



## A comparison of blood glucose meters in Australia

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### Abstract

**Objective:** To assess the accuracy and precision of the five currently available blood glucose meters in Australia.

**Design and setting:** Control solutions from manufacturers were used to determine the precision for each meter. Glucose levels in capillary blood samples from 49 patients attending a diabetes clinic were measured with each meter and with a laboratory reference method.

**Outcome measures:** The coefficient of variation was calculated to determine precision. Bias, Error Grid analysis, and Bland–Altman plots were used to determine accuracy.

**Results:** The CVs of most meters were acceptable at <5%. Bias ranged from 4.0 to 15.5% with only 1 meter satisfying the American Diabetes Association recommendation of <5% bias. Error Grid analysis showed that 94–100% of readings were clinically accurate, and that none of the differences from the reference method would lead to clinical errors. Bland–Altman plots showed that for two meters the magnitude of the difference between the meter and the reference method increased with increasing glucose values, but did not change significantly with glucose level for the other 3 meters.

**Conclusions:** Currently available blood glucose meters show acceptable precision, and any errors (with respect to a laboratory method) are highly unlikely to lead to clinical errors. **However, only the CareSens meter achieved a bias of less than 5%.**

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**Keywords:** Self blood glucose monitoring; Blood glucose meters; Accuracy

### 1. Introduction

It is well established that optimal glycaemic control reduces the long-term risk of complications in diabetes. It is currently recommended by the American Diabetes Association (ADA) that treatment of all individuals with diabetes should aim to lower blood

glucose to normal or near normal levels [1]. Self monitoring of blood glucose levels allows the patient to respond immediately to glucose changes with the appropriate action and is currently recommended as an important component of diabetes care [2]. Adequate glycaemic control is therefore dependent on the accuracy and reliability of the self-blood glucose monitoring (SBGM) system used. Since the introduction of SBGM in 1979, there have been ongoing, competition-driven developments in both meter and strip technology, which have allowed greater accuracy

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and reliability of results, as well as improved patient acceptance. While independent studies exist assessing various models of glucose meters to reference values [3–5] assessment of the accuracy and precision of the latest models available in Australia (Accu-Chek Go, Accu-Chek Advantage (Roche), Optium (Abbott) CareSens (i-Sens) and GlucoMen PC (Menarini)) is limited to the manufacturers' "in house" evaluations. There is a need for a direct and independent comparison to be made in order to alleviate any uncertainty regarding performance of these individual meters.

## 2. Aim

To provide an independent assessment of the accuracy and reliability of the latest models of blood glucose meters available in Australia.

## 3. Patients and methods

The latest models of blood glucose meters available in Australia in September 2004 were studied. The five latest available meters were selected: (1) Accu-Chek Go (Roche), which has the same technology as Accu-Chek Active which it is replacing; (2) Accu-Chek Advantage (Roche); (3) CareSens (i-Sens a new entrant in Australia); (4) GlucoMen PC (Menarini) and (5) Optium (Abbott). The GlucoCare (Diabetes Australia NSW) was not available outside the state of New South Wales and the distributors declined requests to submit a meter for evaluation. One new meter of each type was randomly selected from stock.

Prior to the collection of samples, and after the calibration procedure for new vials of strips, quality control measurements were performed using an aqueous solution supplied by the manufacturer for each meter with the exception of GlucoMen PC, for which a control solution is apparently not available in Australia. Precision was measured by calculating the coefficient of variation (CV) using 25 samples from control solutions. Each meter measured within the recommended ranges for the control solutions on each occasion.

Accuracy was measured using blood samples obtained from 49 patients with diabetes attending the

International Diabetes Institute for their usual clinic visit. Capillary blood was obtained using a sterile lancet fixed in a spring-loaded device, and was applied directly from the fingertip to the reagent strip. Successive drops of blood from the same site were used for simultaneous analysis first with the reference method and then with each meter in random order.

The reference method used was the YSI Glucose Analyser (Yellow Springs Instruments, Ohio, USA) using capillary whole blood collected in a hinge cap vial. All samples were collected and tested by the same operator, a pathology nurse with many years experience using various glucose meters.

