

# Alternative Site Testing of FORA Blood Glucose Monitoring System

## OBJECTIVE

FORA blood glucose monitoring system provides users to test on their limbs with the equivalent results to fingertip testing. This report is intended to assess the accuracy of alternative site testing using FORA blood glucose monitoring system.

## INTRODUCTION

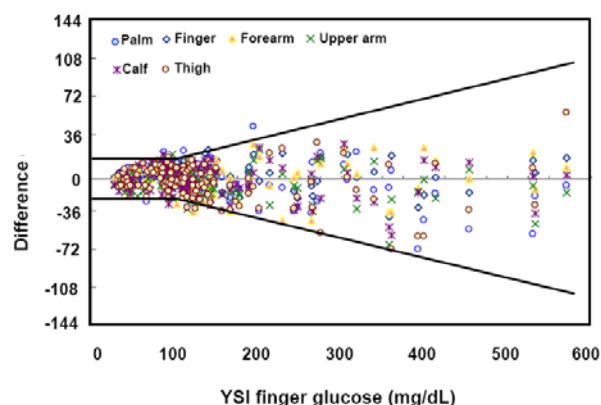
Painful measurement of blood glucose is one of the major burdens of diabetic patients. Alternative site testing (AST) at palm, forearm, upper arm, calf and thigh became good substitute testing areas for fingertip. Compared with the fingertips, the arm has lower density of sensory nerve ending and cause less painful than blood glucose measurements at the fingertips [1,2]. The goal of the study was to compare the parallel measurements of fingertip and alternative site testing using FORA glucose monitoring system with values obtained from the standard reference method.

## MATERIALS AND METHODS

One hundred and twenty subjects, with varying demographics (age, sex and education level), were included and met the requirements of the blood-glucose system's specific intervals in EP9-A. Duplicate readings were from finger and the following sites: forearm, upper arm, thigh and calf. All of the blood was measured by test device and YSI-2300 simultaneously. To avoid the variation of inherent glucose metabolism causing by sampling at different times, glucose tests were completed within 15-20 minutes each subject.

## RESULTS

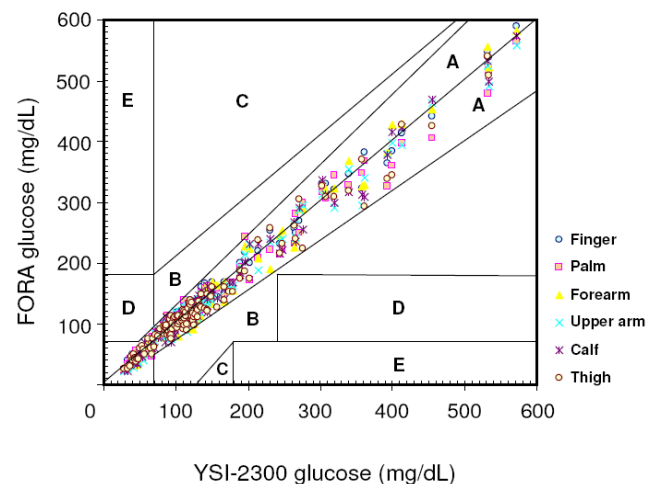
Difference plot of FORA glucose AST compared to YSI-2300 was shown below.



The two bold lines represented the acceptance criteria

from ISO 15197. Tables below are the presentation of difference (between FORA and YSI-2300) results. The results all meet criteria from ISO 15197: 95% of the individual glucose results shall fall within  $\pm 15$ mg/dL when glucose concentration less than 75mg/dL and shall fall within  $\pm 20\%$  when glucose concentration  $\geq 75$ mg/dL.

EGA analysis of FORA glucose measurements and YSI-2300 were shown below.



Zone	% in Zone					
	finger	palm	fore arm	upper arm	calf	thigh
A	100%	98%	97%	98%	98%	98%
B	0%	3%	3%	3%	3%	3%

EGA plot between FORA glucose measurements and YSI reference showed that 100% data located in A zone for finger glucose test and 97-98% data in A zone for AST. In regression analysis, R square value of palm, forearm, upper arm, calf and thigh are 0.981, 0.983, 0.985, 0.982 and 0.973, respectively.

## CONCLUSION

The AST measurement of FORA glucose monitoring system showed high correlation with YSI reference value. Alternative site testing including palm, forearm upper arm, calf and thigh all are able to be applied to FORA glucose monitoring system.

## REFERENCES

1. Carpenter MB, Sutin J. Receptors and effectors. In Human Neuroanatomy Baltimore, Williams & Wilkins 1983:155-77.
2. Fineberg SE, Bergenstal RM, Bernstein RM, Laffel LM, Schwartz SL. Use of an automated device for alternative site blood glucose monitoring. *Diabetes Care* 2001;24:1217-20.
3. Clarke WL, Cox D, Gonder-Frederick LA, Carter W, and Pohl SL. Evaluating clinical accuracy of systems for self-monitoring of blood glucose. *Diabetes Care* 1987; 10: 622-628.