



**Clinical Accuracy of
SOLO V2 Blood Glucose Monitoring System**

Objective

This study is intended to demonstrate: 1) the accuracy of SOLO V2 blood glucose monitoring system when compared to a clinical laboratory reference method (YSI 2300), and 2) the system is easy enough to use that training is not necessary for the lay user.

Standard

This clinical accuracy evaluation was performed according to ISO-guideline 15197^[1].

Introduction

Study 1 System Accuracy Evaluation

Healthcare professionals in the hospital performed the evaluation. One hundred and fifty-nine patients either with or without diabetes were included for clinical accuracy evaluation. Fresh capillary whole blood was tested using SOLO V2 (as the test method) and YSI-2300 glucose analyzer (as the reference method) and the results were compared. Data was presented in compliance with ISO 15197 standard and Error Grid Analysis^[2].

Study 2 User Performance Evaluations

One hundred and thirty-four subjects were involved in this study. Test results were obtained by trained health professionals and compared to the results obtained by lay users. The Error Grid Analysis system was used to assess the clinical significance of any error in the blood glucose monitoring result performed by the lay user.

Materials and Methods

Sample Distribution

One hundred and fifty-nine subjects, with varying demographics (age, sex, and education level), were included. The sample population met the requirements of the blood-glucose system's specified intervals in ISO 15197 standard.

Glucose Concentration (mg/dL)	Number of Samples (for total 159 subjects)	Percentage of Samples (%)
<50	11	6.9%
50 - 80	22	13.8%
80 - 120	40	25.2%
120 - 200	43	27.0%
201 - 300	20	12.6%
301 - 400	12	7.6%
>400	11	6.9%

Materials

1. Three reagent lots were used in this evaluation.
2. Lancet and lancing device.
3. Capillary collection tube: Aqua-Cap Micro dispenser and plunger.
4. Measurements using the blood-glucose monitoring system are performed at stable air -conditioned ($23^{\circ}\text{C}\pm 5^{\circ}\text{C}$) environment.

Testing Procedures

STEP1 Select and clean the puncture site from fingertip and forearm.

STEP2 After reading the instruction manual of the SOLO V2 system, lay users perform glucose tests with SOLO V2 without any help from professionals.

STEP3 Professionals puncture and obtain the capillary whole blood.

STEP4 Professionals apply sample to test strip and measure glucose value with SOLO V2 two times. Two measurements were obtained.

STEP5 Collect sample to capillary collection tube. At least 100uL should be collected. Second puncture is needed if sample volume is not enough at first puncture.

STEP6 Apply the sample from step 5 to YSI-2300 analyzer (the reference instrument).

Data Presentation

Data was presented in the following plots:

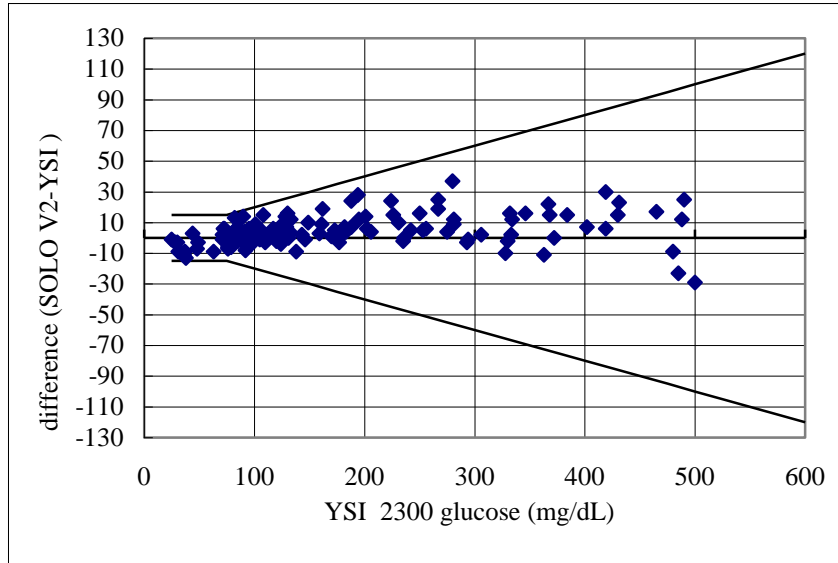
1. *Bias plot*: with YSI-2300 reference value at x-axis and differences (Value SOLO V2 - Value YSI2300 or Value user - Value YSI2300) at y-axis, minimum system accuracy requirement from ISO 15197 is applied and presented: Ninety-five percent (95%) of the individual glucose results shall fall within $\pm 15\text{mg/dL}$ of the results of the YSI-2300 analyzer measurement procedure at glucose concentrations $< 75\text{ mg/dL}$ and within $\pm 20\%$ at glucose concentrations $\geq 75\text{ mg/dL}$.
2. *Regression analysis*: Individual results of the blood glucose test system are plotted as the dependent variable and the reference values (YSI-2300 analyzer) as the independent variable. Slope, y-intercept and correlation coefficient (r) are calculated.
3. *EGA Plot*: Clarke Error Grid Analysis plot^[2] is depicted.

