

# New, small, fast acting blood glucose meters – an analytical laboratory evaluation

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## Abstract

**Background:** Patients and medical personnel are eager to use blood glucose meters that are easy to handle and fast acting. We questioned whether accuracy and precision of these new, small and light weight devices would meet analytical laboratory standards and tested four meters with the above mentioned conditions.

**Methods:** Approximately 300 capillary blood samples were collected and tested using two devices of each brand and two different types of glucose test strips. Blood from the same samples was used for comparison. Results were evaluated using maximum deviation of 5% and 10% from the comparative method, the error grid analysis, the overall deviation of the devices, the linear regression analysis as well as the CVs for measurement in series.

**Results:** Of all 1196 measurements a deviation of less than 5% resp. 10% from the reference method was found for the FreeStyle (FS) meter in 69.5% and 96%, the Glucocard X Meter (GX) in 44% and 75%, the One Touch Ultra (OT) in 29%

and 60%, the Wellion True Track (WT) in 28.5% and 58%. The error grid analysis gave 99.7% for FS, 99% for GX, 98% for OT and 97% for WT in zone A. The remainder of the values lay within zone B. Linear regression analysis resembled these results. CVs for measurement in series showed higher deviations for OT and WT compared to FS and GX.

**Conclusions:** The four new, small and fast acting glucose meters fulfil clinically relevant analytical laboratory requirements making them appropriate for use by medical personnel. However, with regard to the tight and restrictive limits of the ADA recommendations, the devices are still in need of improvement. This should be taken into account when the devices are used by primarily inexperienced persons and is relevant for further industrial development of such devices.

**Key words:** blood glucose meters; laboratory evaluation

## Introduction

After more than twenty years of availability, glucose meters that use whole blood or plasma samples remain the standard method for self monitoring of blood glucose (SMBG) in patients' daily lives. In addition to use in functional insulin treatment following a basal-bolus regimen by use of multiple daily injections or insulin pump, SMBG is being used more and more in diabetic control of patients on conventional insulin treatment or on insulinotropic oral agents with a hypoglycaemic potential. Furthermore, personnel in physicians' offices, hospital wards and nursing homes frequently use glucose meters.

Compared to devices used in the 1980s and 1990s meters are being adapted to patients', educators' and physicians' wishes. Newly marketed glucose meters are smaller, lighter, faster in action and easier to handle. Displays are larger for better legibility and test strips require less amounts of

blood or plasma specimen for measurement with these devices. Most newly developed devices no longer use the reflectance technology but work with electro-chemical methods, e.g. using glucose-oxidase measurements that are converted into electrical signals.

We examined whether some of the new frequently used devices apart from being practical are also analytically exact enough to be recommended for daily use by medical personnel and diabetic patients. Four small, fast acting devices were chosen for evaluation.

### Abbreviations

SMBG	self-monitoring of blood glucose
ADA	American Diabetes Association
CV	Coefficient of variance

## Materials and methods

For the glucose measurements blood samples from capillary finger pricks only were taken at room temperature (approx. 20 °C) from type 1 and type 2 diabetic patients attending our diabetes out-patient clinic. To cover the clinically important glucose ranges samples represent glucose values between 2.2 and 27.7 mmol/L. Samples were taken from consecutively attending patients. Blood glucose was measured using two devices and two different lots of test strips from each of the following brands: FreeStyle (FS) (Abbott Diabetes Care, Alameda, CA, USA), Glucocard X Meter (GX) (Menarini Diagnostics, Florence, Italy), One Touch Ultra (OT) (LifeScan/Johnson & Johnson, Milpitas, CA, USA), Wellion True Track (WT) (Home Diagnostics Inc., Fort Lauderdale, FL, USA). We chose small (<10 × 6 cm), light weight (<50 g), and fast acting (≤10 sec), plasma calibrated meters using electronic sensor technique only. In total 1196, in average 150 measurements per meter, were performed by two experienced laboratory technicians. For the two devices of each brand the same blood sample split into two was compared with our laboratory standard device, a Beckman 2 Analyzer (Beckman Coulter, Fullerton, CA, USA), using the glucose-oxidase method. After the measurement of the first half of the samples per device a different set of test strips was used to exclude a bias by use of only one lot of strips. This procedure was used for all four brands of meters one after the other in consecutively attending patients. The percentage of values in a low (0–5 mmol/L), medium (5–16 mmol/L) and high range (above 16 mmol/L) was in accordance with the usual distribution in consecutive patients and the sample size sufficient for comparison of the different glucose meters. Calibration was performed once daily using calibration strips/chips. All measurements were performed according to recommendations in the manufacturers' manuals. Measurements below 2.2 and above 27.7 mmol/L together with those which indicated "low" or "high" were excluded from the evaluation. Samples with haematocrit values below 30% and above 60% were also excluded.

