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Original Article

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Cross-sectional evaluation of two point-of-care glucose meters against the GOD-PAP reference method

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ABSTRACT

Introduction: Point-of-care testing (POCT) for blood glucose measurement is increasingly used because it provides rapid results for clinical decision-making. However, its analytical performance must be evaluated before routine implementation. This study aimed to compare the precision, accuracy, and agreement of the Easy Touch and Emtech BG Max 1 POCT devices with the Glucose Oxidase–Peroxidase (GOD-PAP) reference method for blood glucose measurement.

Research Methodology: An observational analytic study with a cross-sectional design was conducted at the Buton Tengah Regional General Hospital Laboratory, Indonesia. Fifty venous blood samples were analyzed using the Easy Touch and Emtech BG Max 1 POCT devices and the GOD-PAP laboratory method as the reference standard. Precision was evaluated using the coefficient of variation (CV), accuracy was assessed through percentage bias and compliance with ISO 15197:2013, and agreement was determined using nonparametric Bland–Altman analysis.

Results: The CV values were 5.54% for Easy Touch, 1.76% for Emtech BG Max 1, and 0.80% for the GOD-PAP method. The mean bias was 7.74% for Easy Touch and −5.78% for Emtech BG Max 1. Compliance with ISO 15197:2013 was achieved in 62% of Easy Touch measurements and 90% of Emtech BG Max 1 measurements. Bland–Altman analysis demonstrated good agreement between both POCT devices and the reference method. However, Emtech BG Max 1 showed narrower limits of agreement and closer agreement with GOD-PAP than Easy Touch.

Conclusion: Both POCT devices demonstrated acceptable analytical agreement with the GOD-PAP method for blood glucose testing. However, Emtech BG Max 1 exhibited superior precision, lower analytical bias, and higher compliance with ISO 15197:2013, indicating greater reliability for routine clinical use. Periodic analytical performance evaluation is recommended to maintain the quality and accuracy of POCT-based blood glucose testing.

Keywords: accuracy; blood glucose; Bland–Altman analysis; point-of-care testing; precision

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INTRODUCTION

Blood glucose measurement is a fundamental component of diabetes mellitus diagnosis, treatment monitoring, and therapeutic decision-making. The increasing global burden of diabetes has intensified the demand for reliable and timely blood glucose testing across healthcare settings [1,2]. According to the International Diabetes Federation (IDF), approximately 589 million adults were living with diabetes in 2025, and this number is projected to continue rising over the coming decades [3,4]. In Indonesia, diabetes remains one of the leading non-communicable diseases, contributing substantially to morbidity, mortality, and healthcare expenditure. Timely and accurate blood glucose measurement is therefore essential for preventing acute metabolic complications, optimizing glycemic control, and reducing long-term vascular consequences. In emergency departments, outpatient clinics, and primary healthcare facilities, rapid test results are often required to support immediate clinical decisions, making Point-of-Care Testing (POCT) increasingly indispensable[5,6].

Although conventional laboratory methods remain the analytical reference for blood glucose measurement, their implementation is constrained by laboratory infrastructure, trained personnel, and longer turnaround times. The Glucose Oxidase–Peroxidase (GOD-PAP) method is widely recognized as a reliable enzymatic reference because of its high analytical precision and accuracy [7]. In contrast, POCT devices provide rapid results using portable biosensor technology with minimal sample volume, thereby improving clinical efficiency and patient management. Consequently, POCT has become an integral component of diabetes care, particularly in emergency services, inpatient wards, and remote healthcare facilities where rapid therapeutic decisions are required [8]. However, convenience should not compromise analytical quality. Differences in measurement principles, strip technology, calibration systems, environmental conditions, and operator performance may introduce systematic and random errors that influence the reliability of POCT results [9].

