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User performance 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 rages <100 mg/dl and ≥100 mg/dl

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Abbreviations: CE: Conformite Europeene; ISO: International Organization for Standardization; SMBG: Self-Monitoring of Blood Glucose.

Introduction

Ongoing standardized verification of the accuracy of blood glucose meters systems for self-monitoring post-launch is important clinically and helps confirm appropriate continues performance of self-monitoring blood glucose (SMBG)systems [1]. In addition, publication of such studies is increasingly becoming a component of evidence-based purchase decision making. ISO 15197:2015, [2] for which mandatory compliance is recommended for SMBG systems by 2015, [3] has tighter accuracy requirements than ISO 15197:2003, [4-6] and outlines current minimum accuracy standards necessary in Europe for CE marking.

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. The study was conducted at the Institute of Diabetes "Gerhardt Katsch," Karlsburg, Germany.

Data from N=100 diabetics each (55 women and 45 males) were included in the evaluation of this two studies. The knowledge and signing of the consent form were a prerequisite for participation.

The capillary blood glucose values self measured by the volunteers were compared with those obtained by reference methods.

Participants had the following age distribution: The subjects were given the blood glucose meter GL50 evo (first study) or GL 44 (second study) and the instructions for use, created by Beurer Company (Tables 1 and 2). At this time, the patients did not participate in any other study. They got sufficient time to read the instructions and, if necessary, each of them could perform up to three trial runs. Subjects were asked to puncture their fingertips after washing their hands and disinfecting the skin area, and to measure the blood glucose under use of the GL50 evo/ GL 44 blood glucose meter. This action was done under observation by a healthcare professional who took a reference sample from the subject for measurement in the YSI 2300 Stat Plus (YSI Incorporated, USA) and an additional blood sample to determine the hematocrit value immediately after patient has done its measurement.

Table 1. Age distribution of subjects

Age (years)	Number of subjects for GL50 evo	Number of subjects for GL44
18-29	9	3
30-39	24	12
40-49	13	15
50-59	23	32
60-69	26	27
>70	5	11
Total	100	100

Table 2. Details of educational level

Highest degrees	Number of subjects for GL50 evo	Number of subjects for GL44
No degree	2	0
Secondary school	24	17
High school	3	5
Vocational training	40	47
Technical college, University	31	31
Total	100	100

The self-measurement data of the patients and the mesured reference data were coded recorded by the supervisor in the 'User Performance Evaluation Sheets' (=master data sheets) and compiled in the form of an Excel spreadsheet.

Thereafter the user answered to questions from the standardized questionnaire provided to him. Notes and comments from user/subject were noted by the supervisor.

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The measured data (blood glucose values and hematocrit) appear in coded form in the files and in the test report.

The analysis of data to verify system accuracy by the user was carried out in accordance with the requirements of DIN EN ISO 15197: 2015. The test measurements were compared with the reference measurements done in the YSI (Tables 3-10).

For samples with glucose concentrations <100 mg/dl, the deviations from the mean value of the reference samples were calculated in mg/dl. For samples with glucose concentrations ≥100 mg/dl, the percentage deviation from the mean of the reference samples was calculated. According to the ISO standard, for glucose concentrations <100 mg/dl 95% of the measurement results should not deviate more than ±15 mg/dl from the laboratory reference value and at glucose concentrations ≥ 100 mg/dl 95% of the measurement results should not deviate more than ±15% from the laboratory reference value. In total, 95% of the values must meet the defined quality criteria.

Table 3. System accuracy at glucose concentrations < 100 mg/dL

within ±5 mg/dL	within ±10 mg/dL	within ±15 mg/dL
7/8 (87,5%)	8/8 (100%)	8/8 (100%)

Table 4. System accuracy at glucose concentrations ≥ 100 mg/dL

within ±5%	within ±10%	within ±15%
40/92 (43,5%)	66/92 (71,4%)	87/92 (95%)

Table 5. System accuracy with combined glucose concentrations

within ±5 mg/dL ±5%	within ±10 mg/dL ±10%	within ±15 mg/dL ±15%
47/100 (47%)	74/100 (74%)	95/100 (95%)

Table 6. System accuracy at glucose concentrations <100 mg/dL

within ±5 mg/dL	within ±10 mg/dL	within ±15 mg/dL
7/19 (36.8%)	**14/19 (73.7%)**	**19/19 (100%)**

Table 7. System accuracy at glucose concentrations ≥ 100 mg/dL

within ±5%	within ±10%	within ±15%
39/81 (48.2%)	64/81 (79.0%)	76/81 (94.0%)

Table 8. System accuracy with combined glucose concentrations

within ±5 mg/dL ±5%	within ±10 mg/dL ±10%	within ±15 mg/dL ±15%
46/100 (46%)	78/100 (78%)	95/100 (95%)

Table 9. Answers regarding the operation instructions and device application for GL 50 evo are detailed in the questionnaire

		Answer				
	It does not apply	It does not apply in part	Neutral	It does apply in part	It does apply	n
Instructions for use understandable	0	1	8	22	69	100
Instructions easy to follow	0	0	8	18	74	100
Easy to install measuring strips	2	2	3	9	84	100
Measurement results clearly visible	2	1	0	5	92	100
Blood samples easily taken	3	2	4	10	81	100
Error messages understandable	2	0	6	24	68	100
Results understandable	2	1	3	16	78	100
Meter easy to use	1	4	9	25	61	100
Battery replace easy to handle	3	3	7	14	73	100
Error massage explained well Lancing device was simple to use	1 4	4 11	5 6	28 17	62 62	100

Table 10. Answers regarding the operation instructions and device application for GL44 are detailed in the questionnaire

		Answer				
	It does not apply	It does not apply in part	Neutral	It does apply in part	It does apply	n
Instructions for use understandable	0	1	4	20	75	100
Instructions easy to follow	0	1	1	22	76	100
Easy to install measuring strips	2	2	8	13	75	100
Measurement results clearly visible	1	1	1	5	92	100
Blood samples easily taken	1	1	0	15	83	100
Error messages understandable	1	0	6	20	73	100
Results understandable	1	1	1	11	85	99
Meter easy to use	1	0	3	9	86	99
Battery replace easy to handle	1	1	0	17	80	99
Error massage explained well	0	1	1	19	79	100

Results

For (blood) samples with glucose concentrations <100 mg/dl, the deviations from the mean value of the reference samples were calculated and are depicted in mg/dl. System accuracy of the Beurer GL 44 in the performance evaluation by the user.

Summary performance evaluation by the user: The glucose meters Beurer GL 44 and GL50evo meets the criteria of the EN ISO standard 15197: 2015.

- 95% of all measured values are within the acceptance limits defined by EN ISO standard 15197: 2015.
- The majority of subjects assessed the use of the manual and of the glucose meter as easy or very easy to understand and/or apply.

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Conflicts of interest

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 fur Diabetes, Karlsburg, Germany, which carries out studies evaluating blood glucose meter systems on behalf of various companies.

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