Results

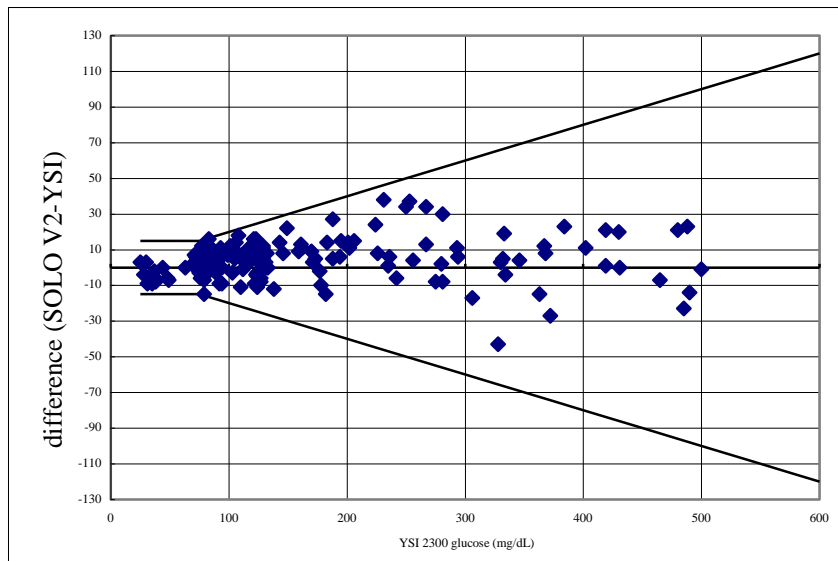
Study 1 System Accuracy Evaluation

1 Bias plot

(a) Finger

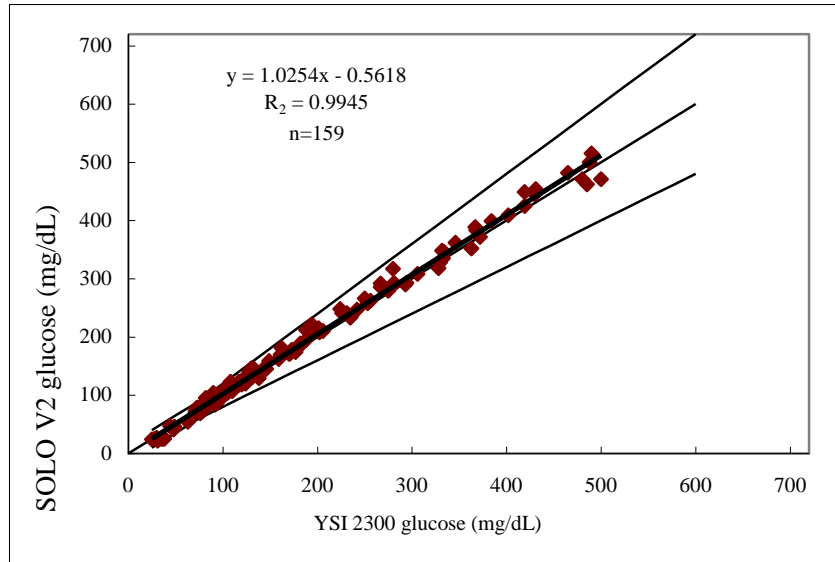


(b) Forearm

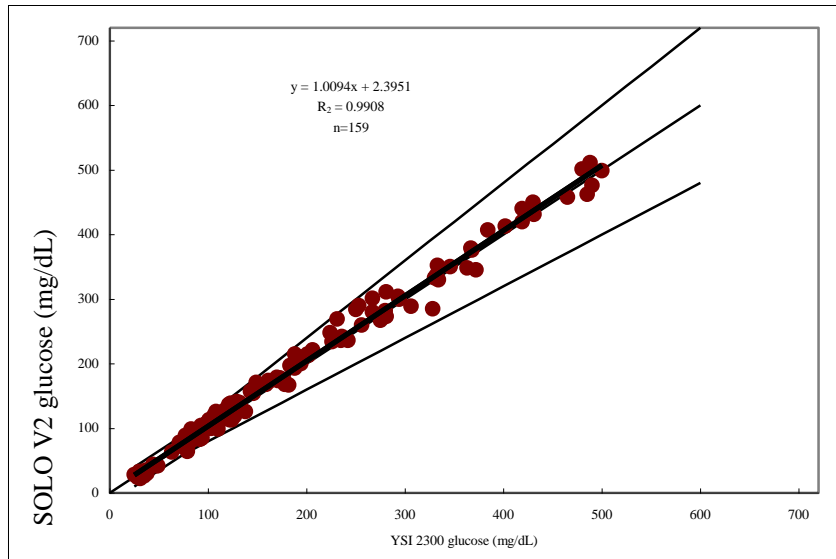


2 Regression analysis

(a) Finger

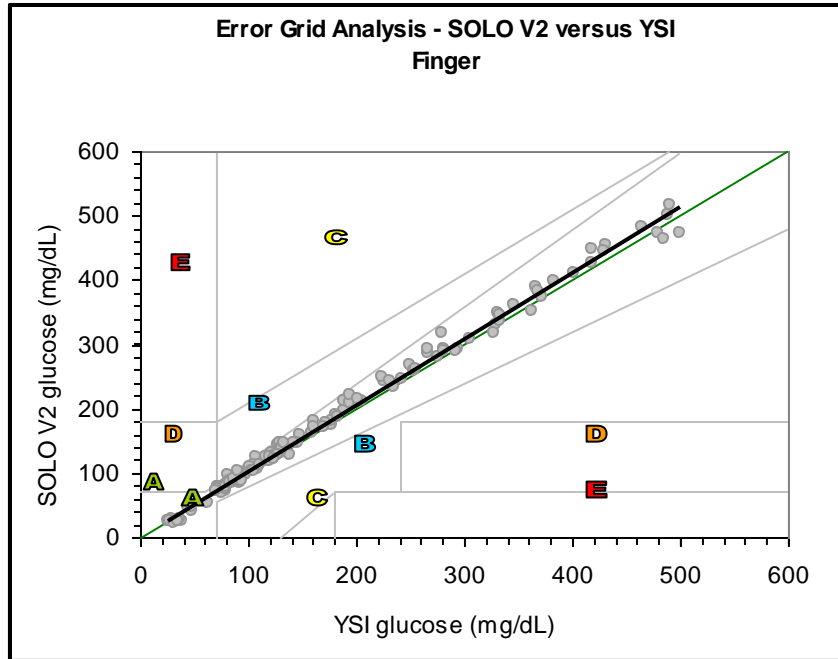


(b) Forearm

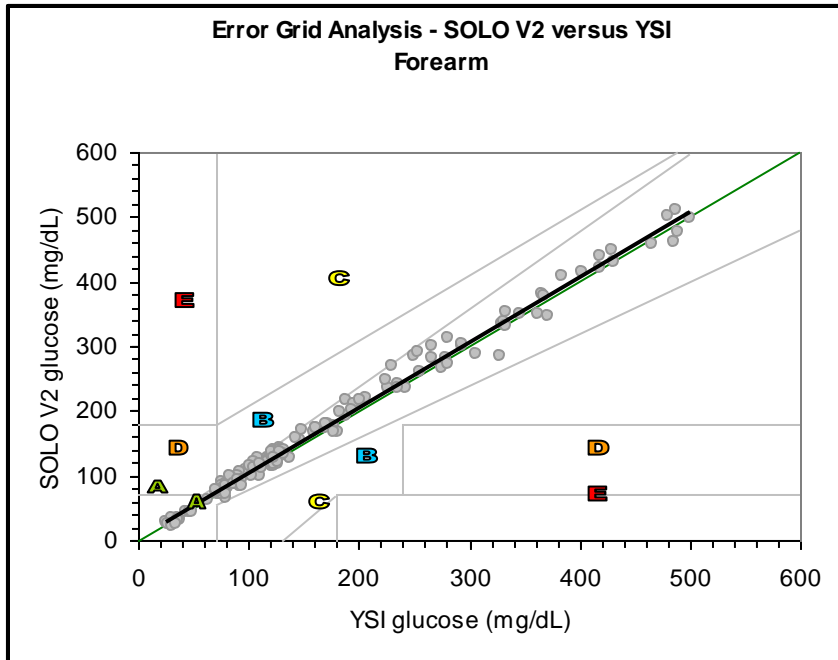


3 GA plot and analysis

(a) Finger



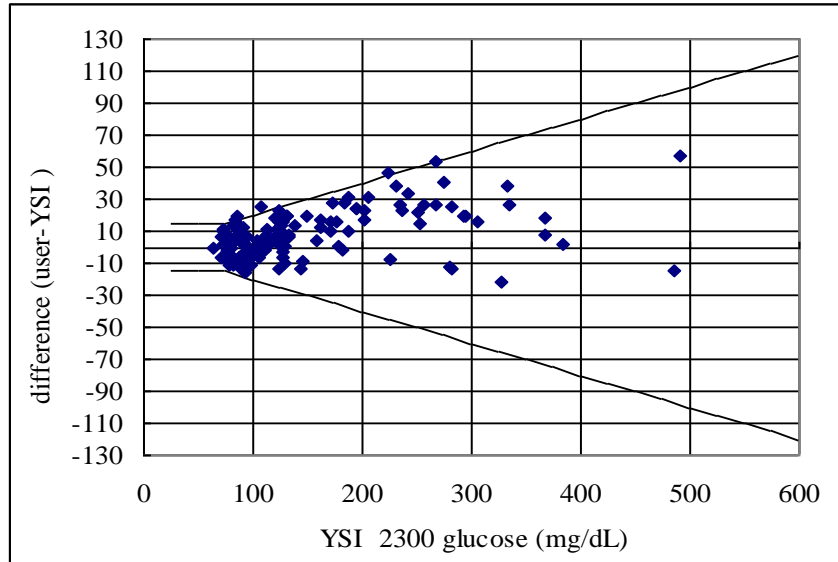
