Final Report

Evaluating performance

of blood glucose monitoring systems for self-testing

OKmeter AcePlus

Project code ***IDT-1104-OT***

Date: 19.APR.2011

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Investigative Site
Institut für Diabetes-Technologie GmbH an der Universität Ulm (IDT)
Helmholtzstrasse 20
D-89081 Ulm / Germany

Study Sponsor
Dr. med. Guido Freckmann
Institut für Diabetes-Technologie GmbH an der Universität Ulm
Helmholtzstrasse 20, D-89081 Ulm / Germany
Tel.: +49 (0)731-5099016
e-mail: guido.freckmann@uni-ulm.de

Principal Investigator
Prof. Dr. med. Cornelia Haug
Institut für Diabetes-Technologie GmbH an der Universität Ulm
Helmholtzstrasse 20, D-89081 Ulm / Germany
Tel.: +49 (0)731-509900
e-mail: cornelia.haug@uniklinik-ulm.de

Project Manager
Dr. biol. hum. Annette Baumstark
Institut für Diabetes-Technologie GmbH an der Universität Ulm
Helmholtzstrasse 20, D-89081 Ulm / Germany
Tel.: +49 (0)731-5099024
e-mail: annette.baumstark@uni-ulm.de

Monitoring
Barbara Schmücker
verified. - Clinical Monitoring & Trial Consulting
Wäldenbronner Strasse 8, D-73732 Esslingen/Neckar / Germany
Tel.: +49 (0) 170-4833973
e-mail: office@schmuecker-monitoring.de

Customer
OK Biotech Co. Ltd.
4F-1, No 83, Sec. 2, Gongdao 5th Rd., 300 Hsinchu, Taiwan
Project Manager: Daniel Wang
e-mail: daniel.wang@okbiotech.com

Independent Ethics Committee
Registrierte Ethikkommission der Universität Ulm, 89069 Ulm

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Regierungspräsidium Tübingen, 72072 Tübingen

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Gothaer Allgemeine Versicherung AG
Gothaer Allee 1
D-50969 Köln / Germany

1 Introduction

Main objective of modern diabetes therapy is to achieve near normal blood glucose (BG) levels in order to prevent late damages. Self monitoring devices allow for metabolic control by patients and doctors and for a flexible therapy adjustment by the patient himself. As insulin therapy is controlled by the measured values high-quality blood glucose monitoring systems are required.

EN ISO 15197 [1] is an international standard specifying requirements for *in vitro* glucose monitoring systems for self-testing in managing diabetes mellitus.

The minimum acceptable accuracy for results produced by a glucose monitoring system shall be as follows: Ninety-five percent (95 %) of the individual glucose results shall fall within ± 0.83 mmol/L (15 mg/dL) of the results of the reference measurement at glucose concentrations < 4.2 mmol/L (< 75 mg/dL) and within ± 20 % at glucose concentrations ≥ 4.2 mmol/L (≥ 75 mg/dL).

In this study, system accuracy evaluation according to EN ISO 15197 was performed for OKmeter AcePlus (OK-A) from OK Biotech.

2 Material and Methods

2.1 Study objective

The aim of this study was to collect measurement data from capillary blood with defined distribution of glucose concentrations in order to perform system accuracy evaluation according to EN ISO 15197 for one test strip lot of OKmeter AcePlus (OK-A) from OK Biotech. The reference measurements were performed on YSI 2300 STAT PLUS.

2.2 Inclusion criteria

- Male or female subjects with diabetes type 1 or 2 or healthy subjects
- For provoked blood glucose excursions: male or female subjects with diabetes type 1 or 2 and intensive conventional insulin therapy or insulin pump
- Written informed consent
- Minimum age of 18 years

2.3 Exclusion criteria

- Pregnancy or lactation period
- Severe acute disease
- Severe chronic disease with potential risk during the trial

2.4 Study duration per subject

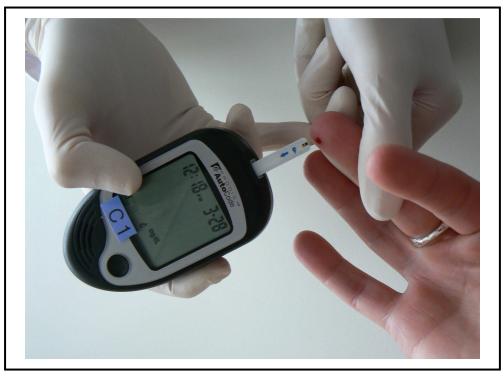
- Up to 6 hours

2.5 Screening

- Information about the study (aims, procedures, risks, duration)
- Written informed consent
- Anamnesis, physical examination and urine pregnancy test (if applicable)

2.6 Study devices

2.6.1 OKmeter AcePlus



- Manufacturer: OK Biotech Co. Ltd.
  Taiwan

- *Technical specifications*

Blood sample:	Capillary whole blood
Sample volume:	0.6 µL
Measuring range:	20 – 600 mg/dL
Analysis time:	7 sec
Operating temperature:	10 – 40 ℃
Operating humidity:	< 85 %
Haematocrit range:	20 – 60 %
Measurement technology:	Glucose oxidase
Calibration:	Plasma
Coding:	Not applicable

- *Meters, test strips, control solutions*

Meters: OKmeter AcePlus (C)	
Serial number	*Study code*
51850-0310320	*C1*
51850-0310319	*C2*
51850-0310302	*C3 (Back-up)*

Test strips: OKmeter AcePlus (C)	
Lot number	Expiry
D110119-1	--

Control solution	Lot number	Expiry	Target range [mg/dL]
Control Solution Level 1	--	--	65 - 115
Control Solution Level 2	--	--	170 - 290

2.6.2 YSI 2300 STAT PLUS

- Manufacturer: YSI Incorporated, Yellow Springs, Ohio, USA
- Method / chemistry: Glucose oxidase (GOD-H_2O_2)
- Certificate of interlaboratory comparison is available

Accuracy and precision

- Accuracy was assessed according to NCCLS EP15-A2 [2] regularly by assaying NERL Glucose Standards (verified against NIST [National Institute of Standards & Technology (NIST)] material), Thermo Fisher SCIENTIFIC
- Precision was assessed according to NCCLS EP15-A2 [2] regularly by assaying Liquid Assayed Multiqual, Bio-Rad Laboratories
- Liquid Assayed Multiqual control samples were measured on each study day to confirm constant accuracy and precision according to the RiliBÄK guideline [3].

2.6.3 Maintenance, adjustment, control procedures

- For all study devices maintenance, adjustment and control procedures were followed in accordance with the manufacturers' instructions.

