B BRAUN
SHARING EXPERTISE

Blood Glucose Measurement

Omnitest® 5

ACCURACY TEST
INTERNATIONAL STANDARD ISO 15197:2013

Omnitest® 5 Accuracy Test

In accordance with the ISO 15197:2013 standard, new criteria for blood glucose meters have been published.

The aim of this document is to present a summary of the key requirements concerning the new and stricter international standard. It describes the different acceptance criteria which are now part of the original ISO document and how Omnitest® 5 meets these new requirements.

THE MAIN TOPICS AT A GLANCE

System Accuracy Evaluation

TEST INFORMATION

SYSTEM ACCURACY

The accuracy of Omnitest® 5 blood glucose monitoring system was assessed by comparing patients' blood glucose results obtained with Omnitest® 5 with those of a standard laboratory instrument, the YSI 2300 auto analyzer.

1) Test date	August 3, 2015 – August 20, 2015
2) Test meter serial number	GAF3DEPD0001 – GAF3DEPD0003 (white model) GAF3DEPD0010 – GAF3DEPD0013 (black model)
3) Test strip lot numbers	F2QF03 (Lot #1), F2QF04 (Lot #2), F2QF05 (Lot #3)
4) Sample numbers	▪ 3 x Omnitest® 5 meter white 3 x Omnitest® 5 meter black ▪ 600 x Omnitest® 5 test strips (three lots) ▪ 1 x YSI 2300 auto analyzer
5) Standard/guidance documents referenced	▪ ISO 15197:2013 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (for data analysis) ▪ CLSI EP09-A3:2013 Method comparison and bias estimating using patient samples ▪ CLSI EP27-A:2012 How to construct and interpret an error grid for quantitative diagnostic assays

SAMPLE DISTRIBUTION

SYSTEM ACCURACY

Glucose concentration mg/dL	Percentage of sample	Sample numbers	Preparation of sample
≤ 50	5 %	5	glycolyzed
> 50 – 80	15 %	15	unaltered
> 80 – 120	20 %	20	unaltered
> 120 – 200	30 %	30	unaltered
> 200 – 300	15 %	15	unaltered
> 300 – 400	10 %	10	unaltered
> 400	5 %	5	supplemented with glucose
Total	100 %	100	

Distribution of glucose concentrations in samples for system accuracy evaluation

System Accuracy Evaluation
Difference Plot

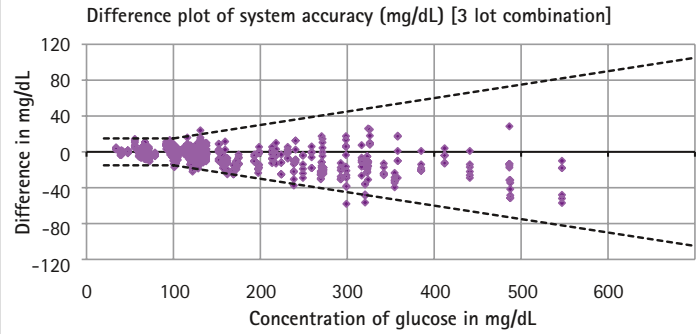
ACCEPTANCE CRITERIA

ACCURACY PLOT – PART 1

Blood glucose concentration & requirements	Tolerance range
< 100 mg/dL	± 15 mg/dL
≥ 100 mg/dL	± 15 %
Minimum requirement: 95 % of all results within tolerance range	

TEST RESULTS

SYSTEM ACCURACY PLOT



Difference plot of system accuracy of 3 x 200 blood glucose samples with Omnitest® 5 compared to YSI 2300 in a hospital using 3 lots of test strips

DATA ANALYSIS

BIAS DISTRIBUTION ANALYSIS
COMPARED WITH YSI 2300

System accuracy results for glucose concentration < 100 mg/dL

Strip lot	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL	Combined lots within ± 15 mg/dL
Lot 1	**77.8 %** [42/54]	**94.4 %** [51/54]	**100.0 %** [54/54]	
Lot 2	**57.4 %** [31/54]	**92.6 %** [50/54]	**100.0 %** [54/54]	
Lot 3	**57.4 %** [31/54]	**90.7 %** [49/54]	**100.0 %** [54/54]	
Combined	**64.2 %** [104/162]	**92.6 %** [150/162]	**100.0 %** [162/162]	**100.0 %** [162/162]

