

Accuracy Test

Omnitest[®] 3 Blood Glucose Monitoring System



B. Braun Diabetes Care

Accuracy Test

Omnitest[®] 3 blood glucose monitoring system according to ISO 15197

The accuracy study of Omnitest[®] 3 blood glucose monitoring system was assessed by comparing patients' blood glucose results obtained with Omnitest[®] 3 with those obtained using the YSI 2300 auto analyzer, a standard laboratory instrument. Glucose levels were measured in 100 patients from three different hospitals.

Test information

A) Test date:	2012.11.26 ~ 2012.12.12	E) Standard/Guidance documents referenced:	
B) Test meter serial number:	GAA2RDMC00049 ~ GAA2RDMC00054	▪ ISO/DIS 15197:2010 In Vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (during clinical trial)	
C) Test strip lot numbers:	G5MJ24, G5MJ25, G5MJ26	▪ ISO 15197:2013 In Vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (for data analysis)	
D) Sample numbers:	<ul style="list-style-type: none">▪ 6 x Omnitest[®] 3 meters▪ 600 x Omnitest[®] 3 test strips (three lots)▪ 1 x YSI 2300 auto analyzer	▪ CLSI EP09-A2: 2004 Method comparison and bias estimating using patient samples	

Acceptance criteria

95% of the individual glucose results shall deviate max. ± 0.83 mmol/L from the results obtained by the hospital laboratory device (YSI 2300) at glucose concentration < 5.5 mmol/L and the deviation should be per maximum $\pm 15\%$ at glucose concentration ≥ 5.5 mmol/L (according to ISO 15197:2013).

Test results | Sample distribution

Glucose concentration mmol/L	Percentage of sample	Sample #	Preparation of sample
≤ 2.77	5%	5	glycolyzed
$> 2.77 - 4.44$	15%	15	unaltered
$> 4.44 - 6.66$	20%	20	unaltered
$> 6.66 - 11.10$	30%	30	unaltered
$> 11.10 - 16.65$	15%	15	unaltered
$> 16.65 - 22.20$	10%	10	unaltered
> 22.20	5%	5	supplemented with glucose
SUM	100%	100	

Table 1 | Distribution of glucose concentrations of samples for system accuracy evaluation

Test results | System accuracy plot

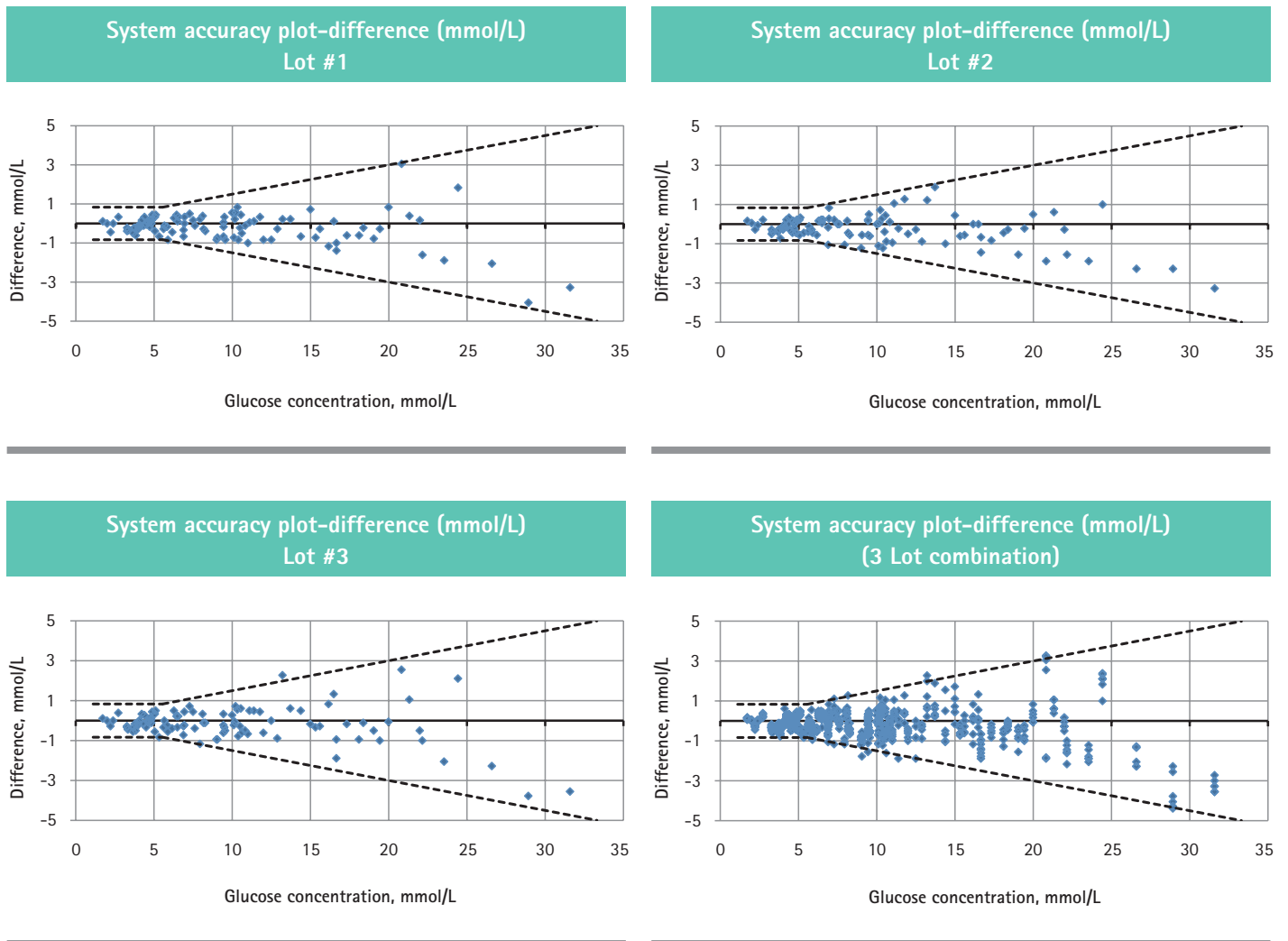
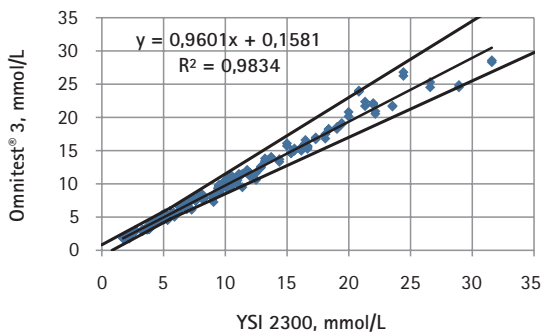


