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Analytical And Clinical Accuracy Of A Locally Manufactured Glucose Test Strips: A Post-Marketing Evaluation Against ISO 15197:2013 In Algeria

Houssem BAGHOUS, Samir AOUICHE, Said AZZOUG, Kamel GASMI, Said GARI

(Department Of Algiers University Hospital & Laboratory Of Endocrinology And Metabolism Algiers 1 University. Diabetology Department University Hospital CHU Mustapha Bacha, Algiers, ALGERIA)
(Medical Affairs Department, Vital Care SPA, Production, Distribution And Logistics, Algiers, ALGERIA)

Abstract:
Background*: Clinical studies and mathematical simulation models have demonstrated that measurement error and systematic bias in capillary blood glucose readings affect glycemic control, hypoglycemia rates, insulin dosing decision and calibration of no factory calibrated continuous glucose monitoring systems. The emergence of local glucose test strips manufacturing in Algeria has the potential to improve patient access to self-monitoring and to reduce healthcare expenditures for health systems. However, the absence of independent post marketing validation of the blood glucose monitoring system raises concerns about glycemic measurement accuracy and the risk for clinical decision-making errors. This study represents an independent post-marketing evaluation of a single-brand, locally manufactured blood glucose test strip in Algeria, with the primary aim to assess its analytical and clinical accuracy in accordance with ISO 15197:2013 criteria, and the secondary aim to characterize glucose concentration-dependent bias across four predefined glycemic measurement ranges.*
Materials and Methods*: This investigator-initiated, prospective, single-center study was conducted in a clinical setting. Capillary blood samples were collected from 180 patients living with type 1 or type 2 diabetes. Glucose concentrations were measured using six imported blood glucose meters of the same model from a single manufacturer with three different batches of locally manufactured glucose test strips from the same supplier, yielding 1080 total measurements. All measurements were compared against the Yellow Springs Instruments 2500 analyzer (YSI 2500) as reference method . We evaluated analytic performance according to ISO 15197:2013 requirement and assessed glucose-bias directionality and magnitude across four different glycemic ranges (< 80 mg/dL, 80 –129 mg/dL, 130–179 mg/dL, and ≥ 180 mg/dL) by using stratified Passing-Bablok regression. Clinical risk of measurement error was evaluated using the Parkes Error Grid and two complementary advanced error grids validated by the Diabetes Technology Society.*
Results*: 98.7% (1066/1080) measurements met ISO 15197:2013 analytical accuracy requirements. All glucose readings (100%) fell within Zone A of the Parkes Error Grid, indicating clinical accurate measurements with no effect on clinical action and no decision-making risk. The two error grids implemented by the Diabetes Technology Society showed that 98.8% - 97.7% of values fell within no risk zone. The overall systematic mean relative bias was 0.1 %. The mean absolute relative difference (MARD) was 7.1 % overall, higher in hypoglycemic range (15.2%) than hyperglycemic(6.0 %) and euglycemic range (4.9 %). Stratified analysis demonstrated a glucose concentration-dependent bias pattern, with overestimation at hypoglycemic levels (< 80 mg/dL:+2.03 mg/dL) and underestimation at hyperglycemic level(≥ 180 mg/dL:-10.11 mg/dL)*
Conclusion: *The locally manufactured glucose test strips brand evaluated in this study demonstrated full compliance with the analytic and clinical accuracy ISO 15197:2013 requirements. However, this post-marketing study revealed a clinically relevant glucose concentration-dependent bias pattern, that was not captured by aggregate ISO 15197 compliance metrics. Glucose range-stratified comparative analysis represents an informative evaluation method, to support evidence-based device benchmarking device selection and optimize patient safety in clinical practice.*

Key Word: *Blood glucose meter (BGM), analytic accuracy, clinical accuracy, bias trends, International Organization for Standardization (ISO) 15197:2013, PARKES error grid (PEG), Surveillance error grid (SEG), Diabetes technology society (DTS) grid, Mean Absolute Relative Difference (MARD), Standard Deviation of Relative Difference (SDRD).*

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I. Introduction

Diabetes is a growing global public health concern, with prevalence increasing both in developed and developing countries [1,2]. The majority of adults with type 2 diabetes (80%) and nearly 20% to 29% of individuals with type 1 diabetes live in low and middle-income countries [3,4].The highest percentage increases in the total number of adults with diabetes across all International Diabetes Federation (IDF) regions by 2045 are projected in Africa, with an increase of 143%, and in the Middle East and North Africa (MENA) region, with an increase of 96% [5]. The prevalence of type 2 diabetes in Algeria was estimated at 14.4% among individuals aged 18-69 years, and the country ranks among the top ten worldwide for type 1 diabetes incidence [5-6].

Within the Global Diabetes Compact (GDC) framework launched by the World Health Organization (WHO) in 2021, key targets by 2030 include achieving good glycemic control in at least 80 % of diagnosed patients and ensuring 100 % access to affordable insulin and self-monitoring of blood glucose for all individuals with type 1 diabetes [7]. However, published data reveal significant global inequalities in the accessibility and affordability of SMBG devices [8,9].

Self-monitoring of Blood Glucose (SMBG) is a cornerstone of diabetes management, enabling patients and healthcare providers to make informed therapeutic decisions, adjust insulin dosages, and prevent acute complications including hypoglycemia and diabetic ketoacidosis [10,11]. The clinical effectiveness of SMBG is dependent not only on the analytical accuracy of the blood glucose monitoring system used but also on the direction of systematic bias and its magnitude [12,13].

