | 30 |
| 5 | >11.10-16.65 | 15 |
| 6 | >16.65-22.20 | 10 |
| 7 | >22.20 | 5 |

## Data Collection

All testing and data collection were consistent with the EN ISO 15197:2015 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 21°C to 25°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, <4.4 mmol/L) or very high glucose concentration (>16.6 mmol/L) 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 37°C until achieving glucose <4.4 mmol/L or <2.8 mmol/L (about 2-4 hours), while high glucose concentrations were obtained by adding glucose to the pooled blood to achieve concentrations >16.6 mmol/L or >22.2 mmol/L. 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 EN ISO 15197:2015 standard, acceptable system accuracy is met when 95% of individual TRUE METRIX GO glucose test results fall within ±0.83 mmol/L of the YSI reference results at glucose concentrations <5.55 mmol/L, and within ±15% at glucose concentrations ≥5.55 mmol/L (**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 EN ISO 15197:2015 standard require 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. EN ISO 15197:2015 Defined Limits for Blood Glucose System Accuracy[3]**

| Glucose concentration | ISO limits | Criteria for accuracy |
|---|---|---|
| <5.55 mmol/L | ±0.83 mmol/L | 95% of all results must be within ISO limits[a] |
| ≥5.55 mmol/L | ±15% | |
| 99% of measured glucose values shall fall within Zones A and B of the Parkes Error Grid. | | |

[a]EN ISO 15197:2015 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 EN ISO 15197:2015 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% |

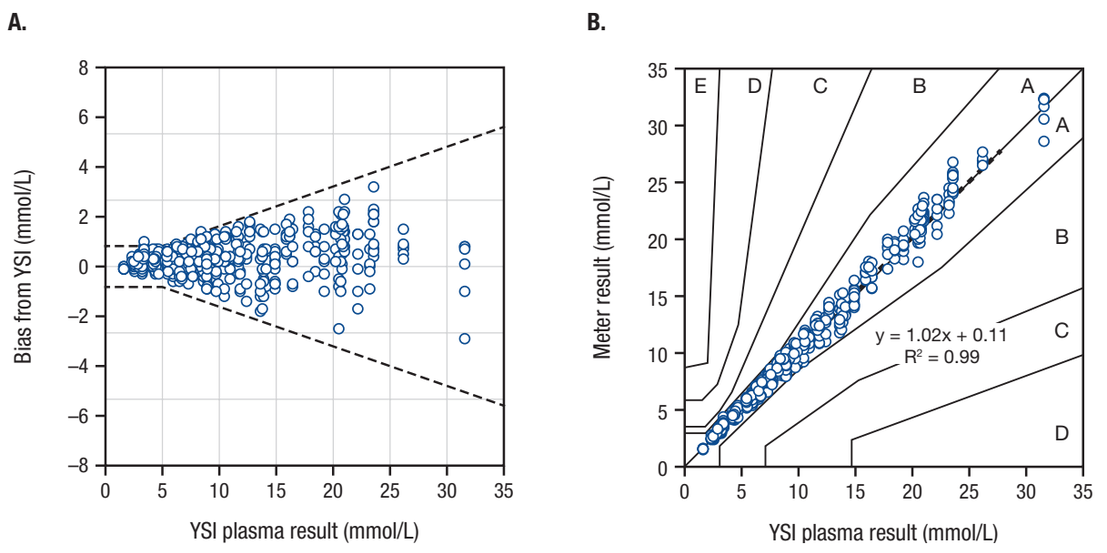
HCP, healthcare professional.

## Device Accuracy

Healthcare professional results using the TRUE METRIX GO System exceeded the EN ISO 15197:2015 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 0.11 (SE ±0.05) mmol/L. The results demonstrated that the TRUE METRIX GO System accurately detects glucose in whole capillary blood when operated by healthcare professionals.

**Table 5. EN ISO 15197:2015 Accuracy Results for Healthcare Professionals Using TRUE METRIX GO Versus YSI Reference Instrument**

| | Within ±0.28 mmol/L | Within ±0.56 mmol/L | Within ±0.83 mmol/L |
|---|---|---|---|
| Results <5.55 mmol/L | 94/156 (60%) | 146/156 (94%) | 155/156 (>99%) |
| | **Within ±5%** | **Within ±10%** | **Within ±15%** |
| Results ≥5.55 mmol/L | 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 EN ISO 15197:2015 accuracy standard.
B, Parkes Error Grid of TRUE METRIX GO results versus YSI reference instrument results.

