# Surveillance Accuracy of Smartphone-Dependent Glucose Meters in the Measurement of Plasma Glucose

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## Abstract

**Background:** Along with stand-alone glucose monitors, smartphone-dependent glucose meters (SDGM) are available for self-monitoring of blood glucose (SMBG). These display-less devices, connected to a smartphone, measure glucose and display report on a smartphone screen, which can be easily shared with doctors. **Aim:** The aim of this study was to check the accuracy of the available SDGMs in relation to the laboratory reference method. **Materials and Methods:** Two available SDGMs: BeatO™ and GlucoMe™ were tested. A total of 104 venous blood samples were tested for glucose in SDGMs and by the reference method. The accuracy of the report was checked by the International Standards Organization (ISO), American Diabetes Association (ADA), and Clinical Laboratory Improvement Amendments (CLIA) criteria. Clarke error grid analysis (CEGA) was carried out to find the suitability of SDGM in clinical usage. **Results:** Mean plasma glucose ($n = 104$) level from laboratory report was $106.48 \pm 44.58$ mg/dL, that from BeatO™ was $105.78 \pm 52.6$, and GlucoMe™ was $99.72 \pm 51.22$. The accuracy was lower than that recommended by ISO 2013 (29.8% and 30.77% error in BeatO™ and GlucoMe™, respectively), ADA (63.46% and 74% error in BeatO™ and GlucoMe™, respectively), and CLIA (42.31% and 46.15% error in BeatO™ and GlucoMe™, respectively) criteria. According to CEGA, BeatO™ and GlucoMe™ can guide correct treatment in diabetes mellitus patients for 74% and 71% of measurement, respectively. **Conclusion:** The accuracy of both the SDGMs was lower than that suggested by ISO, ADA, and CLIA criteria. The result of this study would help patients and doctors in informed choice for the procurement of glucose monitors.

**Keywords:** Accuracy, BeatO, ehealth, GlucoMe, glucometer, home monitoring of blood glucose, self-monitoring of blood glucose, smartphone, telemedicine

## INTRODUCTION

Self-monitoring of blood glucose (SMBG) or home monitoring of blood glucose (HMBG) is the process in which the patients measure their blood glucose, monitor the levels, and report it to the health care system.[1-3] It helps in the prevention of hypoglycemia, adjustment of the dosages of the medication, and fixing the strategy of the physical activity for better maintenance of glycemic status.[4]

### Technology review in brief

In 1970, the first glucose meter was available in the market.[5] In that particular model, the Dextrostix reagent strip was used to estimate blood glucose.[6] Later, in 1987, the electrochemical blood glucose monitors were introduced based on the work on biosensors by Clark and Lyons.[7] The biosensor, in general, has three parts: (a) a bioreceptor which accepts the target molecule, (b) a transducer which converts the physiochemical signal to an electrical signal, and (c) a processing module which converts the electrical signal to a readable format.[8] In the case of modern glucose monitors, the test strips contain the first two components of the biosensor. There is a reagent (i.e., bioreceptor) on the strip which reacts with the blood glucose. There is a mediator reagent (i.e., transducer) present along with the reagent. The reaction of the glucose and reagent causes the mediator to generate electrical current. This electrical current is transferred from the strips to the

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meter (i.e., processing module), which displays the value of blood glucose.[9]

### Common types of glucose monitors for SMBG

There are several types of glucose monitors available in stores and on e-commerce websites. Though the electrochemical sensors remain the major underlying technology for the measurement of glucose, some additional features of the meters are making the devices more user-friendly.[10] Figure 1 shows some of the available glucose meters. Stand-alone glucometers are capable of showing the reading on the device itself. These are the most common type of meters used in hospitals and in SMBG. There are some new stand-alone devices that have optional wireless smartphone connectivity (e.g., Bluetooth). With this facility, the glucose reading can be shared over the internet or short message service or monitored over a time period in the dedicated software application. Smartphone-based glucometers are a new addition to the glucose monitor market.[11]