Previous studies have demonstrated that the analytical performance of blood glucose POCT devices varies considerably across manufacturers and clinical settings [10]. Tonyushkina and Nichols reported that several glucose monitoring systems exhibited clinically significant deviations from laboratory reference methods, particularly at extreme glucose concentrations. Freckmann and colleagues further showed that not all commercially available POCT systems fulfilled the analytical requirements specified by ISO 15197:2013, especially in the hypoglycemic range, where measurement accuracy is clinically critical [11]. Similarly, Wang et al. identified systematic positive bias in several glucose monitoring devices when compared with reference laboratory methods, potentially influencing diagnostic interpretation and therapeutic decisions. Indonesian studies have reported comparable findings. Aini et al. observed significant differences between strip-based POCT and enzymatic GOD-PAP measurements. At the same time, other investigators found that prolonged device use, strip variability, and calibration status may reduce measurement precision and increase analytical bias. Collectively, these studies indicate that analytical performance cannot be generalized across POCT devices and should be verified before routine clinical implementation [12].

Despite growing evidence regarding POCT performance, several important knowledge gaps remain. First, most published studies have evaluated a single POCT device without directly comparing multiple commercially available instruments under identical laboratory conditions. Second, previous investigations have predominantly focused on either accuracy or precision, whereas comprehensive evaluations incorporating analytical precision, systematic bias, compliance with ISO 15197:2013, and agreement analysis using Bland–Altman methods

remain relatively limited [13]. Third, evidence from Indonesian regional hospitals is scarce, despite increasing reliance on POCT for routine clinical services. In particular, no published study has comprehensively compared the analytical performance of Easy Touch and Emtech BG Max 1 against the GOD-PAP reference method in the clinical laboratory setting of Buton Tengah Regional General Hospital. This absence of locally generated evidence limits informed decisions regarding device selection, quality assurance, and laboratory policy.

The novelty of this study lies in its comprehensive analytical comparison of two widely used POCT blood glucose systems within the same clinical population using a standardized reference method. Unlike previous studies that evaluated only selected analytical parameters, this research simultaneously assesses precision through coefficient of variation, analytical accuracy using percentage bias, and ISO 15197:2013 compliance, and measurement agreement through nonparametric Bland–Altman analysis. This integrated analytical approach provides a more complete evaluation of device performance and generates locally relevant evidence for laboratory quality management and clinical decision-making. Furthermore, the inclusion of two commonly used POCT devices enables direct comparison of their analytical capabilities under identical testing conditions, offering practical guidance for healthcare facilities seeking reliable blood glucose monitoring systems.

Therefore, this study aimed to evaluate and compare the analytical performance of the Easy Touch and Emtech BG Max 1 POCT devices against the GOD-PAP reference method for blood glucose measurement at the Buton Tengah Regional General Hospital Laboratory. Specifically, the study assessed analytical precision, accuracy, compliance with ISO 15197:2013, and measurement agreement to determine the suitability of both devices for routine clinical application. The findings are expected to strengthen evidence-based laboratory quality assurance, support appropriate POCT device selection, and contribute to improving the reliability of blood glucose testing in clinical practice.

MATERIALS AND METHODS

Study Design

This study employed an observational analytical study with a cross-sectional design to evaluate and compare the analytical performance of two point-of-care testing (POCT) devices, Easy Touch and Emtech BG Max 1, against the Glucose Oxidase–Peroxidase (GOD-PAP) reference method for blood glucose measurement. A cross-sectional analytical design was considered appropriate because all blood samples were measured simultaneously using the three methods under identical laboratory conditions, allowing direct comparison of precision, accuracy, and analytical agreement without intervention or follow-up. This design is widely recommended for method-comparison and diagnostic performance studies in clinical laboratory research.

Setting and Participants

The study was conducted at the Clinical Laboratory of Buton Tengah Regional General Hospital (RSUD Buton Tengah), Southeast Sulawesi, Indonesia, from April to June 2026. The study population consisted of patients undergoing routine blood glucose testing during the study period. Participants were eligible if they were aged ≥18 years, underwent venous blood collection for clinical blood glucose examination, and provided written informed consent. Blood specimens showing hemolysis, insufficient sample volume, clot formation, or improper handling were excluded to minimize analytical interference.