System accuracy results for glucose concentration ≥ 100 mg/dL

Strip lot	Within ±5 %	Within ±10 %	Within ±15 %	Combined lots within ± 15 %
Lot 1	**50.0 %** [73/146]	**88.4 %** [129/146]	**97.9 %** [143/146]	
Lot 2	**44.5 %** [65/146]	**84.9 %** [124/146]	**95.9 %** [140/146]	
Lot 3	**52.1 %** [76/146]	**90.4 %** [132/146]	**99.3 %** [145/146]	
Combined	**48.9 %** [214/438]	**87.9 %** [385/438]	**97.7 %** [428/438]	**97.7 %** [428/438]

System accuracy results for glucose concentrations between 34 mg/dL and 547 mg/dL **Within ± 15 mg/dL or ± 15 %**	**98.3 %** [590/600]

RESULT	98.3 % of results are within ± 15 mg/dL or ± 15 % for combined lots.
CONCLUSION	Omnitest® 5 exceeds the minimum requirement of 95 % system accuracy.

System Accuracy Evaluation
Consensus Error Grid

ACCEPTANCE CRITERIA

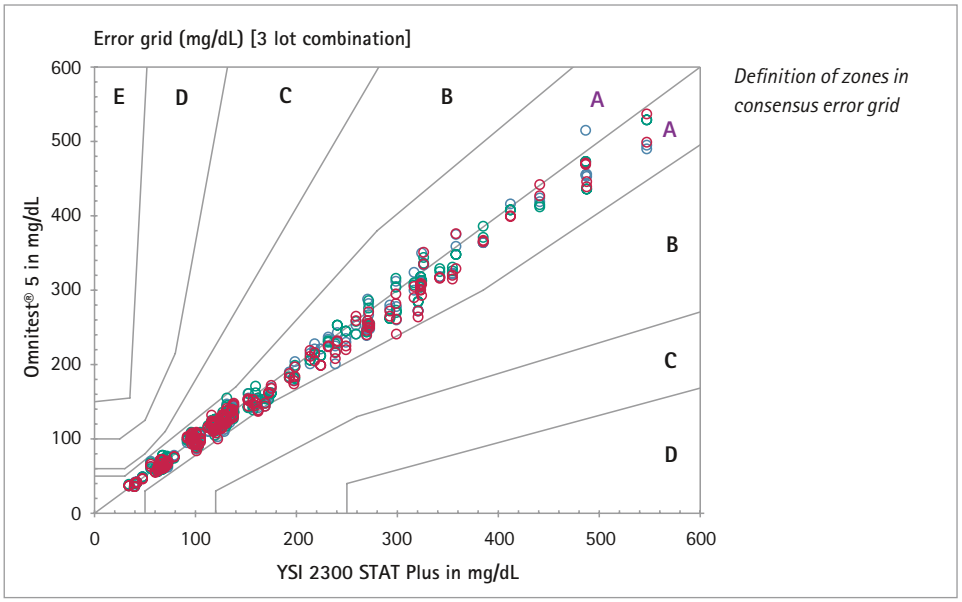
ACCURACY PLOT – PART 2

Test criteria	Tolerance range
Consensus error grid	99 % of results within zones A and B of the consensus error grid for type 1 diabetes

Zone	Classification
A	No effect on clinical action.
B	Altered clinical action – little or no effect on clinical outcome.
C	Altered clinical action – likely to affect clinical outcome.
D	Altered clinical action – could have significant medical risk.
E	Altered clinical action – could have dangerous consequences.

TEST RESULTS

CONSENSUS ERROR GRID



Definition of zones in consensus error grid

DATA ANALYSIS

CONSENSUS ERROR GRID

Strip lot	Zone A	Zone B	Zone C	Zone D	Zone E	Total
Lot 1	**99.5** % [199/200]	**0.5** % [1/200]	0 % [0/200]	0 % [0/200]	0 % [0/200]	**100** % [200/200]
Lot 2	**99.0** % [198/200]	**1.0** % [2/200]	0 % [0/200]	0 % [0/200]	0 % [0/200]	**100** % [200/200]
Lot 3	**100** % [200/200]	**0.0** % [0/200]	0 % [0/200]	0 % [0/200]	0 % [0/200]	**100** % [200/200]
Combined	**99.5** % [597/600]	**0.5** % [3/600]	0 % [0/600]	0 % [0/600]	0 % [0/600]	**100** % [600/600]

RESULT

100 % of results are within zones A and B of the consensus error grid.

CONCLUSION

Omnitest® 5 exceeds the system accuracy requirement that 99 % of results are within zones A and B.