To compare the performance of each meter to the reference method, several analyses were undertaken. The traditional Error Grid analysis [6] was performed to determine the clinical significance of the differences between the meter and reference value. However, it has been suggested that this can be misleading, and that Bland–Altman charts are preferable [7]. In this analysis, the mean blood glucose obtained from the reference and meter measurements is plotted against the difference between the two results (meter minus reference) with a regression line and 95% limits of agreement calculated. The width of the limits of agreement indicates the variability of the difference between the meter and reference methods over the range of glucose values. A significant Pearson's correlation coefficient ( $r$ ) indicates the degree to which the difference changes with the magnitude of the measurement.

Paired reference and glucose meter readings were used to calculate regression equations for each glucose meter. Bias was also calculated for each meter, as the mean of the difference between the reference and test meter as a percentage of the reference value.

## 4. Results

Table 1 shows that the CVs of the meters, using the manufacturers' test solutions, ranged between 2.8 and 5.5%, and were close to the figures given by the manufacturers, except for the Accu-Chek Go.

Table 2 shows that all the meters read higher than the reference device, with only the CareSens meter meeting the ADA recommendation of <5% bias.

Table 1  
Coefficient of variation (CV) of glucose meters, in rank order and compared to product information.

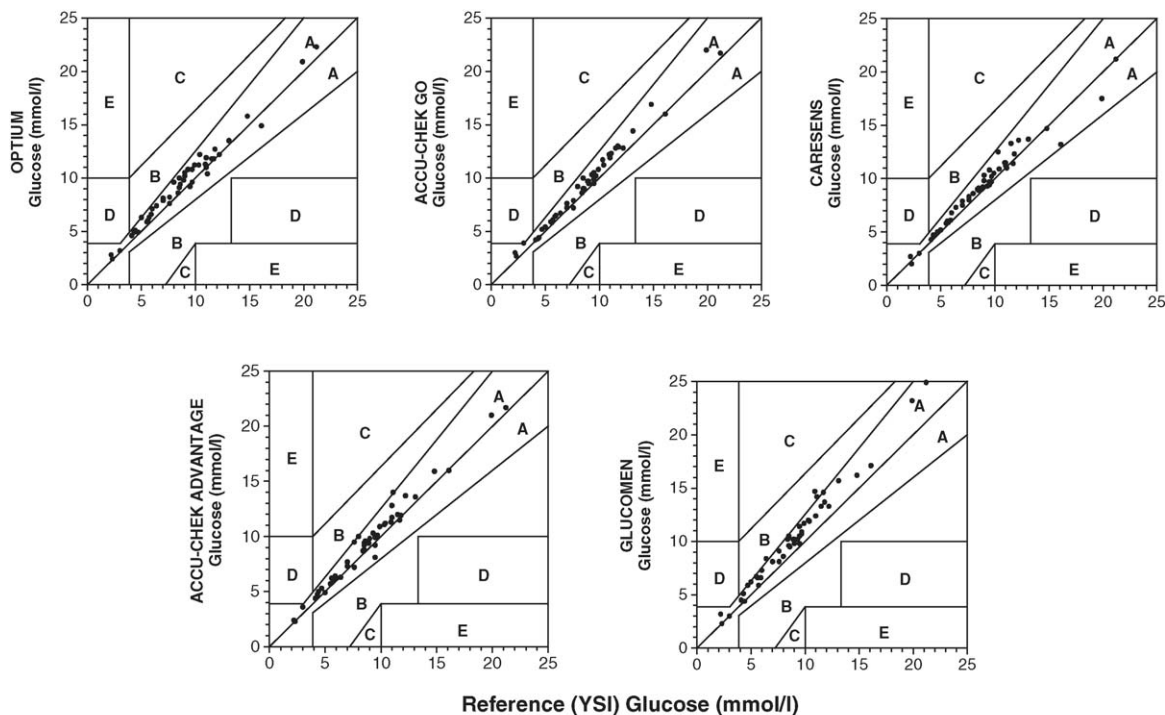
Meter	CV% (low control)	CV% (high control)	Product information
YSI (reference)	–	0.99	NA
CareSens	–	2.83	2.5–3.4
Accu-Chek Advantage	3.64	2.62	<“3.1”
Optium	4.36	3.71	2.9–5.1
Accu-Chek Go	5.51	3.26	1.6
GlucoMen PC	NA	NA	2.79–4.46

Table 2  
Comparison of blood glucose concentrations in 49 patients obtained by glucose meters and reference method (YSI)