**Figure 2. EN ISO 15197:2015 Accuracy Results for Healthcare Professionals Using TRUE METRIX GO Versus YSI Reference Instrument**

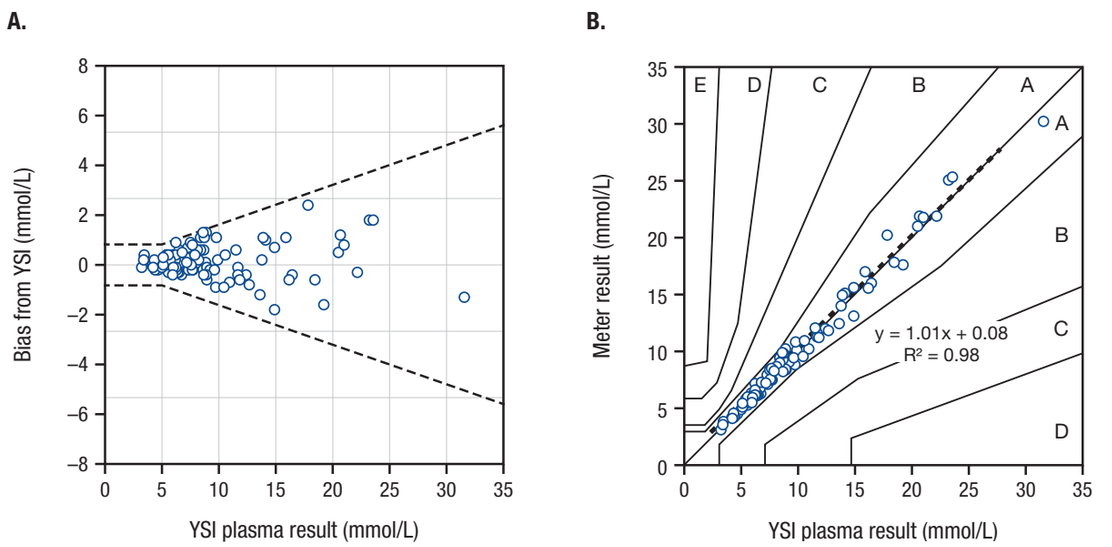
## User Analyses

Patient results for the TRUE METRIX GO System also exceeded the minimum EN ISO 15197:2015 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 0.08 (SE ±0.14) mmol/L. 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. EN ISO 15197:2015 Accuracy Results for Patients Using the TRUE METRIX GO Versus YSI Reference Instrument**

| | Within ±0.28 mmol/L | Within ±0.56 mmol/L | Within ±0.83 mmol/L |
|---|---|---|---|
| Results <5.55 mmol/L | 13/17 (77%) | 17/17 (100%) | 17/17 (100%) |
| | **Within ±5%** | **Within ±10%** | **Within ±15%** |
| Results ≥5.55 mmol/L | 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 EN ISO 15197:2015 accuracy standard.
B, Parkes Error Grid of TRUE METRIX GO results versus YSI reference instrument results.

Figure 3. EN ISO 15197:2015 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 ≥4.8 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? | 4.8 |
| Was the patient able to apply blood correctly? | 4.9 |
| Was the patient able to read the result? | 5.0 |
| Did the patient correctly follow the written instructions? | 4.9 |

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 5.0 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? | 5.0 |
| Did the instructions clearly state how to apply blood to the test strip? | 5.0 |
| Did the instructions clearly state how to read the result? | 5.0 |
| Was the display easy to read? | 5.0 |
| Was the system easy to use? | 5.0 |

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

## CONCLUSIONS

The TRUE METRIX GO Blood Glucose Monitoring System, from Trividia Health, Inc., meets the accuracy requirements of the EN ISO 15197:2015 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 and healthcare professionals with confidence and convenience when monitoring blood glucose levels.

NICO-3519 08/19 © 2019 Trividia Health, Inc.

### REFERENCES

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