Journal of Diabetes Science and Technology
2016, Vol. 10(1) 238–239

DOI: 10.1177/1932296815606471
dst.sagepub.com
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Accuracy Evaluation of a CE-Marked System for Self-Monitoring of Blood Glucose With Three Reagent System Lots Following ISO 15197:2013

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Keywords
self-monitoring of blood glucose, ISO 15197:2013, accuracy, blood glucose, SMBG system

Ongoing standardized verification of the accuracy of blood glucose meters systems for self-monitoring post-launch is important clinically and helps confirm appropriate performance of subsequently released lots of strips.[1] In addition, publication of such studies is increasingly becoming a component of informed comparative purchasing decisions. ISO 15197:2013,[2] for which mandatory compliance is recommended for SMBG systems by 2016,[3] has tighter accuracy requirements than ISO 15197:2003,[4] and outlines current minimum accuracy standards necessary in Europe for CE marking.

In this study, a postmarketing evaluation of the CE-marked and FDA-approved TD-4277 SMBG system was performed in accordance with ISO 15197:2013 protocols and requirements. The TD 4277 system (TaiDioc Technology Corp, Taiwan, ROC) is supplied in the United Kingdom as the GlucoRx Nexus (GlucoRx Ltd., Surrey, England) and in Germany as the GlucoCheck XL (aktivmed GmbH, Rheine, Germany). Three GlucoCheck XL systems, 500 tests from 3 strip lots (TD13J901 BOF, TD13I901 BOF,TD13H201 BOF with expiry dates July, June and May 2015 respectively) were supplied by aktivmed GmbH, Germany, for the study that was conducted from December 10 to December 19, 2013, at the Institute of Diabetes "Gerhardt Katsch," Karlsburg, Germany. Ethical approval for the study was obtained from the Ethics Committee of the University of Greifswald.

Ear lobe capillary blood samples were taken from 121 subjects for duplicate glucose determination using the GlucoCheck XL and the glucose oxidase based YSI2300 STAT PLUS (YSI Incorporated, Yellow Springs, Ohio, USA) plasma glucose reference method. Trueness and precision of the comparison assay were verified using a range of YSI bioanalytical standards and controls. Samples had hematocrit values between 20% and 60% and after examination of glucose concentration ranges using the YSI, 100 subjects were included in the analysis of accuracy.

Table 1. Analytical and Clinical Accuracy of the TD-4277 With 3 Lots of Strips.

SMBG system		ISO 15197:2013 criteria within ±15 mg/dl and ± 15%		
Meter	Strip lot	Individual lots	3 lots combined	Within consensus error grid zones A and B
GlucoCheck XL TD-4277	TD13J901-BOF	192/200 (96%)	584/600 (97.3%)	600/600 (100%)
	TD13I901-BOF	198/200 (99%)		
	TD13H901-BOF	194/200 (97%)		

Numbers and percentages of results within system accuracy limits of ISO 15197:2013.

Table 1 demonstrates performance in relation to the minimum accuracy requirements of ISO 15197:2013 where for each of the 3 lots of strips at least 95% of results must fall within ±15 mg/dl of the comparison measurement results at blood glucose concentrations <100 mg/dl and within ±15% at concentrations ≥100 mg/dl. The standard also requires that at least 99% of individual results fall within consensus error grid zones A and B (5) when clinical accuracy is evaluated with 3 test strip lots. The relative bias according to Bland and Altman (6) ranged from –5.43% to –4.00% and the mean absolute relative difference from 6.24% to 6.99%.

In conclusion, this study demonstrates that the TD-4277 SMBG system fulfils and exceeds the minimum analytical and clinical accuracy requirement of ISO 15197:2013.

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Abbreviations

CE, Conformité Européene; ISO, International Organization for Standardization; SMBG, self-monitoring of blood glucose.

Acknowledgments

TaiDioc Technology Corp, aktivmed GmbH, and GlucoRx Ltd were permitted to review and comment on the manuscript, but final decision on content was retained by the authors.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: All authors are employees of the Institut für Diabetes, Karlsburg, Germany, which carries out studies evaluating blood glucose meter systems on behalf of various companies.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was funded by aktivmed GmbH Oldenburger Str 17, 48429 Rheine Germany.

References

1. Klonoff DC, Prahalad P. Performance of cleared blood glucose monitors. *J Diabetes Sci Technol*. 2015;9(4):895-910.
2. International Organization for Standardization. In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013.
3. Baumstark A, Schmid C, Pleus S, Rittmeyer D, Haug C, Freckmann G. Accuracy assessment of an advanced blood glucose monitoring system for self-testing with three reagent system lots following ISO 15197:2013. *J Diabetes Sci Technol*. 2014;8(6):1241-1242.
4. International Organization for Standardization. In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. EN ISO 15197:2003.
5. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000;23:1143-1148.
6. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*. 1986;1(8476):307-310.