User Performance Evaluation

The user performance evaluation is split into two test components:
accuracy of user performance and user evaluation of the instructions for use.

TEST INFORMATION

USER PERFORMANCE EVALUATION

- 100 lay persons took part in the study, representing different ages (from 26 to 68), genders (57 % male and 43 % female) and educational levels (55 % college educated).
- Participants were given the instructions for use and an Omnitest® 5 test kit.
- No further instructions, training, assistance, feedback or supplementary instructional material were provided.
- Test persons were then asked to measure their blood glucose level with Omnitest® 5, afterwards the results were compared with those measured by the laboratory reference method.

1) Study period	August 10, 2015 – August 28, 2015
2) Test meter serial number	GAF3DEPD0015
3) Test strip lot number	F2QF03
4) Reference laboratory device	YSI 2300 auto analyzer
5) Standard/guidance document referenced	ISO 15197:2013 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

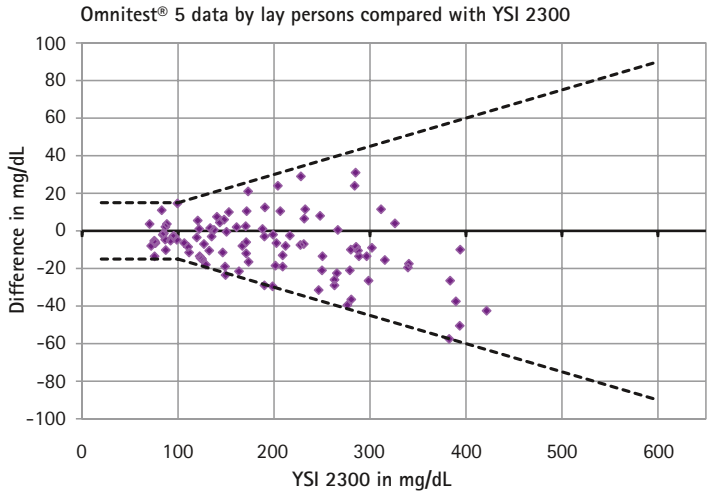
ACCEPTANCE CRITERIA

USER PERFORMANCE EVALUATION

Blood glucose concentration & requirements	Tolerance range
< 100 mg/dL	± 15 mg/dL
≥ 100 mg/dL	± 15 %
Minimum requirement: 95 % of all results within tolerance range	

TEST RESULTS

USER PERFORMANCE EVALUATION



Difference plot of the 100 blood glucose samples of the lay persons compared with YSI 2300

DATA ANALYSIS

LAY PERSONS COMPARED WITH YSI 2300

System accuracy results for glucose concentration < 100 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
50.0 % [9/18]	**77.8** % [14/18]	**100.0** % [18/18]

System accuracy results for glucose concentration ≥ 100 mg/dL

Within ±5 %	Within ±10 %	Within ±15 %
42.7 % [35/82]	**74.4** % [61/82]	**96.3** % [79/82]

System accuracy results for glucose concentrations between 70.4 mg/dL and 421.5 mg/dL **Within ± 15 mg/dL or ± 15 %**	**97.0 %** [97/100]

RESULT	97.0 % of the results within ± 15 mg/dL or ± 15 % for combined lots.
CONCLUSION	Omnitest® 5 exceeds the required system accuracy of 95 % with regards to the user performance evaluation.

User Performance Evaluation

TEST INFORMATION

EVALUATION OF INSTRUCTIONS FOR USE BY LAY PERSONS

The participants had to complete a questionnaire with 17 different statements. They were supposed to indicate their impression on the ease of use of the meter. On a five-point scale the participants determined their degree of agreement (1 = strongly agree, 3 = neutral, 5 = strongly disagree).

ACCEPTANCE CRITERIA

EVALUATION OF INSTRUCTIONS FOR USE BY LAY PERSONS

The average score for each statement should be less than 3.0.
The rate of positive answers to all statements should be higher than 70 percent.