A consecutive sampling technique was used, whereby all eligible patients meeting the

inclusion criteria during the study period were recruited until the required sample size was achieved. The minimum sample size was determined according to the Clinical and Laboratory Standards Institute (CLSI) EP09 guideline for method-comparison studies, which recommends a minimum of approximately 40–50 patient specimens distributed across the analytical measurement range. Consequently, 50 venous blood samples were included, providing sufficient representation of low, normal, and elevated blood glucose concentrations for evaluating analytical agreement.

Variables and Measurement

The independent variable was the blood glucose measurement method, comprising the Easy Touch POCT device, Emtech BG Max 1 POCT device, and the GOD-PAP laboratory reference method. The dependent variables included:

- analytical precision (Coefficient of Variation, CV),
- analytical accuracy (percentage bias),
- compliance with ISO 15197:2013, and
- analytical agreement evaluated using Bland–Altman analysis.

Blood glucose concentrations were measured using commercially available Easy Touch and Emtech BG Max 1 glucose meters according to the manufacturers' instructions. The GOD-PAP enzymatic assay served as the laboratory reference standard.

Instrument validity was ensured through manufacturer calibration and routine laboratory verification before data collection. Reliability was evaluated through repeated internal quality-control measurements and determination of the coefficient of variation (CV). All study data were obtained from primary laboratory measurements generated specifically for this investigation.

Data Collection

Certified medical laboratory technologists collected venous blood specimens following the hospital's standard operating procedures. Each specimen was analyzed using the Easy Touch POCT device, the Emtech BG Max 1 POCT device, and the GOD-PAP reference method under standardized laboratory conditions. To ensure analytical consistency, all instruments were calibrated before testing, reagent strips were checked for expiration dates and storage conditions, and internal quality-control materials were analyzed daily before patient testing. Laboratory personnel performing the analyses followed identical operating procedures throughout the study to minimize operator-related variability. All analytical results were recorded immediately after measurement using standardized data collection forms.

Data Analysis

Descriptive statistics were used to summarize participant characteristics and blood glucose measurements. Continuous variables are presented as means, standard deviations, coefficients of variation, and percentage bias, whereas categorical variables are expressed as frequencies and percentages. Normality of measurement differences was assessed using the Shapiro–Wilk test. Precision was evaluated by calculating the coefficient of variation (CV). Accuracy was assessed through percentage bias and compliance with ISO 15197:2013 performance criteria. Analytical agreement between each POCT device and the GOD-PAP reference method was evaluated using nonparametric Bland–Altman analysis, including estimation of the mean difference and limits of agreement.

Because the study focused on analytical method comparison rather than causal relationships among latent constructs, Structural Equation Modeling (SEM) was not applicable and was therefore not performed. All statistical analyses were conducted using IBM SPSS

Statistics version 29.0. Statistical significance was established at a two-sided α level of 0.05.

Ethical Approval

This study received ethical approval from the Health Research Ethics Committee of Politeknik Sandi Karsa Makassar, Approval Number: 104/S.Ket/KEPK-PSK/VI/2026.

RESULTS

A total of 50 venous blood samples were included in the analysis. The samples represented patients undergoing routine blood glucose testing at the Clinical Laboratory of Buton Tengah Regional General Hospital. Male participants accounted for 56.0% (n = 28), while females represented 44.0% (n = 22). Most samples were obtained from adults aged 46–65 years. Routine random blood glucose testing constituted the largest proportion of examinations.

Table 1. Characteristics of the Study Samples

Variable	n	%
Sex		
Male	28	56.0
Female	22	44.0
Age group (years)		
18–45	16	32.0
46–65	25	50.0
>65	9	18.0
Blood glucose examination		
Random blood glucose	31	62.0
Fasting blood glucose	19	38.0

The study samples represented adult patients requiring routine blood glucose assessment. The distribution reflects routine clinical laboratory services where middle-aged adults comprise the majority of individuals undergoing glucose monitoring.

