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Performance Evaluation of Two Glucometers: RIGHTEST™ GM700S and RIGHTEST™ GM550 from Bionime

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Abstract

Glucometers are medical devices that provide glycemic monitoring. On-site verification of the performance of a glucometer is a requirement of ISO 22870. Thus, the objective of this study was to evaluate the performance of two glucometers (RIGHTEST™ GM700S and GM550). This is a prospective analytical study, carried out at the Biochemistry-Hematology Laboratory of the Fann University Hospital. The parameters studied were venous glycemia and capillary glycemia. The main evaluation parameters used were: repeatability, reproducibility, estimation of accuracy and comparison of methods. The performance criteria used were those of the French Society of Clinical Biology (SFBC) and the DIN EN ISO 15197: 2013 standard. The coefficients of variation of reproducibility (1.88%; 2.2%) and repeatability (1.93%; 1.8%) of the two glucometers complied with the SFBC criteria. The accuracy estimate showed a bias of −15% in accordance with the requirements of DIN EN ISO 15197:2013. The comparison of capillary glycemia values and those obtained with the reference automatons showed satisfactory linearity and good agreement. The glucometers showed acceptable performance compared to the accepted standards. They are suitable for self-monitoring of glycemia levels in diabetic patients.

Keywords

Requirements, Glucometer, Capillary Glycemia, Venous Glycemia, Performance

1. Introduction

Diabetes is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels [1]. It is a public health problem and its prevalence has increased more rapidly in low- and middle-income countries than in high-income countries. Proper diabetes management, therapeutic decisions and patient safety depend on the analytical and clinical performance of the capillary glycemia monitoring system [2]. In fact, the capillary blood sugar values that the patient measures himself using blood sugar meters make it possible to adapt his treatment on a daily basis and to decide on rapid corrective measures in the event of hyper or hypoglycemia [3]. Glucometers, or glycemia meters, are medical devices that monitor glycemia levels by determining the approximate concentration of glycemia [4]. Easy to use, these point of care tests (POCT) allow patients to carry out the test at home, without having to go to their doctor or the hospital. ISO 15197:2013 specifies requirements for systems for monitoring glycemia in capillary blood samples and methods to enable intended users to verify and validate performance. These systems are intended for self-monitoring of diabetes mellitus by patients themselves. ISO 15197:2013 is applicable to manufacturers of these systems as well as to bodies (regulatory authorities and conformity assessment bodies) responsible for evaluating the performance of these systems. In Senegal, the procedure for placing POCT on the market requires the submission of an administrative and technical file in addition to local validation carried out by an approved laboratory. The objective of this study was to evaluate the performance of two Bionime glucometers (RIGHTEST™ GM700S and GM550).

2. Materials and Methods

This is a prospective analytical study, lasting one month from April 1 to 30, 2024. Patient recruitment and biological tests were carried out in the biochemistry laboratory of the Fann University hospital center. Included in this study were patients who came to the laboratory for blood sugar measurement and consented to a capillary sample. Blood samples were taken from the subjects by venipuncture at the level of the elbow crease with a tourniquet. Blood was collected in a sodium fluoride tube for glycemia measurement. The glucometers used in the study for capillary glycemia determination are the RIGHTESTTM GM700S and RIGHTESTTM GM550 (Bionime) which use the enzymes FAD-GDH (flavin-dependent glucose dehydrogenases) and GOD (glucose oxidase), respectively. Venous glycemia measurements were performed using the automated Architect Ci4100 (Abbott) and A15 (biosystems) systems, which were chosen as reference methods in our study. Data recording was performed with Excel software, and exploration was done with XLSTAT 2019. The evaluation parameters used in our study were:

Repeatability: The repeatability test consists of analyzing the same sample (30

dosages) under the following conditions: same operator, same batch of reagents, same instrument, same calibration in the shortest possible time. The control solutions of each glucometer were used.

Reproducibility: The reproducibility test consists of analyzing the same sample (30 dosages) under different conditions by varying at least one of the factors: the operator, the time, the batches of reagents, the calibrations. In our study we made two dosages per day for 15 days and we used the control solutions for each glucometer.