## Statistics

According to the recommendations of the American Diabetes Association (ADA) for the accuracy of blood glucose measuring devices, we determined the percentage of values within a maximum deviation of 5% and 10% from the comparative method [1, 2]. Additionally the clinically relevant error grid analysis method developed by Clarke and co-workers [3, 4] was used to determine accuracy. The error grid compares values measured by the comparative method (x-axis) with values generated by the glucose meters (y-axis). The graphic model describes deviations by use of asymmetrically arranged areas for glucose ranges. The agreement between glucose meter values and comparative glucose values is expressed by different zones representing the accuracy of the meters. Zone A, clinically accurate; zone B, clinically irrelevant deviation by <20% from the comparative values; zone C, unnecessary overcorrection possible; zone D, "dangerous failure to detect and treat" errors; and zone E, "erroneous treatment" danger. We further determined the differences (mean ± SD) between meter-generated values and those measured with our reference comparison method to check for the tendency towards regular over- or underestimation of glucose values by the meter used. To determine the overall deviation from the comparative method we calculated the mean difference (SD) of all values accumulated by each of the devices. Linear regression analysis compiling the correlation coefficient (r), slope (b), slope intercept and standard error of the estimate (95% CI) was used as the usual method to determine analytical accuracy in laboratory evaluations. A linear regression model forcing a zero intercept was fitted on the Beckman comparison method measurements, which means that B1 should not significantly differ from 1, i.e. an increase of 1 mmol/L as measured on the Beckman device leads, on average, to a similar increase of 1 mmol/L measured with the glucose meter. Within-run precision was calculated by determination of the CV for 10 measurements in series for three different clinically relevant blood glucose ranges: 3.0–3.7 mmol/L, 8.8–10.0 mmol/L, and 14.1–16.8 mmol/L.

## Results

The percentage of values within a maximum deviation of 5% and 10% from the comparative method as recommended by the ADA is shown in table 1.

None of the devices reached the most recent ADA criteria of a 100% of readings within a 5% deviation limit. The FS clearly showed the least deviation followed by the GX device. The GX slightly overestimated (positive mean percentage), the other meters especially the OT and the WT

underestimated (negative mean percentage) the comparison method values, the latter by more than 7% (table 1).

Despite this, the error grid analysis, which serves as a basis for clinical decision making based upon the measured glucose values, showed a very good performance for all devices (fig. 1). The FS and GX devices with 99.7% resp. 99% of all measured values within zone A of the error grid performed excellently in our evaluation. All values for the other two glucose meters examined lay within zone A or B, a deviation that is not clinically relevant (table 2).

The linear regression analysis reflects these clinical results, with a very high correlation for all measurements using a model forcing a zero intercept (table 2). Results for the different sets of glucose test strips within each brand did not show a statistically different deviation from one another.

**Table 1**

Percentage of blood glucose values within a ±5% (±10%) deviation from the reference values and differences between glucose meter and reference method values (n = 1196).

Devices:	Percentage of values (%)	Difference, mean (SD, %)
FreeStyle (FS)	69.5 (96)	-2.2 (4.7)
Glucocard X Meter (GX)	44 (75)	1.9 (9.0)
One Touch Ultra (OT)	29 (60)	-7.1 (7.8)
Wellion True Track (WT)	28.5 (58)	-7.5 (8.4)

To determine precision of the devices, mean CVs for measurement in series were obtained for three different glucose levels. The OT gave a

quite high dispersion in the highest glucose range tested, for the WT the same was the case for the lowest glucose range below 3.7 mmol/L (table 3).