(b) Forearm



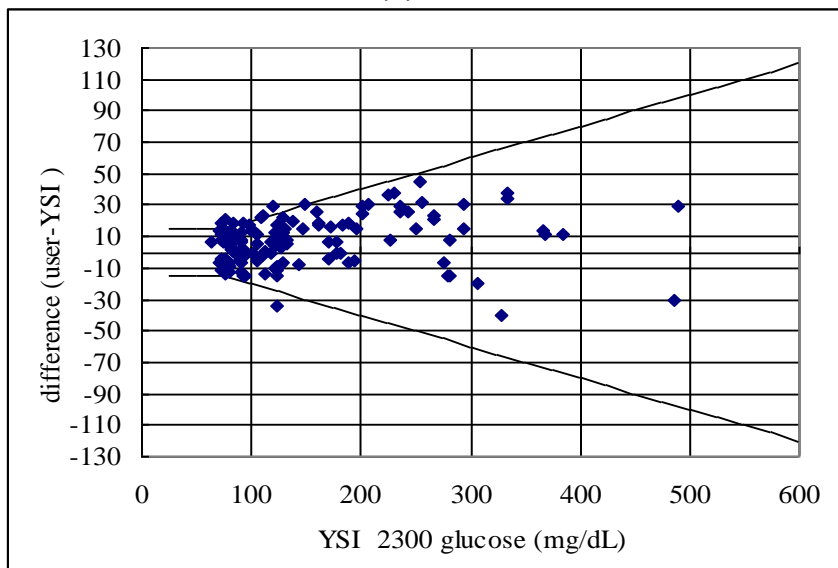
Study 2 User Performance Evaluations

1 Bias plot

(a) Finger

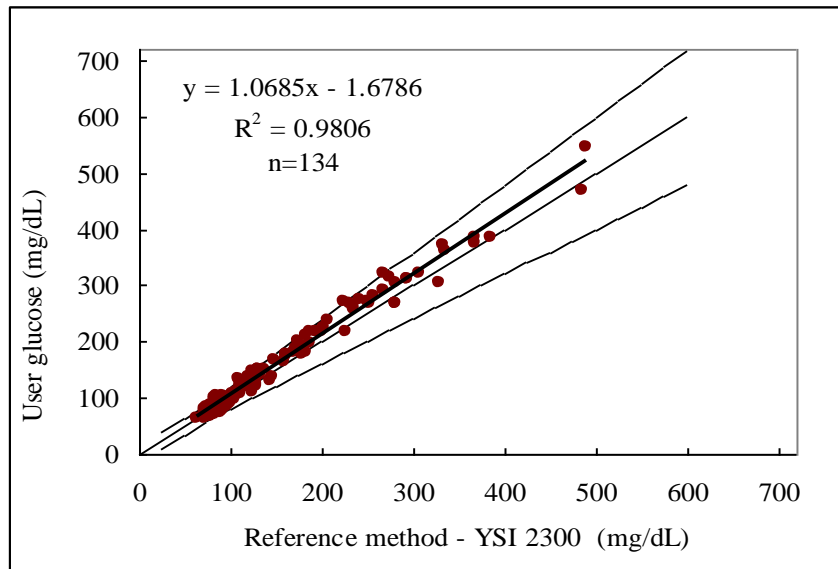


(b) Forearm

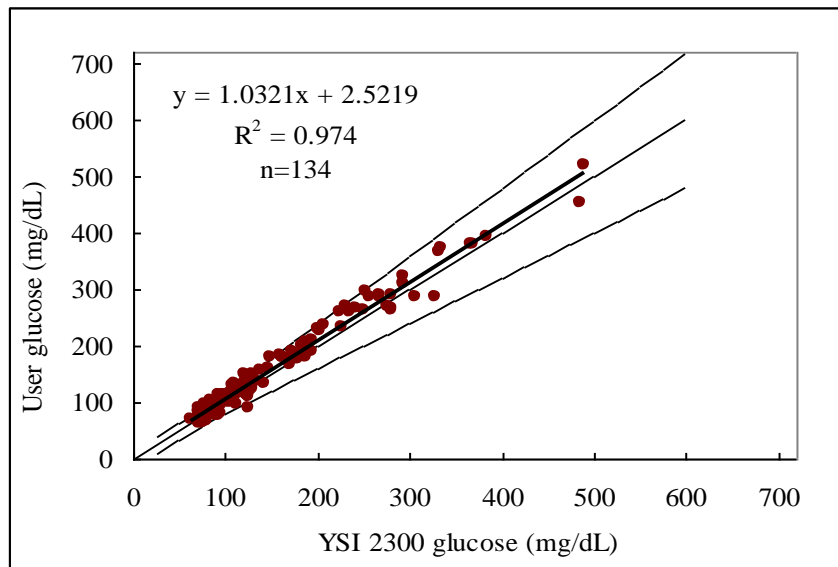


2 Regression analysis

(a) Finger

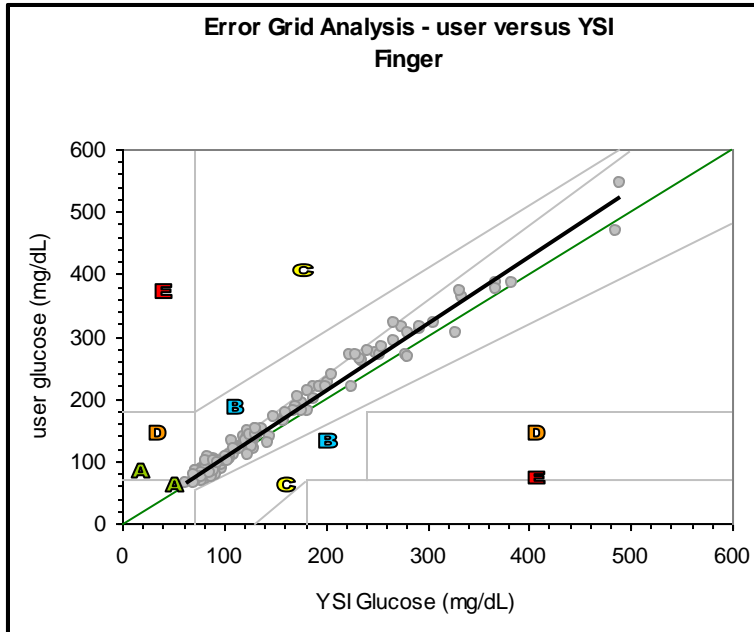


(b) Forearm

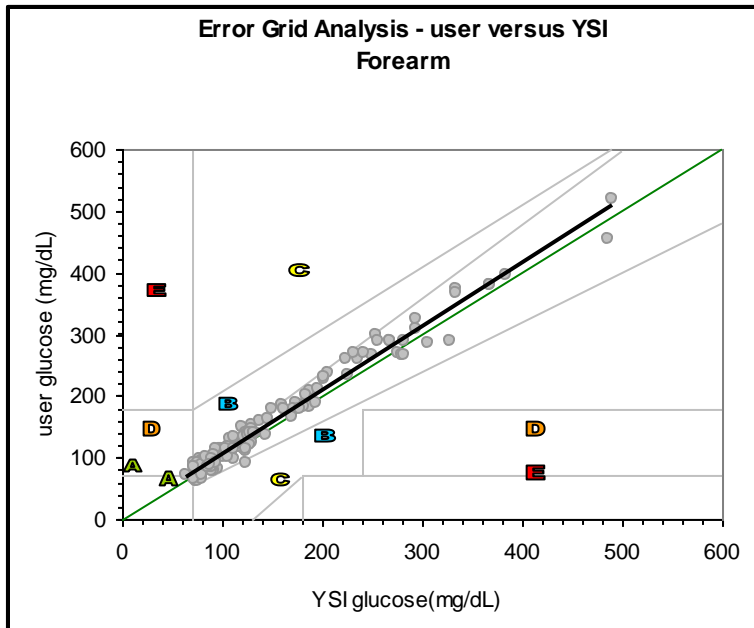


3 EGA plot and analysis

(a) Finger



(b) Forearm



Conclusion