2.7 Experiment

2.7.1 Requirements according to ISO 15197

Samples

- ≥ 100 fresh capillary blood samples collected by skin puncture were prepared, processed and applied according to the manufacturer's instructions
- Only unaltered capillary blood samples were used for glucose concentrations of ≥ 50 - < 400 mg/dl
- For samples of < 50 mg/dl and ≥ 400 mg/dl glucose concentration could be adjusted
- Exclusion criteria for samples were defined based on the manufacturer's instructions for use (see 2.7.2 Additional exclusion criteria for samples)
- Aliquots were removed from each sample immediately before the first and immediately after the last measurement with the blood-glucose monitoring system for duplicate measurement with the reference method.
- Defined distribution of glucose concentrations was obtained

Percentage of samples [%]	Glucose concentration [mg/dl]
5	< 50
15	≥ 50 - < 80
20	≥ 80 - < 120
30	≥ 120 - < 200.5
15	≥ 200.5 - < 300.5
10	≥ 300.5 - < 400
5	≥ 400

  Samples were assigned to the respective category according to the glucose concentration measured with YSI 2300 STAT PLUS
- Once a concentration category was filled, no more samples were added to that category

Reagent system

- One lot of reagent system units was examined for OKmeter AcePlus.
- At least 200 reagent system units from at least 10 packages were used
- Reagent system units were taken from the same package for each sample
- Packages were changed every (~) 10 subjects

Meters

- Users have received proper training
- Devices were properly maintained
- Required adjustment and control procedures were followed in accordance with the manufacturer's instructions
- Samples were measured with 2 different meters

Environment

- Measurements using the blood-glucose monitoring system were performed at 23℃ ± 5℃

Evaluation procedure

- Results from reference methods were evaluated to verify sample stability
  (If change between first and last result > 4 % at glucose > 100 mg/dL or
  > 4 mg/dl at glucose ≤ 100 mg/dL, results for that sample had to be rejected)

2.7.2 Additional exclusion criteria for samples

- Humidity had to be < 85 %
  (based on manufacturer's instructions for use)
- Glucose concentration measured with the reference method had to be within the measurement range of 20 – 600 mg/dL
  (based on manufacturer's instructions for use)
- Haematocrit had to be between 20 and 60 %
  (based on manufacturer's instructions for use)
- Acceptance criterion for double measurements (reference method):
  If values of a double measurement had a coefficient of variation (CV) ≥ 5 %, then the results for that sample had to be rejected.

2.7.3 Determination of haematocrit

- Centrifugation of capillary whole blood in heparinised capillaries
- Reading of haematocrit level on alignment chart
- Double test (if both measurements were successful the mean value was calculated)

2.7.4 Measurement of control solutions

- Control solutions / levels see 2.6 Study devices
- Measurement performed according to manufacturer's instructions
- Unsuccessful control measurements had to be repeated once.
  If the result was still not within the range, the meter had to be cleaned following the system specific cleaning instructions. If the result was still not within the range, the meter had to be changed and the procedure reiterated.

2.7.5 Determination of glucose concentration - sample preparation

- Samples: capillary whole blood from finger prick
  - for measurements with BG-meters: native sample
  - for measurements with reference YSI 2300 STAT PLUS: separated plasma
- Reference samples:
  1. 200 µL of capillary whole blood from finger prick
     collected in LiHep Microvettes (Sarstedt AG & Co., Nümbrecht, D)
  2. Plasma extraction
     (centrifugation: 2000g / 5 min / 20℃)
  3. Determination of plasma glucose as double-test
     (measurement with 2 electrodes on YSI 2300 STAT PLUS)
- For samples designated to be adjusted to < 50 mg/dL or ≥ 400 mg/dL,
  ~ 800 µL of capillary whole blood were collected in LiHep Microvettes.
  Adjustment was performed according to ISO 15197 by either
  - incubation
  - supplementation with glucose (stock solution: 40 % in 0.9 % NaCL)

2.8 Data processing

2.8.1 Processing of results "High" or "Low"

- For data analysis

⇨ Measurement results "Lo" were set to
"lower limit of measuring range" **-1 mg/dL**
(e.g. for OKmeter AcePlus result **"Lo"**: 20 mg/dL – 1 mg/dL = **19 mg/dL**)

2.8.2 Determination of glucose concentration - measurement procedure

- Screening measurement with
  Accu-Chek Aviva Nano, Roche Diagnostics GmbH (optional)
- Determination of haematocrit (before or after measurements with test systems)
- Taking of 1st reference sample
- Measurement with BG meters:
  OKmeter AcePlus C1
  OKmeter AcePlus C2
- Taking of 2nd reference sample
- Plasma extraction and reference measurements

2.9 Data analyses

2.9.1 Analyses according to ISO 15197 [1]

- performed vs. YSI 2300 STAT PLUS

⇨ **System accuracy analysis**

⇨ **Bias analysis according to Bland and Altman [4]**

- Analysis done with *Analyse-it for Microsoft Excel (version 2.21)* [6]

⇨ **Regression analysis according to Passing and Bablok [5]**

- Analysis done with *Analyse-it for Microsoft Excel (version 2.21)* [6]

3 Results

3.1 Time span of experiments

- 25.02.2011 – 24.03.2011

3.2 Study subjects

- Total number of subjects recruited: 112
- Total number of subjects completed: 102
  100 → analysis acc. to ISO 15197

3.3 Equipment failures

- No equipment failures for systems under evaluation

3.4 Adverse Events

- No adverse events

3.5 General data analysis

3.5.1 Measurement of control solutions

- Control solutions were measured every day before measurement of blood samples.
- Measurements of control solutions were in the given target ranges for all tested meters and all concentrations.

3.5.2 Evaluation of exclusion criteria

Temperature

- Measurements were performed in a temperature range of 20.7 – 23.2 °C

Humidity

- Measurements were performed in a humidity range of 32.3 – 45.1 %

Haematocrit

- Samples had haematocrit levels in the range of 36 – 53 %

3.5.3 Samples analysed according to ISO 15197

Tested system	**OKmeter AcePlus (C)**
Samples taken from 102 different subjects	106
Samples rejected because of - *missed stability criterion* - *concentration category was already filled*	 4 2
Range of glucose concentrations (samples included in evaluation) - *minimum [mg/dL]* - *maximum [mg/dL]*	 37.03 527.00

3.6 Summary of system accuracy analysis

n = 200	**Combined system accuracy**	**Criteria of ISO 15197 met?**
OKmeter AcePlus (C)	199 / 200 (99.5 %)	YES

3.7 Summary of bias analysis

n = 200	**Bias [mg/dL]**	**95 % Limits of agreement [mg/dL]**	**Bias [%]**	**95 % Limits of agreement [%]**
OKmeter AcePlus (C)	-9.3	-41.0 – 22. 4	-6.0	-23.1 – 11.1

3.8 Summary of regression analysis

n = 200	**Regression**
OKmeter AcePlus (C)	y = 0.95 x - 1.07

➢ See appendix

4 Summary and Conclusions

- Accuracy evaluation according to EN ISO 15197 was performed for OKmeter AcePlus (OK-A) from OK Biotech
- Reference method: Glucose oxidase / YSI 2300 STAT PLUS
- Minimum acceptable accuracy according to EN ISO 15197:
  ≥ 95% of the individual results shall fall within ± 15 mg/dL of the reference measurement at glucose concentrations < 75 mg/dL and within ± 20% at glucose concentrations ≥ 75 mg/dL.

⇨ In the current evaluation
- 99.5 % of results with OKmeter AcePlus (C)
fell within the limits for system accuracy defined by EN ISO 15197.

- Samples in concentration ranges < 50 mg/dL and > 400 mg/dL show a systematic negative bias compared to the samples between 50 and 400 mg/dL. The reason for the observed deviations could be a problem with coding of the system. Alternatively the deviation could be caused by the procedures which were used to adjust the samples to the designated glucose concentration, e. g. adding anticoagulants or incubating the sample.
  The reason for the deviations should be rechecked.

- ***In summary …***

⇨ OKmeter AcePlus complies with the system accuracy criteria of EN ISO 15197.

