

Accuracy Matters – Importance of accuracy of blood glucose monitoring systems

Background

- Self-monitoring of blood glucose (SMBG) is an integral part of modern diabetes management and blood glucose (BG) data are frequently used in clinical decision making. Thus, it is critical that SMBG systems consistently provide accurate results.¹
- Apart from its daily use by people with diabetes, BG meters are routinely used in physician's offices, in intensive care units and other hospital wards, in emergency units, during dialysis, in aged care facilities and by rescue services.
- While the system accuracy of BG meters (BGM) has been widely studied, little is known about its impact on clinical outcomes.

BGM accuracy: Analytical and clinical accuracy²

Performance of blood glucose meter can be described by **analytical accuracy or clinical accuracy**.

Analytical accuracy^{2,3}

Analytical accuracy is how closely the blood glucose measurement matches the true glucose value.

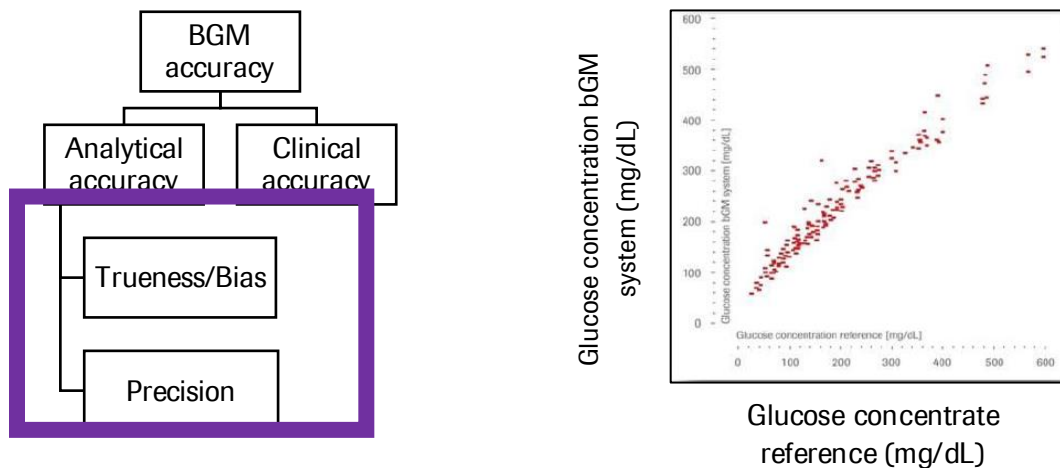


Figure 1: BGM accuracy and representative graph of Analytical accuracy

An effective system for managing analytical quality can be developed based on the concept of total analytical error. Total analytical error consist of combination of:

- Random error (precision)
- Systematic error (bias)
- Other interferences (altitude, hematocrit, galactose etc)

Pre-analytical errors like hand washing and sample collection may also interfere with BG results.

Clinical accuracy^{2,4}

Clinical accuracy is the study of how well blood glucose measurements enable correct therapy decisions.

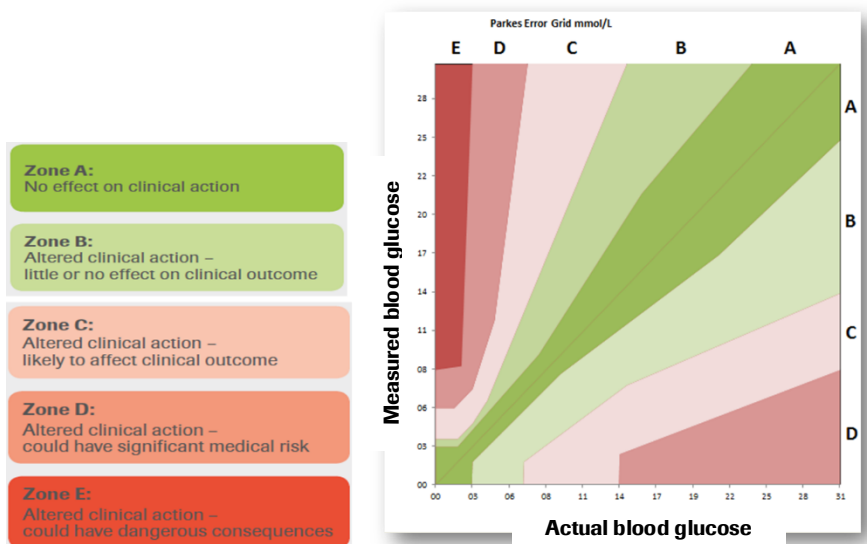


Figure 2: Parker Error Grid mmol/L

A blood glucose error grid is a graph with measured blood glucose value on y-axis and actual blood glucose value on x-axis. 99% of individual glucose measured values should fall within zones A and B of Parkes Error Grid.