DATA ANALYSIS

QUESTIONNAIRE RESULTS FOR OMNITEST® 5

Statement	Mean average
Ability to perform a measurement without any problem	**1.6**
Table of instructions for use content is clear	2.2
Insertion of batteries is easy	1.6
Blood glucose meter settings are easy to understand	2.1
Measurement preparations are easy to carry out	2.1
It is easy to understand how to perform a measurement	1.5
Measurement results on screen are clear and easy to read	1.6
Three buttons on meter are easy to use	2.2
Description of how to maintain meter is easy to understand	2.2
Description of control solution measurement is easy to understand	2.2
Description of how to review results from meter memory is understandable	2.2
Instructions for use clearly explain what to do in case of error message	1.5
Technical specifications are clearly presented	1.5
Symbols used are easy to understand	1.9
All items in short instruction are easy to understand	2.0
Graphs in "Instructions for a correct measurement result" are easy to understand	2.2
All items in extensive instructions for use are easy to understand and to follow	2.1
Total	**1.9**

DATA ANALYSIS

EVALUATION OF INSTRUCTIONS FOR USE BY LAY PERSONS

Scale	Response	Number	Percentage (%)
1	Strongly agree	539	31.7
2	Agree	770	45.3
3	Neutral	389	22.9
4	Disagree	2	0.1
5	Strongly disagree	0	0.0
Total		**1700**	**100**

Altogether, 1700 statements were evaluated (100 participants x 17 questions).

Data evaluation result for ease of use for Omnitest® 5

77 %

very positive or positive

CONCLUSION

The received average scores prove that Omnitest® 5 is easy or very easy to use for lay persons.

Hematocrit Interference Evaluation

TEST INFORMATION

HEMATOCRIT INTERFERENCE EVALUATION

The evaluation of the effect of hematocrit levels was carried out with various blood samples:

- 5 different hematocrit percentages: 20, 30, 42, 50, 60 %
- Adjustment of glucose concentration to 3 levels: 62, 117 and 360 mg/dL
- 20 tests of each sample

1) Test date	November 12, 2015
2) Test meter serial number	GF1DEPD00001 – GF1DEPD00020
3) Test strip lot numbers	F2QF03 (lot #1), F2QF04 (lot #2), F2QF05 (lot #3)
4) Sample numbers	▪ 20 Omnitest® 5 test meters ▪ 1 YSI 2300 auto analyzer ▪ 900 Omnitest® 5 test strips
5) Standard/guidance documents referenced	ISO 15197:2013 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

ACCEPTANCE CRITERIA

HEMATOCRIT INTERFERENCE EVALUATION

Blood glucose concentration	Tolerance range
< 100 mg/dL	± 10 mg/dL [mean bias of normal hematocrit level (= 42 %)]
≥ 100 mg/dL	± 10 % [mean bias of normal hematocrit level (= 42 %)]

DATA ANALYSIS AND CONCLUSION

After analysis of test data according to ISO 15197:2013, Omnitest® 5 can be used within a hematocrit range of 20 – 60 %.

Endogenous and Exogenous Interfering Substances Evaluation

TEST INFORMATION

INTERFERING SUBSTANCES

ISO 15197:2013 includes a list of substances that may appear in blood and have been found to interfere with glucose measurement procedures.

The evaluation was carried out using two glucose concentrations, within the interval of 50 mg/dL to 100 mg/dL and within the interval of 250 mg/dL to 350 mg/dL.

ACCEPTANCE CRITERIA

INTERFERING SUBSTANCES

Blood glucose concentration	Tolerance range
< 100 mg/dL	± 10 mg/dL mean error between the test sample and the control sample
≥ 100 mg/dL	± 10 % mean error between the test sample and the control sample

Substances causing interferences that exceed the acceptance criteria have to be listed in the instructions for use.