References

1. DIN EN ISO 15197: Testsysteme für die in-vitro-Diagnostik – Anforderungen an Blutzuckermesssysteme zur Eigenanwendung beim Diabetes mellitus (ISO 15197:2003); Deutsche Fassung

2. Clinical and Laboratory Standards Institute. User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition. CLSI document EP15-A2 [ISBN 1-56238-574-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 2005

3. Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriums-medizinischer Untersuchungen (RiliBÄK). Deutsches Ärzteblatt 105, Heft 7, 15. Februar 2008, S. A341-355

4. Bland J.M. and Altman D.G. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986, 307-310

5. Passing H. and Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J Clin Chem Clin Biochem 1983, 21; 709-720

6. Analyse-it for Microsoft Excel (version 2.21)
   Analyse-it Software, Ltd. http://www.analyse-it.com

Appendix

Evaluation of OKmeter AcePlus (C) versus YSI 2300 STAT PLUS

Files: *IDT-1104-OT_OKmeter_AcePlus_FR_110411.pdf*
RawData_C_V01.pdf

Signatures

Sponsor

Dr. med. Guido Freckmann
Institut für Diabetes-Technologie GmbH an der Universität Ulm
Helmholtzstrasse 20, D - 89081 Ulm / Germany
Tel.: +49 (0)731-5099016
e-mail: guido.freckmann@uni-ulm.de

26.4.2011

Date *Signature*

Principal Investigator

Prof. Dr. med. Cornelia Haug
Institut für Diabetes-Technologie GmbH an der Universität Ulm
Helmholtzstrasse 20, D - 89081 Ulm / Germany
Tel.: +49 (0)731-509900
e-mail: cornelia.haug@uniklinik-ulm.de

20.4.2011 C Haug

Date *Signature*

Project Manager

Dr. biol. hum. Annette Baumstark
Institut für Diabetes-Technologie GmbH an der Universität Ulm
Helmholtzstrasse 20, D - 89081 Ulm / Germany
Tel.: +49 (0)731-5099024
e-mail: annette.baumstark@uni-ulm.de

21 APR 2011 A. Baumstark

Date *Signature*

Appendix

Evaluation of OKmeter AcePlus (C) versus YSI 2300 STAT PLUS

System Accuracy (ISO 15197)

Test system:	OKmeter AcePlus
Reference system:	YSI2300
Sample:	Whole blood (capillary)

Data file:	IDT-1104-OT_OKmeter_AcePlus_Ausw_110411.xls

System accuracy results for glucose concentration < 4.2 mmol/L (75 mg/dL)

Within ± 0.28 mmol/L (Within ± 5 mg/dl)	Within ± 0.56 mmol/L (Within ±10 mg/dl)	***Within ± 0.83 mmol/L*** *(Within ± 15 mg/dl)*
19 / 40 (48 %)	34 / 40 (85 %)	***40 / 40 (100 %)***

System accuracy results for glucose concentration >= 4.2 mmol/L (75 mg/dL)

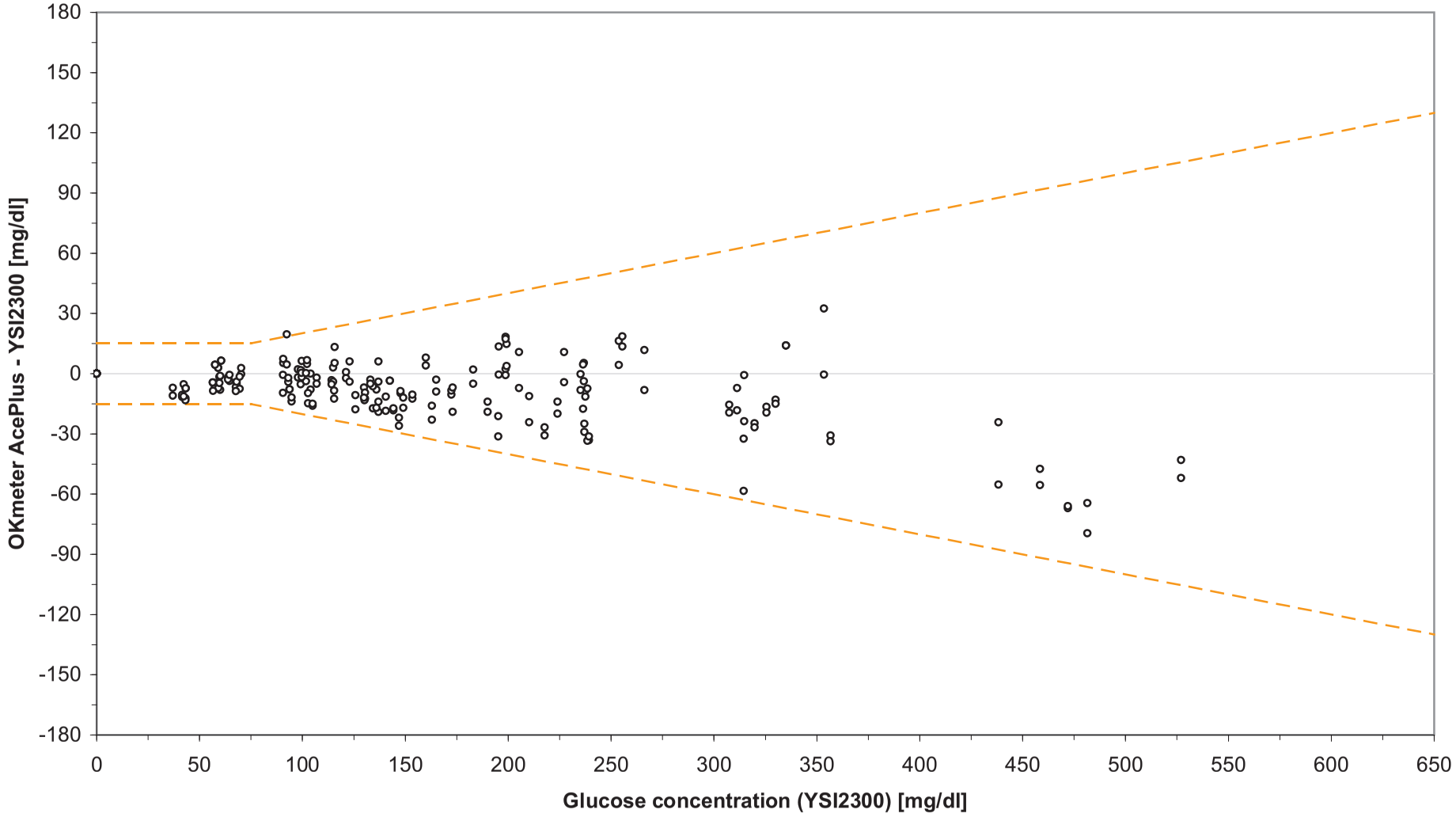
Within ± 5 %	Within ± 10 %	Within ± 15 %	***Within ± 20 %***
64 / 160 (40 %)	118 / 160 (74 %)	154 / 160 (96 %)	***159 / 160 (99 %)***

Combined system accuracy results (absolute and relative deviations)

