Evaluation of the Caresens™ N POP capillary glucose meter

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Written collation of report undertaken by Dr Brett Shand

Index

Background

Point of care testing using meters that measure capillary blood are used widely for the management of diabetes. It is recognised that variation between the meter glucose results and those of a reference method may occur in the preanalytical, analytical and post analytical phases[1,2.] To maintain and improve the quality of diabetes care it is important to set standards for evaluation of glucose meters[2]. Full establishment of the accuracy and reliability of these meters involves determining the technical sources of error and defining operator- and patient-related factors, such as for very high or low glucose concentrations, and extremes of haematocrit and temperature.

Technical accuracy and precision is assessed by examining the agreement between a capillary glucose result measured using a meter and a reference method such as a laboratory plasma glucose. Results may then be displayed in a variety of ways. Error grids such as the Clarke[3] or Consensus[4] grids are a useful shorthand way of displaying results from a clinical perspective as they show the differences in blood glucose values measured by a meter, relative to a reference glucose measurement, in a way that relates to patient management. Other methods used to compare glucose results from meter and laboratory plasma tests include Passing and Bablok regression analysis and Bland-Altman plots[5], which help determine the limits of agreement for two measurements and also whether there is evidence of systematic bias.

The assessment of the Caresens™ N POP meter continues our earlier investigations of blood glucose meters available in New Zealand[6-8]. The desirability of undertaking testing within New Zealand with a focus on detecting systematic bias became apparent shortly after the introduction of one meter/strip system, which in its original iteration was found to have such a problem. Recent studies undertaken by the Christchurch Diabetes Centre on behalf of PHARMAC have typically looked at samples from 50 or more patients, as this number is considered the minimum number for determination of major systematic bias. The current study aimed to recruit 100 patients, as this would give a more robust estimation of bias. A secondary aim of the study was to describe results using Error grid analysis.

Characteristics of the Caresens™ N POP meter

We thank Pharmaco NZ for supplying the following information:

The Caresens™ N POP is new to the New Zealand market and is the most advanced of the CareSens meters, offering LCD backlighting, 500 test value memory, data downloaded to PC Care software, a strip expiration indicator, and no requirement for manual coding required. The meter is therefore ideal for patients testing very frequently and needing to measure their blood glucose levels in low-light conditions.

Table 1. Specifications and operating range of the Caresens™ N POP meter

Product specifications	
Reported result range	1.1-33.3 mmol/L
Sample size	Minimum 0.5 µL
Test time	5 seconds
Sample type	Fresh capillary blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Batter light	1000 tests
Power	2 lithium batteries
Memory	500 test results stored with time and date
Analyses	USB data download 1, 7, 14, 30, 90-day test averaging
Screen	Colour with back-lit LCD display Strip expiration date indicator
Size	95x33x19 mm
Weight with batteries	41.2 g
Operating ranges	
Temperature	10-40^{o}C
Relative humidity	10-90%
Haematocrit	20-60%
The meter shows no interference from maltose.	

Methodology

Collection and analysis of capillary and plasma glucose concentration

Assessment of the accuracy and precision of the Caresens™ N POP meter was done using methodology first described by Florkowski *et al*[8], in 2009. Minor improvements to methodology have been made since that date and are detailed in this and the following paragraph. These improvements relate mainly to recording information in greater detail, about patients and their data that were excluded from analysis. They also relate to improved speed of red cell separation from plasma, with the aim of minimising pre-analytical glycolysis.

The inclusion of a more explicit statement about why patients and their results are omitted from analysis relates primarily to a description of very high glucose values. We believe inclusion of this statement is important as it aids understanding of potential biases. For example, if the capillary glucose reads 'hi' with one or more meters, this may relate to the true (reference) glucose being above the range of the meter, or it may relate to systematic bias, whereby a meter records values that are higher than the reference value. Although it is not possible to record a capillary glucose reading (mmol/L) for a 'hi' meter result, it is nevertheless important to include information about the concomitant reference glucose value, which would be expected to be at or above the upper limit of recording for the meter.

The study was carried out between May and July 2012 at the Diabetes Centre, Christchurch Hospital. All participating patients had diabetes but there was no restriction in patient participation based on prandial status, or on immediate antecedent exercise. Capillary samples were collected by Diabetes Research Nurses using a spring-loaded sterile lancet. Patients were asked to wash and dry their hands under the supervision of the nurses, prior to sample collection. The first drop of capillary blood was wiped from the patient's finger and the second and third drop used for capillary glucose analysis. Capillary glucose concentration was measured in duplicate immediately after blood collection using two different meters. Concomitant venous samples were taken from the antecubital fossa and collected into a lithium heparin PST vacutainer, then centrifuged immediately after collection to separate plasma from red cells. Plasma was visually inspected for obvious haemolysis and further screening for haemolysis was undertaken by the laboratory. The plasma glucose concentration was measured by the hexokinase method using an Abbot ci8200 automated analyzer. Assays were carried out by Canterbury Health Laboratories.

Statistical analysis of data

The mean value of the readings for each patient was used in the analyses. Differences between the capillary and venous glucose concentrations were analysed using the following methods.

1. Error grid analysis using the Clarke and also the modified version, known as the Consensus method (EP Evaluator®9, Data Innovations)

Compares capillary and plasma glucose concentration to determine the potential clinical significance of any difference.

2. Bland-Altman analysis (Sigmastat for Windows ver10)
   Analyzes the agreement between two assays by plotting differences between methods against the average concentration.

3. Passing-Bablok regression analysis
   Determines whether there is a significant deviation from linearity in the differences between the glucose meter measurements and the reference plasma glucose assay.