The International Organization for Standardization (ISO) 15197:2013 establishes performance requirements for in vitro blood-glucose monitoring systems (BGMS) intended for self-testing [14]. Nevertheless, several independent post-market evaluations, have demonstrated inconsistent performance among BGMS approved in Europe and the United States of America [15,16]. The ISO 15197:2013 accuracy criteria assess aggregate performance without requiring the evaluation of concentration-dependent bias directionality across clinically relevant glycemic ranges and specifically hypoglycemic range [17,18,19]. The American Diabetes Association (ADA) clinical standards of care have emphasized a concern about the accuracy variability between glucose monitoring systems [20].

An emerging industrial capacity for manufacturing blood glucose test strips, developed through international technology transfer, is currently available in Africa region [21]. In Algeria, locally manufactured blood glucose test strips have entered a market comprising six commercially available BGMS brands in 2021, none of which have been subjected to independent post-marketing evaluation. The transition from imported to locally-manufactured medical devices introduce critical questions regarding analytical performance, clinical equivalence, and patient safety that extend beyond standard regulatory compliance. Independent post-marketing BGMS surveillance remains scarce in resource-limited settings, particularly in Algeria.

The primary objective of this post-marketing study was to independently evaluate the analytical and clinical accuracy of a BGMS integrating one brand of glucose test strips locally manufactured, in accordance with ISO 15197:2013 criteria. Secondary objectives included quantification of overall systematic bias, mean relative bias, and Mean Absolute Relative Difference (MARD); assessment of glucose-dependent bias directionality and magnitude across four predefined glycemic ranges (< 80, 80–129, 130–179, and ≥ 180 mg/dL) using stratified Passing-Bablok regression and Bland-Altman analysis; and evaluation of clinical accuracy using two complementary advanced error grid analyses validated and published by the Diabetes Technology Society (DTS) [22,23,24,25].

II. Material And Methods

This investigator-initiated, prospective, single-center study was conducted at the Diabetology Clinic of Mustapha University Hospital in Algeria between November and December 2022. The study was approved by an independent Ethics committee dated on 24-10-2022 and health authority on 07-11-2022 number 013/VIT/OBS/DM-DIV/2021.

Sample size was determined based on ISO 15197:2013 requirements for minimum 100 samples with specific distribution across glycemic concentration ranges. Patients living with diabetes who attended the clinic were consecutively screened for eligibility during a defined period. A total of 180 patients were enrolled after providing written informed consent prior to undergoing the study procedures.

Eligible participants were adults older than 19 years with either type 1 or type 2 diabetes and hematocrit levels between 20% and 60%. Exclusion criteria included patients with known hematological disorders, cancer, hypoxia, pregnancy, psychiatric disorders or any condition that could impact blood glucose levels. Patients who had taken ascorbic acid, ibuprofen or acetaminophen within 48 hours before capillary sampling, were excluded to avoid any interferences or confounding factor for BGMS measurements.

Procedure methodology

The manufacturer provided six plasma-calibrated blood glucose monitors (Vital check® MM-1200) imported from Tianjin EMPECS Medical Device co Ltd P.R.C and three glucose test strips lots (Vital check®

MS-2) manufactured in Algeria and randomly selected. The glucose monitors are designed for in vitro diagnostic use by patients living with diabetes. The devices use test strip containing glucose oxidase enzyme which enables highly selective measurement of glucose in fresh capillary blood samples. Each lot consisted of 13 vials corresponding to 650 glucose test strips. To ensure a comprehensive assessment and address any potential within lot variability, vials of glucose test strips were changed every 10 subjects for each lot.

Two levels of control solution, supplied by the manufacturer, were used to verify proper function of the blood glucose monitoring system. Before testing capillary blood samples, daily precision verification was carried out using the two control solutions, one at low glucose level and the other at high glucose level, to promptly identify and address any deviations or inconsistencies in the system's performance. The tolerances were a pooled standard deviation within 7 mg/dL for low glucose levels and a pooled coefficient of variation ≤ 5% for levels above 100 mg/ dL.

The YSI 2500 Analyzer, manufactured by YSI Incorporated, Yellow Springs, USA, which is based on the glucose oxidase method, was used as the comparative and reference method for measuring glucose concentration. This analyzer replaced the YSI 2300 analyzer ,which had been used for a long time to assess device accuracy but it is no longer available or in production. This YSI-2500 analyzer demonstrated linearity within ±5% and precision of ±2%, meeting accepted performance standards for glucose measurement, establishing its suitability as a reference and a practical alternative [26,27,28,29]. All reference measurements were performed per manufacturer specifications with appropriate calibration verification .

Data collection adhered strictly to protocols designed to evaluate glucose meter performance under clinically relevant conditions. We used Case Report Form (CRF) to collect details on all participants demographics (age, sex, diabetes type, diabetes duration, Hemoglobin A1c level and hematocrit), capillary blood sample collection time, and device-specific information such as test strip lot numbers and meter serial numbers.

The case report form recorded glucose measurements performed with each BGMS and test strip lot and included paired values from the Yellow Springs Instruments 2500 analyzer.

On the day of the performance evaluation, qualified personnel obtained capillary blood samples from participants according to standardized procedures (Fingertip capillary blood sampling). A total of 400 µL fresh capillary whole blood samples was collected from each patient's fingertip under hygienic conditions using SARSTEDT company's Microvette 500 Lithium Heparin (SARSTEDT AG & Co. KG Sarstedtstraße, Nümbrecht GERMANY). Each Finger-prick capillary blood sample collected was divided into two aliquots.