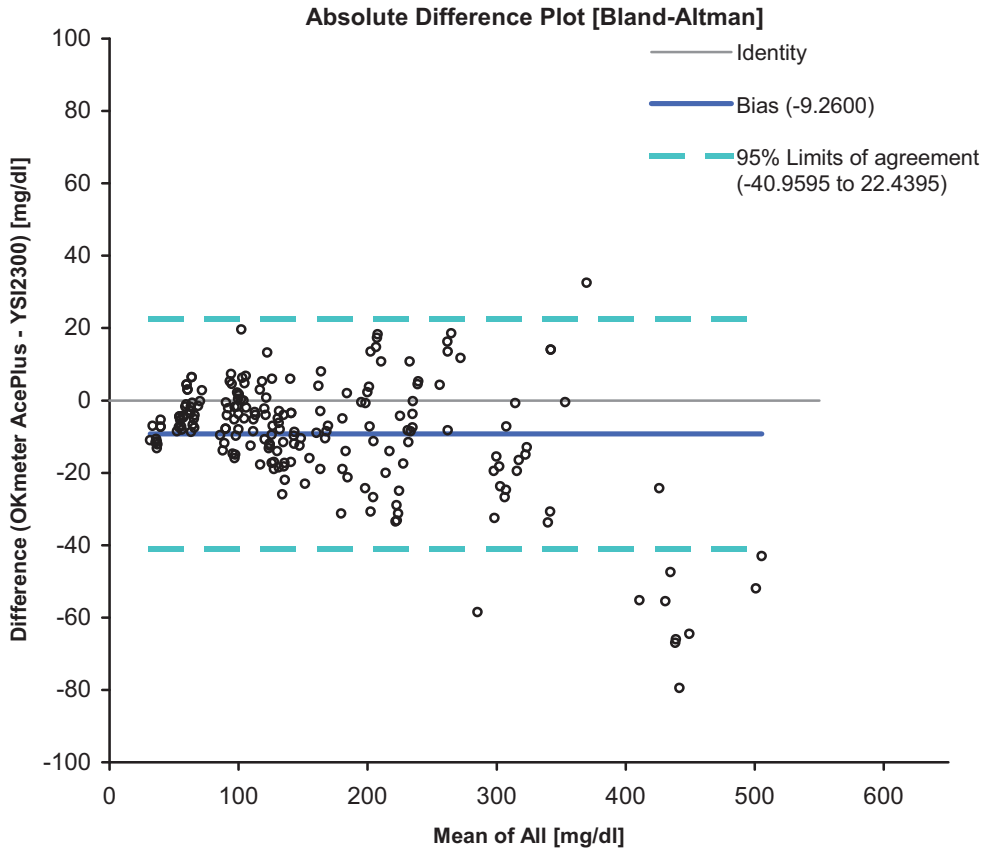
Within ± 0.28 mmol/L & ± 10 % (Within ± 5 mg/dl & ± 10 %)	Within ± 0.56 mmol/L & ± 10 % (Within ± 10 mg/dl & ± 10 %)	Within ± 0.56 mmol/L & ± 15 % (Within ± 10 mg/dl & ± 15 %)	***Within ± 0.83 mmol/L & ± 20 %*** *(Within ± 15 mg/dl & ± 20 %)*
137 / 200 (68.5 %)	152 / 200 (76 %)	188 / 200 (94 %)	***199 / 200 (99.5 %)***

The OKmeter AcePlus blood glucose system complies with the system accuracy requirements of the ISO 15197 Standard. 199 of 200 (99.5%) results meet the requirements.

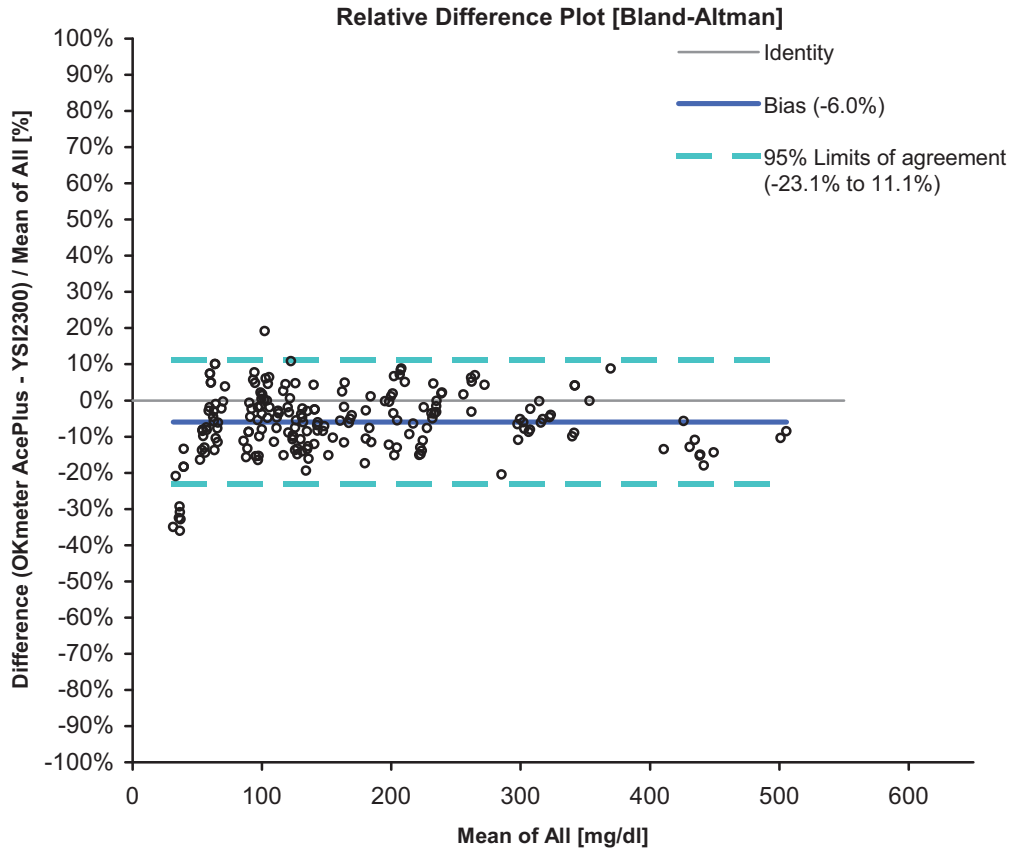
Absolute differences between OKmeter AcePlus and YSI2300



Test	**Agreement - Altman Bland test**		
Performed by	YSI2300 v OKmeter AcePlus Auswertung	Date	11 April 2011



Test	**Agreement - Altman Bland test**		
Performed by	YSI2300 v OKmeter AcePlus Auswertung	Date	11 April 2011



Test	**Method Comparison - Passing & Bablok fit**
	YSI2300 v OKmeter AcePlus
Performed by	Auswertung
Date	11 April 2011

