Clinical Performance of the TRUEyou Blood Glucose Monitoring System (mmol/L) Using EN ISO 15197:2015 Criteria for Accuracy Utilizing GDH-FAD Enzyme

CLINICAL STUDY SUMMARY

EVALUATION OBJECTIVES

This clinical evaluation:

1. Evaluates the accuracy of the TRUEyou System utilizing international standard EN ISO 15197:2015.
2. Compares the performance of the TRUEyou Blood Glucose Monitoring System utilizing EN ISO 15197:2015 accuracy criteria to the performance of the TRUEyou System utilizing the EN ISO 15197:2003 international standard.
3. Proves that lay users of the TRUEyou Blood Glucose Monitoring System can obtain accurate results consistent with those obtained by trained professionals.
4. Proves that the TRUEyou Blood Glucose Monitoring System is easy to use by first-time users.
5. Proves that the TRUEyou Blood Glucose Monitoring System produces precise results when measuring duplicate fingerstick samples.

ISO STANDARD – 15197:2003[1] COMPARED TO EN ISO 15197:2015[2]

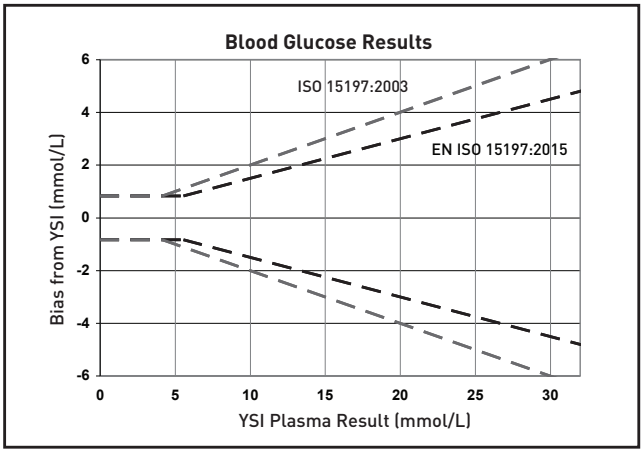
An ISO Standard is developed in response to an identified need in the community, and that will eventually be suitable for implementation on as broad a basis as possible. ISO developed the standard for blood glucose monitoring performance based on a consensus of professionals around the world.

A clinical accuracy study was conducted according to the methodology requirements of EN ISO 15197:2015. The data were assessed and compared using the accuracy bias limits of both EN ISO 15197:2003 and EN ISO 15197:2015. Below is a table outlining the accuracy parameters we evaluate in this study.

Accuracy Parameter	EN ISO 15197:2003	EN ISO 15197:2015
Target blood glucose level from which to base mmol/L bias or % bias	4.2 mmol/L	5.55 mmol/L
Acceptable bias from reference value for lower target glucose levels	+/- 0.83 mmol/L	+/- 0.83 mmol/L
Acceptable bias from reference value for higher target glucose levels	+/- 20%	+/- 15%
Acceptable % of all results within bias limits	95%	95%
Parkes Error Grid	Not required	99% of results within Zones A and B

CLINICAL STUDY SUMMARY

The graph to the right illustrates the comparison of the EN ISO 15197:2003 bias limits compared to EN ISO 15197:2015 criteria for accuracy.



SITES AND SUBJECTS

Clinical evaluations of the TRUEyou System were conducted at 2 clinical institutions across the U.S. In total, 200 subjects completed the protocol across the 2 evaluation sites. Study demographics shown below.

Ethnicity							
Category	**White**	**African American**	**Hispanic**	**American Indian**	**Asian**	**Other**	**Not Recorded**
User Study	24%	74%	0%	2%	0%	0%	0%
Accuracy Study	39%	48%	6%	1%	2%	4%	0%

Gender			
Category	**Male**	**Female**	**Not Recorded**
User Study	46%	53%	1%
Accuracy Study	50%	49%	1%

Age (Years)			
Category	**Average**	**Maximum**	**Minimum**
User Study	59	95	23
Accuracy Study	52	79	21

Years of Education				
Category	**<12**	**12**	**>12**	**Not Recorded**
User Study	11%	47%	42%	0%
Accuracy Study	10%	27%	61%	2%