BGM accuracy approval standards

- Few internationally acknowledged standard such as International Organization of Standardization (ISO) 15197 and Food and Drug Administration (FDA) guidelines, define the performance requirement of BGM systems, including system accuracy.^{4,5,6}
- In Europe, manufacturer of BGM systems have to be provided evidence of conformity with ISO 15197 standards in order to receive the Conformité Européenne (CE) mark or marketing approval for their product.⁷

ISO 15197 standard

It is an international performance standard for bGM systems for self-testing in diabetes mellitus. The first edition of ISO 15197 was released in 2003: ISO 15197:2003. In May 2013 the second, revised edition of the standard was published: ISO 15197:2013.

What has changed with ISO 15197:2013?⁴

Analytical accuracy (Criterion A)	Tighter requirements (so called 15/15 criteria)
Clinical accuracy (Criterion B)	Requirements for a consensus Error Grid analysis have been specified.
Hematocrit and interferences	For the first time acceptance criteria have been specified.
User performance evaluation	For the first time acceptance criteria have been specified.

Difference between ISO 15197:2003 vs ISO 15197:2013^{4,5}

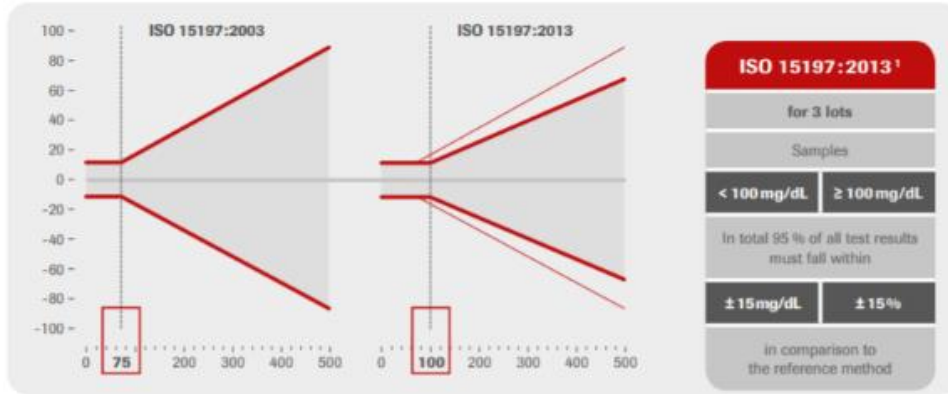


Figure 3a: Tighter criteria for analytical accuracy (Accuracy Criterion A)mmol/L^{4,5}

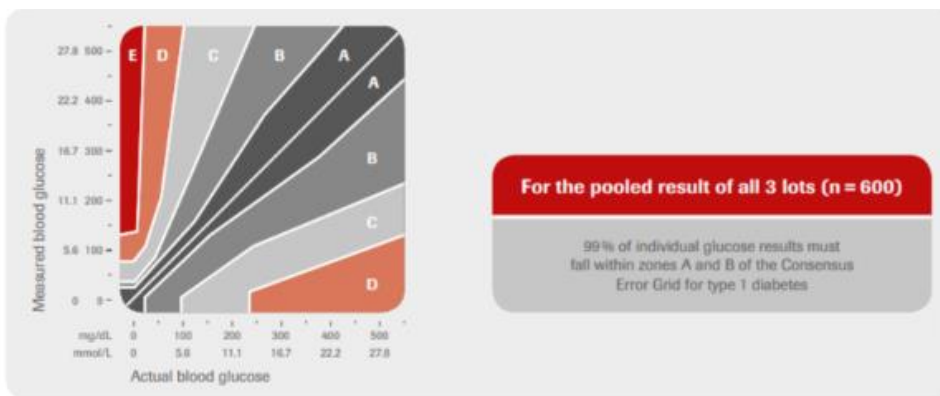


Figure 3b: New criteria for clinical accuracy (Accuracy Criterion B)