Accuracy estimation: Study of the accuracy of the glucometer method: This consists of determining the blood sugar level 10 times on whole blood of which the glucose content is known beforehand (this glucose content was determined by the reference method used in our study).

Comparison of methods: This involves the simultaneous determination of glycemia by the glucometer and by the reference method covering the measurement interval. We used a total of 30 patients for the comparison study. We used XLSAT software to determine the coefficients of variation, the linear regression lines and Bland Altman graph. The performance criteria used were those of the French Society of Clinical Biology for the comparison of coefficients of variation and the criteria of the ISO 15197:2013 standard for the estimation of accuracy. In this study we used the following batches of test strips and control solutions:

Glucometers	Lots of test strips/Expiration date	Lots of controls
RIGHTEST™ GM700S	Lot of test strips: 212412701 Expiration date: 29/01/2026	Lot: 3700WL20A Expiration date: 19/12/2025
RIGHTEST™ GM550	Lot of test strips: 2123A0903 Expiration date: 08/10/25	Lot: 2WK27A Expiration date: 12/11/2025

3. Results

The repeatability and reproducibility of the glucometers were performed with the supplier's control solutions (GC550 and GC700). For each glucometer (RIGHTESTTM GM700S and RIGHTESTTM GM550), the control solution (GC550 and GC700) was analyzed to determine the glycemia 30 times in a row. The coefficients of variation (CV) obtained were consistent compared to those of the supplier and the SFBC (<5% for substrates and <10% for enzymes) (Table 1).

Table 1. Results of the study of the reproducibility and repeatability of the two glucometers.

	Repeatability		Reproducibility	
	RIGHTEST™ GM700S (FAD-GDH)	RIGHTEST™ GM550 (GOD)	RIGHTEST™ GM700S (FAD-GDH)	RIGHTEST™ GM550 (GOD)
Control solutions	GC700	GC550	GC700	GC550
Number of values	30	30	30	30
Average (g/l)	1.09	0.84	1.08	0.84

Continued

Standard deviation (g/l)	0.019	0.016	0.024	0.01
*CV (%)	1.8%	1.93%	2.2%	1.88%
CV (%) supplier	2.4 %	2.1 %	2.4%	2.1%
Acceptable SFBC limits	<5%	<5%	<5%	<5%

*CV = coefficients of variation; Control intervals: GC700: 0.90 - 1.22 g/l; GC550: 0.72 - 0.98 g/l.

The estimation of the accuracy of the glucometers was carried out with two samples whose glycemia levels were obtained from our reference method. For each glucometer, 10 measurements of the glycemia level of the known sample were carried out under the same conditions using the same glucometer. Then, using the results obtained, we calculated the inaccuracy bias (Table 2).

Table 2. Estimated accuracy of the two glucometers.

Dosage Series	Sample 1 Blood sugar = 0.80 g/l		Sample 2 Blood sugar = 1.26 g/l	
	RIGHTEST™ GM700S (FAD-GDH)	RIGHTEST™ GM550 (GOD)	RIGHTEST™ GM700S (FAD-GDH)	RIGHTEST™ GM550 (GOD)
1	0.80	0.75	1.12	1.21
2	0.78	0.76	1.17	1.23
3	0.71	0.71	1.14	1.20
4	0.75	0.72	1.19	1.20
5	0.71	0.70	1.14	1.30
6	0.75	0.70	1.14	1.21
7	0.70	0.70	1.11	1.30
8	0.72	0.70	1.11	1.20
9	0.72	0.76	1.15	1.18
10	0.71	0.74	1.12	1.19
Averages	0.73 ± 0.03	0.72 ± 0.02	1.13 ± 0.02	1.22 ± 0.04
% Bias	**−8.1%**	**−9.5%**	**−9.7%**	**−3.0%**

The comparison of methods was performed on 30 patient samples covering the measuring range of the RIGHTEST™ GM700S glucometer (FAD-GDH) with a mirror device: Architect Ci4100 (glucose determination by hexokinase method). The linear regression diagram shows the existence of a proportionality relationship between Architect Ci4100 and the glucometer with a variability percentage of 82.4% ($R^2 = 0.824$) (Figure 1).

