

Clinical Validation Study List
for Blood Glucose Monitoring System

NO.	STUDY TITLE	DATE / PLACE	SCIENTIST	BRIEF RESULTS	TYPE OF STUDY
01	Certificate of Conformity for FORA Diamond PRIMA DM10 Blood Glucose Monitoring System	Aug 2015 Germany	TÜV SÜD Product Service GmbH (No. 713065869-01)	The BGMS fulfills the requirements of ISO 15197:2013 .	Certificate of Conformity
02	Certificate of Conformity for FORA Diamond MINI DM30 Blood Glucose Monitoring System	Aug 2015 Germany	TÜV SÜD Product Service GmbH (No. 713065869-02)	The BGMS fulfills the requirements of ISO 15197:2013 .	Certificate of Conformity
03	Performance Evaluation and Clinical Study Report for FORA ADVANCED pro GD40g Blood Glucose plus β -Ketone Monitoring System (CE certification under review by LNE-GMED)	Aug 2015 USA	AMCR Institute (Fora031015-01)	Results from the clinical study with 100 subjects demonstrate that the FORA GD40g Blood Glucose plus β -Ketone Monitoring System provides a high level of accuracy over a wide range of hematocrit and hemoglobin values at all testing in this study.	Clinical Validation
04	Performance Evaluation and Clinical Study Report for FORA ADVANCED pro GD40 Blood Glucose plus β -Ketone Monitoring System (CE certification under review by LNE-GMED)	Jun 2015 Taiwan	ForaCare Laboratory	This study showed that the GD40g β -Ketone monitoring system exceeded the minimum acceptable accuracy standard of β-Ketone when compared the test results with a laboratory reference.	Clinical Validation



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05	Performance Evaluation and Clinical Study Report for FORA GOLD Advance Blood Glucose Monitoring System <small>(CE certification under review by LNE-GMED)</small>	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 99.0%, 99.5% and 99.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
06	Performance Evaluation and Clinical Study Report for FORA COMFORT pro GD40 Blood Glucose Monitoring System	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 98.5%, 100.0% and 99.5% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
07	Performance Evaluation and Clinical Study Report for FORA GD20 Blood Glucose Monitoring System	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 98.5%, 99.0% and 98.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
08	Performance Evaluation and Clinical Study Report for FORA COMFORT basic G20 Blood Glucose Monitoring System	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 97.0%, 95.5% and 98.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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09	Performance Evaluation and Clinical Study Report for FORA Diamond MINI DM30b Blood Glucose Monitoring System	Apr 2015 Germany	Institut für Diabetes Technologie (IDT-1451-FS)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 97.0%, 96.5% and 98.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
10	Performance Evaluation and Clinical Study Report for FORA ADVANCED pro GD40 Blood Glucose Monitoring System	Mar 2015 France	Centre de Biologie Sud Centre Hospitalier LYON SUD	This meter is in agreement with all the acceptance criteria of the ANSM .	Clinical Validation
11	Performance Evaluation and Clinical Study Report for FORA Diamond PRIMA DM10 Blood Glucose Monitoring System	Mar 2015 France	Centre de Biologie Sud Centre Hospitalier LYON SUD	This meter is in agreement with all the acceptance criteria of the ANSM .	Clinical Validation
12	Certificate of Conformity for FORA COMFORT pro GD40a Blood Glucose Monitoring System	Dec 2014 Taiwan	TUV Rheinland LGA Products GmbH (AK 50300925 0001)	The device has been tested and was found to be in accordance with ISO 15197:2013 , clause 6.3.3.	Certificate of Conformity



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13	Statement Letter for FORA COMFORT basic G20 Blood Glucose Monitoring System	Oct 2014 The Netherlands	DEKRA Certification B.V. (Ref. BLM/14-530)	DEKRA Certification B.V. declares that the following mentioned products of FORACARE SUISSE AG fulfill the minimum system accuracy performance criteria according to EN ISO 15197:2013 , section 6.3.3a. This declaration is based on a review of which the result is reported in letter 2175155RL01.	Statement Letter
14	Performance Evaluation and Clinical Study Report for FORA COMFORT voice V30 Blood Glucose Monitoring System	Oct 2014 USA	AMCR Institute (Fora092614-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 95.0%, 95.0% and 96.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
15	Performance Evaluation and Clinical Study Report for FORA Diamond MINI DM30b Blood Glucose Monitoring System	Oct 2014 USA	AMCR Institute (Fora092614-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 99.0%, 99.5% and 97.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
16	Performance Evaluation and Clinical Study Report for FORA COMFORT pro GD40a Blood Glucose Monitoring System	Oct 2014 USA	AMCR Institute (Fora092614-01)	This BGMS complies with the requirements of ISO 15197:2013 . System accuracy results are 98.5%, 98.5% and 99.0% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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17	Performance Evaluation and Clinical Study Report for FORA COMFORT pro GD40a Blood Glucose Monitoring System	May 2014 Germany	Institut für Diabetes Technologie (IDT-1404-FS)	This BGMS complies with the requirements of ISO 15197:2013 . The system accuracy results are 96.0%, 96.0% and 96.5% within ± 15 mg/dL & $\pm 15\%$. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
18	Performance Evaluation and Clinical Study Report for FORA COMFORT pro GD40a Blood Glucose Monitoring System in Neonatal Period	Feb 2014 Taiwan	Pediatrics department of Buddhist Tzu Chi General Hospital Taipei Branch (BTCGHTB IRB No. 00-IRB-006-FS)	This BGMS complies with the requirements of ISO 15197:2013 . The system accuracy results are 98.1% within ± 15 mg/dL & $\pm 15\%$ in the neonatal testing set. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
19	Attestation of Conformity for FORA DM10, DM20, DM30, DM40 and GD50 Blood Glucose Monitoring System	Oct 2013 The Netherlands	DEKRA Certification B.V. (No. 2166783AoC01)	DEKRA Certification B.V. declares that the above mentioned products of FORACARE SUISSE AG fulfil the minimum system accuracy performance criteria according to EN ISO 15197:2013 , section 6.3.3a. This declaration is based on a review of which the result is reported in letter BLM/13-980.	Attestation of Conformity

