



Declaration of Equivalence

We at ForaCare Suisse AG are committed to continuously improve our products. As part of this effort, we conduct clinical validations, both internally and externally, that are above and beyond the regulations and CE requirements.

In striving to provide our patients with the most advanced technologies, ForaCare regularly conducts clinical validations using a blood glucose monitoring system (BGMS) that is identical to another system.

We hereby declare that devices validated by the following institutes use the same test strip formulas / 4365 / GDH-FAD / 0.5uL / 5 seconds and the IC chip on the BGM system and is therefore identical in nature and manufacturing to FORA® Diamond PRIMA (DM10), FORA® Diamond VOICE (DM20), FORA® Diamond MINI (DM30) and the FORA® Diamond GD50 (GD50) for the BGM capability.

Study Title	Date / Place	Institute	Brief Result
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 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.
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 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 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%.



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Study Title	Date / Place	Institute	Brief Result
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%.
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.
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.