4. Spearman Rank correlation analysis of difference
   Determines systemic bias and the effect of haematocrit.

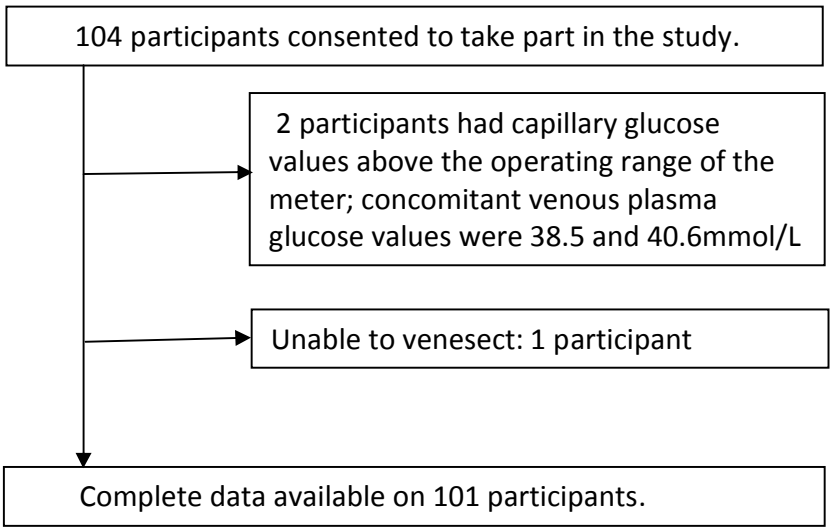
The samples were collected across a narrow temperature range, with a minimum of 19^{o}C and a maximum of 23^{o}C (as recorded on the glucose meters).

The precision of the meter was also determined by replicate analysis (n= 20) of high-, low- and very low glucose quality control solutions. Two different batches of test strips were tested with each meter and the percentage variation calculated.

This study was approved by the Upper South A Regional Ethics Committee (Ethics reference URA/11/06/022).

Results

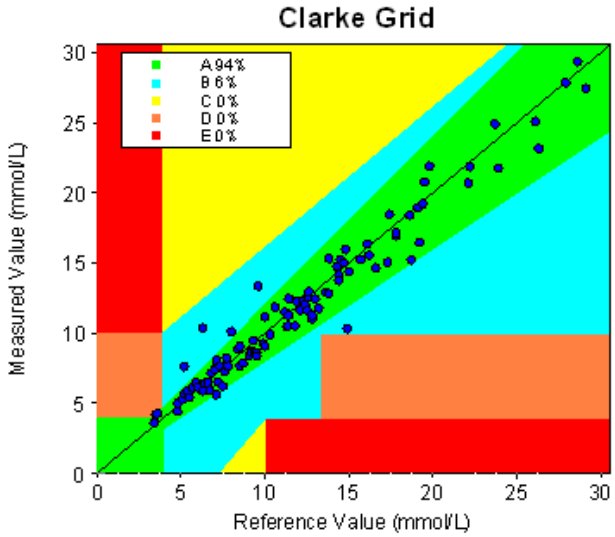
Figure 1. Flow diagram of study participants (patients)



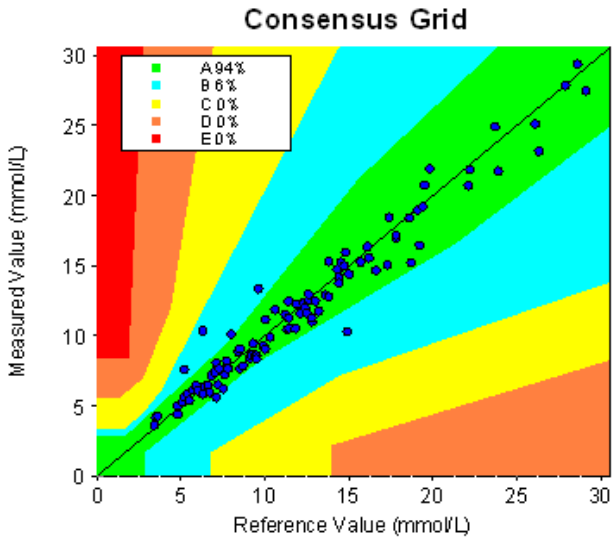
Characteristics of the 101 study participants

Males	61
Females	40
Type 1 diabetes	n = 39
Type 2 diabetes	n = 62
Mean age	53.1 (SD ± 15.8) yr, range 18 – 84 yr
Mean haematocrit	0.41 (SD ± 0.04), range 0.31 – 0.49, no patient had a haematocrit <0.30.

