

## Evaluating the performance of the FORA V30 blood glucose monitoring system

### INTRODUCTION

The population of diabetic patients is growing rapidly all over the world. Long-term studies have shown that keeping blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60% (1). Self-monitoring of blood glucose allows the patients to have better glycemic control, leading to improved therapy outcomes, and decreasing the risk of long term complications. We have evaluated the performance of the FORA V30 blood glucose

monitor and the strips according to the international standard, EN ISO 15197 (2), and error grid analysis according to Clarke (3,4) was performed. The FORA V30 uses the enzyme, Glucose Oxidase (GOD), which enables the determination of the glucose level more accurately. The results demonstrated the accuracy of the FORA V30, making it a very valuable tool for SMBG.

### TECHNICAL SPECIFICATIONS OF THE V30:

Blood sample:	Capillary and venous whole blood
Sample volume:	0,5 µL
Measuring range:	20 – 600 mg/dL
Analysis time:	5 sec
Operating temperature:	10 – 40 °C
Operating humidity:	< 85 %
Hematocrit range:	20 – 60 %
Measurement technology:	Glucose Oxidase (GOD)
Calibration:	Plasma
Coding:	Not required



### STUDY METHOD

Testing was performed using the FORA V30 glucose test strips.

- The results were obtained from capillary blood samples via fingertip puncture of the adults.
- Warming of the puncture site was conducted in order to increase the blood supply within the area for three to five minutes.
- The puncture site was cleaned with a sterile alcohol pad and waiting to dry.
- The operator used a lancing device with lancet to puncture the fingertip skin. The first drop of blood was wiped off with a dry sterile gauze pad.

- The fingertip was then squeezed gently to form a large drop of blood.
- The strip was inserted into the meter and it was allowed to lightly touch this large drop of blood until enough samples had been applied.
- Special care was taken for the skin puncture site, consistent with the procedures of our institution

The samples were then compared to a reference with whole blood glucose concentrations measured by the Beckman Unicel DxC 800 with the Synchron LX20.

### RESULTS

#### Zone definitions of the Clarke Error Grid Analysis:

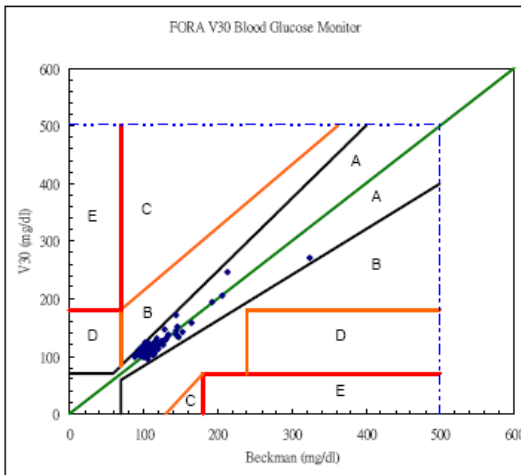
Zone A: Clinically accurate.

Zone B: Deviating from the reference method by more than 20% but would lead to benign or no treatment error.

- Zone C: Deviating from the reference method by more than 20% and would lead to unnecessary corrective treatment errors.
- Zone D: Potentially dangerous failure to detect and treat blood glucose levels outside of desired target range.
- Zone E: Would result in erroneous treatment.

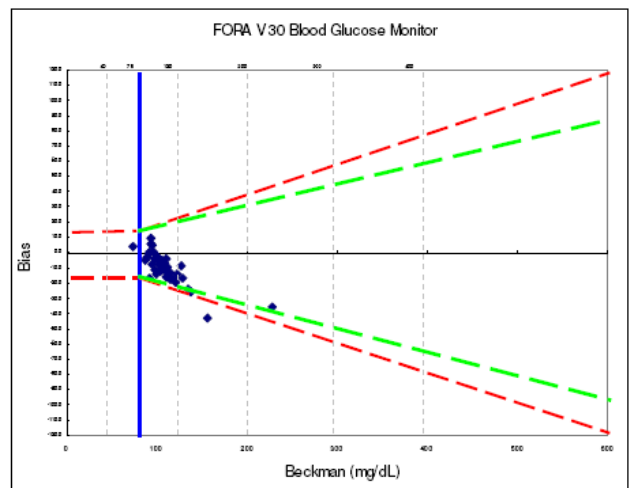
**Clarke Error Grid graph**

The test results fell within Zone A and Zone B of the error grid.



**Summary of bias analysis**

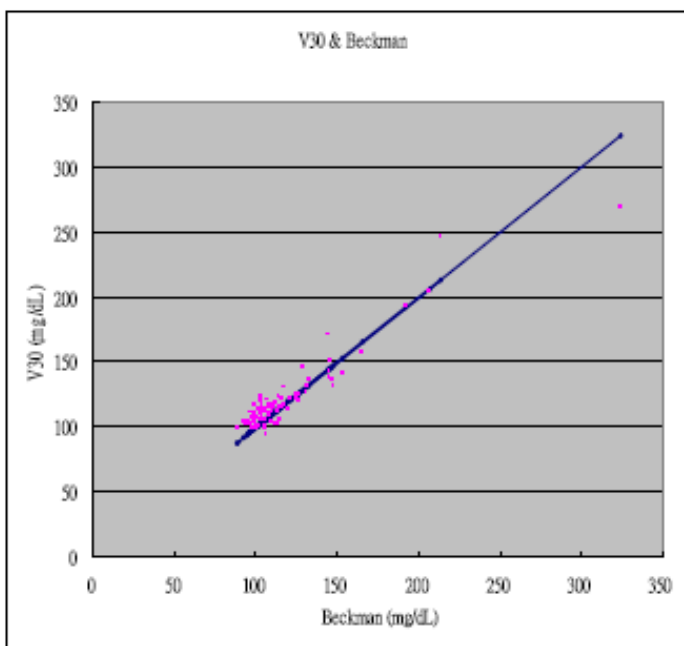
98% of FORA V30 glucose results fell within  $\pm 20\%$ .



**Summary of linear regression analysis**

Glucose range: 88 to 376 mg/dL					
N	Slope (95% CI)	y-interval (95% CI)	Syx*	R square	P value
94	1.01 (0.99 to 1.03)	0	10.63	0.99	p<0.001

\*Syx= Standard Error of the estimate (standard deviation of the residuals)



## CONCLUSION

The study evaluated the FORA V30 blood glucose monitoring systems, and found them accurate and appropriate for use by diabetic patients. The results obtained by the FOR A V30 blood glucose monitoring systems compared well to the reference method as international standards.

## REFERENCES

1. American Diabetes Association, Diabetes Control and Complications Trial, 1993.
2. ISO 15197 International Standards. In vitro

diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2003(E).

3. Clarke, W.L.; Cox, D.; Gonder-Frederik, L.A.; Carter, W.; Pohl, S.L.: Evaluating clinical accuracy of systems for self-monitoring of blood glucose. Diabetes Care 1987, 10(5); 622-628.

4. Clarke, W.L.: The Original Clarke Error Grid Analysis (EGA). Diabetes Technology & Therapeutics 2005, 7(5); 776-779.

---

## INVESTIGATION SITE



University Hospital Malmö  
Klinisk forskningsenhet  
Medicin Ingång 33, plan 2, UMAS  
205 02 Malmö

## PRINCIPLE INVESTIGATOR

Prof. Dr. Peter M Nilsson, MD, PhD