

ISO 15197: 2013 Evaluation of a Blood Glucose Monitoring System's Measurement Accuracy

Nina Jendrike, MD¹, Annette Baumstark, PhD¹,
Ulrike Kamecke, MEng¹, Cornelia Haug, MD¹,
and Guido Freckmann, MD¹

Keywords

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

Requirements for blood glucose monitoring systems (BGMS) for self-testing are regulated, for example, in the international standard ISO 15197:2013¹ (harmonized in the European Union as EN ISO 15197:2015²). Regarding measuring accuracy of a BGMS, ISO 15197:2013 specifies the following criteria: (1) compared to a traceable laboratory method at least 95% of BGMS results have to be within ± 15 mg/dl at glucose concentrations < 100 mg/dl and within $\pm 15\%$ at ≥ 100 mg/dl; (2) in a consensus error grid analysis at least 99% of results have to be within zones A and B.

This study was an ISO 15197:2013 accuracy evaluation at the Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm (accredited by the Deutsche Akkreditierungsstelle GmbH (DAkkS) as testing laboratory according to DIN EN ISO/IEC 17025:2005 and 98/79/EC in terms of test procedures according to DIN EN ISO 15197) in compliance with all applicable regulatory requirements. The BGMS GlucoDr. auto™ AGM-4000 (All Medicus, Co, Ltd, Anyang-si, Republic of Korea) was tested. According to a statement of the manufacturer, this system is marketed in the UK as Glucozen.auto™ AGM-4000 (GlucoZen Ltd, Dudley, UK). Meters and three different lots of test strips were provided by the manufacturer. A YSI 2300 STAT Plus glucose analyzer (YSI Inc, Yellow Springs, OH, USA) that is traceable according to ISO 17511³ was used for comparison measurements; trueness and precision were verified throughout the study. The BGMS was used according to its labeling and daily control measurements were performed. Each of the three test strip lots was tested in duplicate in 100 subjects; glucose concentrations of the capillary blood samples were distributed as specified in ISO 15197:2013. The accuracy criteria described above were applied to the BGMS and the relative bias⁴ was calculated.

Over the whole glucose concentration range, the BGMS had 98.5% (Lot 1), 97% (Lot 2) and 96% (Lot 3) of results

Journal of Diabetes Science and Technology
2017, Vol. 11(6) 1275–1276
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DOI: 10.1177/1932296817727550
journals.sagepub.com/home/dst
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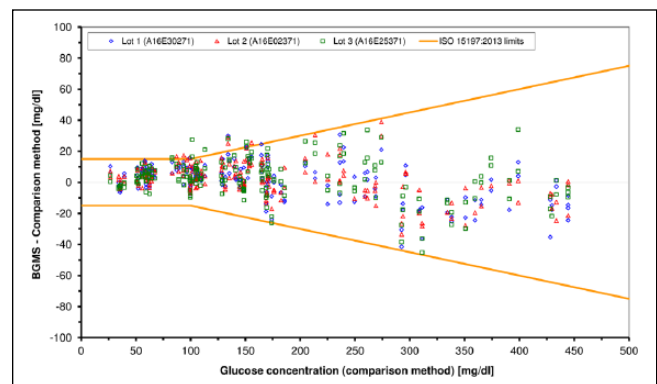


Figure 1. System accuracy for each individual lot: Absolute differences between BGMS results and comparison measurement results. For each lot, 200 data points are shown (100 samples measured in duplicate).

within the limits stipulated by ISO 15197:2013 (Figure 1). Percentages of results within the limits were 98.3%, 95%, and 98.3%, respectively, for glucose concentrations < 100 mg/dl and 98.6%, 97.9%, and 95%, respectively, for glucose concentrations ≥ 100 mg/dl. All results of the three test strip lots were within zones A and B of the consensus error grid. The relative bias was 2.7% (Lot 1) and 2.6% (Lot 2 and Lot 3).

In this study, the system showed more than the minimally required 95% of results within the ISO 15197 system accuracy limits and did not show obvious variations between the evaluated test strip lots.

¹Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Ulm, Germany

Corresponding Author:

Nina Jendrike, MD, Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Helmholtzstrasse 20, Ulm 89081, Germany.
Email: nina.jendrike@idt-ulm.de

Abbreviation

BGMS, blood glucose monitoring system.

Acknowledgments

The authors would like to thank Delia Waldenmaier (IDT) for her support in writing the manuscript and Stefan Pleus (IDT) for data analysis and reviewing the manuscript.

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: GF is general manager of the IDT (Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Ulm, Germany), which carries out clinical studies on the evaluation of BG meters and medical devices for diabetes therapy on its own initiative and on behalf of various companies. GF/IDT have received speakers' honoraria or consulting fees from Abbott, Ascensia, Bayer, Berlin-Chemie, Becton-Dickinson, Dexcom, LifeScan, Menarini Diagnostics, Novo Nordisk, Roche, Sanofi, Sensile, and Ypsomed. NJ, AB, UK, and CH are employees of the IDT.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was funded by All Medicus Co, Ltd, writing of the manuscript was supported by GlucoZen Ltd and All Medicus Co, Ltd.

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