### Smartphone-dependent glucose monitors

These devices are relatively smaller in size as they do not have any display. These devices must be connected to a smartphone for its functionality (visual presentation of the reading is on the smartphone screen). Henceforth, in this manuscript, this type of device is called a smartphone-dependent glucose monitor (SDGM). All the readings from the device are stored in the smartphone application and can be viewed for the trend of glucose level over time. This eliminates the need for keeping a logbook. These devices are often bundled with a facility of consultation with a doctor over the internet. Hence, these devices have the potential to be used by a huge number of smart patients. In India, there are two such devices available. Figure 2 shows these devices. Figure 2a shows the BeatO™ (3.5 mm jack connected) glucose monitor with a smartphone, and Figure 2b shows the GlucoMe™ (wireless, acoustic data transfer method) glucose monitor with a smartphone. Both of these devices are "second generation" glucose monitor, which use Flavin-Adenine-Dinucleotide-Dependent Glucose Dehydrogenases (FAD GDH) on the test strips and the electrochemical reaction is as follows[12,13]:
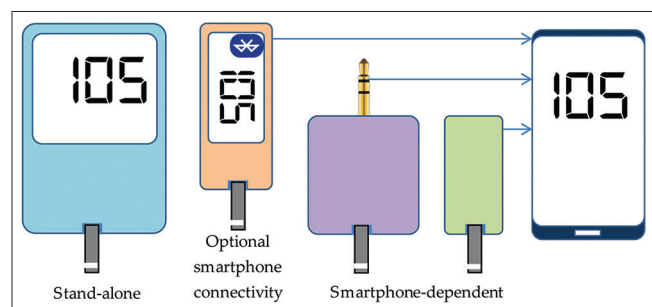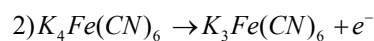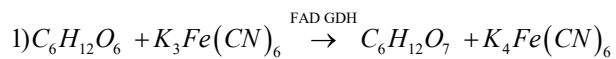
$$1) C_6H_{12}O_6 + K_3Fe(CN)_6 \xrightarrow{\text{FAD GDH}} C_6H_{12}O_7 + K_4Fe(CN)_6$$

$$2) K_4Fe(CN)_6 \rightarrow K_3Fe(CN)_6 + e^-$$

### Background of this study

The accuracy is the foremost criterion to choose glucose monitor for SMBG according to the Food and Drug Administration (FDA).[14] The accuracy of six stand-alone glucose meters has been reported from India by Ullal *et al*.[15] A large scale study by Ekhlaspour *et al.* reported the accuracy of 17 glucose monitors with variable accuracy.[16] To the best of our knowledge, the accuracy of SDGM has not been ascertained in any published literature. Along with this, one of our colleagues, while testing his blood glucose by a stand-alone device and one of the SDGM, found a huge difference between the two readings. This difference may be attributed to different types of factors from the operator level, condition of the strips, accuracy of device, etc. However, this incident made us more curious to find out the accuracy of SDGM in the measurement of blood glucose with the laboratory reference method.

## MATERIALS AND METHODS

### Ethical statement

This study was approved by the Institutional Ethics Committee of Fakir Mohan Medical College and Hospital, Balasore, Odisha, India (No: 09/IEC, Approval date: 14th August 2019). The study was conducted with research participants whose age was above 18 completed years. The study procedure was explained to the participants and those who provided written consent were included in the study. They were informed that they may exit from the study at any point of time without stating any reason. We further declare that the study was conducted with full accordance with the Declaration of Helsinki (updated in 2013).
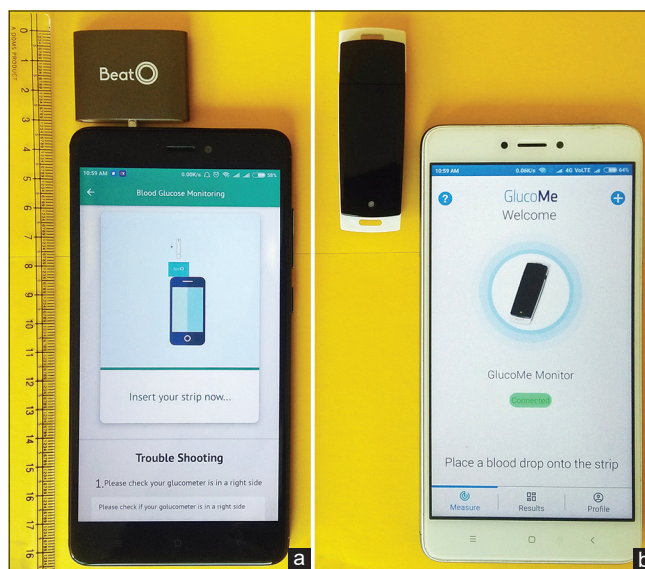