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20	FORA GD20 - Comparison of glucose meters with heparinized whole blood	Sep 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within $\pm 4.08\%$ (average) at glucose level of 15.57 mmol/L. Results fell within $\pm 5.18\%$ (average) at glucose level of 15.25 mmol/L.	Clinical Validation
21	FORA COMFORT pro GD40 - Comparison of glucose meters with heparinized whole blood	Sep 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within $\pm 2.53\%$ (average) at glucose level of 15.57 mmol/L. Results fell within $\pm 10.56\%$ (average) at glucose level of 15.25 mmol/L.	Clinical Validation
22	FORA COMFORT lux GD50 - Comparison of glucose meters with heparinized whole blood	Sep 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within $\pm 6.97\%$ (average) at glucose level of 15.57 mmol/L. Results fell within $\pm 8.26\%$ (average) at glucose level of 15.25 mmol/L.	Clinical Validation
23	FORA Diamond MINI DM30 - Comparison of glucose meters with heparinized whole blood	Jul 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within ± 0.19 mmol/L (average) at glucose level of 4.01 mmol/L. Results fell within ± 0.29 mmol/L (average) at glucose level of 3.99 mmol/L.	Clinical Validation

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24	Performance Evaluation and Clinical Study Report for FORA COMFORT pro GD40 Blood Glucose Monitoring System	Jul 2013 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of ISO 15197:2013 . 99.8% results fell within $\pm 15\%$ at glucose levels of 100 mg/dL or above. 100% results fell within ± 15 mg/dL at glucose levels below 100 mg/dL.	Clinical Validation
25	Performance Evaluation and Clinical Study Report for FORA COMFORT Basic G20 Blood Glucose Monitoring System	Mar 2013 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of ISO/DIS 15197:2011 . 95.9% results fell within $\pm 15\%$ at glucose levels of 100 mg/dL or above. 100% results fell within ± 15 mg/dL at glucose levels below 100 mg/dL.	Clinical Validation
26	Evaluation of system accuracy of FORA COMFORT plus voice V30 blood glucose monitoring system	Jan 2013 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of ISO/DIS 15197:2011 . 98.1% results fell within $\pm 15\%$ at glucose levels of 100 mg/dL or above. 100% results fell within ± 15 mg/dL at glucose levels below 100 mg/dL.	Clinical Validation

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27	Evaluation of system accuracy of FORA Diamond PRIMA blood glucose monitoring system	Jan 2013 Czech	Dr. Tomáš Zima Reference Laboratory of the Ministry of Health for Clinical Chemistry	This BGMS complies with the requirements of ISO/DIS 15197:2011 . 98.5% results fell within $\pm 15\%$ at glucose levels of 5.56 mmol/L or above. 98.6% results fell within ± 0.83 mmol/L at glucose levels below 5.56 mmol/L.	Clinical Validation
28	Evaluation of system accuracy of FORA Diamond MINI blood glucose monitoring system	Jan 2013 Czech	Dr. Tomáš Zima Reference Laboratory of the Ministry of Health for Clinical Chemistry	This BGMS complies with the requirements of ISO/DIS 15197:2011 . 98.4% results fell within $\pm 15\%$ at glucose levels of 5.56 mmol/L or above. 100% results fell within ± 0.83 mmol/L at glucose levels below 5.56 mmol/L.	Clinical Validation
29	FORA COMFORT pro GD40 - Comparison of glucose meters with heparinized whole blood	Dec 2012 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within $\pm 7.19\%$ (average) at glucose level of 16.47 mmol/L. Results fell within ± 0.26 mmol/L (average) at glucose level of 5.07 mmol/L.	Clinical Validation
30	FORA Diamond MINI DM30 - Comparison of glucose meters with heparinized whole blood	Dec 2012 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within $\pm 13.28\%$ (average) at glucose level of 16.47 mmol/L. Results fell within ± 0.56 mmol/L (average) at glucose level of 5.07 mmol/L.	Clinical Validation



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31	Comparison of FORA COMFORT pro GD40 blood glucose monitoring system with a hexokinase method	Nov 2011 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of ISO/DIS 15197:2011 .	Clinical Validation
32	Assessment of the reliability of FORA COMFORT advance G31b blood glucose monitoring system	Aug 2011 France	Dr. Joëlle Goudable Centre Hospitalier Lyon sud	Excellent repeatability and reproducibility, and met accuracy requirements. This meter is in agreement with all the acceptance criteria of the ANSM .	Clinical Validation