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ISO 15197:2013 / EN ISO 15197:2015
Clinical Validation Study List
for FORA® Blood Glucose Monitoring Systems

No.	Study Title	Date / Place	Scientist	Brief Results	Type of Study
01	Certificate of Conformity for **FORA 6 Connect** Multi-Functional Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1803005)	FORA 6 Connect fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity
02	Certificate of Conformity for **FORA 6 Plus** Multi-Functional Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1703002)	FORA 6 Plus fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity
03	Certificate of Conformity for **FORA 6 Smart** Blood Glucose Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1703002)	The BGMS fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity
04	Certificate of Conformity for **FORA Diamond GD50** Blood Glucose Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1803003)	The BGMS fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity
05	Certificate of Conformity for **FORA COMFORT plus (FORA G30a)** Blood Glucose Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1803003)	The BGMS fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity
06	Certificate of Conformity for **FORA Diamond VOICE** Blood Glucose Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1803004)	The BGMS fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity
07	Certificate of Conformity for **FORA COMFORT check (FORA G40)** Blood Glucose Monitoring System	Jan 2019 Germany	TÜV SÜD Product Service GmbH (TW1803004)	The BGMS fulfills the requirements of **ISO 15197:2013 / EN ISO 15197:2015**.	Certificate of Conformity

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08	TÜV Rheinland Certificate for **FORA 6 Connect**	Jun 2018 Netherland	TÜV Rheinland (TRN Report 89210894-1)	FORA 6 Connect fulfils the requirements of the **TÜV Rheinland Guidelines PG/TG/01.044/2013 and PG/TG/01.045/2013**.	Clinical Study
09	Intermediate measurement precision evaluation of **FORA 6 Connect** Multi-functional Monitoring System based on ISO 15197:2013 / EN ISO 15197:2015	Jan 2018 Germany	Institut für Diabetes Technologie IDT-1739(4)-A-FS	Analysis of intermediate measurement precision showed SD ≤2.2 mg/dl and CV ≤2.3% based on the requirements of the section 6.2.4 of **ISO 15197:2013 / EN ISO 15197:2015**. The results were found to be similar in comparison to those reported for other BGMS in the literature.	Clinical Study
10	System Measurement repeatability evaluation of **FORA 6 Connect** Multi-functional Monitoring System based on ISO 15197:2013 / EN ISO 15197:2015	Dec 2017 Germany	Institut für Diabetes Technologie IDT-1739(3)-A-FS	Analysis of measurement repeatability showed SD ≤2.1 mg/dl and CV ≤2.4% based on the requirements of the section 6.2.3 of **ISO 15197:2013 / EN ISO 15197:2015**. The results were found to be similar in comparison to those reported for other BGMS in the literature.	Clinical Study
11	System accuracy evaluation of **FORA 6 Connect** Multi-functional Monitoring System based on ISO 15197:2013 & EN ISO 15197:2015	Nov 2017 Germany	Institut für Diabetes Technologie IDT-1739(2)-FS	FORA 6 Connect complies with system accuracy criteria of **ISO 15197:2013 & EN ISO15197:2015.** (Comparison measurements with the laboratory analyzer, Cobas Integra® 400 plus, were performed.)	Clinical Study

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12	System Accuracy Evaluation of **FORA GoldAdvance Plus*** Blood Glucose Monitoring System–POC Study	Mar 2017 USA	AMCR Institute 120816-02	The FORA GoldAdvance Plus (FORA 6 Connect) has met the new FDA standard (**ISO 15197:2013 & EN ISO 15197:2015**) compared to the laboratory analyzer of YSI 2300 STAT PLUS™. **The BGM of FORA GoldAdvanced plus is called the FORA 6 Connect in European Market.*	Clinical Study
13	Interference Testing of **FORA 6 Connect** Multi-functional Monitoring System based on ISO 15197:2013 / EN ISO 15197:2015	Oct 2016 Taiwan	ForaCare Laboratory	The FORA 6 Connect fulfills the requirements of the **ISO 15197:2013 & EN ISO 15197:2015**	Clinical Study
14	Evaluation the Accuracy of **FORA 6 Plus** Self-monitoring system using specimens from venous and capillary blood	Jun 2015 Taiwan	Chang Gung Medical Foundation & ForaCare	The results demonstrated that 100% of readings met the accuracy equirements of the **ISO 15197:2013 & EN ISO 15197:2015**	Clinical Study
15	System Accuracy Evaluation of **FORA GOLD**** Blood Glucose Monitoring System	Apr 2015 USA	AMCR Institute 031015-01	The FORA GoldAdvance Plus (FORA 6 Connect) has met the **ISO 15197:2013** guidelines compared to the laboratory analyzer of YSI 2300 STAT PLUS™. *** The BGM of FORA Gold is called the FORA 6 Connect in European Market.*	Clinical Study

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16	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
17	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
18	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
19	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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20	Performance Evaluation and Clinical Study Report for **FORA GOLD Advance** Blood Glucose Monitoring System(CE certification under review by LNE-GMED)	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
21	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
22	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
23	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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No.	Study Title	Date / Place	Scientist	Brief Results	Type of Study
24	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
25	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
26	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
27	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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No.	Study Title	Date / Place	Scientist	Brief Results	Type of Study
28	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
29	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
30	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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No.	Study Title	Date / Place	Scientist	Brief Results	Type of Study
31	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
32	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 ±15mg/dL & ±15%. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
33	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 ±15mg/dL & ±15% in the neonatal testing set. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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No.	Study Title	Date / Place	Scientist	Brief Results	Type of Study
34	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
35	**FORA GD20** - Comparison of glucose meters with heparinized whole blood	Sep 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within ±4.08% (average) at glucose level of 15.57 mmol/L. Results fell within ±5.18% (average) at glucose level of 15.25 mmol/L.	Clinical Validation
36	**FORA COMFORT pro GD40** - Comparison of glucose meters with heparinized whole blood	Sep 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within ±2.53% (average) at glucose level of 15.57 mmol/L. Results fell within ±10.56% (average) at glucose level of 15.25 mmol/L.	Clinical Validation
37	**FORA COMFORT lux GD50** - Comparison of glucose meters with heparinized whole blood	Sep 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within ±6.97% (average) at glucose level of 15.57 mmol/L. Results fell within ±8.26% (average) at glucose level of 15.25 mmol/L.	Clinical Validation
38	**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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39	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 ±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
40	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 ±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
41	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 ±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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42	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 ±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
43	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 ±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
44	**FORA COMFORT pro GD40** - Comparison of glucose meters with heparinized whole blood	Dec 2012 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within ±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
45	**FORA Diamond MINI DM30** - Comparison of glucose meters with heparinized whole blood	Dec 2012 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within ±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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46	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
47	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