**Figure 1:** Types of glucose meters for self-monitoring of blood glucose



**Figure 2:** Smartphone-dependent glucose meters and user interface on smartphone application (a) BeatO™ (b) GlucoMe™

## Device procurement

We procured the two glucose monitors from two popular e-commerce website and later we procured the required number of strips from those two websites. The serial number of BeatO™ (Changsha Sinocare Inc., People's Republic of China; Marketed in India by Health Arx Technologies Pvt. Ltd.) was 1WJ4GR01155 and GlucoMe™ (All Medicus Co., Ltd, Republic of Korea; under licence of GlucoMe Co. Ltd., Israel; Distributed in India by Apollo Sugar Clinics Ltd.) was GA18CA04244. Details of the strips are available and can be obtained via email from the corresponding author.

## Minimum research participant calculation

According to the company claimed accuracy, for both the SDGMs, 95% of the values fall within ±15% if glucose concentration is ≥100 mg/dL. Assuming this to be true (alternative hypothesis), we considered to get a mean blood glucose value to be 100 in the laboratory reference report and the mean value from SDGM to be 115 (or 85). Along with this, as per the result of a previous study, the standard deviation was estimated to be 13.[15] The calculated minimum sample size was 39.[17] However, this rough estimation was to get the minimum sample size required for a statistically significant result. After reviewing previous literature (105 research participants in the study by Ullal *et al*.[15] and 100 blood samples in the study by Kumar *et al*.[18]), the final sample size was considered as 105.

## Recruitment of research participants

We used a convenience sampling method for this study. The research participants were recruited from a tertiary care hospital in the eastern part of the state of Odisha, India. Apparently, healthy individuals (for normal glucose level) accompanying patients and diabetes mellitus patients (for higher glucose level) both were included. After briefing about the study protocol, patients or their attendants of age ≥18 completed years (declared by the participant) providing written consent were included in the study. Persons having dehydration or hypotension or being exposed to acetaminophen, ascorbic acid, ibuprofen, icodextrin, maltose, methyldopa, salicylic acid, and xylose were excluded from the study at the recruitment level.[19] As this study used a convenience sample from a hospital, subjects were being recruited until we reach the desired number.

## Test procedure

All the tests were carried out in the institutional central laboratory. The average noise level of the laboratory was 50.25 ± 3.91 dB (minimum 30–maximum 80). The relative humidity was 64%. The temperature was minimum 23°C and a maximum of 31°C in test days. The altitude of the area where tests were conducted is 16 m. Two ml of venous blood was collected by venepuncture maintaining proper aseptic precaution. The whole blood was applied to the test strips. Both the strips use capillary action and there is no interference of the report if there is some added blood on and below the

strips. The test reports from the smartphone application user interface were noted on the report sheet for further analysis.

The strip of the BeatO™ meter comes in an individual sealed pack with desiccant. Hence, there is no added precaution needed for preservation. For the GlucoMe™, at a time five strips were taken in a separate airtight container having desiccant below the lid and the container having rest of the strips was kept closed. This precaution was taken to avoid any exposure to humidity.

Immediately, after collection of the blood, it was taken to a vacutainer containing sodium fluoride/potassium oxalate as an anticoagulant. The test performed within 1 h after the collection. Laboratory reference glucose was measured by glucose oxidase-peroxidase (GOD-POD) method from plasma in an automatic biochemistry analyzer (prietest TOUCH, Robonik, India) with a photometric accuracy of ±2%.

## Statistical analysis

Data were presented in mean, standard deviation, range, and 95% confidence interval. Along with the percentage of accuracy, correlation and Clarke error grid analysis (CEGA) were carried out. Percentage of accuracy was compared with the different criteria (ADA, ISO 2013, CLIA). Statistical analysis was carried out in Microsoft Excel 2010® (Microsoft Corporation, USA), GraphPad Prism 6.01 (GraphPad Software, CA, USA). CEGA was carried out manually on graph paper and a digital image of the grid was generated from Microsoft Excel scatterplot and manual insertion of grid lines according to the original CEGA plot.[20-22]

## RESULTS

A total of 104 (56 male, 48 female) blood sample was used in this study. Among the collected 105 samples, one was hemolyzed. Hence, it was not included in the analysis. The mean age of the research participants was 36.45 ± 3.6 completed years.

