

## System Accuracy Evaluation of 43 Blood Glucose Monitoring Systems for Self-Monitoring of Blood Glucose according to DIN EN ISO 15197

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### Abstract

#### **Background:**

The accuracy of systems for self-monitoring of blood glucose is important, as reliable measurement results are a prerequisite for therapeutic decisions.

#### **Methods:**

This system accuracy evaluation study was performed according to DIN EN ISO 15197:2003 for 43 Conformité Européenne (CE)-labeled blood glucose (BG) monitoring systems. Measurement results of each system were compared with results of the designated comparison method (manufacturer's measurement procedure): glucose oxidase method (YSI 2300 glucose analyzer) or hexokinase method (Hitachi 917/ cobas 501).

#### **Results:**

Complete assessment according to the International Organization for Standardization (ISO) standard was performed for 34 out of 43 systems, and 27 (79.4%) meet the requirements of the standard, i.e.,  $\geq 95\%$  of their results showed at least the minimum acceptable accuracy. For 9 of the 43 systems, complete accuracy assessment was not performed due to an oxygen sensitivity (manufacturer's labeling). The bias (according to Bland and Altman) of all 43 evaluated systems ranged from -14.1% to +12.4%.

#### **Conclusions:**

From the 34 systems completely assessed, 7 systems did not fulfill the minimal accuracy requirements of the ISO standard. The CE mark apparently does not guarantee that all BG systems provide accuracy according to the standard. Because inaccurate systems bear the risk of false therapeutic decisions, regular and standardized evaluation of BG meters and test strips should be requested in order to ensure adherence to quality standards.

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**Abbreviations:** (BG) blood glucose, (CE) Conformité Européenne, (GOx) glucose oxidase, (HK) hexokinase, (ISO) International Organization for Standardization, (NIST) National Institute of Standards and Technology, (SMBG) self-monitoring of blood glucose

**Keywords:** blood glucose monitoring systems, Conformité Européenne mark, DIN EN ISO 15197:2003, self-monitoring of blood glucose, system accuracy

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