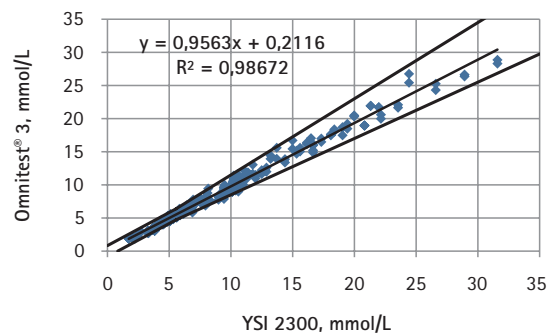
Figure 1 | System accuracy plot-differences of the 3 x 200 blood glucose samples with the Omnitest® 3 BGMS vs. YSI 2300 at hospital using 3 lots of test strips

Test results | System accuracy plot

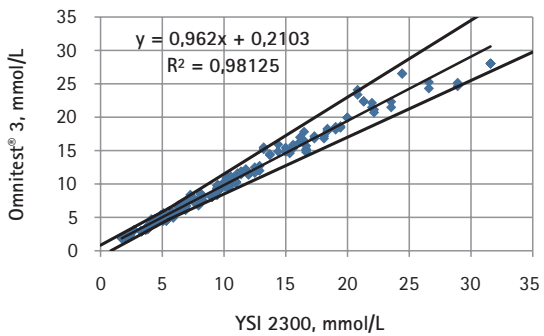
System accuracy plot
Lot #1



System accuracy plot
Lot #2



System accuracy plot
Lot #3



System accuracy plot
(3 Lot combination)

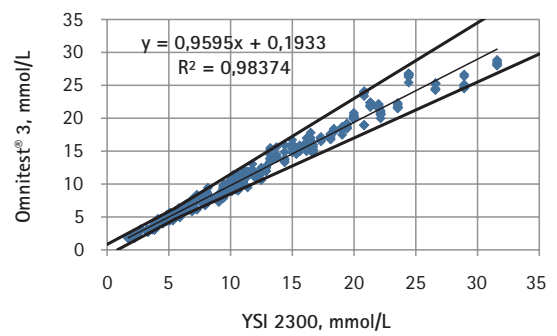


Figure 2 | Linear regression of the 3 x 200 blood glucose samples with the Omnitest® 3 BGMS vs. YSI 2300 at hospital using 3 lots of test strips

Data analysis | Bias distribution analysis against YSI 2300

Strip Lot	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Lot 1	46/62 (74.2%)	58/62 (93.5%)	62/62 (100.0%)
Lot 2	40/62 (64.5%)	59/62 (95.2%)	62/62 (100.0%)
Lot 3	36/62 (58.1%)	58/62 (93.5%)	62/62 (100.0%)
Combined	122/186 (65.6%)	175/186 (94.1%)	186/186 (100.0%)

Table 2 | System accuracy results for Glucose concentration < 5.5 mmol/L

Strip Lot	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
Lot 1	77/138 (55.8%)	126/138 (91.3%)	132/138 (95.7%)
Lot 2	70/138 (50.7%)	122/138 (88.4%)	134/138 (97.1%)
Lot 3	68/138 (49.3%)	118/138 (85.5%)	133/138 (96.4%)
Combined	215/414 (51.9%)	366/414 (88.4%)	399/414 (96.4%)

Table 3 | System accuracy results for Glucose concentrations ≥ 5.5 mmol/L

Consensus error grid analysis against YSI 2300:

The evaluation of the distribution of the test results within the consensus error grid shows that 600 out of 600 measurements (100%) are within the zones A and B.

Conclusion

A good and direct correlation between a standard hospital laboratory device (YSI 2300) and Omnitest[®] 3 were confirmed in the 600 blood samples (100 patients) with a combined correlation coefficient $R^2 = 0.9837$. The results indicate that the use of the Omnitest[®] 3 blood glucose monitoring system generate similar results as the YSI 2300 auto analyzer, a laboratory instrument used in hospitals to test for glucose concentration.

The data shown prove that the results are within the accuracy standard of the ISO 15197:2013 thus within the acceptance criteria.

References

1. ISO/DIS 15197:2010 In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
2. ISO 15197:2013 In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
3. CLSI EP09-A2: 2004 Method comparison and bias estimating using patient samples
4. Parkes J.L. et al. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood-glucose. Diabetes Care. 2000, 23 (8) pp. 1143-1148