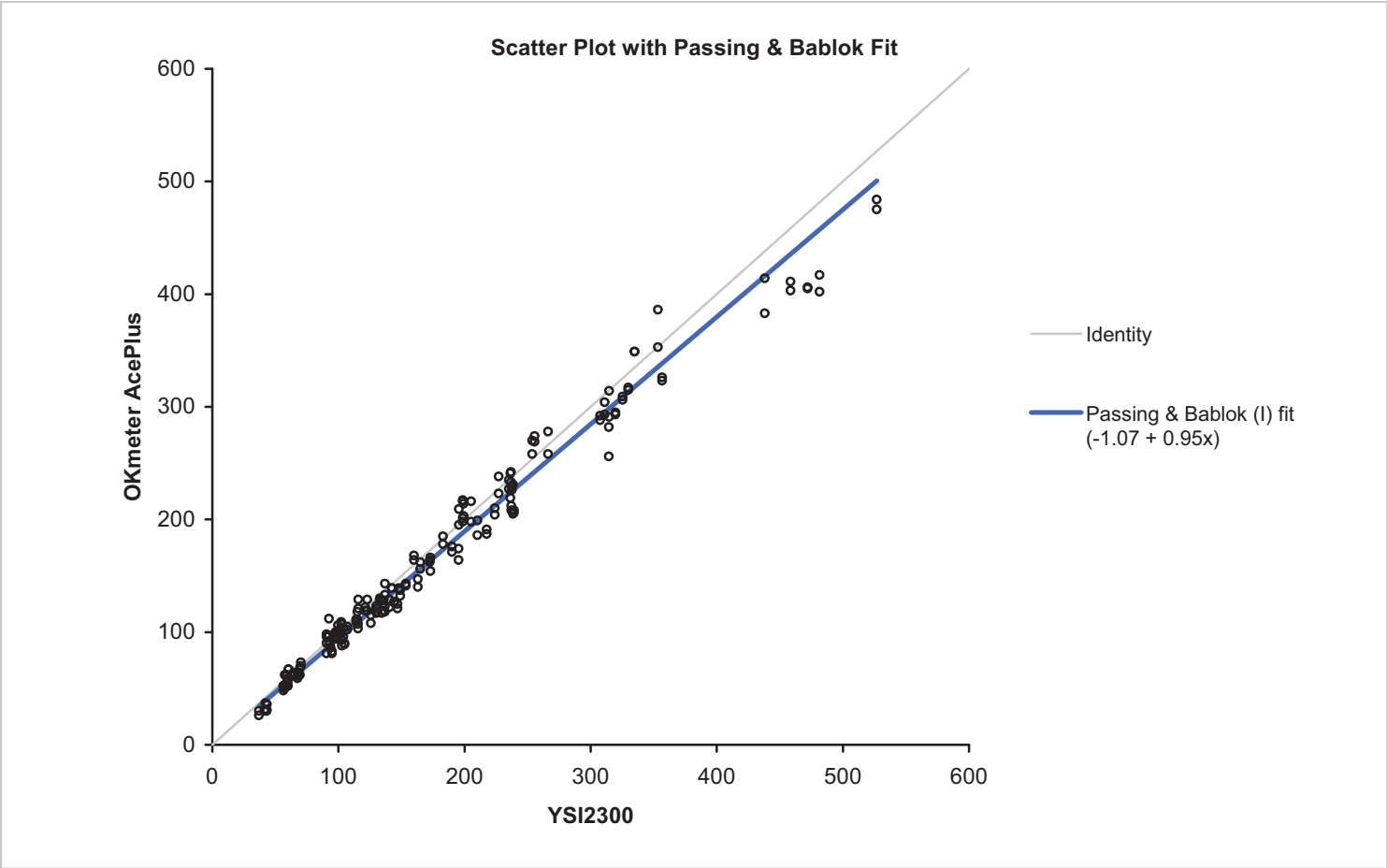
n	200
Range	37.0250 to 527.0000

	Replicates
YSI2300	1
OKmeter AcePlus	1

	Bias	95% CI
Constant	-1.07	-3.97 to 2.01
Proportional	0.95	0.93 to 0.97

H_0: Constant bias = 0. H_1: Constant bias ≠ 0.

H_0: Proportional bias = 1. H_1: Proportional bias ≠ 1.



Raw data

										C - OKmeter AcePlus	
Subject ID	Sex [m / f]	Age	Diabetes type	Haematocrit-value 1	Haematocrit-value 2	C - YSI1 V1	C - YSI1 V2	C - YSI2 V1	C - YSI2 V2	C1 value	C2 value
68011	m	67	Type 2	47	46	198	196	202	201	214	203
68012	m	67	Type 2	42	43	102	103	102	102	107	109
68013	m	62	Type 2	37	37	200	200	198	197	201	198
68001	f	44	Type 1	42	41	59.5	59.7	58.3	58.7	62	62
68002	m	53	Type 2	49	50	163	164	162	163	140	147
68003	f	51	Type 2	39	38	90.5	90.7	90.6	91	96	98
68004	f	40	Type 1	40	41	312	308	307	303	292	288
68005	m	46	Type 2	45	44	121	122	121	121	122	119
68006	f	39	Type 2	40	39	159	159	161	161	168	164
68007	f	32	Type 1	40	39	327	323	328	324	309	306
68008	f	58	Type 2	46	47	125	125	121	121	129	119
68009	f	71	Type 2	42	42	146	147	147	148	121	125
68014	m	59	Type 1	47	-	56.7	58.8	56.5	57.6	52	50
68015	m	73	Type 2	42	42	236	236	239	239	229	226
68016	f	71	Type 2	42	43	325	322	317	315	295	293
68017	m	72	Type 2	45	46	173	175	170	172	162	164
68018	m	59	Type 2	46	46	136	137	137	138	118	123
68019	f	68	Type 2	38	39	193	194	197	197	174	164
68020	f	64	Type 2	42	43	135	136	133	133	117	128
68021	m	46	Type 1	45	44	67.5	68.2	68	68.6	63	64
68022	m	63	Type 2	40	41	130	130	130	131	118	117
68023	m	64	Type 2	45	46	218	218	217	218	191	187
68024	m	63	Type 2	40	41	183	185	181	183	178	185
68025	f	62	Type 2	36	36	239	239	231	232	235	227
68026	m	61	Type 2	43	43	143	144	141	142	139	139
68027	m	73	Type 1	43	44	60	60.7	60.4	61.2	67	67
68028	f	52	Type 1	37	37	55.8	56.5	56.2	57.3	52	52
68029	f	59	Type 2	41	41	172	172	174	174	154	166
68030	m	73	Type 2	41	41	224	225	230	230	238	223
68031	f	55	Type 2	47	47	98.8	99.4	96.2	97	100	96
68032	f	73	Type 2	40	41	251	252	256	256	270	258
68033	m	63	Type 2	43	44	237	238	235	236	219	241
68034	m	71	Type 2	48	48	136	137	135	136	128	119
68035	f	39	Type 1	42	41	359	355	360	353	326	323
68036	f	62	Type 2	41	42	115	116	114	115	118	111
68037	m	73	Type 2	43	44	153	154	153	154	141	143
68010	f	49	Type 1	42	41	63	63.7	64	64.7	62	61
68038	m	55	Type 2	42	42	196	196	195	195	209	195
68039	f	56	Type 2	41	41	191	192	188	189	171	176
68041	f	55	Type 1	41	40	310	306	317	312	304	293
68042	f	64	Type 2	41	40	141	142	139	140	122	129
68043	m	70	Type 2	44	45	236	235	238	238	242	233
68044	f	74	No Diabetes	40	40	40.9	42	41.3	42.4	30	31
68045	m	75	No Diabetes	45	45	43	43.7	42.8	43.6	36	36
68046	f	45	No Diabetes	43	43	42.5	43.1	43.1	44.1	31	30
68047	m	71	No Diabetes	48	48	42.2	43	41.6	42.5	37	31
68048	f	54	No Diabetes	41	41	37.1	37.7	36.2	37.1	30	26
68049	f	65	No Diabetes	43	43	461	455	462	456	411	403
68050	m	67	No Diabetes	40	40	483	476	487	480	417	402
68051	f	53	No Diabetes	39	39	528	526	533	521	475	484
68052	f	61	No Diabetes	39	39	438	433	444	438	414	383
68053	f	58	No Diabetes	44	44	472	457	488	471	405	406
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68056	m	61	Type 2	43	42	321	319	311	308	291	314
68057	m	69	Type 2	43	44	224	225	223	224	204	210
68058	m	51	Type 1	49	50	321	317	312	308	256	282
68059	m	69	Type 2	42	43	137	138	136	137	133	143