Analytical Performance of POCT Devices

The Emtech BG Max 1 demonstrated superior analytical performance compared with the Easy Touch device. The coefficient of variation (CV) was substantially lower for Emtech BG Max 1 (1.76%) than for Easy Touch (5.54%), indicating better repeatability. Mean analytical bias was 5.78% for Emtech BG Max 1 and 7.74% for Easy Touch. Compliance with ISO 15197:2013 reached 90% for Emtech BG Max 1 compared with 62% for Easy Touch. Bland–Altman analysis further demonstrated acceptable agreement for both devices, although Emtech BG Max 1 exhibited narrower limits of agreement and measurements closer to the GOD-PAP reference method.

Table 2. Comparative Analytical Performance of POCT Devices

Analytical parameter	Easy Touch	Emtech BG Max 1
Precision (CV, %)	5.54	1.76
Mean bias (%)	7.74	−5.78
ISO 15197:2013 compliance (%)	62	90
Agreement with GOD-PAP	Good	Better

Emtech BG Max 1 showed higher analytical precision, lower systematic bias, and greater

compliance with international quality standards than Easy Touch. These findings indicate that Emtech BG Max 1 provides measurements that are analytically closer to the laboratory reference method.

The present findings demonstrate that not all commercially available POCT devices provide equivalent analytical performance despite serving the same clinical purpose. Although both devices showed acceptable agreement with the GOD-PAP reference method, Emtech BG Max 1 consistently outperformed Easy Touch across all evaluated analytical indicators, including precision, analytical bias, and compliance with ISO 15197:2013. These results highlight that selecting a POCT device should extend beyond considerations of cost or operational convenience and should prioritize analytical quality to support accurate clinical decision-making. From a laboratory quality management perspective, routine verification of analytical performance is essential before implementing POCT devices in daily clinical practice. Periodic internal quality control, calibration verification, and compliance monitoring with international analytical standards should become integral components of laboratory governance.

Furthermore, the observed differences between devices reinforce the importance of local validation because analytical performance may vary according to clinical settings, environmental conditions, and operational practices. Hospitals and primary healthcare facilities should therefore establish evidence-based procurement policies that incorporate independent analytical evaluations rather than relying solely on manufacturer specifications. Such strategies will enhance diagnostic reliability, minimize measurement errors, strengthen patient safety, and improve confidence in POCT-based glucose monitoring across diverse healthcare environments.

DISCUSSION

The findings of this study demonstrate that although both point-of-care testing (POCT) devices showed acceptable agreement with the laboratory reference method, their analytical performance differed substantially. Among the two devices evaluated, Emtech BG Max 1 consistently exhibited superior analytical characteristics, as reflected by its lower coefficient of variation, smaller analytical bias, and higher compliance with ISO 15197:2013 when compared with Easy Touch. These findings indicate that not all POCT devices provide equivalent measurement quality, despite serving the same clinical purpose. Analytical performance remains a critical determinant of the clinical value of POCT because inaccurate glucose measurements may directly influence diagnostic decisions, therapeutic adjustments, and patient monitoring. The present findings reinforce the importance of evaluating analytical quality before adopting POCT devices in routine healthcare settings rather than assuming comparable performance across commercially available instruments.

The superior precision observed for Emtech BG Max 1 suggests greater measurement repeatability, an essential characteristic for devices intended for frequent glucose monitoring. Precision reflects the consistency of repeated measurements under identical analytical conditions and is fundamental for ensuring that changes in glucose concentration represent biological variation rather than instrument-related error [14]. The lower coefficient of variation achieved by Emtech BG Max 1 indicates greater measurement stability and reduced random error, thereby enhancing confidence in serial glucose assessments. In contrast, the higher variability observed with Easy Touch suggests that repeated measurements may be more susceptible to analytical fluctuations, particularly when monitoring patients who require tight glycaemic control [15]. Although both devices remained clinically usable, differences in repeatability should be considered when selecting POCT instruments for hospital laboratories or primary healthcare facilities [16].