Blood glucose levels, measured by the laboratory reference method and by two SDGMs along with correlation coefficients, are shown in Table 1. Both the meters showed a significant positive correlation with the reference method.

### Table 1: Correlation of glucose reading from reference method and from glucose monitors

| | Glucose reading from | | |
| --- | --- | --- | --- |
| | Laboratory reference | BeatO™ | GlucoMe™ |
| Glucose (mg/dL) mean±SD | 106.48±44.58 | 105.78±52.6 | 99.72±51.22 |
| *r* | - | 0.93 | 0.94 |
| 95% CI | - | 0.896-0.951 | 0.911-0.958 |
| *P* | - | <0.0001 | <0.0001 |

SD=Standard deviation, *r*=Pearson correlation coefficient, CI=Confidence interval

**Table 2: Accuracy of the glucose monitors according to different criteria in 104 sample**

| Glucose meter | ADA (*n*, %) | | CLIA (*n*, %) | | ISO 2013 (*n*, %) | |
|---|---|---|---|---|---|---|
| | Yes | No | Yes | No | Yes | No |
| BeatO™ | 38, 36.54 | 66, 63.46 | 60, 57.69 | 44, 42.31 | 73, 70.19 | 31, 29.81 |
| GlucoMe™ | 27, 26 | 77, 74 | 56, 53.85 | 48, 46.15 | 72, 69.23 | 32, 30.77 |

ADA: within ±5% in all measurements, CLIA: within ±10% in all measurements, ISO 2013: within ±15 mg/dL if reference glucose <100 mg/d and within ±15% if reference glucose ≥100 mg/dL in 95% of measurement
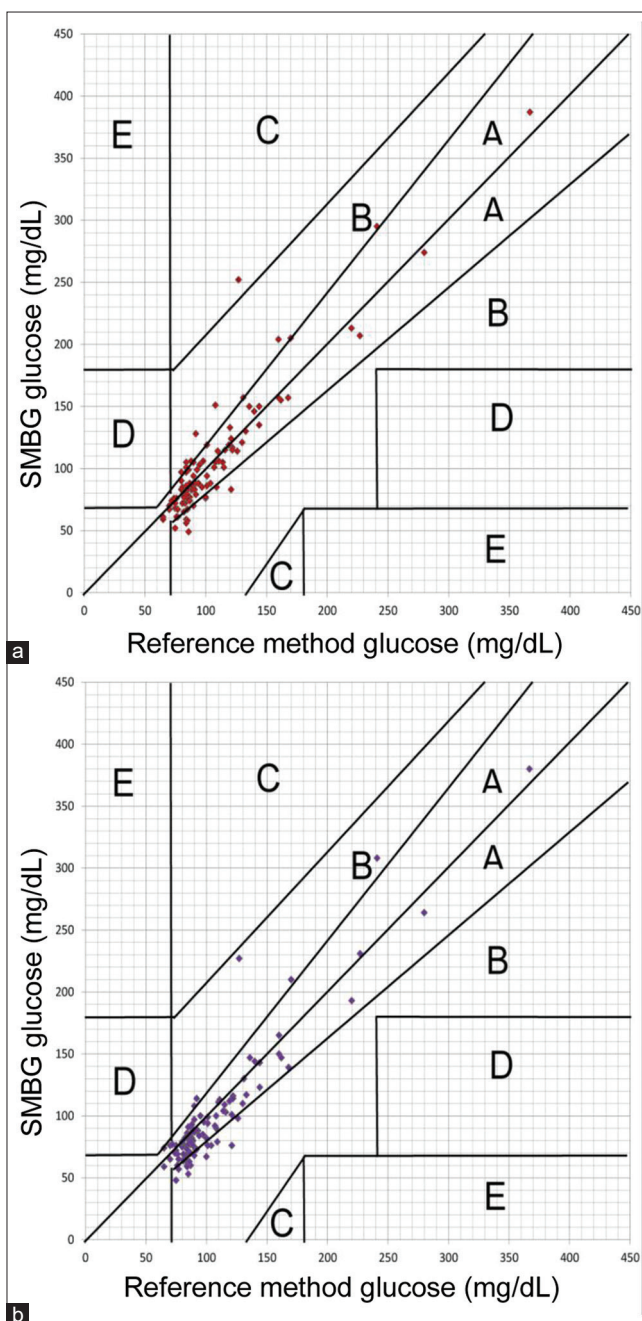
**Figure 3:** Clarke error grid analysis of glucose meters—(a) BeatO™ (b) GlucoMe™

The accuracy of the SDGM, according to ISO 2013, ADA, and CLIA criteria, is shown in Table 2. Both the meters showed a lower level of accuracy than the suggested accuracy of the standard organizations.