The first aliquot was centrifuged within 5 minutes of collection and glucose concentration was measured using the YSI 2500 analyzer to establish the reference value. The second one was used for all measurements with SMBG devices. We used six glucose meters to minimize the time between replicate measurements. For each lot, glucose testing was conducted using two BGMS , each performing 180 measurements, yielding 360 readings per lot. Following these measurements, the second aliquot was centrifuged , and glucose level in plasma was measured using the YSI 2500 analyzer to ensure consistency and no discrepancy with the first aliquot. Capillary blood samples exhibiting a significant deviation between the first and second measurement, defined as a difference > 4 mg/dL for glucose concentrations below 100 mg/dL or > 4% for concentrations at and above 100 mg/dL were excluded from final analysis.

To comply with ISO 15197:2013 requirements, capillary whole blood samples were categorized into seven glucose concentration ranges based on YSI 2500 measurements. To ensure sufficient samples in the lowest and highest concentration intervals, samples were obtained either by incubation to achieve target low glucose concentrations via natural glycolysis or by supplementation with glucose solution to achieve target high glucose concentrations.

Trained operators recorded paired results immediately. This methodology generated the paired dataset for calculating analytic accuracy and to draw the PARKES Error Grid analysis across the full glycemic range. The tests were performed under controlled ambient temperature (23 ± 5 °C).

The procedures in the study follow the Helsinki declaration guidelines laid down in 2000.

Statistical analysis

Demographic data and clinical characteristics were recorded in a Microsoft Excel spreadsheet. Descriptive statistics were calculated for all quantitative variables, reported as mean ± standard deviation (SD), and categorical variables were summarized as frequencies and percentages.

Analytical accuracy was assessed according to ISO 15197:2013 standard by comparing each blood glucose monitor measurement against the corresponding YSI 2500 reference value. For glucose concentration below 100 mg/dL, absolute deviation was calculated in mg/dL , while for values at and above 100 mg/dL, percent of relative deviation was applied. ISO 15197:2013 requires that at least 95% of results fall within ±15 mg/dL of the reference for concentrations below 100 mg/dL and within ±15% for concentrations at or above

100 mg/ dL . For clinical accuracy , 99% of results shall fall within zones A and B of the Parkes Error Grid (EGA) for type 1 diabetes.

Passing-Bablok regression was used to quantify proportional and fixed systematic bias between BGMS and YSI 2500 measurements. A slope with 95% confidence interval excluding 1 was interpreted as evidence of proportional bias; an intercept with 95% confidence interval excluding 0 indicated fixed bias. Agreement between BGMS and YSI 2500 was assessed using modified Bland-Altman analysis : Overall bias (mean difference), mean relative bias, and 95% limits of agreement (mean ± 1.96 SD) are reported.

The mean absolute relative difference (MARD), standard deviation of relative difference (SDRD), Surveillance Error Grid (SEG) and Diabetes technology science Error Grid (DTS EG) analyses were obtained after data upload in a comma -separated values (CSV) file on the validated online software available on the website of Diabetes Technology Society (DTS; https://www.diabetestechnology.org/dtseg/).

III. Result

Among 195 patients initially screened ,180 met the inclusion criteria and were enrolled in the study. Fifteen patients were excluded due to insufficient data or unstable plasma sample. Our study population included 100 men (55.6%) and 80 women (44.4%) . The mean age of patients was 52.0 ± 15.5 years . One hundred thirty-five patients (75.0 %) were living with type 2 diabetes and forty-five (25.0 %) with type 1 diabetes. Mean hematocrit was 39.5 ± 3.9 % .The mean duration of diabetes was 10.5 ± 8,9 years, and the mean hemoglobin A1c (HbA1c) was 8.5 ± 2.6 %. Ninety-one patients (50.6%) were receiving insulin therapy.

Intermediate precision was evaluated across the three-test strip lots and the six BGM devices over 19-day period. At glucose concentration below 100 mg/ dL, the mean standard deviation was 3.4 mg/dL (range: 2.73- 4.08 mg/dL). At concentrations ≥ 100 mg/dL, the mean coefficient of variation (CV) was 4.41% (range: 3.7- 4.9%). All values were within the tolerance limits specified by the manufacturer , confirming inter-device agreement across the six glucometers evaluated.

The 180 fresh capillary blood samples covered a broad glucose concentration range from 22.3 mg/dL to 520 mg/dL as measured by YSI 2500 reference analyzer . One hundred thirty-six (75.6%) had glucose concentrations at or above 100 mg/dL, the remaining forty-four (24.4%) had glucose concentrations below 100 mg/dL. To ensure the performance evaluation covers the full clinically relevant glycemic range (from hypoglycemia to severe hyperglycemia), glucose concentrations were categorized into seven groups. To satisfy the ISO 15197:2013 minimum distribution requirement, 24 samples (13.3%) were modified:18 samples (10.0 %) in the hypoglycemic range below 80 mg/dL and 6 samples (3.3 %) in the 300 – 400 mg/dL range . Recruiting patients with extreme values was challenging ; categories 2 (≤ 80 mg/dL) and 7 (> 400 mg/dL) each comprised only 3.8% of the total sample, slightly below the 5% target. Despite this minor deviation, the final sample distribution remains representative of the ISO requirements to support the evaluation of the blood glucose monitoring system. The final sample distribution across all glycemic interval specifications for the analytical validation studies is presented in Table n° 1.