										C - OKmeter AcePlus	
Subject ID	Sex [m / f]	Age	Diabetes type	Haematocrit-value 1	Haematocrit-value 2	C - YSI1 V1	C - YSI1 V2	C - YSI2 V1	C - YSI2 V2	C1 value	C2 value
68060	m	75	Type 2	51	52	125	125	126	127	108	115
68061	m	62	Type 1	37	37	338	332	339	331	349	349
68062	f	72	Type 2	38	39	153	154	162	163	144	146
68062	f	72	Type 2	38	39	162	163	167	168	162	156
68063	m	65	Type 2	38	39	115	115	116	117	121	129
68064	f	48	Type 1	43	43	56.9	57.6	52	52.8	54	51
68064	f	48	Type 1	43	43	65.6	66.4	69.3	69.6	61	59
68065	m	73	Type 2	43	-	150	151	147	148	132	137
68066	m	71	Type 2	41	41	201	202	195	197	217	216
68067	m	71	Type 2	46	46	207	208	213	213	186	199
68068	f	45	Type 1	43	43	361	354	355	344	353	386
68069	f	70	No Diabetes	46	47	91.1	92.1	92.4	94.2	97	112
68070	m	65	Type 2	48	47	98.7	99.7	98.8	99.8	94	101
68071	m	39	Type 1	47	47	60.7	61.5	58.7	59.6	52	59
68072	m	63	Type 2	46	46	337	331	330	322	317	315
68073	m	64	Type 2	47	47	129	130	131	132	118	121
68074	m	68	Type 1	40	40	339	331	346	336	322	324
68075	f	68	Type 1	44	45	75.6	76.3	81.6	82.7	79	73
68075	f	68	Type 1	44	45	62	63.2	57	58.2	59	60
68075	f	68	Type 1	44	45	67.6	68.2	70.8	71.7	62	68
68076	f	66	Type 2	47	47	146	148	148	149	138	139
68077	f	50	Type 2	39	40	131	132	134	135	130	128
68078	m	59	Type 1	45	46	59.9	60.9	58.5	59.5	58	55
68079	f	47	Type 2	44	44	116	118	113	115	103	107
68080	f	45	Type 2	44	45	143	145	144	145	126	127
68081	f	53	Type 1	39	39	57.5	58.8	56.5	57.6	62	62
68082	f	72	Type 2	43	43	130	131	129	130	123	118
68083	f	76	Type 2	40	39	271	268	265	261	258	278
68084	m	53	Type 2	45	45	256	255	255	256	269	274
68085	m	42	No Diabetes	46	45	104	104	104	104	104	96
68086	m	76	No Diabetes	53	53	106	106	108	108	105	102
68087	f	72	No Diabetes	46	46	114	111	117	115	111	109
68088	m	81	Type 2	45	45	243	242	236	236	206	208
68089	m	67	Type 2	44	45	239	238	236	235	208	212
68090	m	45	No Diabetes	47	-	99.5	99.5	99.9	100	106	98
68091	f	50	No Diabetes	46	45	90.3	89.8	91.4	90.9	81	90
68092	f	18	No Diabetes	42	42	95.2	94.4	95.2	94.5	81	83
68092	f	18	No Diabetes	42	42	86.8	86.4	0	0	0	0
68093	m	61	Type 2	47	46	239	238	238	239	205	231
68094	m	72	No Diabetes	48	49	103	102	103	103	88	93
68095	f	70	No Diabetes	40	40	100	99.9	99.3	99.3	101	100
68096	f	24	No Diabetes	39	39	92.7	92.1	94	93.7	89	91
68097	f	45	No Diabetes	41	42	104	104	106	106	89	90
68098	m	44	No Diabetes	49	49	93.9	93.2	94.3	93.8	86	86
68099	f	65	No Diabetes	40	41	102	101	102	102	98	102
68101	m	50	Type 1	45	45	64.6	64.5	64.6	64.9	61	64
68100	f	24	Type 1	40	40	70.1	70.1	70.4	70.3	70	73
68102	f	39	Type 1	43	44	57.3	57.1	56.1	55.8	52	48
68103	m	71	Type 2	48	47	169	169	163	164	161	160

System Accuracy (ISO 15197:2013)

Test System: OKmeter AcePlus
Reference System: YSI 2300
Sample: Whole blood (capillary)

Data File: IDT-1104-OT_OKmeter_AcePlus_Ausw_110411.xls

Data summary:

For glucose concentration < 100mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
34/66 (51.5%)	57/66 (86.4%)	65/66 (98.5%)

For glucose concentration ≥ 100mg/dL

Within ±5%	Within ±10%	Within ±15%
58/146 (39.7%)	108/146 (74.0%)	141/146 (96.6%)

System accuracy results for glucose concentrations between 37.0 mg/dL and 527 mg/dL

Within ±15 mg/dL and ±15%
206/212 (97.2 %)

The OKmeter AcePlus blood glucose system complies with the system accuracy requirements of the ISO 15197:2013 Standard. 206 of 212 (97.2%) results.

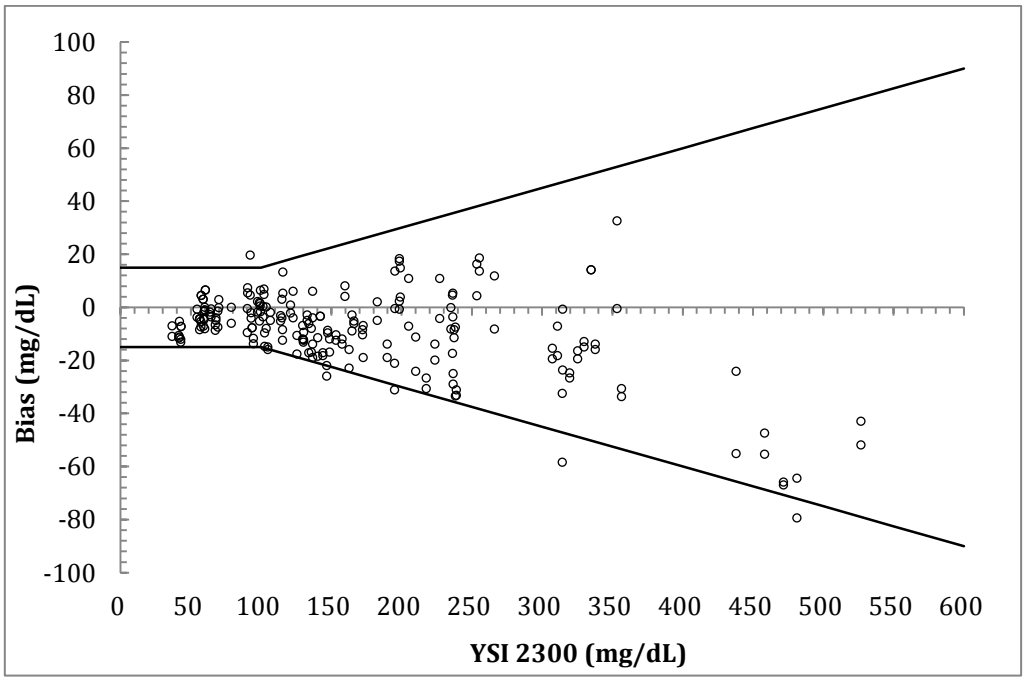

Fig. 1 System accuracy plot of the measurements of OKmeter AcePlus Blood Glucose Monitoring System versus Glucose Analyzer YSI 2300.