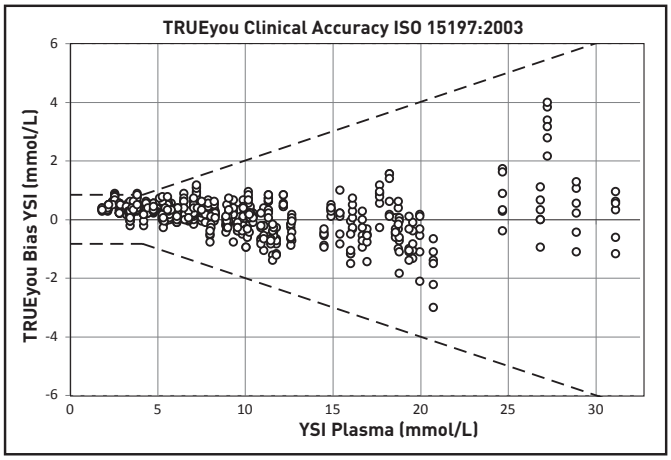
CLINICAL EVALUATION METHODS

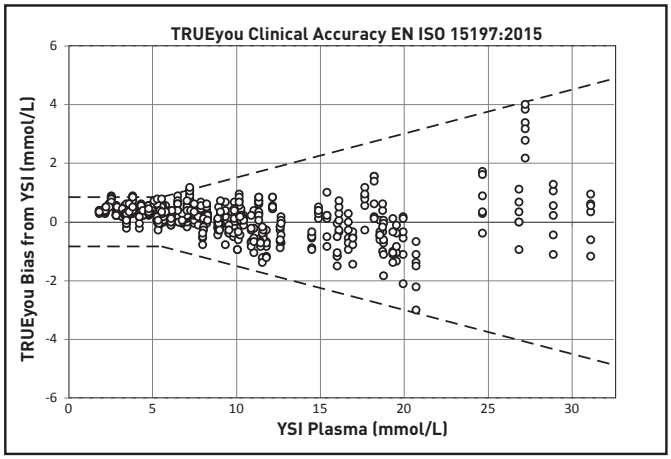
Clinical Evaluations performed using the TRUEyou Blood Glucose Monitoring System:

1. Accuracy of fingerstick results obtained by patients and healthcare professionals (HCP) compared to the laboratory reference (three test strip lots used).
2. Accuracy of fingerstick results obtained by healthcare professionals compared to the laboratory reference using Parkes Error Grid analysis (three test strip lots used).
3. User performance evaluation including healthcare professional feedback on first-time user testing technique (one test strip lot used).

TOPLINE RESULTS USING ISO CRITERIA

In this study using fingerstick samples obtained by healthcare professionals, the TRUEyou System produced 99.3% of results within the bias limits for EN ISO 15197:2003 and 99.3% within the bias limits for EN ISO 15197:2015.





EN ISO 15197:2015 requires 3 lots of test strips to be used in the evaluation

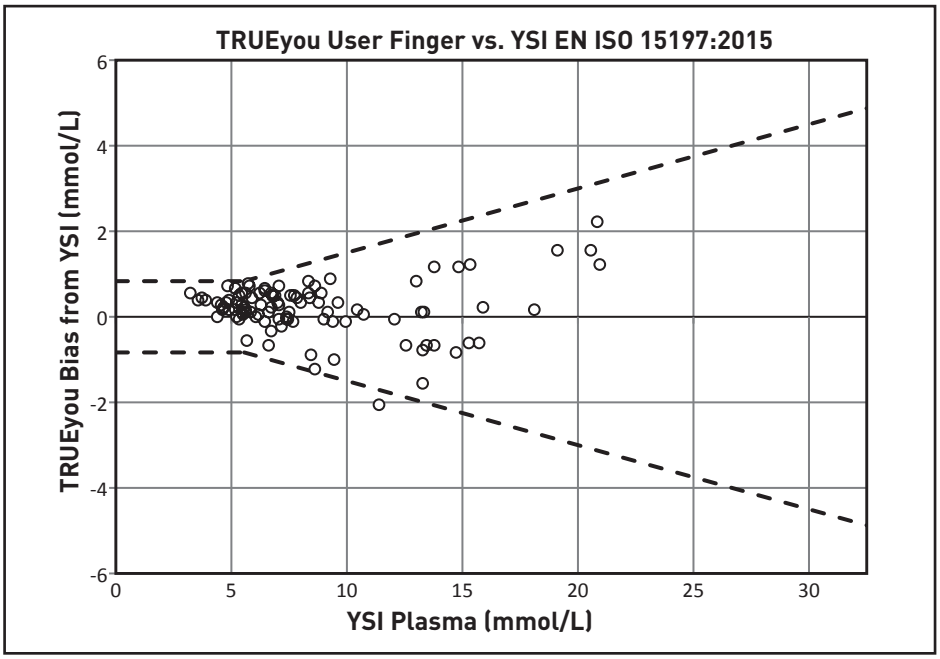
Summary of TRUEyou System accuracy against the YSI reference method using EN ISO 15197:2003 and EN ISO 15197:2015.