Figure 2. Error grid analysis



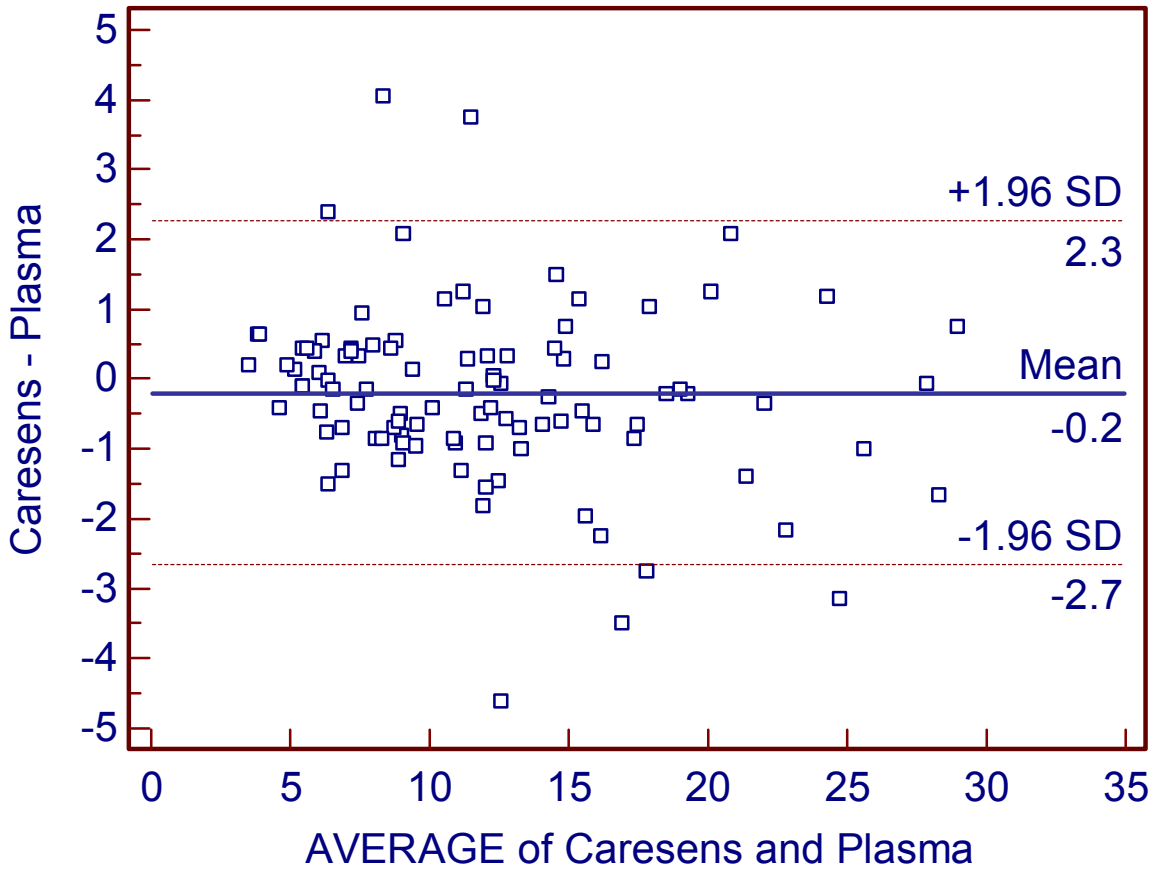
Region	Count	Percent	Cum Percent
A	95	94%	94%
B	6	6%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	101		



Region	Count	Percent	Cum Percent
A	95	94%	94%
B	6	6%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	101		

A - <20% deviation
B - deviation that leads to no change in treatments
C - overcorrection of an acceptable glucose level
D - dangerous failure to detect and treat abnormal glucose levels
E - erroneous treatment

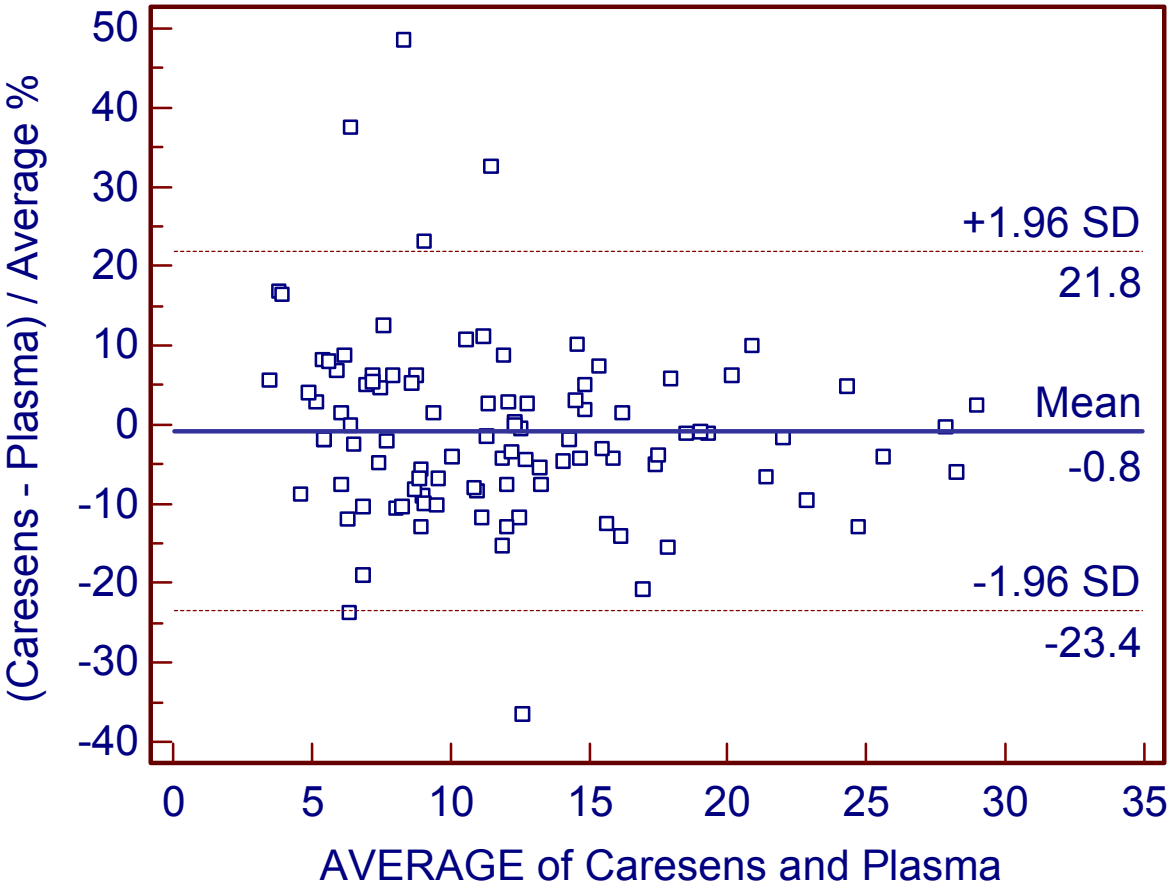
Figure 3. Bland Altman plot - Difference between methods



