

# 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 <b>FORA Diamond PRIMA DM10</b> Blood Glucose Monitoring System	Aug 2015 Germany	TÜV SÜD Product Service GmbH (No. 713065869-01)	The BGMS fulfills the requirements of <b>ISO 15197:2013</b> .	Certificate of Conformity
02	Certificate of Conformity for <b>FORA Diamond MINI DM30</b> Blood Glucose Monitoring System	Aug 2015 Germany	TÜV SÜD Product Service GmbH (No. 713065869-02)	The BGMS fulfills the requirements of <b>ISO 15197:2013</b> .	Certificate of Conformity
03	Performance Evaluation and Clinical Study Report for <b>FORA ADVANCED pro GD40g</b> Blood Glucose plus $\beta$ -Ketone Monitoring System <sup>(CE)</sup> <small>certification under review by LNE-GMED)</small>	Aug 2015 USA	AMCR Institute (Fora031015-01)	Results from the clinical study with 100 subjects demonstrate that the FORA GD40g Blood Glucose plus $\beta$ -Ketone Monitoring System provides a high level of accuracy over a wide range of <b>hematocrit and hemoglobin</b> values at all testing in this study.	Clinical Validation
04	Performance Evaluation and Clinical Study Report for <b>FORA ADVANCED pro GD40</b> Blood Glucose plus $\beta$ -Ketone Monitoring System <sup>(CE)</sup> <small>certification under review by LNE-GMED)</small>	Jun 2015 Taiwan	ForaCare Laboratory	This study showed that the GD40g $\beta$ -Ketone monitoring system exceeded the minimum acceptable accuracy standard of <b><math>\beta</math>-Ketone</b> when compared the test results with a laboratory reference.	Clinical Validation
05	Performance Evaluation and Clinical Study Report for <b>FORA GOLD Advance</b> 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 <b>ISO 15197:2013</b> . System accuracy results are 99.0%, 99.5% and 99.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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<b>06</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT pro GD40</b> Blood Glucose Monitoring System	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 98.5%, 100.0% and 99.5% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>07</b>	Performance Evaluation and Clinical Study Report for <b>FORA GD20</b> Blood Glucose Monitoring System	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 98.5%, 99.0% and 98.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>08</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT basic G20</b> Blood Glucose Monitoring System	May 2015 USA	AMCR Institute (Fora031015-01)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 97.0%, 95.5% and 98.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>09</b>	Performance Evaluation and Clinical Study Report for <b>FORA Diamond MINI DM30b</b> Blood Glucose Monitoring System	Apr 2015 Germany	Institut für Diabetes Technologie (IDT-1451-FS)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 97.0%, 96.5% and 98.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>10</b>	Performance Evaluation and Clinical Study Report for <b>FORA ADVANCED pro GD40</b> 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 <b>ANSM</b> .	Clinical Validation

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<b>11</b>	Performance Evaluation and Clinical Study Report for <b>FORA Diamond PRIMA DM10</b> 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 <b>ANSM</b> .	Clinical Validation
<b>12</b>	Certificate of Conformity for <b>FORA COMFORT pro GD40a</b> 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 <b>ISO 15197:2013</b> , clause 6.3.3.	Certificate of Conformity
<b>13</b>	Statement Letter for <b>FORA COMFORT basic G20</b> 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 <b>EN ISO 15197:2013</b> , section 6.3.3a. This declaration is based on a review of which the result is reported in letter 2175155RL01.	Statement Letter
<b>14</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT voice V30</b> Blood Glucose Monitoring System	Oct 2014 USA	AMCR Institute (Fora092614-01)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 95.0%, 95.0% and 96.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>15</b>	Performance Evaluation and Clinical Study Report for <b>FORA Diamond MINI DM30b</b> Blood Glucose Monitoring System	Oct 2014 USA	AMCR Institute (Fora092614-01)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 99.0%, 99.5% and 97.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation

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<b>16</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT pro GD40a</b> Blood Glucose Monitoring System	Oct 2014 USA	AMCR Institute (Fora092614-01)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . System accuracy results are 98.5%, 98.5% and 99.0% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>17</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT pro GD40a</b> Blood Glucose Monitoring System	May 2014 Germany	Institut für Diabetes Technologie (IDT-1404-FS)	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . The system accuracy results are 96.0%, 96.0% and 96.5% within $\pm 15$ mg/dL & $\pm 15\%$ . Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>18</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT pro GD40a</b> 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 <b>ISO 15197:2013</b> . The system accuracy results are 98.1% within $\pm 15$ mg/dL & $\pm 15\%$ in the neonatal testing set. Results within Consensus Error Grid zones A and B is 100%.	Clinical Validation
<b>19</b>	Attestation of Conformity for <b>FORA DM10, DM20, DM30, DM40</b> and <b>GD50</b> Blood Glucose Monitoring System	Oct 2013 The Netherlands	DEKRA Certification B.V. (No. 2166783A0C01)	DEKRA Certification B.V. declares that the above mentioned products of FORACARE SUISSE AG fulfil the minimum system accuracy performance criteria according to <b>EN ISO 15197:2013</b> , 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