EN ISO 15197:2003			
Samples ← 4.2 mmol/L			
± 0.28 mmol/L	± 0.56 mmol/L	± 0.83 mmol/L	
36/90	79/90	89/90	
40.0%	87.8%	98.9%	
Samples ↗ 4.2 mmol/L			
± 5%	± 10%	± 15%	± 20%
301/510	454/510	502/510	507/510
59.0%	89.0%	98.4%	99.4%

EN ISO 15197:2015		
Samples ← 5.55 mmol/L		
± 0.28 mmol/L	± 0.56 mmol/L	± 0.83 mmol/L
74/180	155/180	178/180
41.1%	86.1%	98.9%
Samples ↗ 5.55 mmol/L		
± 5%	± 10%	± 15%
272/420	395/420	418/420
64.8%	94.0%	99.5%

TOPLINE RESULTS USING ISO CRITERIA

In this study, first-time users of the TRUEyou System obtained accurate results compared to the laboratory reference method.



EN ISO 15197:2015 requires 100 data points from user self-testing

Samples ← 5.55 mmol/L		
± 0.28 mmol/L	± 0.56 mmol/L	± 0.83 mmol/L
11/23	21/23	23/23
47.8%	91.3%	100.0%

Samples ↗ 5.55 mmol/L		
± 5 %	± 10 %	± 15 %
38/77	66/77	76/77
49.4%	85.7%	98.7%

TRUEyou System Accuracy Results for total glucose concentrations.

Within +/- 0.83 mmol/L and within +/-15%
99/100 (99%)

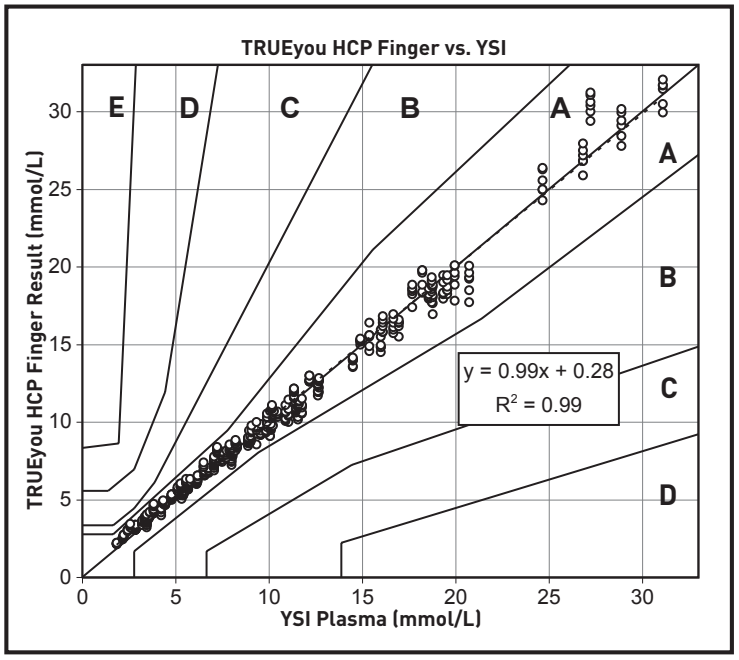
TOPLINE RESULTS USING PARKES ERROR GRID

PARKES ERROR GRID[3]

Parkes et al. developed an error grid to analyze the clinical significance of the bias between blood glucose system results and lab reference results. For analysis, data points are assigned into one of the five Zones (A-E) on the error grid. Results, or data points, falling into Zones A and B are defined as clinically acceptable, where any observed bias from lab results would not lead to treatment decisions that may put a patient at risk. As the bias, or difference, increases (Zones C, D, and E), there is greater risk of undertreating or overtreating a patient based on the glucose system result.