Reference/glucose meter	Glucose concentration (mmol/l). Mean (S.D.)	Bias (%)	Regression equation
YSI (reference)	8.933 (3.886)		
Optium	9.533 (3.91)	6.7	$y = 0.99x + 0.67$
Accu-Chek Go	9.619 (4.16)	7.7	$y = 1.06x + 0.12$
CareSens	9.288 (3.70)	4.0	$y = 0.93x + 0.95$
Accu-Chek Advantage	9.510 (4.06)	6.5	$y = 1.03x + 0.29$
GlucoMen	10.317 (4.52)	15.5	$y = 1.15x + 0.03$

The Error Grid analysis (see Fig. 1) showed that all measurements from all meters lay in zones A and B. GlucoMen had three measurements (6.1%) and Accu-Chek Advantage had one measurement (2%) in zone

zone E, glucose meter; x, YSI (reference). Regression equations were calculated from paired values obtained from the reference method and each glucose meter.



- Zone A: Clinically accurate, within +/- 20% of the reference
- Zone B: Error greater than +/- 20%, but would lead to benign differences in or no difference in treatment
- Zone C: Errors would lead to unnecessary corrective treatment
- Zone D: Potentially dangerous failure to detect hypo- or hyperglycemia
- Zone E: Erroneous treatment of hypo- or hyperglycemia

Fig. 1. Error Grid analysis.

B. All other values for these meters and all values for the other meters were in zone A.

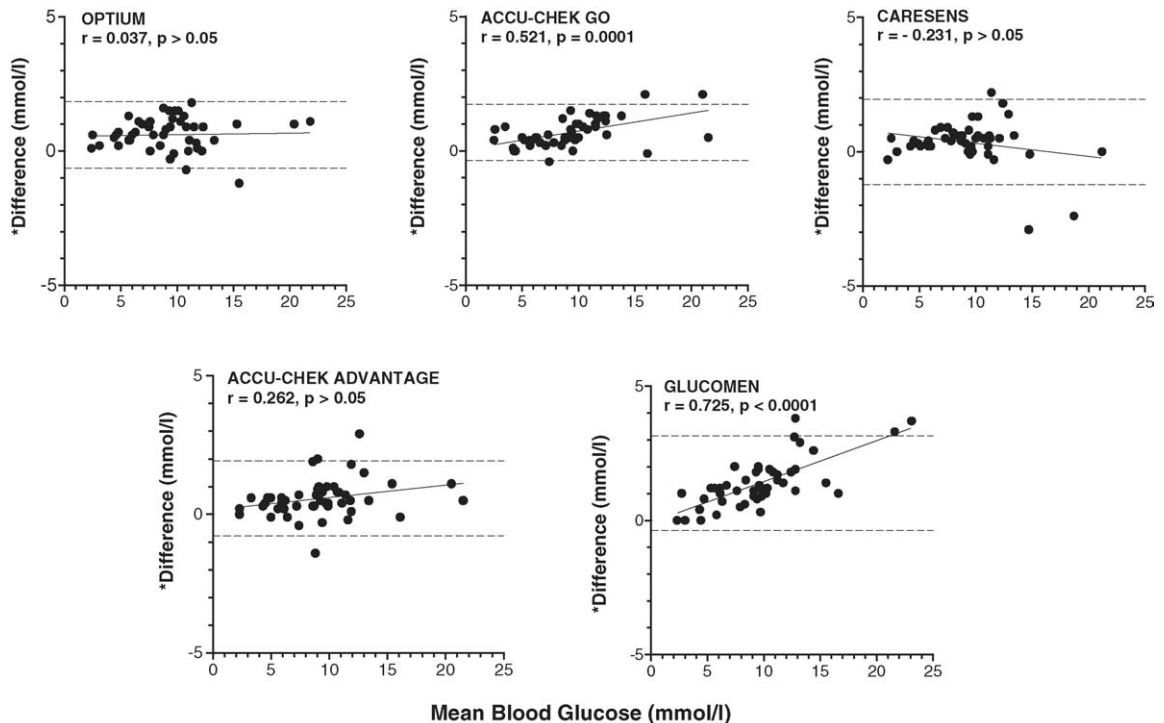
The Bland–Altman analyses (see Fig. 2) showed a significant correlation between the absolute difference (between the meter and the reference method) and the mean of the two methods for the Accu-Chek Go and GlucoMen PC meters, while for the other meters the difference between the meter values and the reference method was the same at lower and higher glucose values. Most meter readings were higher than the reference device, with the mean differences being 0.6 mmol/l for the Optium, 0.7 mmol/l for the Accu-Chek Go, 0.4 mmol/l for the CareSens, 0.6 mmol/l for the Accu-Chek Advantage and 1.4 mmol/l for the GlucoMen.