Method A	Caresens™ N POP
Method B	Plasma
Sample size	101
Arithmetic mean difference (95% CI)	-0.2015 (-0.45 to 0.04)
Standard deviation	1.26
Lower limit (95%CI)	-2.66 (-3.10 to -2.24)
Upper limit (95%CI)	2.26 (1.84 to 2.69)
Arithmetic mean	-0.43

Visual inspection suggests evidence of minor systematic bias – negative bias of meter readings at higher glucose values.

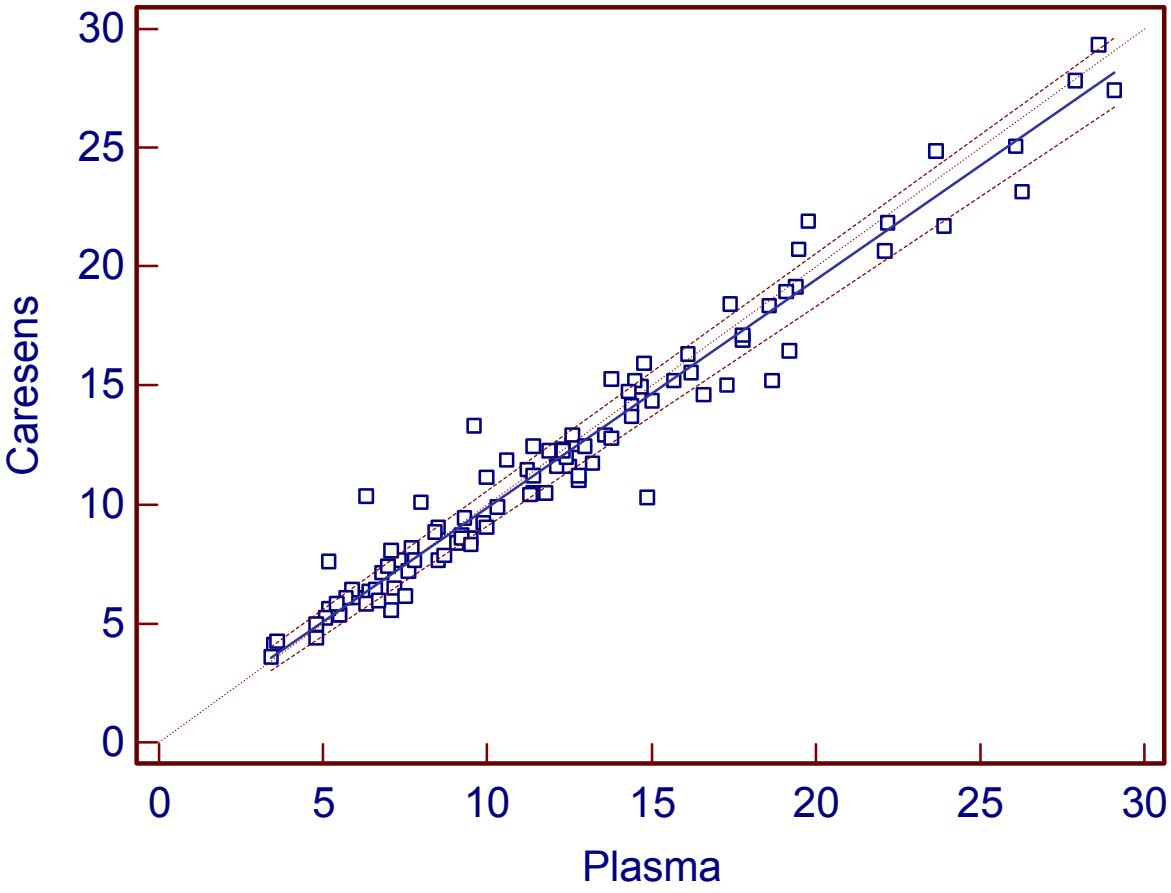
Figure 4. Bland Altman plot – Percentage difference between methods



Method A	Caresens™ N POP
Method B	Plasma
Sample size	101
Arithmetic mean (95% CI)	-0.81 (-3.09 to 1.46)
Standard deviation	11.53
Lower limit (95%CI)	-23.42 (-27.33 to -19.52)
Upper limit (95%CI)	21.80 (17.89 to 25.70)
Arithmetic mean	-2.25%

Visual inspection suggests evidence of minor systematic bias – negative bias of meter readings at higher glucose values.

Figure 5. Passing and Bablok regression



y = 0.2701 + 0.9578 x	
Intercept A	0.27
95% CI	-0.13 to 0.62
Slope B	0.96
95% CI	0.92 to 0.99
Cusum test for linearity	No significant deviation from linearity (P>0.10)

Table 2. Spearman rank correlation

Variable Y	Difference: Caresens™ N POP - Plasma
Variable X	Mean glucose
Sample size	101
Spearman's coefficient of rank correlation (rho)	-0.21
Significance level	P=0.0377
95% Confidence Interval for rho	-0.39 to -0.01

Significant inverse correlation indicates small proportional bias – i.e. meter tends to read lower at higher mean glucose, confirming the impression obtained from visual inspection of Figures 3 and 4.

