



Certificate

3rd February 2016

The TaiDoc TD4272 / BRUNO GD40 DELTA Blood Glucose & β -Ketone Monitoring Systems from TaiDoc Technology Corporation have demonstrated the ability to meet all requirements of **ISO 15197:2013**.^{1,*}



TaiDoc TD4272 / BRUNO GD40 DELTA Series with 5-Electrode Test Strip

A clinical study done in May 2014 was conducted by the Institute for Diabetes-Technology (IDT) at the University of Ulm in Germany, the TaiDoc TD4272 Blood Glucose Monitoring System is evaluated with three reagent system lots and compared with Cobas Integra[®] 400 Plus glucose analyzer as the reference system. The report indicates that 100% of the results from samples < 100mg/dL (5.55mmol/L) fall within ± 15 mg/dL (± 0.83 mmol/L) criteria while 98% from samples > 100 mg/dL (5.55mmol/L) fall within $\pm 15\%$ criteria.**

Jim Jan
Management Representative
TaiDoc Technology Corporation

*As assessed by TÜV Rheinland LGA Products GmbH, declared that TaiDoc TD4272 Blood Glucose Monitoring System fulfils the minimum system accuracy performance criteria according to EN ISO 15197:2013, section 6.3.3a.²

**The studies were conducted at Institut für Diabetes Technologie, gesellschaft mbH an der Universität Ulm, D-89081 Ulm, Germany. Study period: 2014-04-10~04-28.³

Reference Standard

1. International Organization for Standardization. In vitro diagnostic test systems requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland: International Organization for Standardization.
2. TÜV Rheinland LGA Products GmbH. Certificate of Conformity with EN ISO 15197:2013 section 6.3.3 Minimum system accuracy performance criteria, subsection a). Dec 30th, 2014. Registration No.: AK 50300925 01. Report No.: 10049597 001.
3. Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm. TaiDoc TD4272 vs. Cobas Integra[®] 400 Plus. Sep. 9th, 2014. Report No.: IDT-1404-FS.