Consensus Error Grid analysis⁴

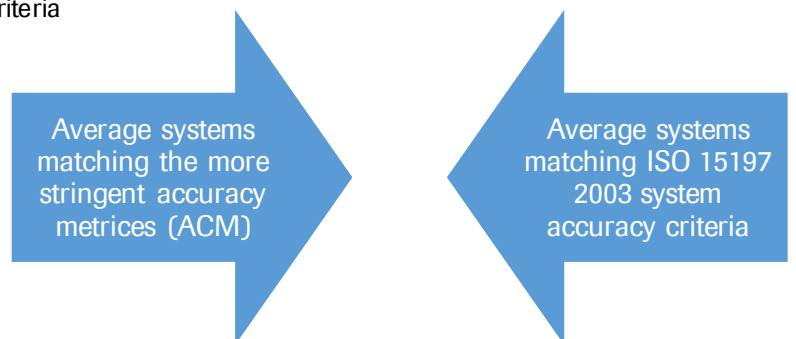
A modelling approach to assess the clinical and economic impact of the difference in system accuracy between BGM systems^{8,9}

Short and long-term consequences of BGM systems' accuracy on well-being of people with diabetes

Using the BGM systems' accuracy data, BGM systems were grouped according to the ISO 15197 standards into following three groups;

- Those adhering to the ISO 15197:2013 accuracy criteria
- Those adhering to the ISO 15197:2003 accuracy criteria
- Those not adhering to any system accuracy criteria

Furthermore, in order to explore the impact of BGM systems achieving a system accuracy even tighter than the ISO 15197:2013, the group of meters which fulfills the ISO 15197:2013 system accuracy criteria was further divided into two subgroups, namely top (with over 50% of all values in 5%/5mg/dL) and bottom 50%.



When comparing the **average of systems matching the more stringent accuracy metrics (SAM) with the average of systems matching ISO 15197 2003 system accuracy criteria**, the difference in accuracy potentially leads to short- and long-term consequences on patients by the less accurate meter, including:⁸

- **Higher number of severe hypoglycemic events**
- **Increase in HbA1c and the consequent long-term complications**
- **Improper insulin dosing**
- **Inconvenience of increased finger sticking**

The difference was even higher with tighter accuracies, as seen when comparing to the average of the upper 50% of BGM adhering to the ISO 15197:2013 subgroup.

BGM systems' accuracy may also impact the healthcare budget for diabetes^{9,10}

- Additional negative consequences that patients potentially experience when using BGM system with lower accuracy may also result in negative consequences on healthcare budget available for the management of diabetes.
- Considering the financial effect of using different BGM systems' accuracies, the budget impact will also look different.

Costs	Average of systems matching ISO 15197 2003 system accuracy criteria	Average of systems matching the more stringent accuracy metrics (SAM)			
Additional SMBG tests	€19,273.08	€5,421.79			
Additional insulin consumption	€23,074.86	€8,398.02			
Additional HbA _{1c} related complications	-€6,035.62	€0.00			
Additional SHE	€48,734.58	€11,686.63			
Budget impact	€85,046.90	- €25,506.44	=	€59,540.46	Savings per year

Using BGM systems with **higher system accuracy** can potentially lead to **€59,540** total budget savings over **1 year**.

Accuracy of Accu-Chek products

- Recent studies have confirmed the good system accuracy of Accu-Chek BGM systems that they have shown over the years.^{11,12}
- All Accu-Chek BGM systems tested exhibit a high level of system accuracy and comply with both ISO 15197:2003 and the new ISO 15197:2013 standard, even with stricter system accuracy requirements.

Summary

- BGM systems' inaccuracy can negatively impact patients by causing:⁸
 - Poor glycemic control
 - Failure to detect hypoglycemic events
 - Improper insulin dosing
 - Inconvenient increase in finger sticking
- Accurate BGM system won't only positively impact patients' health outcomes, but also prevent additional costs.
- The Accu-Chek BGM systems have a system accuracy that is in line with ISO 15197 system accuracy criteria and even exceed that criteria.

Disclaimer: This article is rewritten by Medical and Scientific Affairs team, Roche Diabetes Care India and reviewed by Dr. Shishir Kumar, Chief diabetologist, Bombay hospital, Mumbai, India.

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