The comparison of methods was performed on 30 patient samples covering the measurement range of the RIGHTEST™ GM550 glucometer (GOD) with a mirror device: A15, Biosystem (Glucose determination by the glucose oxidase method). The linear regression diagram shows the existence of a proportionality relation-

ship between the A15 machine and the GM550 glucometer with a variability percentage of 82.7% ($R^2 = 0.827$) (Figure 2).

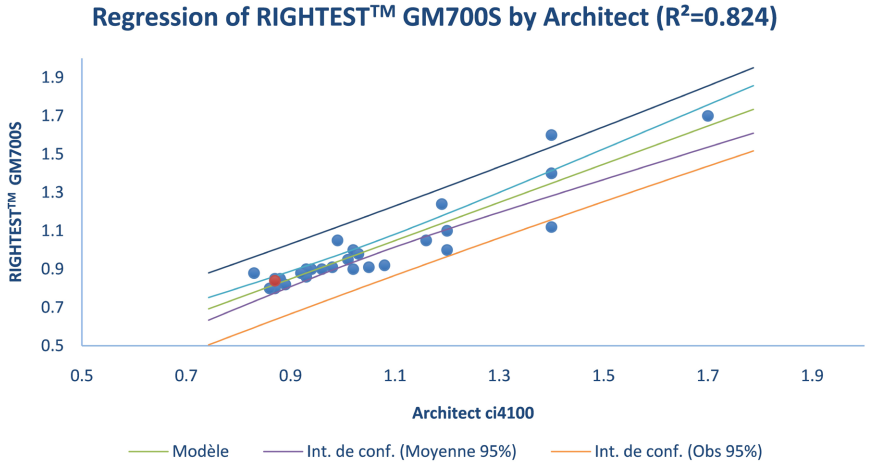

Figure 1. Linear regression line of RIGHTEST™ GM700S by Architect Ci4100 (Abbot).

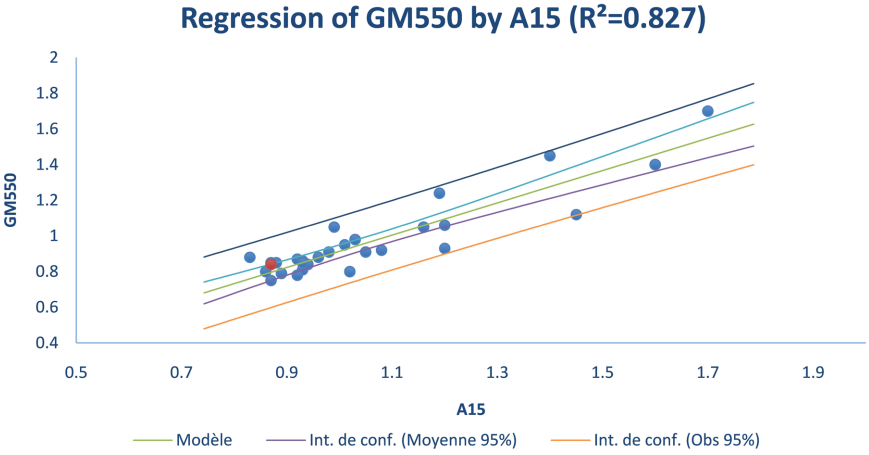

Figure 2. Linear regression line of RIGHTEST™ GM550 by A15 Biosystems.