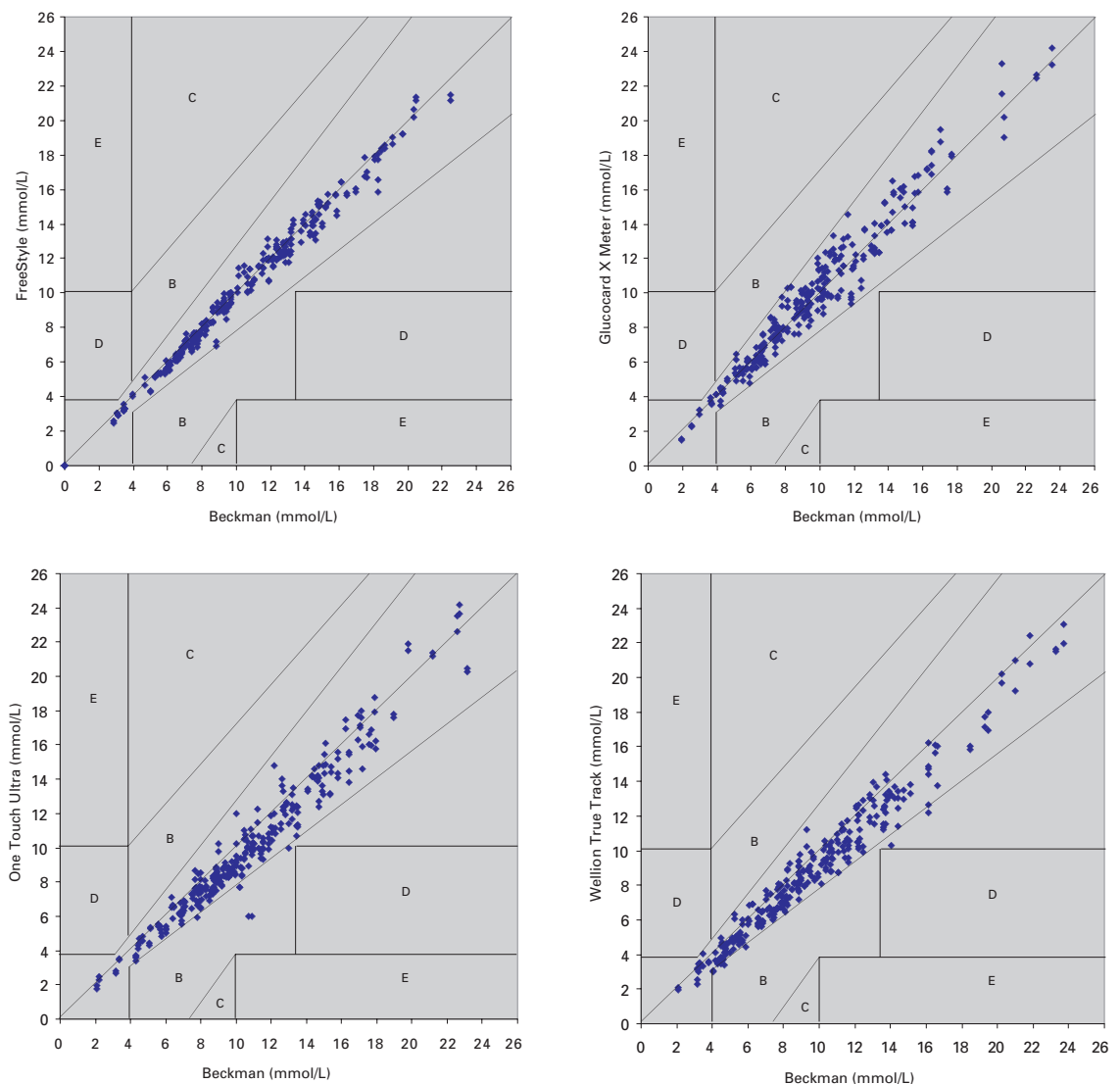
**Table 2**

Linear regression analysis and results of Clarke's Error Grid Analysis (for graphs see fig. 1) for the devices compared to the standard comparison method (n = 1196).

Devices	Regression analysis		Error grid analysis
FreeStyle	r = 0.992, B1 = 0.979	95% CI: 0.972 to 0.986	zone A: 99.7; zone B: 0.3%
Glucocard X Meter	r = 0.976, B1 = 1.019	95% CI: 1.005 to 1.033	zone A: 99.0; zone B: 1.0%
One Touch Ultra	r = 0.976, B1 = 0.938	95% CI: 0.926 to 0.950	zone A: 98.0; zone B: 2.0%
Wellion True Track	r = 0.982, B1 = 0.925	95% CI: 0.913 to 0.937	zone A: 97.0; zone B: 3.0%

**Figure 1**

Error grid analysis for the four blood glucose meters. Readings of glucose meters are plotted against values from the comparison method. The agreement of glucose meter values and reference glucose values is expressed by different zones and thus gives the accuracy of the meters: zone A, clinically accurate; zone B, clinical irrelevant deviation >20% from the reference; zone C, unnecessary overcorrection possible; zone D, dangerous failure to detect and treat errors; zone E, erroneous treatment.