DATA ANALYSIS

INTERFERING SUBSTANCES

Substance tested	Substance concentration	Tolerance range with glucose 50 – 100 mg/dL	Tolerance range with glucose 250 – 350 mg/dL	Criteria
Acetaminophen	10 mg/dL	7.3 mg/dL	5.3 %	Passed
Ascorbic acid	6 mg/dL	2.8 mg/dL	2.0 %	Passed
Bilirubin	4 mg/dL	- 6.6 mg/dL	- 4.2 %	Passed
Cholesterol	500 mg/dL	- 6.9 mg/dL	- 5.4 %	Passed
Creatinine	4 mg/dL	- 5.2 mg/dL	- 3.7 %	Passed
Dopamine	0.09 mg/dL	- 5.6 mg/dL	0.7 %	Passed
EDTA	180 mg/dL	5.0 mg/dL	- 0.1 %	Passed
Ethanol	400 mg/dL	- 2.5 mg/dL	- 6.0 %	Passed
Galactose	15 mg/dL	- 4.9 mg/dL	- 3.7 %	Passed
Gentistic acid	2 mg/dL	0.0 mg/dL	- 1.1 %	Passed
Glutathione	3 mg/dL	0.3 mg/dL	- 1.3 %	Passed
Hemoglobin	200 mg/dL	- 7.1 mg/dL	- 6.6 %	Passed
Heparin	6800 mg/dL	- 2.2 mg/dL	- 1.2 %	Passed
Ibuprofen	21 mg/dL	6.9 mg/dL	4.2 %	Passed
Icodextrin	500 mg/dL	2.8 mg/dL	2.9 %	Passed
Lactose	100 mg/dL	3.0 mg/dL	3.7 %	Passed
Levodopa	1 mg/dL	- 0.3 mg/dL	- 4.8 %	Passed
Maltose	300 mg/dL	2.2 mg/dL	1.3 %	Passed
Mannitol	600 mg/dL	3.5 mg/dL	1.6 %	Passed
Methyldopa	2 mg/dL	1.4 mg/dL	- 3.2 %	Passed
Penicillin	12 mg/dL	3.1 mg/dL	0.1 %	Passed
Pralidoxime iodide	20 mg/dL	8.5 mg/dL	4.3 %	Passed
Salicylic acid	60 mg/dL	- 4.3 mg/dL	- 1.6 %	Passed
Sorbitol	70 mg/dL	3.0 mg/dL	- 0.1 %	Passed
Tetracycline	2 mg/dL	1.7 mg/dL	- 4.1 %	Passed
Triglyceride	3000 mg/dL	- 7.0 mg/dL	- 5.8 %	Passed
Tolazamide	5 mg/dL	- 0.3 mg/dL	- 3.2 %	Passed
Tolbutamide	32 mg/dL	- 4.5 mg/dL	- 2.5 %	Passed
Urea	260 mg/dL	- 4.1 mg/dL	- 1.8 %	Passed
Uric acid	24 mg/dL	- 2.5 mg/dL	- 0.7 %	Passed
Warfarin	1 mg/dL	0.7 mg/dL	- 0.1 %	Passed
Xylose	10 mg/dL	8.7 mg/dL	5.9 %	Passed

For further details, refer to the instructions for use for the test strips.

CONCLUSION

All 32 substances tested do not significantly interfere with the performance of Omnitest® 5.

Precision Test and Repeatability Evaluation

TEST INFORMATION

PRECISION TEST

The precision of Omnitest® 5 was assessed by using venous whole blood samples. The glucose concentration in the venous whole blood samples was adjusted by supplementing the sample with an aqueous glucose solution.
To achieve lower glucose concentration, anticoagulant blood samples were allowed to age until the glucose is depleted to the desired level.

The glucose levels in the blood samples were measured using the laboratory reference equipment (YSI 2300 auto analyzer). The five glucose levels were tested with three lots of test strips and on ten different meters ten times each.

ACCEPTANCE CRITERIA

PRECISION TEST

ISO 15197:2013 does not specify acceptance criteria for the precision test. Therefore, B. Braun has set the following criteria:

Standard deviations (SD) of each glucose concentration
< 100 mg/dL should be below 5 mg/dL.

Coefficient variations (CV) of each glucose concentration
≥ 100 mg/dL should be below 5 %.

DATA ANALYSIS

PRECISION TEST

		< 100 mg/dL		≥ 100 mg/dL		
Lot 1	Mean	48 mg/dL	86 mg/dL	136 mg/dL	227 mg/dL	382 mg/dL
	SD	2.2 mg/dL	3.3 mg/dL	NA	NA	NA
	CV	NA	NA	3.2 %	3.0 %	3.0 %
Lot 2	Mean	46 mg/dL	85 mg/dL	136 mg/dL	223 mg/dL	374 mg/dL
	SD	2.1 mg/dL	2.9 mg/dL	NA	NA	NA
	CV	NA	NA	3.7 %	3.3 %	3.2 %
Lot 3	Mean	47 mg/dL	86 mg/dL	137 mg/dL	226 mg/dL	379 mg/dL
	SD	2.0 mg/dL	3.4 mg/dL	NA	NA	NA
	CV	NA	NA	3.6 %	3.5 %	3.4 %
Total	**Grand mean**	**47 mg/dL**	**86 mg/dL**	**136 mg/dL**	**225 mg/dL**	**378 mg/dL**
	Pooled SD	**2.2 mg/dL**	**3.2 mg/dL**	**NA**	**NA**	**NA**
	Pooled CV	**NA**	**NA**	**3.5 %**	**3.4 %**	**3.3 %**

CONCLUSION

Omnitest® 5 has proven excellent precision and repeatability at all blood glucose levels tested.

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