Table 3. Summary statistics for haematocrit

Variable	Haematocrit
Sample size	101
Lowest value	0.3100
Highest value	0.4900
Arithmetic mean	0.4135
95% CI for the mean	0.4060 to 0.4210
Median	0.4200
95% CI for the median	0.4100 to 0.4200

Table 4. Spearman rank correlation for haematocrit against [capillary-plasma] glucose difference.

Variable Y	Difference: Caresens™ N POP - Plasma
Variable X	Haematocrit
Sample size	101
Spearman's coefficient of rank correlation (rho)	-0.278
Significance level	P=0.0054
95% Confidence Interval for rho	-0.449 to -0.087

This table shows an inverse correlation between haematocrit and [capillary-plasma] glucose difference.

Figure 6. Meter tends to read lower as haematocrit increases

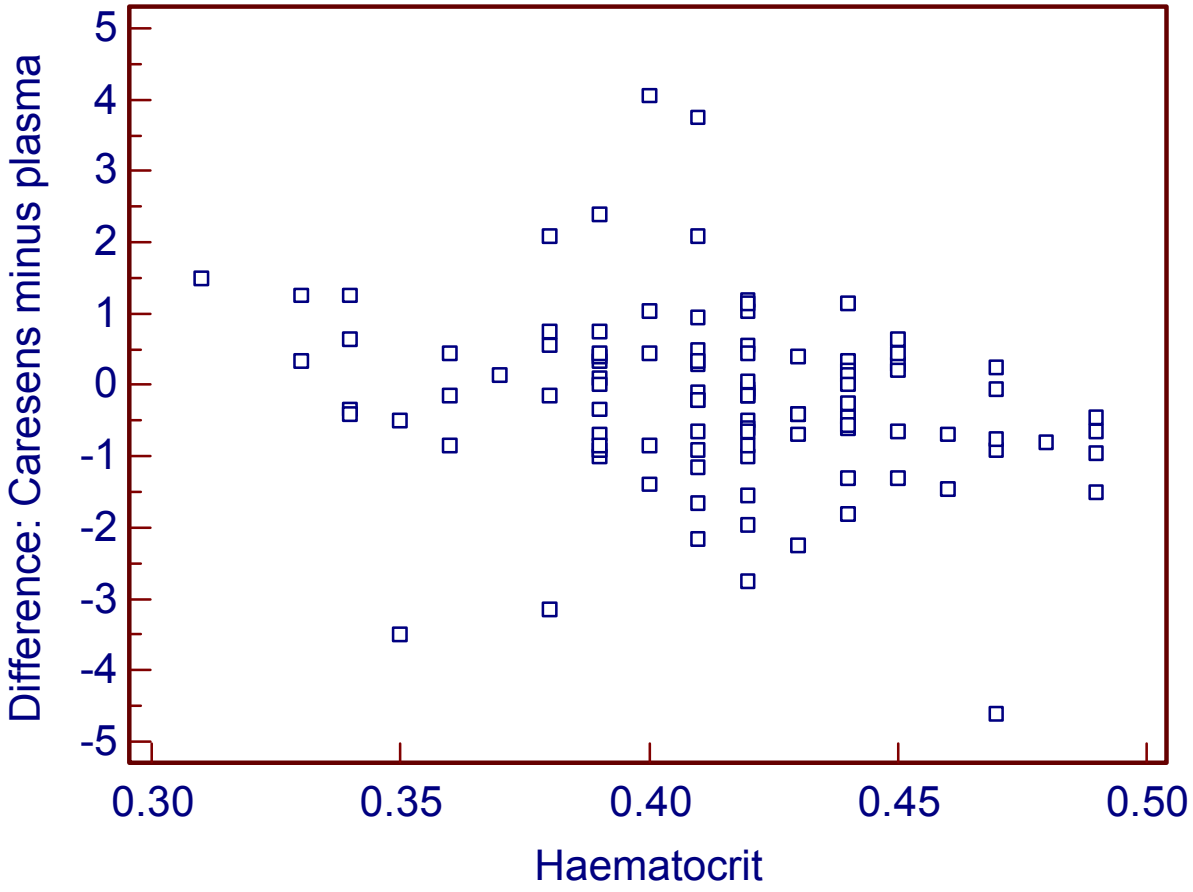


Table 5. Percentage variation (CV %) in replicate testing (n=20)

Meter 1

Very low glucose level		Low glucose level		High glucose level	
Mean (SD)	% variation	Mean (SD)	% variation	Mean (SD)	% variation
2.67 (0.13)	1.82	7.44 (0.24)	5.62	13.54 (0.60)	3.61

Meter 2

Very low glucose level		Low glucose level		High glucose level	
Mean (SD)	% variation	Mean (SD)	% variation	Mean (SD)	% variation
2.42 (0.15)	2.38	7.75 (0.53)	2.84	13.50 (0.45)	2.05

Table 6. Comparison of measurements between Caresens™ N POP meters and plasma glucose assessed in the laboratory.

	Caresens™ N POP		Abbot ci8200
	Meter 1	Meter 2	
Mean (mmol/L)	11.94	11.94	12.14
Std deviation	5.76	5.77	5.98
Std error	0.57	0.57	0.59
Median	11.2	11.2	11.4

Summary of results

- Error grid analysis. On error grid analysis (see Figure 2) all results lay within Zones A and B. Results in this range would not be expected to cause a bias that might lead to an inappropriate change in treatment.

- The Bland–Altman plots showed evidence of minor systemic bias (negative bias at higher glucose concentrations confirmed).

- On Passing and Bablok regression (Figure 5), the deviation from linearity for difference between the two methods was minor, with a 95% CI for the slope lying between 0.92 and 0.99.