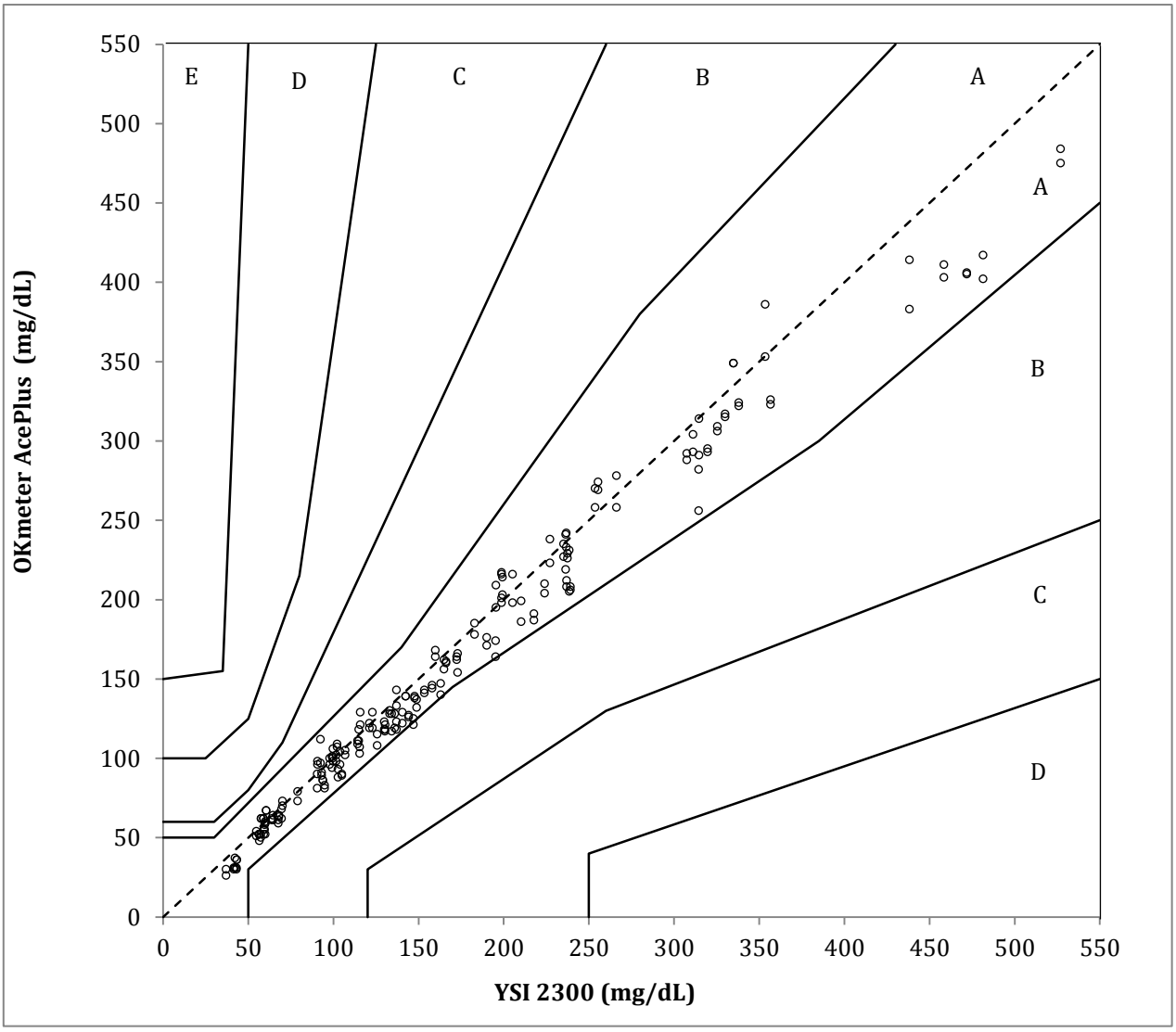

Fig. 2 Consensus error grid analysis of the measurements of OKmeter AcePlus Blood Glucose Monitoring System versus Glucose Analyzer YSI 2300.

➢ Summary and Conclusions

- Accuracy evaluation according to EN ISO 15197 was performed for OKmeter AcePlus (OK-A) from OK Biotech
- Reference method: Glucose oxidase / YSI 2300 STAT PLUS
- Minimum acceptable accuracy according to EN ISO 15197:2013
  ≥ 95% of the individual results shall fall within ± 15 mg/dL of the reference measurement at glucose concentrations < 100 mg/dL and within ± 15% at glucose concentrations ≥ 100 mg/dL.
- In the current evaluation
  - 97.2 % of results with OKmeter AcePlus (C) fell within the limits for system accuracy defined by EN ISO 15197:2013.
- In summary
  - OKmeter AcePlus complies with the system accuracy criteria of EN ISO 15197:2013.

Below is from OK Biotech analysis of remove venous whole blood from raw data subject 68044 - 68053.
Total 6 pages

Raw Data

Subject ID	C - YSI1 V1	C - YSI1 V2	C - YSI2 V1	C - YSI2 V2	YSI mean	C1 value	C2 value
68001	59.5	59.7	58.3	58.7	59.1	62	62
68002	163	164	162	163	163.0	140	147
68003	90.5	90.7	90.6	91	90.7	96	98
68004	312	308	307	303	307.5	292	288
68005	121	122	121	121	121.3	122	119
68006	159	159	161	161	160.0	168	164
68007	327	323	328	324	325.5	309	306
68008	125	125	121	121	123.0	129	119
68009	146	147	147	148	147.0	121	125
68010	63	63.7	64	64.7	63.9	62	61
68011	198	196	202	201	199.3	214	203
68012	102	103	102	102	102.3	107	109
68013	200	200	198	197	198.8	201	198
68014	56.7	58.8	56.5	57.6	57.4	52	50
68015	236	236	239	239	237.5	229	226
68016	325	322	317	315	319.8	295	293
68017	173	175	170	172	172.5	162	164
68018	136	137	137	138	137.0	118	123
68019	193	194	197	197	195.3	174	164
68020	135	136	133	133	134.3	117	128
68021	67.5	68.2	68	68.6	68.1	63	64
68022	130	130	130	131	130.3	118	117
68023	218	218	217	218	217.8	191	187
68024	183	185	181	183	183.0	178	185
68025	239	239	231	232	235.3	235	227
68026	143	144	141	142	142.5	139	139
68027	60	60.7	60.4	61.2	60.6	67	67
68028	55.8	56.5	56.2	57.3	56.5	52	52
68029	172	172	174	174	173.0	154	166
68030	224	225	230	230	227.3	238	223
68031	98.8	99.4	96.2	97	97.9	100	96
68032	251	252	256	256	253.8	270	258
68033	237	238	235	236	236.5	219	241
68034	136	137	135	136	136.0	128	119
68035	359	355	360	353	356.8	326	323

