

# Clinical Accuracy Evaluation of FORA Blood Glucose Monitoring System

## OBJECTIVE

Evaluate the clinical accuracy of FORA blood glucose monitoring system when used by professional technician and lay users.

## INTRODUCTION

The test is following ISO-guide 15197 [1]. The FDA recommending guideline EP9-A [2], is also involved as the reference of glucose concentration distribution.

Two hundred and forty patients, with varying demographics (age, sex and education level), were included and met the requirements of the blood-glucose system's specified intervals in EP9-A (table 1). The test results were respectively obtained from trained health professionals and lay users.

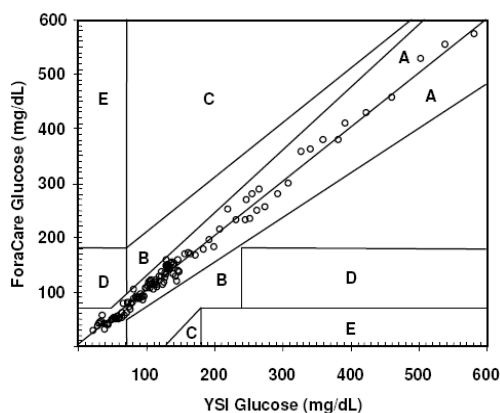
## MATERIALS AND METHODS

Fresh capillary whole blood was using in FORA blood glucose monitor (as the test) and YSI-2300 glucose analyzer (as the reference). Data was presented in compliance with ISO 15197 standard and Error Grid Analysis (EGA). The accuracy was determined by comparing the test results obtained by participants using FORA test results to the test results obtained by YSI-2300.

One hundred and twenty subjects were tested by professional technician. One hundred and twenty subjects were tested by patients themselves. Each lay user was asked to read through the instruction manual without professional's help and perform blood glucose tests.

## RESULTS

### Professional Technician Study Results:

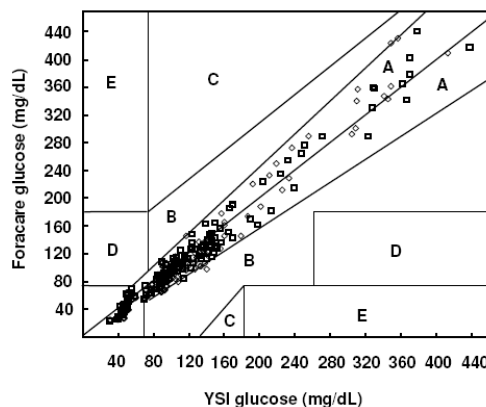


Regression Analysis  
 $Y = 1.0052X + 1.7264$   $R^2 = 0.9896$   $N = 120$

Zone	Indication	% in Zone
A	test value within $\pm 20\%$	98%
B	deviating from the reference more than 20% but would lead to benign or no treatment	2%
C	deviating from the reference more than 20% would lead to unnecessary corrective treatment errors	0%
D	potentially dangerous failure to detect and treat blood glucose levels outside of desired target range	0%
E	resulting in erroneous treatment	0%

One hundred and twenty participants with glucose concentration ranged from 30-400 mg/dL were tested by professional technician. The regression analysis showed slope, y-intercept and R square value was 1.0052, 1.7264 and 0.9896, respectively. The EGA graph was divided into four zones which definitions were shown in table above. Zone A of the error grid contains 98% of the measurements, and the other 2% are located in Zone B. The results of FORA glucose monitoring system demonstrated excellent correlation with the results of YSI.

### Lay Users and Professional Technician Comparison:



Regression Analysis  
 $Y = 1.0356X - 8.0867$   $R^2 = 0.9715$   $n = 240$

Zone	Indication	% in Zone
A	test value within $\pm 20\%$	96%
B	deviating from the reference more than 20% but would lead to benign or no treatment	4%
C	deviating from the reference more than 20% would lead to unnecessary corrective treatment errors	0%
D	potentially dangerous failure to detect and treat blood glucose levels outside of desired target range	0%
E	resulting in erroneous treatment	0%

One hundred and twenty patients were tested by themselves followed by reading the instruction manual. The data performed by lay users and professional

technician were plotted together and compared. Regression Analysis showed slope, y-intercept and R square are 1.0356, -8.0867, and 0.9715, respectively. For EGA analysis, Zone A of the error grid contains 96% of the measurements, and the other 4% are located in Zone B. Measurements developed by lay users showed good correlation with YSI reference.

## CONCLUSION

FORA blood glucose monitoring system correlate well with those values measured by YSI-2300 within claimed dynamic range 20-600 mg/dL. Measurements from lay users correlate well with those value measured by health professional over a wide range of glucose values.

## 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. *NCCLS, EP9-A: Method comparison and bias estimation using patient samples; approved guideline, volume 15, no. 17, 1995.*
3. *Clarke WL, Cox D, Gonder-Frederick LA, et al: Evaluation clinical accuracy of systems for self-monitoring of blood glucose. Diabetes care 10:622-628, 1987.*