Table no 1: Distribution and proportion of blood glucose concentrations samples

Glucose concentrations category	Number of capillary samples (%) per ISO 15197 : 2013	**Glucose concentrations (mg/dl)** per ISO 15197 : 2013	**Number of patients**
1	5%	≤50	**7 (3.8%)** (Modified samples)
2	15%	>50-80 At least 8 unaltered samples between >50 and 80 mg/dl	**25 (13.8%)** (9 modified samples)
3	20%	> 80-120	**44 (24.4%)**
4	30%	>120-200	**50 (27.7%)**
5	15%	>200-300	**27 (15%)**
6	10%	>300-400 At least 5 unaltered samples between >300 and 400 mg/dl	**20 (11.1%)** (4 modified samples)
7	5%	>400	**7 (3.8%)**
Total capillary samples	**100%**		**180**

Analytical accuracy

A total of 1080 measurements were obtained across the three-test strip lots (360 measurements per lot). The mean glucose concentration as measured by BGMS was 169.3 mg/dL (range: 28.0 –507.0 mg/dL), compared with 173.0 mg/dL (range: 22.3–520.0 mg/dL) by the YSI 2500 . Paired t-test analysis revealed a mean bias of −3.72 mg/dL (SD 14.24 mg/ dL; 95% CI: −4.56 to −2.87; $p < 0.0001$), corresponding to relative bias of -2.15%, indicating a small but statistically significant systematic underestimation by the glucometer.

ISO 15197:2013 accuracy requirement was met for 1066 of 1080 measurements (98.7%). For glucose concentrations below 100 mg/dL, 257 of 264 measurements (97.34%) fell within ±15 mg/dL of the reference value across all three lots (Lot A: 85/88, 96,59% ; B: 86/88, 97.72%; Lot C: 86/88, 97,72 %). For concentrations at or above 100 mg/dL, 809 of 816 measurements (99.14 %) fell within ±15% of the reference value (Lot A: 271/272, 99.63% ; Lot B: 270/272, 99.26% ; Lot C: 268/272, 98.52%). These results are summarized in Table no 2.

Table no 2: Analytic accuracy for each lot results and all three lots combined as per ISO 15197:2013 criteria

Glucose concentration < 100mg/dL	**Number of results within specified limits (%)**		
	± 5 mg/dL	**± 10 mg/dL**	**± 15 mg/dL**
Lot A (BWF3057*) Number of measurements (n= 88)	(42/88) 47,72%	(73/88) 82,95%	(85/88) 96,59 %
Lot B (BWH 2771*) Number of measurements (n= 88)	(43/88) 48.86 %	(74/88) 84,09%	(86/88) 97,72%
Lot C (BWH2772*) Number of measurements (n= 88)	(37/88) 42,04%	(69/88) 78,40%	(86/88) 97,72%
Three lots combined Number of measurements (= 264)	(122/264) 46,21%	(216/264) 81,81%	(257/264) 97,34%
Glucose concentration ≥ 100mg/dL	**Number of results within specified limits (%)**		
	± 5%	**± 10 %**	**± 15 %**
Lot A (BWF3057) Number of measurements (n= 272)	(155/272) 56,98%	(241/272) 88,60%	(271/272) 99,63%
Lot B (BWH 2771) Number of measurements (n= 272))	(139/272) 51,1%	(241/272) 88,60%	(270/272) 99,26%
Lot C (BWH2772) Number of measurements (n= 272))	(137/272) 50,36%	(234/272) 86,02%	(268 /272) 98,52%
Three lots combined Number of measurements (n= 816)	(431/816) 52,81%	(716/816) 87,74%	(809/816) 99,14%

* number of glucose test strip lot

All three lots individually exceeded the 95% compliance threshold required by ISO 15197:2013, yielding a combined overall accuracy of 98.7% across the full evaluated glucose (22.3-520.0 mg/dL) and hematocrit (26.2-51.0%) ranges

Clinical accuracy

All 1080 measurements (100%) fell within Zone A of the Parkes Error Grid Analysis for type 1 diabetes, indicating no clinically significant risk of erroneous treatment decisions across the entire measurement range. No measurements were classified in zones B, C, D, or E. The distribution of paired measurements is shown in figure no1.

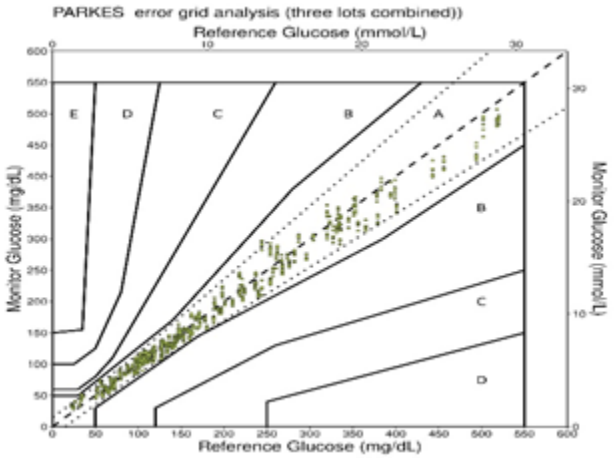

Fig 1 : Parked error grid : Distribution of 1080 paired measurements comparing BGMS with YSI 2500 reference values. axis denotes: YSI 2500 reference glucose (mg/dl) and Y axis denotes: Glucose monitor (mg/dl). Zone A, clinically accurate (no effect on clinical action); zone B, clinically acceptable (altered clinical action-little or no effect on clinical outcome); zone C, altered clinical action-likely to affect clinical outcome; zone D, altered clinical action-may have significant medical risk; and zone E, altered clinical action-may have dangerous consequences

Regression and agreement analysis

Linear regression of BGMS against YSI 2500 reference values yielded the equation y = 0.9338x + 7.74 (R^2 = 0.9857), indicating a linear relationship across the full measurement range of 22.3–520.0 mg/dL (Figure no 2). The slope of 0.9338 reflects a proportional bias of approximately −6.62% (95% CI:−7.30% to −5.95% p < 0.0001), indicating progressive BGMS underestimation at higher glucose concentrations. The positive intercept of 7.74 mg/dL (95% CI: + 6.37 to + 9.12; p < 0.0001) reflects a constant positive bias at lower glucose concentrations.