All meters tested were very compact and portable. Obtaining a BG measurement was straightforward for all meters. All models now use electrochemical technology, apart from Accu-Chek Go, which uses photo-reflectance technology. Sample volume requirements have decreased since our previous analysis [3],

with CareSens having the smallest blood sample volume requirement (0.5  $\mu$ l). Accu-Chek Go and CareSens had the fastest testing time of 5 s. The Optium is the only meter that also performs blood testing of ketones, a recommended part of sick day management in Type 1 diabetes.

## 5. Discussion

Based primarily on the results of the DCCT, the ADA recommends that individuals with diabetes aim at achieving and maintaining blood glucose levels as close as is safely possible to the normal range and SBGM is recommended to assist in achieving this goal. Glucose meters are designed specifically for patient use in determining glucose concentrations in capillary blood. As the accuracy and precision of glucose meters vary, the ADA also recommends calibration and validation of glucose meters.



\*meter minus reference (YSI) method

Fig. 2. Bland–Altman analysis: solid line represents the regression line; dotted lines show 95% limits of agreement.

Precision and accuracy are generally greater with the newer generation models of blood glucose monitors compared to older devices [8,9]. This is reflected in the tightening of the ADA recommendations regarding acceptable limits of deviation from laboratory reference methods [10,11]. Recent studies have assessed various models of glucose meters in relation to reference values. However, despite significant improvements, some meters still fail to satisfy the current recommendations of <5% deviation from reference methods [4,8,12,13].

All meters examined in this study yielded mean glucose concentrations slightly higher than the reference (YSI) method. The current study found the CareSens and Accu-Chek Advantage meters to be the two most precise meters. **The error measured as bias was smallest for the CareSens (4.0%) and Accu-Chek Advantage (6.5%) and largest for GlucoMen (15.5%), with the CareSens meter being the only one which met the ADA recommendation of <5% deviation from the reference method.**

The Bland–Altman analysis showed that the difference between the meter and the reference method was constant across all glucose levels for all meters except the Accu-Chek Go and the GlucoMen. The small difference between the YSI and the meters is probably due to the test strips being calibrated to plasma rather than whole blood glucose values. (The formula used by each manufacturer is unknown, but the conversion factor usually used is 1.11.)

Nevertheless, based on Error Grid analysis results, we have shown adequate clinical accuracy of currently available meters in the hands of an experienced pathology nurse. **All measurements from all meters lay in zones A (clinical accuracy) or B (no or benign treatment differences).** GlucoMen had three measurements (6.1%) and Accu-Chek Advantage had one measurement (2%) in zone B, while all readings from the other meters were in zone A. As the interaction between user and device can be a large source of variability [2], this is potentially a limitation of the current study, which takes no account of patient/user error.

We did not study alternate sites e.g., forearm, that may be used with some meters, but other studies have shown in some circumstances, changes in blood glucose at these sites may lag behind the changes at the finger tip.

## 6. Operating features

The latest meters are an improvement on previous models. They are quicker and easier to both learn and teach, and this represents a significant savings in staff and patient time.

The convenience of using Accu-Chek Advantage, Accu-Chek Go and CareSens which all have a 5 s test may also encourage more frequent testing.

Many clinicians and patients use the computer-downloading feature of these meters. This obviates the need for patients to manually record the results in a diary. It also facilitates the analysis of blood glucose levels, for example, revealing diurnal patterns that assist with altering insulin regimens. However, this feature requires the patient to maintain the correct time and date in the meter on first use, and when changing batteries. Although the actual operation of all meters is simple, the resetting of the date and time is often beyond the ability of many less technically minded people. This is particularly difficult for the optimum meter, which only has a single button for all the control features.

## 7. Conclusion

The information provided in this study indicates good precision and accuracy for all the meters studied, and should provide confidence in their role in achieving optimal glycemic control through SBGM.

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