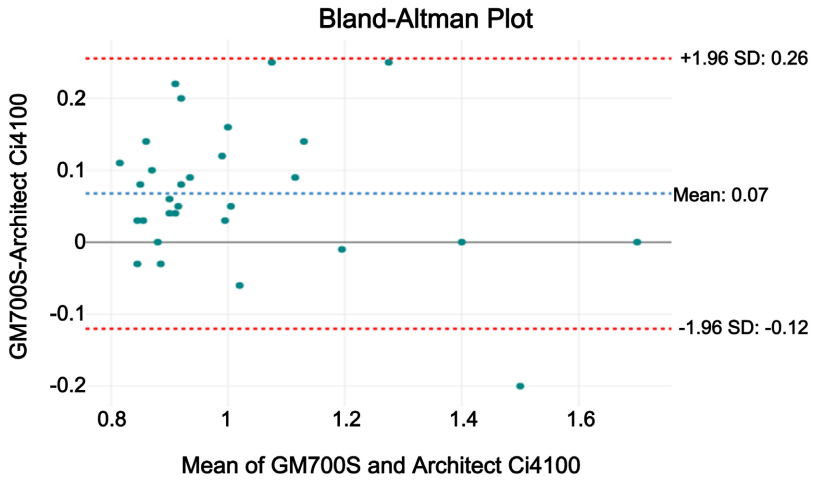

Figure 3. Bland and Altman graph (RIGHTEST™ GM700S/Architect Ci4100).

The assessment of the agreement between glucometers and reference methods by the Bland-Altman plot shows a mean systematic deviation (bias) of 0.07 with 95% CI (−0.12 - 0.26) for RIGHTEST™ GM700S/Architect Ci4100 (Figure 3).

The assessment of the agreement between glucometers and reference methods by the Bland-Altman plot shows a mean systematic deviation (bias) of 0.09 with 95% CI (−0.09 - 0.28) respectively for RIGHTESTTM GM550/A15 Biosystems (Figure 4).

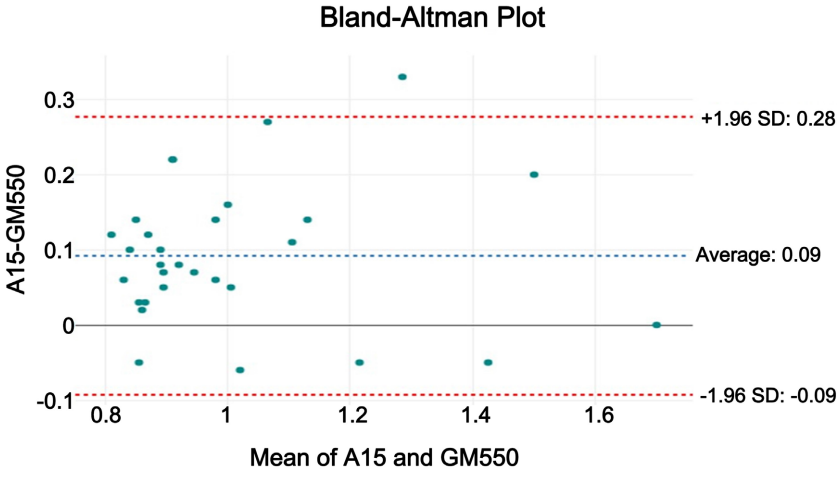

Figure 4. Bland and Altman plot (RIGHTEST™ GM550/A15 Biosystems).

By evaluating and comparing the two glucometers, we found the existence of a proportionality relationship with a variability percentage of 98% ($R^2 = 0.980$) (Figure 5).