<b>20</b>	<b>FORA GD20</b> - 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
<b>21</b>	<b>FORA COMFORT pro GD40</b> - 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
<b>22</b>	<b>FORA COMFORT lux GD50</b> - 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
<b>23</b>	<b>FORA Diamond MINI DM30</b> - Comparison of glucose meters with heparinized whole blood	Jul 2013 Switzerland	Dr. R. Fried University Hospital Zurich	Results fell within $\pm 0.19$ mmol/L (average) at glucose level of 4.01 mmol/L. Results fell within $\pm 0.29$ mmol/L (average) at glucose level of 3.99 mmol/L.	Clinical Validation
<b>24</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT pro GD40</b> Blood Glucose Monitoring System	Jul 2013 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of <b>ISO 15197:2013</b> . 99.8% results fell within $\pm 15\%$ at glucose levels of 100 mg/dL or above. 100% results fell within $\pm 15$ mg/dL at glucose levels below 100 mg/dL.	Clinical Validation

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<b>25</b>	Performance Evaluation and Clinical Study Report for <b>FORA COMFORT Basic G20</b> Blood Glucose Monitoring System	Mar 2013 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of <b>ISO/DIS 15197:2011</b> . 95.9% results fell within $\pm 15\%$ at glucose levels of 100 mg/dL or above. 100% results fell within $\pm 15$ mg/dL at glucose levels below 100 mg/dL.	Clinical Validation
<b>26</b>	Evaluation of system accuracy of <b>FORA COMFORT plus voice V30</b> blood glucose monitoring system	Jan 2013 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of <b>ISO/DIS 15197:2011</b> . 98.1% results fell within $\pm 15\%$ at glucose levels of 100 mg/dL or above. 100% results fell within $\pm 15$ mg/dL at glucose levels below 100 mg/dL.	Clinical Validation
<b>27</b>	Evaluation of system accuracy of <b>FORA Diamond PRIMA</b> 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 <b>ISO/DIS 15197:2011</b> . 98.5% results fell within $\pm 15\%$ at glucose levels of 5.56 mmol/L or above. 98.6% results fell within $\pm 0.83$ mmol/L at glucose levels below 5.56 mmol/L.	Clinical Validation
<b>28</b>	Evaluation of system accuracy of <b>FORA Diamond MINI</b> 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 <b>ISO/DIS 15197:2011</b> . 98.4% results fell within $\pm 15\%$ at glucose levels of 5.56 mmol/L or above. 100% results fell within $\pm 0.83$ mmol/L at glucose levels below 5.56 mmol/L.	Clinical Validation

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<b>29</b>	<b>FORA COMFORT pro GD40</b> - 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 $\pm 0.26$ mmol/L (average) at glucose level of 5.07 mmol/L.	Clinical Validation
<b>30</b>	<b>FORA Diamond MINI DM30</b> - 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 $\pm 0.56$ mmol/L (average) at glucose level of 5.07 mmol/L.	Clinical Validation
<b>31</b>	Comparison of <b>FORA COMFORT pro GD40</b> blood glucose monitoring system with a hexokinase method	Nov 2011 Taiwan	ForaCare Laboratory	This BGMS complies with the requirements of <b>ISO/DIS 15197:2011</b> .	Clinical Validation
<b>32</b>	Assessment of the reliability of <b>FORA COMFORT advance G31b</b> 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 <b>ANSM</b> .	Clinical Validation
<b>33</b>	Evaluation of system accuracy of <b>FORA Diamond PRIMA DM10</b> blood glucose self-monitoring system	Aug 2011 Germany	IDT*	100% results fell within the $\pm 20\%$ limit specified in ISO 15197:2003	Clinical Validation
<b>34</b>	Evaluation of system accuracy of <b>COMFORT advance G31a</b> blood glucose self-monitoring system	Aug 2011 Germany	IDT*	99.5% results fell within the $\pm 20\%$ limit specified in ISO 15197:2003	Clinical Validation

