System accuracy evaluation of the systems for self-monitoring of blood glucose GL50 evo and GL 44 following DIN EN ISO 15197:2015: A comparison of accuracy in glucose concentration ranges <100 mg/dL and ≥100 mg/dL

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Abstract
Ongoing standardized verification of the accuracy of blood glucose meters systems for self-monitoring post-launch is important clinically and helps confirm appropriate continuous performance of self-monitoring blood glucose (SMBG) systems. In addition, publication of such studies is increasingly becoming a component of evidence-based purchasing decision making. ISO 15197:2015, for which mandatory compliance is recommended for SMBG systems by 2015, has tighter accuracy requirements than ISO 15197:2003 and outlines current minimum accuracy standards necessary in Europe for CE marking.

Introduction
In the present study, a post marketing evaluation of the CE-marked GL50 evo and GL44 systems were performed in accordance with ISO 15197:2015 protocols and requirements. The GL50 evo and GL44 systems were supplied in Germany from the Beurer GmbH, Germany. A declaration of conformity from the manufacturer of the two measuring systems was available before the start of the study, so that only the GL50 evo was used in the tests, but the results documented the quality of both systems. Two GL50 evo systems (serial number: GL55 T1 and GL55 T2) and strips from 3 different lots (A 10/1, A 10/3, A 10/4) with expiry dates March 2017 respectively) were supplied by the manufacturer. The study was conducted from April 21 to May 05, 2015, 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 in July 2014 [1-3].

Ear lobe capillary blood samples were taken from 118 subjects for duplicate glucose determination using the GL50 evo 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. The prescribed limits for the hematocrit values, to be between 20% and 60%, were reached by the patient samples and after examination of glucose concentration ranges using the YSI, 100 subjects were included in the analysis of accuracy [4].

In the glucose range <100 mg/dL in summary 98.8 % of the values and in the range ≥ 100 mg/dL in summary 98.6 % full filled the quality criteria of the ISO 15197. Important differences between the three tested lots were not shown; detailed data are presented in Tables 1 and 2. The Table 3 demonstrates performance in relation to the minimum accuracy requirements of ISO 15197:2015 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 when clinical accuracy is evaluated with 3 test strip lots [5] (Figure 1).

In conclusion, this study demonstrates that the GL50 evo and GL44 SMBG systems fulfills and exceeds the minimum analytical and clinical accuracy requirement of ISO 15197:2015. There are now differences in the accuracy between the glucose values upper and below 100 mg/dL.

Table 1. System accuracy of Beurer GL50 evo/ GL44 for glucose concentrations <100 mg/dL

| Strip lot | within ±5mg/dL | within ±10mg/dL | within ±15mg/dL |
|-----------|----------------|-----------------|-----------------|
| A 10/1    | 28/56 (50.00%) | 53/56 (94.64 %) | 56/56 (100 %)   |
| A 10/3    | 30/56 (53.57 %) | 54/56 (96.43 %) | 55/56 (98.21 %) |
| A 10/4    | 43/56 (76.79 %) | 54/56 (96.43 %) | 55/56 (98.21 %) |
| Three lots in summary | 101/168 (60.12 %) | 161/168 (95.83 %) | 166/168 (98.81 %) |

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Table 2. System accuracy of Beurer GL50 evo/ GL44 for glucose concentrations ≥100 mg/dL

| Strip lot | ISO 15197:2015 criteria | Total | % | % | % |
|-----------|-------------------------|-------|---|---|---|
| A 10/1    | within ± 5 %             | 58/144 (40.28%) | 112/144 (77.78%) | 142/144 (98.61%) |
| A 10/3    | within ± 10 %            | 62/144 (43.06%) | 119/144 (82.64%) | 142/144 (98.61%) |
| A 10/4    | within ± 15 %            | 62/144 (43.06%) | 127/144 (88.19%) | 142/144 (98.61%) |
| Three lots in summary | within ± 15 % | 182/432 (42.13%) | 358/432 (82.87%) | 426/432 (98.61%) |

Table 3. Analytical and Clinical Accuracy of the GL50 evo with 3 Lots of Strips

| SMBG system | ISO 15197:2015 criteria within ±15 mg/dL and ±15 % |
|-------------|---------------------------------------------------|
| GL50 evo/   | Meter     | Strip lot | Individual lots | 3 lots combined | Within consensus error grid zones A and B |
| GL44       | GL50 evo/ | A 10/1    | 198/200 (99.0%) | 592/600 (98.7%) | 600/600 (100%) |
| GL44       | GL44     | A 10/3    | 197/200 (98.5%) | 600/600 (100%) | 600/600 (100%) |
| GL44       | GL44     | A 10/4    | 197/200 (98.5%) | 600/600 (100%) | 600/600 (100%) |

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Declaration of conflicting interests

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References

1. Klonoff DC, Prahalad P (2015) Performance of Cleared Blood Glucose Monitors. J Diabetes Sci Technol 9: 895-910. [Crossref]
2. International Organization for Standardization (2013) In vitro diagnostic test systems-requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197.
3. Baumstark A, Schmid C, Pleus S, Rittmeyer D, Haug C, et al. (2014) 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 8: 1241-1242. [Crossref]
4. Parkes JL, Slatin SL, Paro S, Ginsberg BH (2000) A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care 23: 1143-1148.
5. Bland JM, Altman DG (1986) Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1: 307-310. [Crossref]

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