- Spearman rank correlation analyses showed minor systematic biases. As glucose values increased, the meter tended to read lower compared to plasma values (Table 2). Higher haematocrit values were associated with lower glucose readings (Table 3).

- Replicate testing confirmed the meters had acceptable precision at high, low and very low glucose concentrations (Table 5).

Additional study limitations

There were no patients in the hypoglycaemic range, thus meter performance at very low glucose levels was not assessed. This study was carried out under controlled (ideal) conditions by a research team experienced in meter validation. This limits the generalisability of the findings to the real world setting of more extreme testing conditions and variable use of meters by patients.

As with previous local meter studies, venous plasma was used as the reference standard, as New Zealand patients and their caregivers expect their capillary glucose meter results to read as venous plasma equivalent. This is the relevant reference standard when looking for systematic bias but it does no allow full validation of a meter for the following reasons: There are well documented differences between the concentration of glucose in venous and capillary samples [1,2], and these physiological differences are enhanced post prandially. Without having a capillary reference standard, it is therefore difficult to determine whether 'outlier' values are due to meter/strip system inaccuracy or relate to physiological capillary-venous differences. A more robust assessment of meter performance against ISO standards would require reference method assessment of both capillary as well as venous samples[10], but this methodology can be problematic due to issues related to collecting sufficient sample volume[1].

Conclusions

1. The observed systemic biases were minor and were in a direction that may be expected when considering the differences between capillary whole blood and venous plasma. For example when haematocrit increases, the proportion of water in the sample decreases, thus the meter reads lower.
2. This study did not aim to directly compare the Caresens™ N POP meter with other meters. No conclusion should therefore be drawn about the performance of the Caresens™ N POP meter relative to other meter systems, based only on the results presented in this and earlier studies done by us on behalf of PHARMAC.
3. As discussed in the 'Study Limitation' section above, the current study methodology was not explicitly designed to assess the Caresens™ N POP meter against ISO standards.

Acknowledgements

We thank patients for their participation. It would not have been possible to undertake this study without the help of the Diabetes Centre staff, particularly Sue Paul and Kit Hoeben. We appreciated the help of study nurses Helen Heenan and Jo Yardley. We also thank the Canterbury Health Laboratory staff for carrying out the venous plasma glucose assays.

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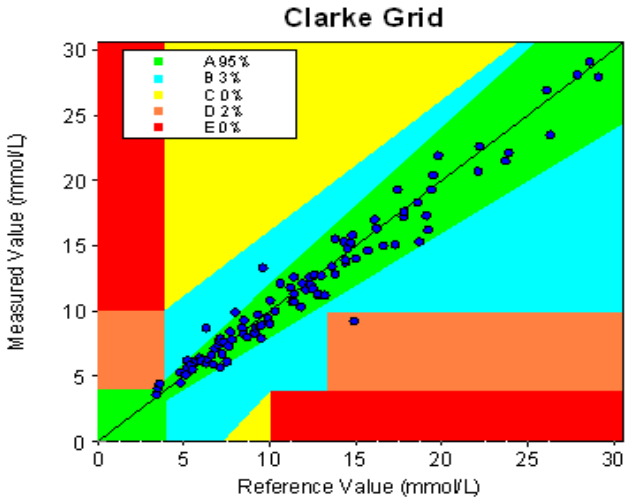
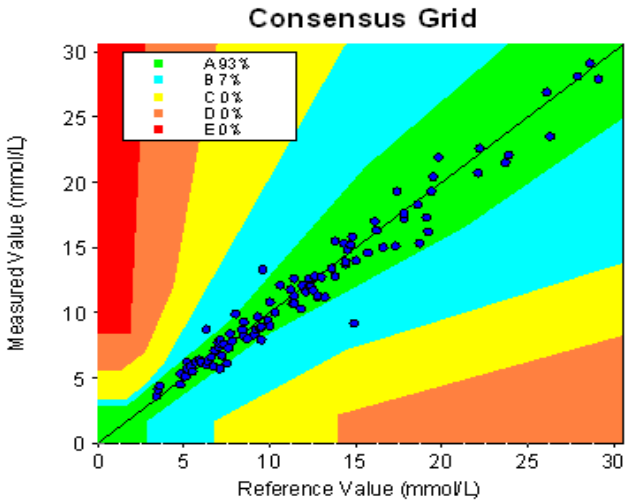
Appendix

Figure 7 **Separate error grid analyses of the two Caresens™ N POP meters evaluated.**

Figure 7a **Meter 1**



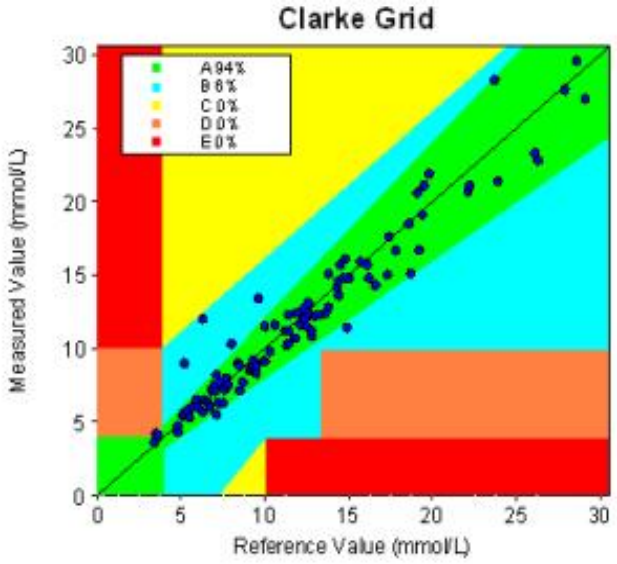
Region	Count	Percent	Cum Percent
A	96	95%	95%
B	3	3%	98%
C	0	0%	98%
D	*2*	*2%*	*100%*
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	101		