Analytical accuracy represents another important dimension of diagnostic performance. The observed differences in percentage bias indicate that systematic measurement error varied between the two devices [17]. Smaller analytical bias reduces the likelihood that measured glucose concentrations consistently deviate from the true value determined by the laboratory reference method [18]. From a clinical perspective, systematic overestimation or underestimation of glucose concentrations may influence diagnostic classification and therapeutic decision-making, particularly near clinically important thresholds [19]. Consequently, evaluating analytical bias should be regarded as an essential component of POCT validation before implementation in clinical practice. The higher level of compliance with ISO 15197:2013 demonstrated by Emtech BG Max 1 further strengthens confidence in its analytical performance because internationally accepted quality standards provide objective benchmarks for evaluating measurement accuracy and reliability [20].

The Bland–Altman analysis provides additional evidence regarding the interchangeability of POCT devices with laboratory-based methods. Rather than focusing solely on statistical correlation, agreement analysis evaluates whether two measurement techniques can be used interchangeably across the range of observed glucose concentrations [21]. The present study found acceptable agreement between both POCT devices and the GOD-PAP reference method, although Emtech BG Max 1 demonstrated measurements that were consistently closer to the laboratory reference [22]. This distinction is clinically meaningful because high correlation alone does not necessarily indicate satisfactory agreement. Two instruments may correlate strongly while still producing clinically unacceptable measurement differences. Therefore, agreement analysis offers more meaningful evidence for evaluating the suitability of POCT devices in routine diagnostic practice [23].

The present findings are consistent with previous investigations reporting that the analytical performance of POCT glucose meters varies considerably among manufacturers and technologies. Previous studies have shown that modern glucose monitoring systems capable of maintaining lower analytical bias and higher precision generally demonstrate better compliance with international quality standards and produce measurements that more closely approximate laboratory reference methods [24]. These observations support the growing consensus that device-specific evaluation should precede clinical implementation rather than relying solely on manufacturer specifications. Independent analytical validation performed under routine laboratory conditions provides more realistic estimates of instrument performance than controlled experimental evaluations.

Several studies have similarly emphasized that compliance with ISO 15197:2013 represents one of the most important indicators of glucose meter quality. International standards were developed to minimize clinically significant analytical errors that could compromise patient management [25]. Devices that consistently satisfy these criteria are more likely to provide reliable glucose measurements across a broad concentration range. The comparatively higher compliance achieved by Emtech BG Max 1, therefore, suggests that this device may be more appropriate for clinical settings requiring greater analytical confidence [26]. Nevertheless, compliance with international standards should be viewed as one component of a broader quality assurance framework that also includes calibration verification, operator competency, environmental monitoring, and continuous internal quality control.

The findings also highlight broader implications for laboratory management and healthcare systems. The increasing use of POCT reflects the need for rapid diagnostic information that supports timely clinical decision-making. However, expanding access to rapid testing should not compromise analytical quality [27]. Healthcare institutions frequently prioritize operational efficiency, cost reduction, and rapid turnaround time when selecting POCT devices, whereas analytical performance may receive comparatively less attention. The present study suggests that procurement decisions should integrate objective evidence regarding precision, analytical bias, agreement with reference methods, and compliance with internationally recognized quality standards. Such evidence-based procurement strategies would strengthen laboratory governance while promoting safer diagnostic practices.

Beyond laboratory practice, the findings have implications for healthcare policy. The widespread adoption of POCT technologies in hospitals, emergency departments, community health centres, and remote healthcare facilities requires standardized evaluation procedures before implementation. National laboratory accreditation systems and hospital quality assurance programmes should encourage routine verification of analytical performance whenever new POCT devices are introduced into clinical services. Establishing standardized evaluation protocols would reduce variability between institutions and improve consistency in glucose monitoring across different levels of healthcare delivery. Such system-level quality assurance is particularly important in resource-limited settings where POCT devices often function as the primary diagnostic modality.

Although the present study provides meaningful evidence regarding the comparative analytical performance of two commercially available glucose meters, several limitations should be acknowledged. First, the study was conducted in a single hospital laboratory, which may limit the generalisability of the findings to other healthcare settings with different patient populations, laboratory infrastructures, or environmental conditions. Second, the sample size, while appropriate for analytical method-comparison studies, remains relatively modest and may not fully represent the entire spectrum of glucose concentrations encountered in routine clinical practice. Third, the investigation evaluated only two POCT devices. Because numerous glucose monitoring systems are currently available, the results should not be interpreted as representing the performance of all commercially marketed devices. Finally, analytical performance may be influenced by operator technique, environmental temperature, humidity, strip storage conditions, and instrument maintenance, variables that were controlled as much as possible but cannot be eliminated during routine clinical testing.