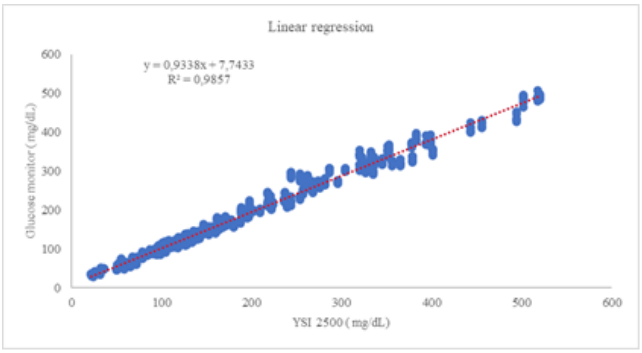

Fig 2: Linearity of glucose concentrations measured for three lots combined

Bland-Altman analysis showed a mean systematic negative bias of −3.72 mg/dL (95% CI: -4.65 to -2.87 mg/dL) relative to the YSI 2500. The 95% limits of agreement (LoA) were −31.62 to +24.19 mg/dL. The asymmetry of these limits, with the lower limit of agreement substantially wider than the upper is consistent with proportional bias . This indicates that absolute measurement error increases with glucose concentration, confirming a systematic, concentration-dependent bias. (Figure no 3).

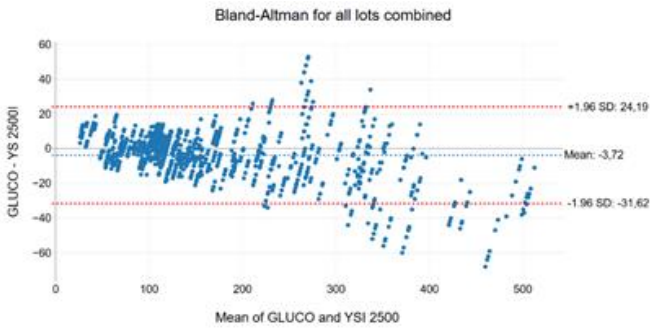

Fig 3 : Bland Altman plot for the three lots : Bland Altman plots between BGMS and YSI 2500. BGMS values minus YSI 2500 value for each participant (y-axis) is plotted against the mean of the two measurements/2 (x-axis) and are represented by the blue dots. The horizontal doted dark line through zero is the line of perfect agreement between the two measurements; the parallel solid blue line is the mean bias. The plot shows the difference between BGMS and YSI 2500 measurements against the mean of both methods, with 95% limits of agreement (−31.62 to +24.19 mg/dL).

The modified Bland Altman version plots the relative (percentage) difference against the reference value to show whether the proportional (relative) bias is constant across the range or error is proportional to glucose concentration. The absolute differences between the BGMS and YSI method grow larger at higher glucose concentrations indicating a proportional error.

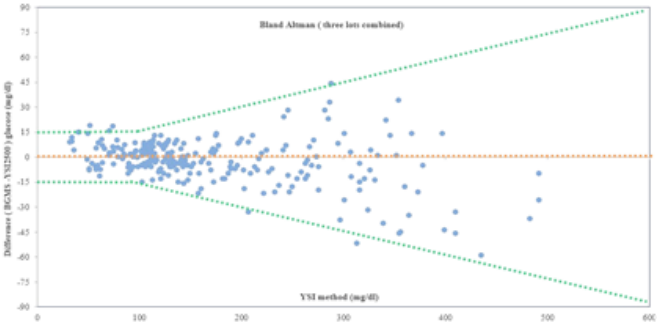

Fig 4 : Modified Bland Altman plot for the three lots : BGMS values minus YSI 2500 value for each measurement (y-axis) is plotted against the YSI 2500 measurement value (x-axis)

The overall Mean Absolute Relative Difference (MARD) between BGMS results and YSI 2500 measurements was 7.1%, with a Standard Deviation of Relative Difference (SDRD) estimated to 10.7% (95% limits of agreement: −20.9% to +21.1%). MARD varied across predefined glycemic ranges as detailed in Table no3 . The highest MARD was observed in the hypoglycemic range below 80 mg/dL (MARD: 15.2%). The overall mean relative bias across the full measurement range was 0.1%.

Table no 3: Analytic accuracy, systematic bias and MARD across different blood glucose levels

Glucose range (mg/dL) Number of measurements (n=)	< 80 n=132	≥80-130 n=162	>130-<180 n=132	≥ 180 n=234
Bias	7.9%	0.6%	-2.6%	-2.9%
MARD	15.2%	4.9%	4.9%	6%
SDRD	19.6%	6.1%	5.3%	6.6%
Lower 95% Limit of Agreement (%)	-30.7	-11.4	-13.0	-15.9
Upper 95% Limit of Agreement (%)	46.5	12.6	7.9	10.2%

Stratified accuracy by glycemic range

Passing-Bablok regression for all three combined lots yielded a slope of 0.9358 (95% CI: 0.9323-0.9395) and an intercept of 6.44 (95% CI: 5.78-7.04). We observed a close agreement between Ordinary Least Squares Regression and Passing-Bablok regression.