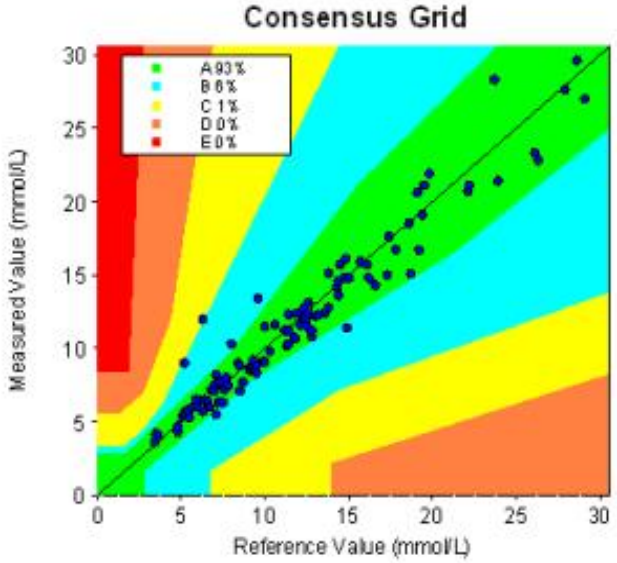
Region	Count	Percent	Cum Percent
A	94	93%	93%
B	7	7%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	101		

A - <20% deviation
B - deviation that leads to no change in treatments
C - overcorrection of an acceptable glucose level
D - dangerous failure to detect and treat abnormal glucose levels
E - erroneous treatment

Figure 7b Meter 2



Region	Count	Percent	Cum Percent
A	95	94%	94%
B	6	6%	100%
C	0	0%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	101		



Region	Count	Percent	Cum Percent
A	94	93%	93%
B	6	6%	99%
C	1	1%	100%
D	0	0%	100%
E	0	0%	100%
Excluded	0		
Out/Bnds	0		
Total	101		

A - <20% deviation
B - deviation that leads to no change in treatments
C - overcorrection of an acceptable glucose level
D - dangerous failure to detect and treat abnormal glucose levels
E - erroneous treatment

Table 7. Glucose values (mmol/L) for capillary meter readings including average capillary glucose, venous plasma glucose and haematocrit for the 101 diabetic participants

Meter1	Meter2	**Avg Meter**	Plasma Ref	Haematocrit
5.5	5.3	**5.40**	5.5	0.42
5.5	5.3	**5.40**	5.5	0.41
15.8	16.1	**15.95**	14.8	0.44
20.4	21.1	**20.75**	19.5	0.34
19.3	17.6	**18.45**	17.4	0.40
10.0	9.8	**9.90**	10.3	0.43
11.8	11.2	**11.50**	11.2	0.41
26.9	23.3	**25.10**	26.1	0.42
4.1	4.2	**4.15**	3.5	0.45
17.2	16.7	**16.95**	17.8	0.40
6.2	6.0	**6.10**	6.0	0.39
6.3	6.5	**6.40**	6.4	0.39
7.6	7.7	**7.65**	7.3	0.44
8.8	8.4	**8.60**	9.4	0.48
5.7	5.6	**5.65**	5.2	0.40
9.3	8.8	**9.05**	8.5	0.38
12.7	12.4	**12.55**	12.6	0.47
18.3	18.5	**18.40**	18.6	0.41
11.3	11.2	**11.25**	11.4	0.38
13.4	12.4	**12.90**	13.6	0.39
15.1	15.0	**15.05**	17.3	0.43
8.7	12.0	**10.35**	6.3	0.40
17.6	16.7	**17.15**	17.8	0.41
21.5	28.3	**24.90**	23.7	0.42
12.8	12.8	**12.80**	13.8	0.39
6.4	6.5	**6.45**	5.9	0.42
8.7	8.7	**8.70**	9.2	0.42
8.3	8.5	**8.40**	9.1	0.46
16.3	14.8	**15.55**	16.2	0.49
7.3	7.2	**7.25**	7.6	0.39
6.2	9.0	**7.60**	5.2	0.39
6.0	5.7	**5.85**	6.3	0.49
8.9	8.3	**8.60**	9.5	0.41
17.0	15.7	**16.35**	16.1	0.47
14.6	15.9	**15.25**	15.7	0.44
28.1	27.6	**27.85**	27.9	0.42

Meter1	Meter2	**Avg Meter**	Plasma Ref	Haematocrit
3.6	3.6	**3.60**	3.4	0.44
8.4	8.0	**8.20**	7.7	0.41
8.2	7.1	**7.65**	8.5	0.42
9.9	10.3	**10.10**	8.0	0.38
15.2	14.8	**15.00**	14.7	0.45
7.4	7.5	**7.45**	7.0	0.36
29.1	29.6	**29.35**	28.6	0.39
12.6	12.3	**12.45**	11.4	0.42
12.0	12.7	**12.35**	12.3	0.42
10.8	11.5	**11.15**	10.0	0.42
20.7	20.7	**20.70**	22.1	0.40
12.8	13.1	**12.95**	12.6	0.33
14.8	15.7	**15.25**	14.5	0.38
19.3	19.1	**19.20**	19.4	0.41
8.7	8.5	**8.60**	9.2	0.42
4.5	4.3	**4.40**	4.8	0.43
13.3	13.4	**13.35**	9.6	0.41
11.7	11.5	**11.60**	12.5	0.47
7.9	8.8	**8.35**	9.5	0.41
15.0	14.3	**14.65**	16.6	0.42
17.3	20.6	**18.95**	19.1	0.42
10.7	10.3	**10.50**	11.4	0.39
7.1	7.2	**7.15**	6.8	0.39
11.2	12.3	**11.75**	13.2	0.46
12.1	12.4	**12.25**	11.9	0.41
11.2	10.8	**11.00**	12.8	0.44
6.2	6.0	**6.10**	5.7	0.43
10.3	10.7	**10.50**	11.8	0.45
16.2	16.7	**16.45**	19.2	0.42
8.7	9.0	**8.85**	8.4	0.42
15.3	15.1	**15.20**	18.7	0.35
5.1	5.4	**5.25**	5.1	0.44
13.7	14.6	**14.15**	14.4	0.44
6.7	6.3	**6.50**	7.2	0.43
23.5	22.8	**23.15**	26.3	0.38
5.3	4.7	**5.00**	4.8	0.45
7.8	7.5	**7.65**	7.8	0.36
9.4	9.1	**9.25**	9.9	0.42
13.9	13.6	**13.75**	14.4	0.45
5.9	5.8	**5.85**	5.4	0.45
11.6	11.6	**11.60**	12.1	0.35