These limitations also identify opportunities for future investigation. Multicentre studies involving larger and more diverse patient populations would provide stronger external validity and facilitate comparisons across different healthcare environments. Future research should also evaluate additional POCT technologies, including next-generation glucose monitoring systems that incorporate advanced biosensor technologies and digital connectivity. Comparative cost-effectiveness analyses would further assist healthcare administrators in balancing analytical performance with economic considerations during procurement. Moreover, future studies should investigate the long-term impact of POCT analytical quality on clinical outcomes, including therapeutic decision accuracy, glycaemic control, patient safety, and healthcare resource utilization. Such evidence would extend the current focus from analytical validation toward demonstrating the broader clinical and organisational value of high-quality POCT implementation.

Overall, this study contributes to the growing body of evidence supporting rigorous analytical evaluation of POCT devices before their routine clinical use. The findings demonstrate that differences in precision, analytical bias, agreement, and compliance with international quality standards may substantially influence the reliability of blood glucose measurements. Rather than viewing POCT devices as interchangeable technologies, healthcare institutions should recognize that analytical performance varies across manufacturers and should therefore be independently verified under local laboratory conditions. Strengthening analytical quality assurance through systematic evaluation, continuous quality control, and adherence to international standards will improve diagnostic reliability, support evidence-based clinical decision-making, and ultimately contribute to safer and more effective patient care.

CONCLUSIONS

This study demonstrated that both the Easy Touch and Emtech BG Max 1 point-of-care testing (POCT) devices showed acceptable analytical agreement with the GOD-PAP laboratory reference method for blood glucose measurement. However, their analytical performance was not equivalent. Emtech BG Max 1 consistently achieved superior

performance, evidenced by a lower coefficient of variation, smaller analytical bias, and higher compliance with the ISO 15197:2013 standard, indicating greater precision, accuracy, and measurement reliability than the Easy Touch device. These findings directly address the study objective by confirming that comparative evaluation of POCT devices is essential, as differences in analytical quality may influence the accuracy of clinical decision-making and patient management. The findings support the integration of independent analytical validation into routine laboratory quality assurance before POCT devices are implemented in clinical practice. Healthcare institutions should adopt procurement policies that prioritize demonstrated analytical performance in addition to operational efficiency and cost considerations. Strengthening compliance with international quality standards, conducting regular quality control, and periodically reassessing device performance are recommended to improve diagnostic accuracy, enhance patient safety, and ensure more consistent blood glucose monitoring across healthcare settings. Future multicentre studies involving larger populations and additional POCT technologies are warranted to further the evidence base for evidence-informed laboratory policy and clinical practice.

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Conflict of Interest
The authors declare that they have no financial or non-financial conflicts of interest that could have influenced the design, conduct, analysis, interpretation, or reporting of this study.

Authors' Contributions
Muhammad Jalil Razak: Conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, Writing – Original Draft.
Nur Ismi: Methodology, Investigation, Validation, Data Curation, Writing – Review & Editing.
Suprapto: Conceptualization, Supervision, Methodology, Formal Analysis, Writing – Review & Editing, Project Administration.
Marisca Jenice Sanaky: Validation, Visualization, Writing – Review & Editing, Resources.

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Declaration of Generative AI Use
During the preparation of this manuscript, the authors used generative artificial intelligence solely to improve language clarity, grammar, and readability. All scientific content, study design, data analysis, interpretation of findings, and conclusions were developed, verified, and approved by the authors. The authors accept full responsibility for the accuracy, integrity, and originality of the published work.

Data Availability Statement
The datasets generated and analyzed during the current study are not publicly available because they contain information that could compromise participant confidentiality and institutional privacy. De-identified data may be made available by the corresponding author upon reasonable request, subject to approval by the participating institution and applicable ethical requirements.

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