Stratified analysis showed that BGMS accuracy varies with glucose concentration (table no 4). In the hypoglycemic range (< 80 mg/dL, n = 192), the BGMS demonstrated a positive bias of +2.03 mg/dL (+3.58%), and Passing-Bablok regression yielded a slope of 0.76 (95% CI: 0.702–0.822), indicating significant proportional bias . In the near-normoglycemic range (80–129 mg/dL, n = 318), bias was negligible (+ 0.45 mg/dL; p = 0.227) and ISO compliance reached 100%. In the 130–179 mg/dL range (n = 192), Passing-Bablok regression showed no demonstrable systematic or proportional bias. In the hyperglycemic range (≥ 180 mg/dL, n = 378), underestimation was most pronounced (−10.11 mg/dL; −3.41%), with the widest limits of agreement (−49.63 to +29.40 mg/dL), consistent with the concentration-dependent proportional bias identified in the overall Bland-Altman analysis (r = −0.457).

Despite these concentration-dependent differences, all four ranges exceeded the ISO 15197:2013 minimum 95% compliance threshold (range: 96.35%–100%).

Table no 4: shows results of Passing Bablok for each glucose range and overall range of glucose

Glucose concentration range	< 80 mg/dL	80–129 mg/dL	130–179 mg/dL	≥ 180 mg/dL	OVERALL
Number of measurements	192	318	192	378	1,080
Mean Bias	+ 2.03 mg/dL	+ 0.45 mg/dL	− 3.77 mg/dL	−10.11 mg/dL	−3.72 mg/dL
Relative Bias	+3.58%	+0.42%	−2.50%	−3.41%	−2.15%
Standard Deviation difference (mg/dL)	7.78	6.69	8.08	20.16	14.24
Upper Low Agreement (mg/dL)	+17.27	+13.56	+12.07	+29.40	+24.19
Lower Low Agreement (mg/dL)	−13.21	−12.65	−19.61	−49.63	−31.62
p-value	0.0004	0.2269 (NS)	<0.0001	<0.0001	<0.0001
Passing Bablok Slope	0.76	0.8858	1.0476	0.9043	0.9358
ISO 15197 %	**96.35%**	**100%**	**100%**	**98.15%**	**98.70%**

Clinical risk assessment

Clinical risk associated with measurement error was evaluated using two validated Diabetes Technology Society grids . The Surveillance Error Grid (SEG) analysis classified 97.7% of measurements in the no-risk zone and 2.3% in the mild-risk zone, with 100% of measurements falling within the combined clinically acceptable range (Figure no 5). The DTS Error Grid analysis similarly showed that 98.8% of measurements were in the no-risk zone and 1.2% in the slight-risk zone. (Figure no 6).

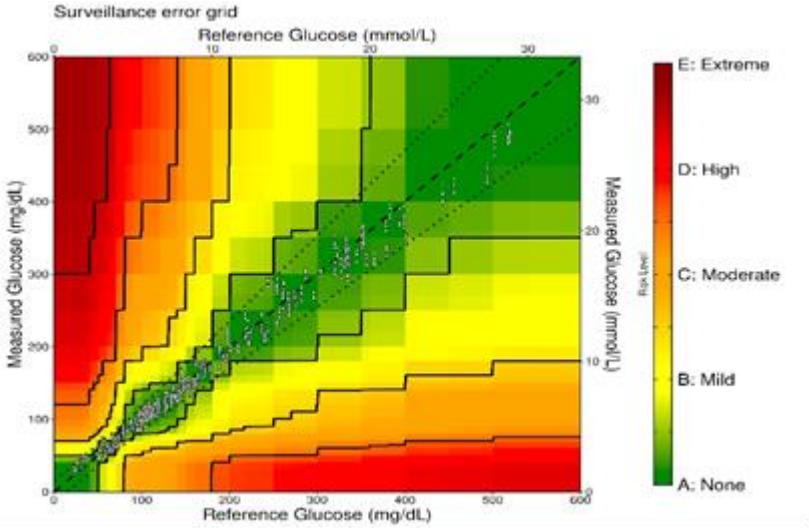

Figure 5: Surveillance error grid (SEG): Surveillance error grid analysis to evaluate the clinical risk associated with BGMS inaccuracy. The level of clinical risk associated with each pair of BGMS and reference results is represented by a color on the grid

The DTS Error Grid used in this study represents the most current and clinically validated tool for assessing glucose monitor accuracy. Unlike the Parkes Error Grids, it reflects contemporary diabetes management practices, and classifies errors based on their actual clinical risk to patients rather than purely statistical deviation

