

FORA® 6



Outstanding Accuracy

FORA® 6 Multi-functional Monitoring Systems meet ISO 15197:2013 / EN ISO 15197:2015 standards.



6in1

FORA® 6 Plus

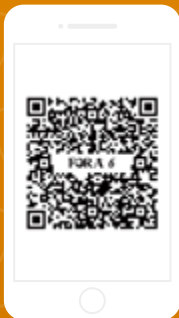


6in1

FORA® 6 Connect

FORA® delivers accurate, easy-to-use and high-quality monitors for people with diabetes to help manage their diabetes control. FORA® 6 product line is clinically validated and meets ISO 15197:2013 and EN ISO 15197:2015 standards. Now we are proud to share with you the white paper. Validations have been performed by the AMCR Institute, the Institut für Diabetes Technologie (IDT), and the Foracare Laboratory.

Multi-Language White Paper Available! Scan QR code to read.



REF:Ver.0.0, Juli 5th, 2018



All FORA® 6 Multi-functional Monitoring Systems use FORA® 6 Blood Glucose Test Strips.



Discover more: www.foracare.ch

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System Accuracy: Section 6.3.3 ISO 15197:2013^[1] / EN ISO 15197:2015^[2]

The system shall meet both of the following minimum criteria for acceptable system accuracy.

- a) 95% of the measured glucose values shall fall within either $\pm 0,83$ mmol/l (± 15 mg/dl) of the average measured values of the reference measurement procedure at glucose concentrations $< 5,55$ mmol/l (<100 mg/dl) or within $\pm 15\%$ at glucose concentrations $\geq 5,55$ mmol/l (≥ 100 mg/dl).
- b) 99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG) for type 1 diabetes.

Introduction and Scope

The study was conducted by Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm with Project No. IDT-1739(2)-FS^[3] in between 30 November 2017 and 19 December 2017. The capillary whole blood samples taken from 113 different subjects with 600 glucose values were obtained (200 from each of 3 reagent system lots).

Test Result

System accuracy result for glucose concentrations < 100 mg/dL (5.55 mmol/L)

Reagent System Lot	Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
WG17H104-CEE	17 / 52 (32.7%)	35 / 52 (67.3%)	51 / 52 (98.1%)
WG17H604-CEE	23 / 52 (44.2%)	44 / 52 (84.6%)	52 / 52 (100%)
WG17H904-CEE	12 / 52 (23.1%)	36 / 52 (69.2%)	51 / 52 (98.1%)

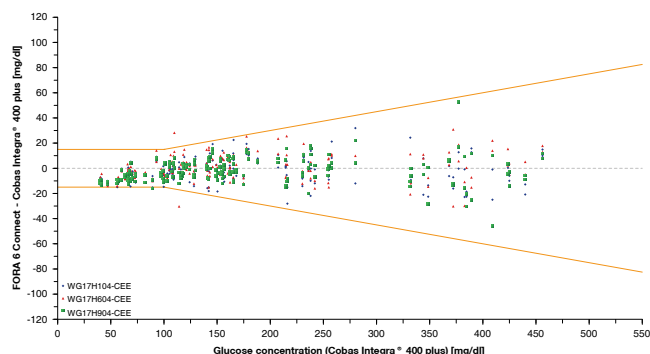
System accuracy result for glucose concentrations ≥ 100 mg/dL (5.55 mmol/L)

Reagent System Lot	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
WG17H104-CEE	104 / 148 (70.3%)	137 / 148 (92.6%)	148 / 148 (100%)
WG17H604-CEE	100 / 148 (67.6%)	136 / 148 (91.9%)	146 / 148 (98.6%)
WG17H904-CEE	103 / 148 (69.6%)	144 / 148 (97.3%)	148 / 148 (100%)

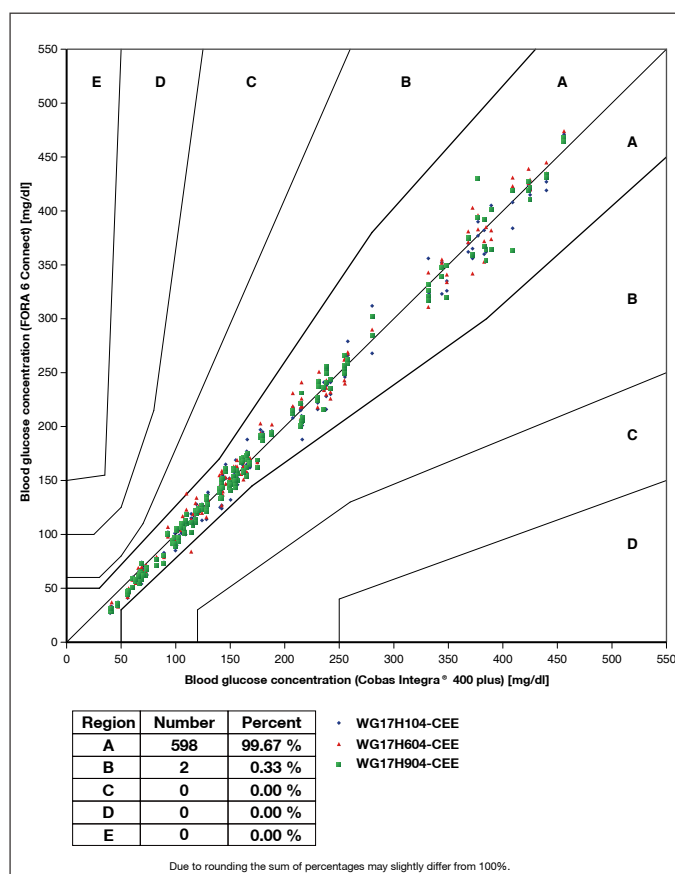
System accuracy result for glucose concentrations between 40 mg/dL (2.22 mmol/L) and 456 mg/dL (25.3 mmol/L)

Reagent System Lot	Within ± 5 mg/dL & $\pm 5\%$ (Within ± 0.28 mmol/L & $\pm 5\%$)	Within ± 10 mg/dL & $\pm 10\%$ (Within ± 0.56 mmol/L & $\pm 10\%$)	Within ± 15 mg/dL & $\pm 15\%$ (Within ± 0.83 mmol/L & $\pm 15\%$)
WG17H104-CEE	121 / 200 (60.5 %)	172 / 200 (86 %)	199 / 200 (99.5 %)
WG17H604-CEE	123 / 200 (61.5 %)	136 / 148 (91.9%)	198 / 200 (99.0 %)
WG17H904-CEE	115 / 200 (57.5 %)	180 / 200 (90 %)	199 / 200 (99.5 %)

Absolute differences between FORA 6 Connect and Cobas Integra® 400 plus



Consensus Error Grid for FORA 6 Connect with three reagent system lots



Conclusion

This study shows that the FORA 6 Connect Multi-functional Monitoring System is in compliance with ISO 15197:2013 / EN ISO 15197:2015 when comparing the test results to a laboratory reference. In addition, 100% of individual glucose values measured fall within zones A and B of the Consensus Error Grid (CEG).

Reference

- International Organization for Standardization. In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013.
- European Committee for Standardization. In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. EN ISO 15197:2015.
- Institut für Diabetes Technologie (2018, January 16). System accuracy evaluation of FORA 6 Connect Multi-functional Monitoring System based on ISO 15197:2013 & EN ISO 15197:2015. Project no.: IDT-1739(2)-FS