Analysis of data using the Parkes Error Grid is a requirement in EN ISO 15197:2015.

The TRUEyou System, in the hands of healthcare professionals, is proven to provide accurate fingerstick results that are comparable to the YSI reference method.



ZONE COUNT		
		% Results In Zone
Zone	# Points	%
A	600	100%
B	0	0%
C	0	0%
D	0	0%
E	0	0%
Total	600	100%

TOPLINE RESULTS USING STANDARD DEVIATION

The TRUEyou System, in the hands of healthcare professionals, is proven to provide precise results that are comparable to the laboratory reference method.

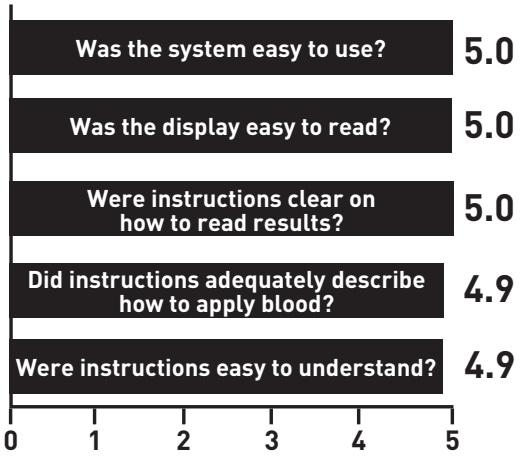
The Standard Deviation for Duplicate Measurements[4] is a statistical calculation that measures how close the individual data points, for each pair of duplicate data points, are to each other. Meter results are more precise with a lower Standard Deviation (S.D.) value.

	EN ISO 15197:2015
S.D. Value	2.5%

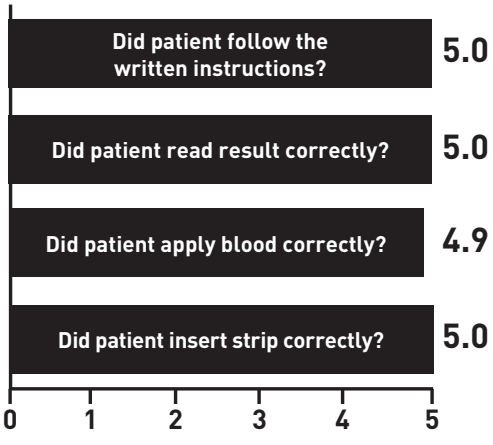
$$S.D. = \sqrt{(\Sigma d^2/(2n))}$$

The Standard Deviation for Duplicate Measurements is calculated by using the above equation – where **d** is the Percent Difference between duplicate data points and **n** is the number of patient samples.

First-time users of the TRUEyou System agreed that the system was easy to use and achieved accurate and precise results. Healthcare professionals positively ranked first-time users' compliance with the instructions for using the TRUEyou System.



User Evaluation



HCP Evaluation

CONCLUSION

- In this study, the TRUEyou System demonstrated accurate performance in the hands of both healthcare professionals and first-time users.
- Clinical data obtained by both first-time users and healthcare professionals exceeded the minimum accuracy criteria for EN ISO 15197:2003 and the more rigorous minimum accuracy criteria for EN ISO 15197:2015.
- First-time users of the TRUEyou System agreed that the instructions were easy to understand and the system was easy to use.
- The TRUEyou System produced precise results as evidenced by a Standard Deviation value of 2.5%.

1. International Organization for Standardization. In vitro diagnostic test systems. Requirements for blood glucose monitoring system for self testing in managing diabetes mellitus. Reference number EN ISO 15197:2003 (E). Geneva: International Organization for Standardization; 2003. 2. European Committee for Standardization. *In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus.* Reference number EN ISO 15197:2015 (E). Brussels: European Committee for Standardization; 2015. 3. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000; 23(8):1143–1148. 4. Westgard, James O. Ph.D. *Basic Method Validation 3rd Edition*. Westgard QC, Inc., 2008.

ADDRESS WRITTEN REQUEST TO:

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