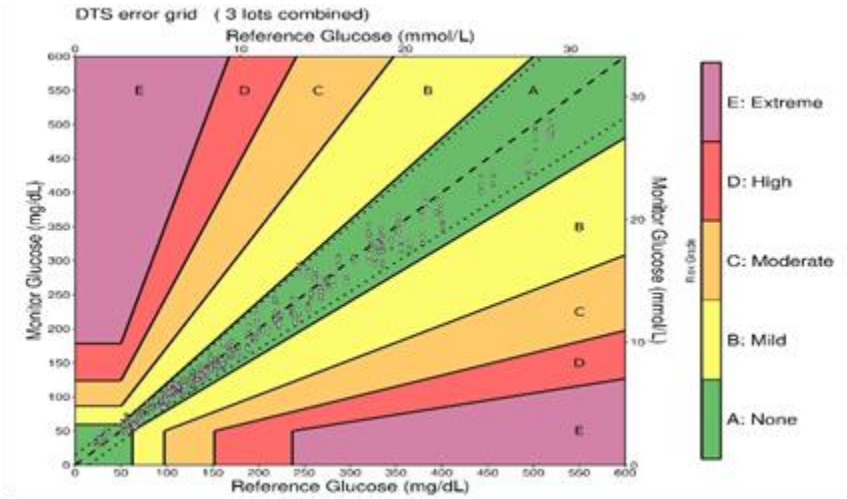

Figure 6: Diabetes technology society error grid (DTS error grid)

Reactovigilance and materiovigilance

No adverse events, reactovigilance incidents, or materiovigilance reports were recorded during the study period.

IV. Discussion

Self-Blood glucose monitoring is essential for daily management of diabetes. Patients living with diabetes and health care professionals are dependent on the accuracy and precision of readings obtained by BGMS for therapeutic decision-making [10,11].

Studies have shown that not all BGMS systems with the CE mark or cleared by FDA, meet the accuracy requirements outlined in the ISO 15197:2013 standard. For instance, Pleus. S and colleagues tested 18 blood glucose-monitoring systems available in Europe and found that 4 out of 18 (22%) did not meet the ISO 15197:2013 accuracy requirement when their tested reagent system lot was evaluated [30] . Similarly, Klonoff and Prahalad's research revealed that only 15 out of 31 (48.3%) of blood glucose monitoring systems cleared by the US-FDA met the ISO 15197:2013 requirement in all the studies in which they were evaluated [31]. These findings were consistent in the Asia-Pacific region and in a Sub-Saharan African country as well [32-33]. Wang Yu-Fei

conducted a study assessing the system accuracy of 19 BGMs and found that only 4 out of 19 (21%) of them conformed to ISO 15197:2013 standards [32].

To our knowledge, this study represents the first independent post-marketing analytic and clinical accuracy of locally manufactured glucose test strips according to ISO 15197:2013 requirement in Africa region, addressing a critical evidence gap in Algeria where local glucose test strips manufacturing is emerging as a strategic healthcare priority. In contrast to previous reports in Africa region, our protocol for analytical comparability employed the same capillary blood sample and glucose oxidase method for both measurements to avoid any methodological bias attributable to matrix or enzyme system discordance [33,34,35].

Our evaluation under optimal and standardized conditions confirmed that all three locally manufactured glucose test strips lots met ISO 15197:2013 analytic and clinical accuracy requirement . Overall, 98,7% of 1080 BGMS measurements fell within ± 15 mg/dL and ± 15% of the YSI2500 references values, and all measurements (100%) fell within zone A of Parkes error grid. Despite a statistically significant inter-lot difference by one-way ANOVA ($p < 0.0001$), effect size analysis indicated negligible lot-to-lot variability with mean assay values of 98.88%, 98.88%, and 98.33% for Lots A, B, and C respectively, collectively supporting manufacturing consistency across independent production batches.

BGMS readings showed a systematic negative bias relative to the YSI 2500 reference analyzer, with a mean difference of −3.72 mg/dL (95% CI : −4.56 to −2.87; $p < 0.0001$), indicating a small but statistically significant underestimation of true glucose values. This finding contrasts with reports by Choukem et al. , who found overestimation by four BGMS devices compared to venous laboratory reference values [33]. Similarly, Harada et al., in a 25-year review of BGMS performance in Japan, found underestimation in 39% of comparisons and overestimation in 57% [36]. Several methodological differences may account for the discrepancy, including blood sampling matrix (capillary versus venous), reference systems (glucose oxidase versus hexokinase) and device enzyme system (glucose oxidase versus glucose dehydrogenase). The clinical significance of this systematic underestimation must be considered in addition to its direction and its magnitude. In silico modeling showed that systematic measurement bias inversely correlates with HbA1c and directly correlates with the frequency of severe hypoglycemia. However, measurement errors predict severe hypoglycemic events without affecting HbA1c in unbiased systems [12,13]. These computational findings explain why bias magnitude and directionality are clinically more consequential than imprecision when evaluating BGMS safety profiles.

According to The German/Austrian Diabetes Prospective Documentation Initiative systematic inaccuracies in BGMS measurements impact clinical outcomes in diabetes management. Sustained underestimation, defined as BGMS values measuring ≥14.4 mg/dL below laboratory obtained glucose levels was associated with poorer long-term glycemic control. On the other hand, persistent overestimation (BGMS readings ≥10.8 mg/dL higher than laboratory values) correlated with increased frequency and severity of hypoglycemic events [37,38] . The mean underestimation of 3.72 mg / dL observed in our study falls below these clinically concerning threshold.

Systematic bias in BGM measurements underlies most continuous blood monitoring (CGM) inaccuracies. During calibration, this bias transferred to the CGM sensor, causing persistent deviations in all subsequent readings. Non-factory-calibrated CGMs use BGM inputs to adjust sensor gain and bias. Random BGM errors (imprecision) are partially filtered by calibration algorithms, but systematic errors integrate into the CGM's signal processing, distorting trend arrows and rate-of change calculations [39]. The ADA Standards of Care emphasize that reliable BGMS remains essential, recommending that people using CGM devices maintain access to blood glucose monitoring at all times [20].