**Table 3**

Mean CVs (%) for 10 measurements in series for three different blood glucose concentrations.

	Sample A 3.0–3.7 mmol/L	Sample B 8.8–10.0 mmol/L	Sample C 14.1–16.8 mmol/L
FreeStyle	2.6	1.5	2.0
Glucocard X Meter	2.7	3.1	1.3
One Touch Ultra	1.9	1.9	5.6
Wellion True Track	6.9	3.1	3.3

## Discussion

A variety of glucose meters for self-monitoring of blood glucose and measurements in physicians' offices as well as hospitals has been developed during recent years. Devices are becoming smaller and faster, quality and size of the displays have improved, sample volumes have been reduced far below 5  $\mu$ L, and capacity to store over 100 values, which may be reviewed by different software modules in the form of tables or graphs, are helpful and have become usual features. Furthermore, test strips and auxiliaries for finger pricks have been improved. However, are these technical innovations able to keep track with the analytical laboratory requirements for performance and precision? Our evaluation tried to answer this question by measuring analytical and clinical accuracy using appropriate statistical methods together with ADA recommendations and Clarke's error grid analysis. Furthermore a linear regression model for the evaluation of the analytical performance was performed. As already presented in former studies of our own [5, 6] meters improved clearly in the late 90s of the last century. The percentage of blood glucose values within a  $\pm 5\%$  deviation from the reference values rose to between 50 and 60% compared to only 30 to 50% for devices developed five to ten years earlier. An assessment of glucose meters used by patients in a French hospital with more than 20,000 capillary measurements did, however, show a decrease in analytical performance from 1990 to 1996, which was thereafter restored between 1997 and 1999 [7]. The meters used in their study are not named according to their brand and there is no information upon the number of different meters, respectively the amount of measurements per brand. These devices may therefore not be comparable to meters used in our former studies or other recent publications on the performance of glucose meters [8–10]. When trying to compare evaluations it is furthermore important to look into the different statistical methods and clinical assessments used. In our study all four devices gave 100% of values within zone A and B of the error grid, which means that clinical decisions made upon the measured values are absolutely accurate and on the safe side. On the other hand, taking the  $\pm 5\%$  deviation according to ADA recommendations we found a maximum difference of 49% between the tested meters. For OT and WT less than 30% of glucose values reached the stringent ADA goal, which shows that the technology is still far from perfect. Even when questioning the clinical importance of these criteria it has to be taken into account that measurements by a technician in a laboratory setting are more precise than those performed by patients, which may extend a slight deviation from a reference

value to a relevant deviation in home blood glucose control. To underline this fact, according to a study by Skeie et al. the difference for CVs for five different meters was 7 to 20% in the hands of the patients compared to only 2.5 to 6% for technicians [11]. An FDA report on meter problems by consumers further confirms these differences. Calibration problems, use of incorrect glucose meter strips, as well as unexplainable false high values, false low values and erratic glucose values stress the need for a standardized and recurrent evaluation of meters used by the patients together with intensive patient education [12].

According to our evaluation the small and fast acting glucose meters currently used do not perform equally exactly despite a very good performance depicted by the error grid analysis and a comparable correlation with the Beckman results when using a linear regression model.

Compared to evaluations of glucose meters developed during the last ten years, it has to be stated that there was definitely a clear improvement when using these standards, but there is still room for new technologies with respect to the high requirements recommended by the ADA. Glucose meters should not be used for diagnostic purposes like oral glucose tolerance testing or the determination of single glucose values taken to exclude or diagnose impaired glucose tolerance or diabetes mellitus.

As devices of each brand were evaluated against the comparative method one after the other, comparisons of the glucose meters against each other are limited by our design.

In summary we may claim that all glucose meters evaluated in our study showed a performance that allows clinically safe use for medical personnel. In order to extrapolate this to patients, even provided that proper education and application according to the manufacturers' recommendations is granted, studies are pending.

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