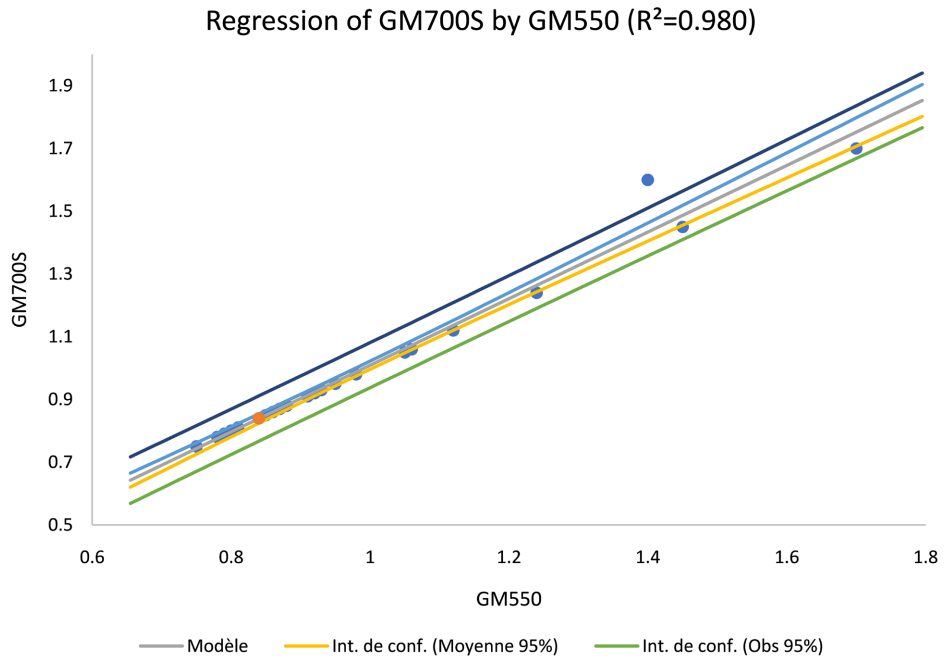

Figure 5. Linear regression line of RIGHTEST™ GM700S by RIGHTEST™ GM550.

The assessment of the concordance between the two glucometers by the Bland-Altman plot shows a mean systematic deviation (bias) of 0.01 with 95% CI (−0.06 - 0.08) (Figure 6).

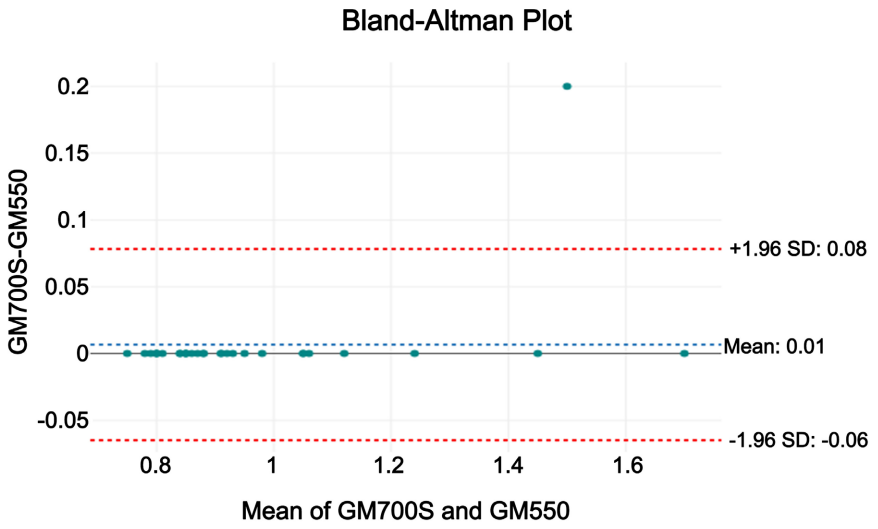

Figure 6. Bland and Altman chart (RIGHTESTTM GM700S/RIGHTESTTM GM550).

4. Discussion

The evolution of diabetes is marked by the development of chronic complications which, in addition to affecting health, also affect the quality of life of patients [5]. Self-monitoring of glycemia using glucometers as an essential part of diabetes management is increasing because it is a simple to implement and cost-effective approach. Glucometer measurements are used to guide patients in adjusting insulin doses in type 1 diabetes, and many patients with type 2 diabetes also use a glucometer to monitor their glycemia levels [6]. Thus, the analytical performance of the glucometer is of considerable importance because serious inaccuracies, imprecisions or interferences can lead to inadequate treatment and adverse reactions. On-site verification of glucometer performance is a requirement of ISO 22870:2016 [7]. This standard provides specific requirements for point-of-care medical biology examinations and is intended to be used in conjunction with ISO 15189. The analytical performance of these glucometers should be evaluated initially before use and over time during use to ensure the reliability of patient results. The RIGHTESTTM GM700S and RIGHTESTTM GM550 glucometers (Bionime) use the enzymes FAD-GDH (flavin-dependent glucose dehydrogenase) and GOD (glucose oxidase) respectively for the determination of capillary glycemia. Repeatability and reproducibility studies carried out using the supplier's control samples showed coefficients of variation that were generally satisfactory for both glucometers: RIGHTESTTM GM700S (CV repeatability = 1.8%; reproducibility = 2.2%) and RIGHTESTTM GM550 (CV repeatability = 1.93% CV reproducibility = 1.88%). According to the limits established by SFBC the coefficient of variation must not exceed 5% for substrates and 10% for enzymes [8]. In a similar