CEGA of the two SDGMs are shown in Figure 3. Zone wise distribution for BeatO™ showed 74% in Zone A, 25% in Zone B, and 1% in Zone C. Hence, for clinical usage, this meter can provide correct treatment guide for 74% of the cases and in 25% cases, it would cause benign treatment error. GlcucoMe showed 71% in Zone A and 29% in Zone B. Hence, GlucoMe can guide toward correct treatment in 71% cases and in 29%, there may be benign treatment error.

## DISCUSSIONS

### What is already known in this topic?

Stand-alone glucose monitors have shown various levels of accuracy in comparison to laboratory reference methods. According to a study by Kumar *et al*., "Sugar check advance" glucose monitor showed 89% of the readings followed by "Accu check active" with 86% reading in zone A in CEGA.[18] Among the meters studied by Ullal *et al*., "Johnson Ultra 2" showed the highest accuracy (97.14% in Zone A) followed by "Accucheck Performa" (92.38% in Zone A) and "Accucheck active" (88.57% in Zone A).[15] The study by Ekhlaspour *et al*. found only two out of 17 meters (viz., "Contour Next" and "StatStrip Xpress") to meet the ISO 2013 criteria for accuracy.

The accuracy may vary inter-manufacturer and inter-model of the same manufacturer and comparison of CEGA and ISO 2013 criteria is clinically difficult. Patients and doctors should be careful in the selection of the glucose monitors according to published noninfluential studies. The surveillance accuracy of SDGMs is still not available in the literature.

### What does this study add?

This study adds the surveillance accuracy of SDGM available in India. It is found that the accuracy is lower than the claimed accuracy of the manufacturer according to ADA, CLIA, and ISO 2013 criteria. The accuracy level of the SDGM is lower than that of other stand-alone glucose meters found by other studies.[15,18] However, this comparison is just a rough comparison as those studies were conducted in different settings. However, this rough comparison would help patients and doctors for an informed choice.

### Why accuracy of SDGM was important to explore?

Due to ever-increasing diabetes load in all age groups in India, a significant number of patients can procure the SDGM due to its convenience of smartphone connectivity. Patient can

send the report to their doctors or even can get a consultation from the smartphone application. However, the accuracy of the monitor is the prerequisite for the effective management of diabetes. Hence, exploration of the accuracy of SDGM was need of the hour.

### Novelty of this study

This is the first study to find the surveillance accuracy of SDGMs available in India. Medical and paramedical personnel may use this finding for recommending glucose monitors for their patients. For the test, we have screened the patients for the usage of substance which can interfere with the glucose level. Hence, this surveillance accuracy is solely dependent on the accuracy of the device. In addition, this study was not funded by any external agency and both the devices and strips were procured from the online marketplace which is readily available for usage by consumers.

### Limitation of the study

One sample among the 105 was not included due to the hemolysis of the blood sample. However, we had an adequate sample in comparison to the required sample for a statistically valid study. We took the utmost care to prevent humidity-related alteration and conducted the test with the least possible time period. However, intraday fluctuation of humidity, if any, was beyond our control. We did not measure the hematocrit, uric acid level, total cholesterol, and triglyceride of the patients due to the limitation of funds and manpower. Though it was not mandatory for testing surveillance accuracy, level of hematocrit, uric acid, and altered lipid profile may cause a slight deviation in glucose concentration.[23-25] Furthermore, we did not test reliability (i.e. if the device provides the same result in repeated measurement) of the devices due to lack of fund.

## Conclusion

The surveillance accuracy of two SDGMs (viz., BeatO™ and GlucoMe™) revealed that the accuracy of both the monitors is lower than that of claimed accuracy by the manufacturer. However, these devices can help in formulating treatment guideline for approximately three fourth diabetic patients. The cost of the device and strips, its convenience of using on the smartphone should be considered along with its accuracy for an informed choice for usage of the devices. Future multicenter study with more number of study participants may be carried out to find surveillance accuracy of the devices in future.

### Conflicts of interest

Second author used both the glucose monitors for testing glucose level of his family members before the conception of this study.

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