- 1 The SOLO V2 Blood Glucose Monitoring System correlates well with the YSI-2300 analyzer over a wide range of glucose levels. The SOLO V2 Blood Glucose Monitoring System meets the bias analysis requirement of ISO 15197.
- 2 The SOLO V2 Blood Glucose Monitoring System will provide the same results for a lay user as a trained laboratory professional.

References

[1] ISO15197, first edition 2003, 05, 01 :In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

[2] Clarke WL, Cox D, Gonder-Frederick LA, et al: Evaluation clinical accuracy of systems for self-monitoring of blood glucose. Diabetes cares 10:622-628, 1987.

[3] World Health Organization ICD version 2007--
<http://apps.who.int/classifications/apps/icd/icd10online/>

Interference Testing

In the interference studies, four exogenous and one endogenous substance were tested for possible drug interference of SOLO V2 glucose monitoring system. Only one drug interference was found among all tested five substances in the studies.

Table Summary of Interference Testing with SOLO V2 Blood Glucose Test Strip

Substance	Therapeutic Level (mg/dL)	No Interference Level (mg/dL)
Exogenous		
Acetaminophen	1~3	6.2
Ascorbic Acid (Vitamin C)	0.4~2.0	4.5
Ibuprofen	1~7	37.5
L-Dopa	5	1.9
Endogenous		
Uric acid	2.5~8.0	10.9