Meter1	Meter2	**Avg Meter**	Plasma Ref	Haematocrit
9.0	9.1	**9.05**	10.0	0.49
7.7	7.1	**7.40**	7.0	0.39
10.7	10.2	**10.45**	11.3	0.39
12.1	11.6	**11.85**	10.6	0.33
9.2	11.4	**10.30**	14.9	0.47
27.9	27.0	**27.45**	29.1	0.41
6.1	6.3	**6.20**	7.5	0.44
22.1	21.4	**21.75**	23.9	0.41
5.7	5.5	**5.60**	7.1	0.49
12.7	12.2	**12.45**	13.0	0.44
11.3	11.2	**11.25**	12.8	0.42
8.0	7.7	**7.85**	8.7	0.36
6.6	6.3	**6.45**	6.6	0.42
15.5	15.1	**15.30**	13.8	0.31
9.7	9.2	**9.45**	9.3	0.37
7.9	8.2	**8.05**	7.1	0.41
5.9	6.0	**5.95**	6.7	0.47
4.4	4.1	**4.25**	3.6	0.34
15.3	14.2	**14.75**	14.3	0.39
12.0	12.0	**12.00**	12.4	0.34
21.9	21.9	**21.90**	19.8	0.41
12.6	12.0	**12.30**	12.3	0.44
14.0	14.8	**14.40**	15.0	0.44
22.6	21.1	**21.85**	22.2	0.34

The ISO15197 requirements state that a minimum of 95% of the individual glucose results shall fall with ±0.83 mmol/L at glucose concentrations of <4.2 mmol/L and within ±20% at glucose concentrations ≥4.2 mmol/L[10]. This study was not designed to assess the meter against ISO standards but we note in passing that, when considering individual capillary glucose readings, 192/202 (95%) are within the tolerance allowable under ISO requirements.

Comments on the use of the Caresens™ N POP meter from Florence Logan, Senior Research Nurse, Christchurch Diabetes Centre.

"I found the length of the strips very short and as a consequence they were difficult to handle. I felt I was therefore 'over-handling' the strips, compared to strip handling for other meter studies. It was more difficult not to touch the strip inadvertently compared to other systems. For example, when taking the strip out of the container, I sometimes ended up touching a lot of the other strips in the container. A further comment was that the mechanism for loading the strip into the meter did not feel natural or easy. If the meter LCD was upright the strip was loaded with my left hand, which felt 'clumsy' ".

Effect of maltose on meter performance

The CareSens strip which uses glucose oxidase has little specificity to most sugars including maltose and hence, the blood glucose measurement with the CareSens strip and meter does not exhibit any interfering response to maltose.

Comparison of the study findings with a similar study carried out in 2010 in Korea by Huh *et al*.

We note with interest the paper by Huh H-J *et al*[9], from Korea that evaluated the CareSense™ N glucometer in an ambulatory setting and compared its performance with two other brands of meter. Because the current study and the Huh study share some similarities, we are including a comment on this paper in this Appendix.

In general the findings of the two studies were similar with linearity and precision of the readings being within acceptable limits (<5% coefficient of variation), and the correlation coefficient between the venous sample and Caresens™ N POP meter results being similar (Huh r^2=0.961, r=0.980 vs current study r=0.978). Both studies showed that the Caresens™ N meter tended to read low at high haematocrit values. The Huh study demonstrated this minor proportional bias by comparing haematocrit with the ratio of capillary glucose to laboratory venous glucose values, whereas our study used the capillary-plasma difference. A minor difference noted between the two studies was our finding of several outliers at low glucose levels with the Caresens ™ N POP meter.

However, it is not possible to compare directly the results of the two studies as they had multiple minor methodological differences, either stated or implied. For example, Huh *et al* did not include error grid analyses, relying instead to identify meter readings that fell outside designated levels of percentage differences with the plasma glucose assay. Huh *et al* also measured venous plasma glucose twice and calculated the mean value, whereas our study measured venous plasma glucose only once, The Huh study is therefore likely to give a slightly more precise measure of true venous plasma glucose. The Huh paper however used only one capillary sample to compare the three meters in the study, whereas we used the mean of two capillary samples to evaluate the CareSens™ N POP meter. Patient characteristics were also likely to differ slightly between the two studies, as Koreans with diabetes are likely to be predominantly type 2, whereas one-third of the patients in the current study had type 1 diabetes. It is also unknown how many of the patients in the Korean study were fasting, as a fasting sample will minimise the known venous-capillary glucose gradient that occurs post-prandially. (Blood samples in our study were collected in the non-fasting state).