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<b>35</b>	Evaluation of system accuracy of <b>FORA COMFORT basic GD20</b> blood glucose self-monitoring system	Aug 2011 Germany	IDT*	100% results fell within the $\pm 20\%$ limit specified in ISO 15197:2003	Clinical Validation
<b>36</b>	Evaluation of system accuracy and precision of <b>FORA COMFORT lux GD50</b> blood glucose monitoring system	Jun 2011 Taiwan	Fora Care Laboratory	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
<b>37</b>	Evaluation of system accuracy of <b>FORA COMFORT Pro GD40</b> blood glucose monitoring system	Oct 2010 Germany	IDT*	98.5% results fell within the $\pm 20\%$ limit specified in ISO 15197:2003	Clinical Validation
<b>38</b>	Clinical validation of <b>FORA COMFORT basic G20</b> Blood Glucose self-monitoring system	Jun 2010 Sweden	Prof. Peter M Nilsson The Malmö University	100% results fell within the $\pm 20\%$ limit	Clinical Validation
<b>39</b>	Clinical validation of <b>FORA COMFORT plus voice V30</b> blood glucose self-monitoring system	Jun 2010 Sweden	Prof. Peter M Nilsson The Malmö University	97% results fell within the $\pm 20\%$ limit	Clinical Validation



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<b>40</b>	Survey of the accuracy of 12 different systems for self-measurement of blood glucose according to DIN EN ISO 15197 ( <b>FORA G11 equivalent to Glucotest 4230</b> )	May 2010 Germany	IDT*	99% results fell within the ISO standard limits	Clinical Validation
<b>41</b>	Clinical validation of <b>FORA S10a POCT</b> blood glucose monitoring system	May 2010 Sweden	Prof. Peter M Nilsson The Malmö University	97% results fell within the $\pm 20\%$ limit	Clinical Validation
<b>42</b>	Accuracy of <b>FORA G10</b> blood glucose monitoring system	Taiwan	Fora Care Laboratory	100% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical Validation
<b>43</b>	Performance evaluation and clinical study report for <b>FORA G20</b> blood glucose monitoring system	Taiwan	Fora Care Laboratory	98% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical Validation
<b>44</b>	Performance evaluation and clinical study report for <b>FORA G30</b> blood glucose monitoring system	Taiwan	Fora Care Laboratory	99% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical Validation
<b>45</b>	Performance evaluation and clinical study report for <b>FORA COMFORT basic voice V10</b> blood glucose monitoring system	Taiwan	Fora Care Laboratory	100% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical Validation

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<b>46</b>	Accuracy report for <b>FORA V11</b> blood glucose monitoring system	Taiwan	Fora Care Laboratory	97% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical Validation
<b>47</b>	Accuracy report for <b>FORA V12</b> blood glucose monitoring system	Taiwan	Fora Care Laboratory	99% of individual results fell within $\pm 20\%$ indicating clinical accuracy.	Clinical Validation
<b>48</b>	Clinical evaluation of <b>FORA G10</b> 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
<b>49</b>	Inspection report relating to blood glucose monitor with type: <b>FORA G11</b> , according to the TNO quality guidelines PG / TG / 2001.044 and PG / TG / 2001.045	Germany	Fora Care Laboratory	The blood glucose monitor <b>FORA G11</b> meets the requirements of measurement accuracy and reproducibility as stated in the above mentioned TNO Quality Guidelines.	Clinical Validation
<b>50</b>	Performance evaluation of glucose monitoring system <b>FORA G12</b>	Germany	Fora Care Laboratory	The blood glucose monitor <b>FORA G12</b> meets the criteria of ISO 15197:2003 that was tested.	Clinical Validation
<b>51</b>	The clinical accuracy evaluation of <b>FORA G11</b>	Taiwan	Fora Care Laboratory	The measured values of different site perform well in correlation with a standard reference YSI 2300 analyzer and Lab. reference Beckman analyzer.	Clinical Validation
<b>52</b>	Accuracy of <b>FORA G10</b> meter in clinical use.	Dec 2009 China	J&J LifeScan, Shanghai	<b>FORA G10</b> passed the comparison test against YSI.	Comparison between two groups

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<b>53</b>	Correlation analysis of HbA1c and pre-prandial plasma glucose in diabetes complications. <b>FORA Tele-Health System</b> 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
<b>54</b>	Evaluation of SMBG behavior models and the performance of continuous health education in diabetes. <b>FORA Tele-Health System</b> was used.	Sep 2009 Taiwan	H.L. Wu	Significant difference was demonstrated, HbA1c improved from 7,64 to 7,38. Significant reduction of HbA1c level	Comparison between two groups
<b>55</b>	Application of ADRR combination with HbA1c for evaluation of SMBG. <b>FORA Tele-Health System</b> was used.	Oct 2009 Taiwan	H.L. Wu	Significant reduction of HbA1c level in patients with poor metabolic control.	Comparison between two groups
<b>56</b>	Long term experiences evaluation of improved glycemic control, in 6 years diabetes cohort. <b>FORA Tele-Health System</b> 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