study by Fonfrede *et al.*, the comparison of the results of 5 readers and deviation from the laboratory venous glycemia showed for all glucometers CVs <7.5% and <10% respectively for repeatability and reproducibility [9]. Compared to the SFBC specifications and the CVs declared by the supplier we can deduce that the results of repeatability and reproducibility are satisfactory with both glucometers. The accuracy estimation revealed biases of −8.1% and −9.5% for a glycemia concentration of 0.80 g/l respectively for RIGHTESTTM GM700S et RIGHTESTTM GM550. For a concentration of 1.26 g/l the biases were −9.7% and −3.0% respectively for RIGHTESTTM GM700S et RIGHTESTTM GM550. In a study on the analytical performance of glucometers used for routine self-monitoring of glycemia in diabetic patients, Solnica *et al.*, 2003 found a bias of less than 5% with the exception of the One TouchR glucometer [10]. The results of our study meet the requirements of the ADA [11] which recommend that the accuracy of a glucometer be <5% of the measured value, however, many glucometers do not meet this criterion. According to the ISO 15197:2013 standard, the minimum requirements that a capillary glycemia measuring system must meet are established. These criteria are based on the difference between the value given by the reader and that measured on a reference system, evaluating the deviation according to the glycemic level. Despite this underestimation, the glucometer meets the ISO 15197:2013 criteria for glycemia levels below and above 100 mg/dL:

- For glycemia levels < 100 mg/dL, 95% of the measurements were within the ±15 mg/dL limit, thus meeting the requirements of the standard.

- For glycemia levels > 100 mg/dL, 100% of the measurements were within the ±15% limit, demonstrating good compliance of the glucometer.

Linearity assessed between glucometers and reference methods gave r(2) values of 0.824 and 0.827 respectively for RIGHTESTTM GM700S et RIGHTESTTM GM550. Our results are similar to those of solnica *et al.*, 2003, who found r(2) values of 0.86 to 0.98 with eight glucometers studied. Bland and Altman plots and linear regression diagrams show no significant difference between reference methods and glucometers. In our study we found lower glycemia values with glucometers compared to the reference methods. Indeed, many authors have reported that the technology and methods of glucometers are less accurate than those used in laboratory automation [12]. Comparing the two glucometers we found a mean systematic deviation (bias) of 0.01 with 95% CI (−0.06 - 0.08). Comparing the mean between the two glucometers by the student t test shows a non-significant difference ($p = 0.910$) even if the two glucometers use different principles. Indeed, the RIGHTESTTM GM700S glucometer uses flavin adenine dinucleotide-dependent glucose dehydrogenase (FAD-GDH) which is independent of oxygen (interference), unlike the principle of the RIGHTESTTM GM550 glucometers which uses glucose oxidase.

5. Conclusion

Strict control of glycemia is important to reduce diabetes complications, the use

of glucometers for self-monitoring of glycemia remains one of the fundamental modalities of treatment. The on-site verification we carried out showed good performance against the specifications of the SFBC and ISO 15197:2013 standard. Thus, Bionime RIGHTEST™ GM700S and RIGHTEST™ GM550 glucometers are suitable systems for monitoring glycemia in diabetic patients.

Consent

Written and informed consent was obtained from each.

Conflicts of Interest

The authors have declared no conflict of interest.

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