Regression analysis revealed a proportional bias with underestimation around 6.62 % at hyperglycemic range and an overestimation at lower glucose values, which together explain a characteristic bidirectional bias pattern. When comparing the linear equation found to meta-analysis evidence , our finding aligns closely with the home pooled correlation (0.930) and it may reflect a class effect of enzyme-based electrochemical test rather than a manufacturing defect specific to devices tested [40] .

The key finding of this study is not simply the overall bias, but how the bias changes with glucose concentration. While Bland-Altman analysis identified statistically significant proportional error , Passing-Bablok regression for the full data set (1080 measurements) confirmed the presence of both proportional and systematic bias. Stratified analysis further characterized the concentration-dependent bias pattern across the four glycemic ranges. The device performs optimally in the near-normal to mildly hyperglycemic range (80–179 mg/dL), with residual bias that remains within clinically acceptable limits across all range .

The Mean Absolute Relative Difference (MARD) has been widely used in literature to quantify accuracy of BGMS and as single numerical value to distinguish between the different devices' performance [41] . The overall MARD of 6.7% observed in the present study warrants careful interpretation. This value exceeds the probabilistic thresholds established by Pardo & Simmons [42] , who modeled that MARD values between 3.25% and 5.25% are theoretically necessary to satisfy ISO 15197:2013 accuracy standards. However, the

relationship between MARD and ISO compliance is not straightforward. Freckmann et al. reported that BGMS with MARD values as low as 6.1% failed to achieve ≥ 95% ISO 15197:2013 compliance [41]. Conversely, some systems with higher MARD values (> 7%) met ISO criteria, attributable to favorable bias distributions and error patterns that minimized clinical risk despite higher average deviations. Our findings, an overall MARD of 6.7% coexisting with 98.7% ISO compliance, provide concrete evidence supporting the growing consensus that MARD alone is an insufficient surrogate for ISO compliance and should not be used as the primary accuracy metric.

MARD varied across the predefined glycemic range:15.2% in the hypoglycemic range (<80 mg/dL), 4.9% in the near-normoglycemic range (80–129 mg/dL), 4.9% in the 130–179 mg/dL range, and 6.0% in the hyperglycemic range (≥180 mg/dL). These results are broadly concordant with stratified MARD data reported in the literature [43,44]. The evaluation of glucose meter performance in the hypoglycemic range is subject to specific methodological constraints that warrant transparent acknowledgment. First, prospective collection of native capillary blood samples from diabetic patients with glucose concentrations in the range of 50–80 mg/dL carries significant ethical and safety risks, limiting sample availability without modification. Second, the ex vivo preparation of hypoglycemic samples through glucose consumption incubation alters blood oxygen partial pressure (pO_2), potentially introducing systematic bias in glucose oxidase-based measurement systems [44,45]. The incorporation of fasting non-diabetic volunteers, as recommended by the Diabetes Technology Society, represents a methodologically alternative that avoids both the ethical risks of diabetic hypoglycemia induction and the oxygen-dependent interference of incubated preparations [45]. The elevated MARD of 15.2% observed in the hypoglycemic range should therefore be interpreted with appropriate caution, acknowledging that it may partly reflect preparation-related matrix effects rather than true device performance under physiological hypoglycemia.

While the Parkes Error Grid is recommended by ISO 15197:2013 , its zone definitions , based on expert consensus and clinical scenario modeling, have been criticized. To address this , we performed an additional evaluation of clinical accuracy and risk stratification using the advanced graphical tool implemented by the Diabetes Technology Society, which offers enhanced risk stratification particularly for minor deviations. The proportion of results falling within the clinically acceptable SEG zones (A+B) was (100%) (97.9%/2.1%) and the distribution across DTS Error Grid zones was: Zone A: (99.4%), Zone B: (0.6%). This distribution aligns with the model proposed by Kovatchev et al., who demonstrated that devices with ≤ 3% of values outside Zone A predict compliance with ISO 15197:2013 accuracy standards [46]. Our results (2.3% outside Zone A) meet this threshold, indicating minimal clinical risk and no expected treatment errors.

This study had several limitations. First, test strips were provided by the manufacturer, which may introduce selection bias if the supplied lots were not fully representative of commercially distributed products. Second, the YSI 2500 was employed as the reference method; while it has not received formal FDA regulatory clearance specifically for this purpose. Third, although the glucose-dependent bias was statistically well defined, its mechanistic basis was not established it therefore remains unclear whether this bias originates from electrochemical limitations, strip manufacturing variability, or interference effects at extreme glucose concentrations, and this warrants further investigation in future studies.

V. Conclusion

This study represents the first independent post-marketing evaluation of locally manufactured blood glucose test strips in Algeria . The evaluated brand met the analytical and clinical accuracy requirements of ISO 15197:2013 , achieving an overall ISO compliance rate of 98.7% with all measurements (100%) within Zone A of the Parkes Error Grid. However, a bidirectional bias pattern dependent on glucose concentration was observed across glycemic ranges. Our results highlight the need to assess not only overall accuracy of BGMS but also bias trends across all glycemic ranges to ensure patients safety and effective diabetes management. The integration of concentration-dependent bias analysis into post-marketing evaluation protocols offers a more thorough and clinically relevant method for the comparative assessment and benchmarking of blood glucose monitoring systems available on the Algerian market.

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