

## Evaluating the performance of the FORA GD40 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 GD40 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 GD40 utilizes strips with the GDH-FAD enzyme system. The results demonstrated the superior accuracy of the FORA GD40 which exceeded the standards, making it a very valuable tool for SMBG.

### TECHNICAL SPECIFICATIONS OF THE GD40:

Blood sample:	Capillary and venous whole blood
Sample volume:	1.1 µL
Measuring range:	10 – 600 mg/dL
Analysis time:	5 sec
Operating temperature:	10 – 40 °C
Operating humidity:	< 85 %
Hematocrit range:	0 – 70 %
Measurement technology:	Glucose dehydrogenase (GDH-FAD)
Calibration:	Plasma
Coding:	Not applicable



**FORA GD40**

### STUDY METHOD

Testing was performed using the FORA GD40 glucose test strips. 128 fresh capillary blood samples collected by skin puncture were prepared, processed and applied for measurement.

Per the ISO standard, blood glucose meter results must lie within the following ranges for the meters tested as stated in the table 1.

Blood was then collected into capillary tubes, which were then centrifuged to extract the plasma. The plasma glucose concentration was then

measured with an YSI 2300 STAT PLUS Blood Glucose Analyzer, which was the reference measurement.

Percentage of samples [%]	Glucose concentration [mg/dl]
5	< 50
15	≥ 50 - < 80
20	≥ 80 - < 120
30	≥ 120 - < 200.5
15	≥ 200.5 - < 300.5
10	≥ 300.5 - < 400
5	≥ 400

Table 1: ISO standard of blood glucose range

### 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.

**System accuracy results for glucose concentration < 75 mg/dL**

Within ± 5 mg/dl	Within ± 10 mg/dl	Within ± 15 mg/dl
27 / 38 (71 %)	35 / 38 (92 %)	37 / 38 (97 %)

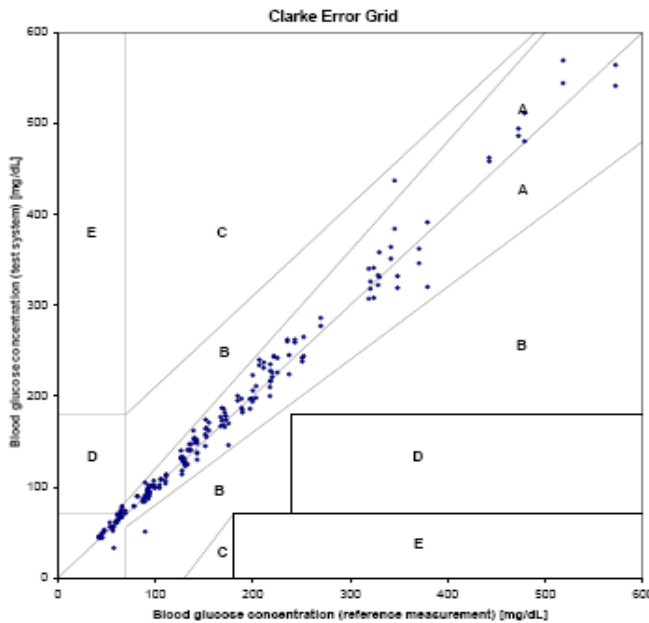
**System accuracy results for glucose concentration ≥ 75 mg/dL**

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
90 / 162 (56 %)	140 / 162 (86 %)	155 / 162 (96 %)	160 / 162 (99 %)

**Combined system accuracy results (absolute and relative deviations)**

Within ± 5 mg/dl & ± 10 %	Within ± 10 mg/dl & ± 10 %	Within ± 10 mg/dl & ± 15 %	Within ± 15 mg/dl & ± 20 %
167 / 200 (83.5 %)	175 / 200 (87.5 %)	190 / 200 (95 %)	197 / 200 (98.5 %)

**Clarke Error Grid graph**



Region	Number	Percent
A	198	99.0%
B	2	1.0%
C	0	0.0%
D	0	0.0%
E	0	0.0%

**Summary of bias analysis**

n=200	Bias [mg/dL]	95% Limits of agreement [mg/dL]	Bias [mg/dL]	95% Limits of agreement [mg/dL]
FORA GD40 (B)	4.01	-23.717 – 31.75	2.2	-14.4 – 18.7

**Summary of regression analysis**

n=200	Regression
FORA GD40 (B)	$y = 1.03 \quad x + 0.05$

## CONCLUSION

The FORA GD40 blood glucose monitoring system provides highly accurate results and it complies with the system accuracy requirements of the ISO 15197 Standard. 197 of 200 (98.5%) of the results meet and exceed the requirements. It is worthy to note that 190 of 200 (95%) of the results were within  $\pm 15\%$  proving its superior accuracy.

## REFERENCES

1. American Diabetes Association, Diabetes Control and Complications Trial, 1993.
2. DIN EN ISO 15197: Testsysteme für die

in-vitro-Diagnostik – Anforderungen an Blutzuckermesssysteme zur Eigenanwendung beim Diabetes mellitus (ISO 15197:2003); Deutsche Fassung.

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

Institut für Diabetes-Technologie GmbH an der Universität Ulm (IDT)  
Helmholtzstrasse 20  
D-89081 Ulm / Germany

## PRINCIPLE INVESTIGATOR

Dr. biol. hum. Annette Baumstark  
Institut für Diabetes-Technologie GmbH an der Universität Ulm  
Helmholtzstrasse 20  
D-89081 Ulm / Germany  
Tel.: +49 (0)731-5099024  
e-mail: [annette.baumstark@uni-ulm.de](mailto:annette.baumstark@uni-ulm.de)