



List of Clinical Validation Studies

for the FORA Blood Glucose Monitoring Products

NO.	STUDY TITLE	DATE/PLACE	SCIENTIST	BRIEF RESULTS	TYPE OF STUDY
01	Evaluation of system accuracy of Diamond Prima DM10 blood glucose self-monitoring system	Aug 2011 Germany	IDT*	100% results fell within the $\pm 20\%$ limit specified in ISO15197	Clinical validation (Unpublished)
02	Evaluation of system accuracy of Comfort Advance G31a blood glucose self-monitoring system	Aug 2011 Germany	IDT*	99.5% results fell within the $\pm 20\%$ limit specified in ISO15197	Clinical validation (Unpublished)
03	Evaluation of system accuracy of GD20 blood glucose self-monitoring system	Aug 2011 Germany	IDT*	100% results fell within the $\pm 20\%$ limit specified in ISO15197	Clinical validation (Unpublished)
04	Evaluation of system accuracy and precision of Comfort Lux GD50 blood glucose monitoring system	Jun 2011 Taiwan	FORA internal study	Slope of regression line were 1.0059 and 0.9964 for capillary and venous blood respectively. Coefficient of variation was well below 5%	Clinical validation
05	Evaluation of system accuracy of Comfort Pro GD40 blood glucose monitoring system	Oct 2010 Germany	IDT*	98.5% results fell within the $\pm 20\%$ limit specified in ISO15197	Clinical validation (Unpublished)
06	Clinical validation of Comfort Basic G20 blood glucose self-monitoring system	Jun 2010 Sweden	Prof. Peter M Nilsson	100% results fell within the $\pm 20\%$ limit	Clinical validation
07	Clinical validation of Comfort Plus Voice V30 blood glucose self-monitoring system	Jun 2010 Sweden	Prof. Peter M Nilsson	97% results fell within the $\pm 20\%$ limit	Clinical validation
08	Survey of the accuracy of 12 different systems for self-measurement of blood glucose according to DIN EN ISO 15197 (FORA G11 equivalent to Glucotest 4230)	May 2010 Germany	IDT*	99% results fell within the ISO standard limits	Clinical validation
09	Clinical validation of FORA S10a POCT blood glucose monitoring system	May 2010 Sweden	Prof. Peter M Nilsson	97% results fell within the $\pm 20\%$ limit	Clinical validation
10	Accuracy of FORA G10 Blood Glucose Monitoring System	Taiwan	FORA internal study	100% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation
11	Performance Evaluation and Clinical Study Report for FORA G20 Blood Glucose Monitoring System	Taiwan	FORA internal study	98% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation
12	Performance Evaluation and Clinical Study Report for FORA G30 Blood Glucose Monitoring System	Taiwan	FORA internal study	99% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation
13	Performance Evaluation and Clinical Study Report for FORA V10 Blood Glucose Monitoring System	Taiwan	FORA internal study	100% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation

* IDT = Institut für Diabetes-Technologie GmbH

NO.	STUDY TITLE	DATE/PLACE	SCIENTIST	BRIEF RESULTS	TYPE OF STUDY
14	Accuracy Report for FORA V11 Blood Glucose Monitoring System	Taiwan	FORA internal study	97% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation
15	Accuracy Report for FORA V12 Blood Glucose Monitoring System	Taiwan	FORA internal study	99% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation
16	Clinical evaluation of FORA G10 Blood Glucose Monitoring System with Capillary Whole Blood	China	Yen-Ni Chang	100% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical validation
17	Inspection Report Relating to Blood Glucose Monitor with Type: FORA G11 , According to the TNO Quality Guidelines PG / TG / 2001.044 and PG / TG / 2001.045	Germany	FORA study	The blood glucose monitor FORA G11 meets the requirements of measurement accuracy and reproducibility as stated in the above mentioned TNO Quality Guidelines.	Clinical validation
18	Performance Evaluation of Glucose Monitoring System FORA G12	Germany	FORA study	The blood glucose monitor FORA G12 meets the criteria of ISO 15197:2003 that was tested.	Clinical validation
19	The Clinical Accuracy Evaluation of FORA G11	Taiwan	FORA study	The measured values of different site perform well in correlation with a standard reference YSI 2300 analyzer and Lab. reference Beckman analyzer.	Clinical validation
20	Accuracy of FORA G10 Meter in Clinical Use.	Dec 2009 China	J&J LifeScan, Shanghai	FORA G10 passed the comparison test against YSI.	Clinical validation
21	Correlation Analysis of HbA1c and Pre-prandial Plasma Glucose in Diabetes Complications. FORA Tele-health System was Used.	May 2009 Taiwan	Yen-Ni Chang	HbA1c might not provide a relevant assay for glycemic control in nephropathy and neuropathy patients. Increased A1c in retinopathy patients.	Comparison between two groups
22	Evaluation of SMBG Behavior Models and the Performance of Continuous Health Education in Diabetes. FORA Tele-health System was Used.	Sep 2009 Taiwan	H.L. Wu	Significant difference was demonstrated, HbA1c improved from 7,64 to 7,38.	Comparison between two groups
23	Application of ADRR Combination with HbA1c for Evaluation of SMBG. FORA Tele-health System was Used.	Oct 2009 Taiwan	H.L. Wu	Significant reduction of HbA1c level in patients with poor metabolic control.	Comparison between two groups.
24	Long Term Experiences Evaluation of Improved Glycemic Control, in 6 year Giabetes Cohort. FORA Tele-health System was Used.	Oct 2009 Taiwan	K.D. Chen	Quality of diabetes care was improved by the cooperative model. Good improvement of HbA1c.	Comparison between two groups