User Performance Evaluation in Visually Impaired Subjects
SOLO V2 Blood Glucose Monitoring System

Objective

This study is intended to demonstrate:

1. The SOLO V2 blood glucose monitoring system can be easily used according to the Package Insert and user guide and that training is not necessary for the lay user who is visually impaired.
2. The audio messages from the meter will help those users with low vision to use the device effectively.

Standard

SOLO V2 has had a complete clinic study report following ISO-guideline 15197[1]. This user performance study is an extra study for visually impaired subjects.

Introduction of User Performance Evaluation

Fifty subjects were involved in this study. Test results were obtained by trained health professionals and compared to the results obtained by lay users who are visually impaired.

Materials and Methods

Sample Distribution

Fifty visually impaired subjects, 24% male and 76% female, were included. Among the 50 subjects, 52% were diagnosed as low vision and 48% as blindness. The subjects categorized as "Low vision" or "Blindness" include subjects with vision level from 1 to 5, diagnosed per WHO Guidelines as ICD Version 2007[2].

Category of Visual Impairment[2]		**Number of Samples**	**Percentage of Samples**
Low Vision	**1**	7	14%
	2	19	38%
Blindness	**3**	14	28%
	4	8	16%
	5	2	4%
Total		50	100%

Materials

1. SOLO V2 meter and one reagent lot 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℃±5℃) environment.

Testing Procedures

STEP1 Obtain Informed Consent from subject.

STEP2 Measure the subject's eye vision and write down the result.

STEP3 Select and clean the puncture site from fingertip.

STEP4 After receiving the total product package of the SOLO V2 system, lay users perform glucose tests with SOLO V2. (The subject was informed this is a talking meter in advance.)

STEP5 The professionals perform glucose test from subjects' fingertip samples using the SOLO V2 device.

STEP6 The professionals perform glucose test from the subjects' fingertip sample using a reference instrument (YSI 2300).

Data Presentation

Data was presented in the following analysis:

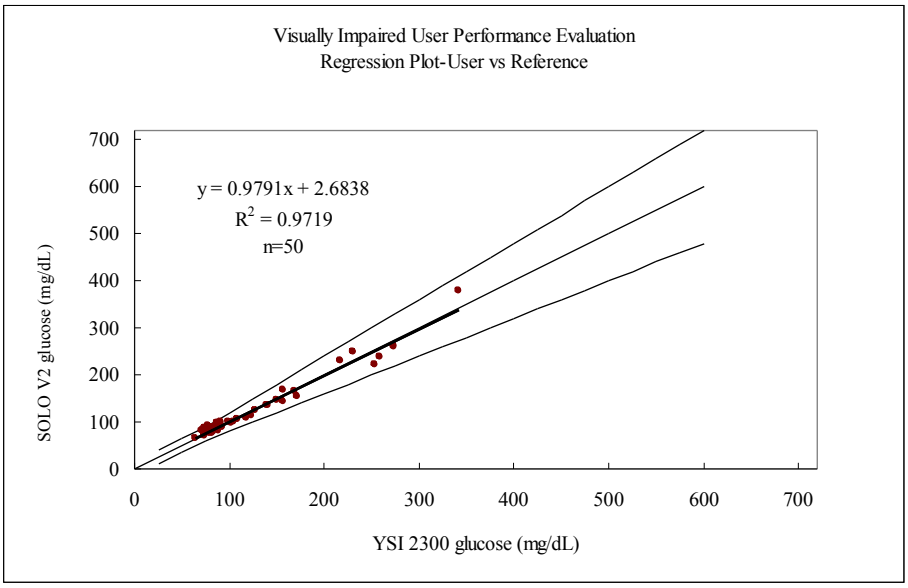
1. *Regression Analysis*: Individual results of the blood glucose test system are plotted as the dependent variable and the reference values (YSI-2300 analyzer or Professional test result) as the independent variable. Slope, y-intercept and correlation coefficient (r) are calculated.
2. *User Performance Assessment*: with YSI-2300 reference value, minimum system accuracy requirement from ISO 15197 is applied and presented: Ninety-five percent (95%) of the individual glucose results shall fall within ±15mg/dL of the results of the YSI-2300 analyzer measurement procedure at glucose concentrations <75 mg/dL and within ±20% at glucose concentrations ≧75 mg/dL.

Results

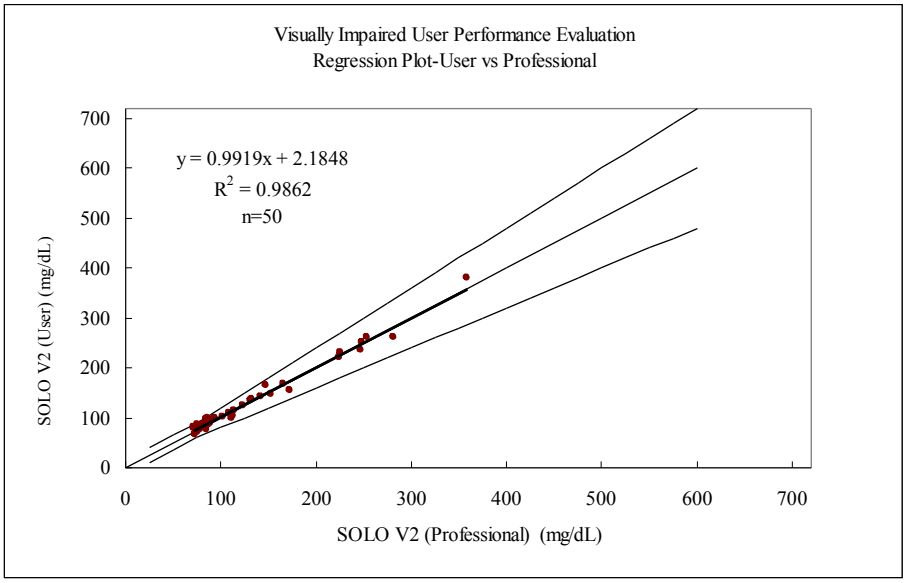
Regression Analysis

The regression plots presented below show that the lay user performance correlates well with the laboratory reference instrument and results from professionals. The regression analysis data were within the acceptance criteria (R^2 ≧0.95).

User vs. Reference



1.2 User vs. Professional



User Performance Assessment

System accuracy requirement (as prescribed by ISO15197:2003):

95% of the individual glucose results shall fall within ±15 mg/dL of the results of the reference measurement procedure at glucose concentrations ＜75 mg/dL and within ±20% at glucose

concentrations ≧75 mg/d

Conclusion of User Performance Assessment

50 subjects tested their own blood glucose and then tested by the professionals using the SOLO V2 Glucose Test System Model 6131 and the YSI 2300 instrument. 4 of 4 hypoglycemic samples were within ±15mg/dL at glucose concentration <75 mg/dL and 46 of the 46 samples with glucose concentration ≧75 mg/dL were within ±20% of the reference YSI values. Therefore, 50 of 50 samples (100%) were within the requirement as prescribed by ISO15197:2003.

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] World Health Organization ICD version 2007--http://apps.who.int/classifications/apps/icd/icd 10online/