68036	115	116	114	115	115.0	118	111
68037	153	154	153	154	153.5	141	143
68038	196	196	195	195	195.5	209	195
68039	191	192	188	189	190.0	171	176
68041	310	306	317	312	311.3	304	293
68042	141	142	139	140	140.5	122	129
68043	236	235	238	238	236.8	242	233
~~68044~~	~~40.9~~	~~42~~	~~41.3~~	~~42.4~~	~~41.7~~	~~30~~	~~31~~
~~68045~~	~~43~~	~~43.7~~	~~42.8~~	~~43.6~~	~~43.3~~	~~36~~	~~36~~
~~68046~~	~~42.5~~	~~43.1~~	~~43.1~~	~~44.1~~	~~43.2~~	~~31~~	~~30~~
~~68047~~	~~42.2~~	~~43~~	~~41.6~~	~~42.5~~	~~42.3~~	~~37~~	~~31~~
~~68048~~	~~37.1~~	~~37.7~~	~~36.2~~	~~37.1~~	~~37.0~~	~~30~~	~~26~~
~~68049~~	~~461~~	~~455~~	~~462~~	~~456~~	~~458.5~~	~~411~~	~~403~~
~~68050~~	~~483~~	~~476~~	~~487~~	~~480~~	~~481.5~~	~~417~~	~~402~~
~~68051~~	~~528~~	~~526~~	~~533~~	~~521~~	~~527.0~~	~~475~~	~~484~~
~~68052~~	~~438~~	~~433~~	~~444~~	~~438~~	~~438.3~~	~~414~~	~~383~~
~~68053~~	~~472~~	~~457~~	~~488~~	~~471~~	~~472.0~~	~~405~~	~~406~~
68054	60.5	61.3	57	58.2	59.3	55	52
68055	202	204	206	209	205.3	198	216
68056	321	319	311	308	314.8	291	314
68057	224	225	223	224	224.0	204	210
68058	321	317	312	308	314.5	256	282
68059	137	138	136	137	137.0	133	143
68060	125	125	126	127	125.8	108	115
68061	338	332	339	331	335.0	349	349
68062	153	154	162	163	158.0	144	146
68062	162	163	167	168	165.0	162	156
68063	115	115	116	117	115.8	121	129
68064	56.9	57.6	52	52.8	54.8	54	51
68064	65.6	66.4	69.3	69.6	67.7	61	59
68065	150	151	147	148	149.0	132	137
68066	201	202	195	197	198.8	217	216
68067	207	208	213	213	210.3	186	199
68068	361	354	355	344	353.5	353	386
68069	91.1	92.1	92.4	94.2	92.5	97	112
68070	98.7	99.7	98.8	99.8	99.3	94	101
68071	60.7	61.5	58.7	59.6	60.1	52	59
68072	337	331	330	322	330.0	317	315

68073	129	130	131	132	130.5	118	121
68074	339	331	346	336	338.0	322	324
68075	62	63.2	57	58.2	60.1	59	60
68075	67.6	68.2	70.8	71.7	69.6	62	68
68075	75.6	76.3	81.6	82.7	79.1	79	73
68076	146	148	148	149	147.8	138	139
68077	131	132	134	135	133.0	130	128
68078	59.9	60.9	58.5	59.5	59.7	58	55
68079	116	118	113	115	115.5	103	107
68080	143	145	144	145	144.3	126	127
68081	57.5	58.8	56.5	57.6	57.6	62	62
68082	130	131	129	130	130.0	123	118
68083	271	268	265	261	266.3	258	278
68084	256	255	255	256	255.5	269	274
68085	104	104	104	104	104.0	104	96
68086	106	106	108	108	107.0	105	102
68087	114	111	117	115	114.3	111	109
68088	243	242	236	236	239.3	206	208
68089	239	238	236	235	237.0	208	212
68090	99.5	99.5	99.9	100	99.7	106	98
68091	90.3	89.8	91.4	90.9	90.6	81	90
68092	95.2	94.4	95.2	94.5	94.8	81	83
68093	239	238	238	239	238.5	205	231
68094	103	102	103	103	102.8	88	93
68095	100	99.9	99.3	99.3	99.6	101	100
68096	92.7	92.1	94	93.7	93.1	89	91
68097	104	104	106	106	105.0	89	90
68098	93.9	93.2	94.3	93.8	93.8	86	86
68099	102	101	102	102	101.8	98	102
68100	70.1	70.1	70.4	70.3	70.2	70	73
68101	64.6	64.5	64.6	64.9	64.7	61	64
68102	57.3	57.1	56.1	55.8	56.6	52	48
68103	169	169	163	164	166.3	161	160

Summary Report

Remove Venous Glucose subject 68044-68053

System Accuracy (ISO 15197:2013)

Test System: OKmeter AcePlus
Reference System: YSI 2300
Sample: Whole blood (capillary)

Data File: IDT-1104-OT_OKmeter_AcePlus_Ausw_110411.xls

Data summary:

For glucose concentration < 100mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
34/56 (60.7%)	53/56 (94.6%)	55/56 (98.2%)

For glucose concentration ≥ 100mg/dL

Within ±5%	Within ±10%	Within ±15%
58/136 (42.6%)	105/136 (77.2%)	132/136 (97.1%)

System accuracy results for glucose concentrations between 37.0 mg/dL and 527 mg/dL

Within ±15 mg/dL and ±15%
187/192 (97.4 %)

The OKmeter AcePlus blood glucose system complies with the system accuracy requirements of the ISO 15197:2013 Standard. 187of 192 (97.4%) results.

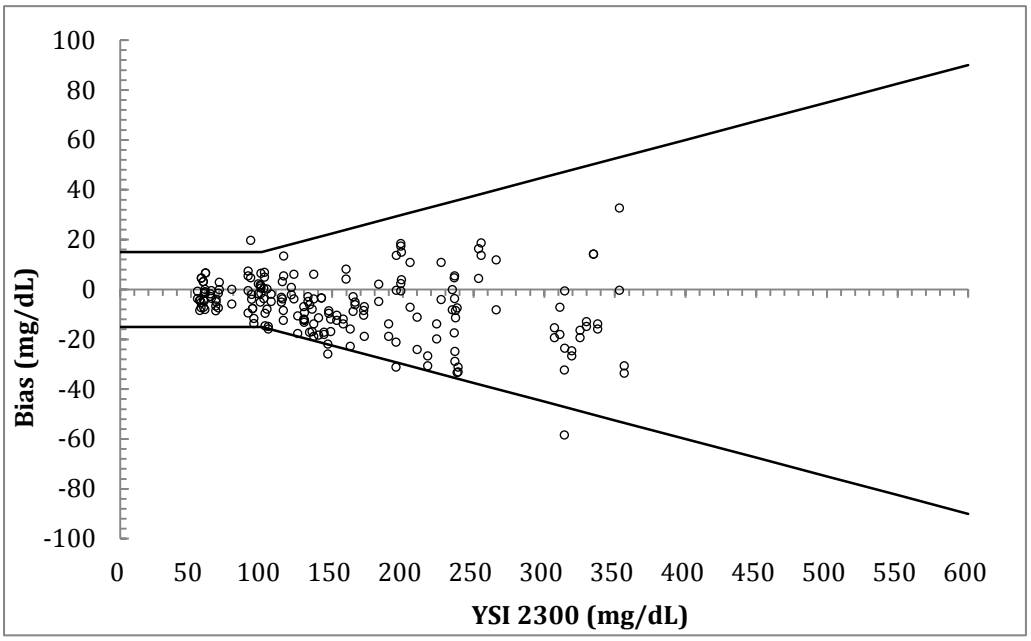

Fig. 1 System accuracy plot of the measurements of OKmeter AcePlus Blood Glucose Monitoring System versus Glucose Analyzer YSI 2300.

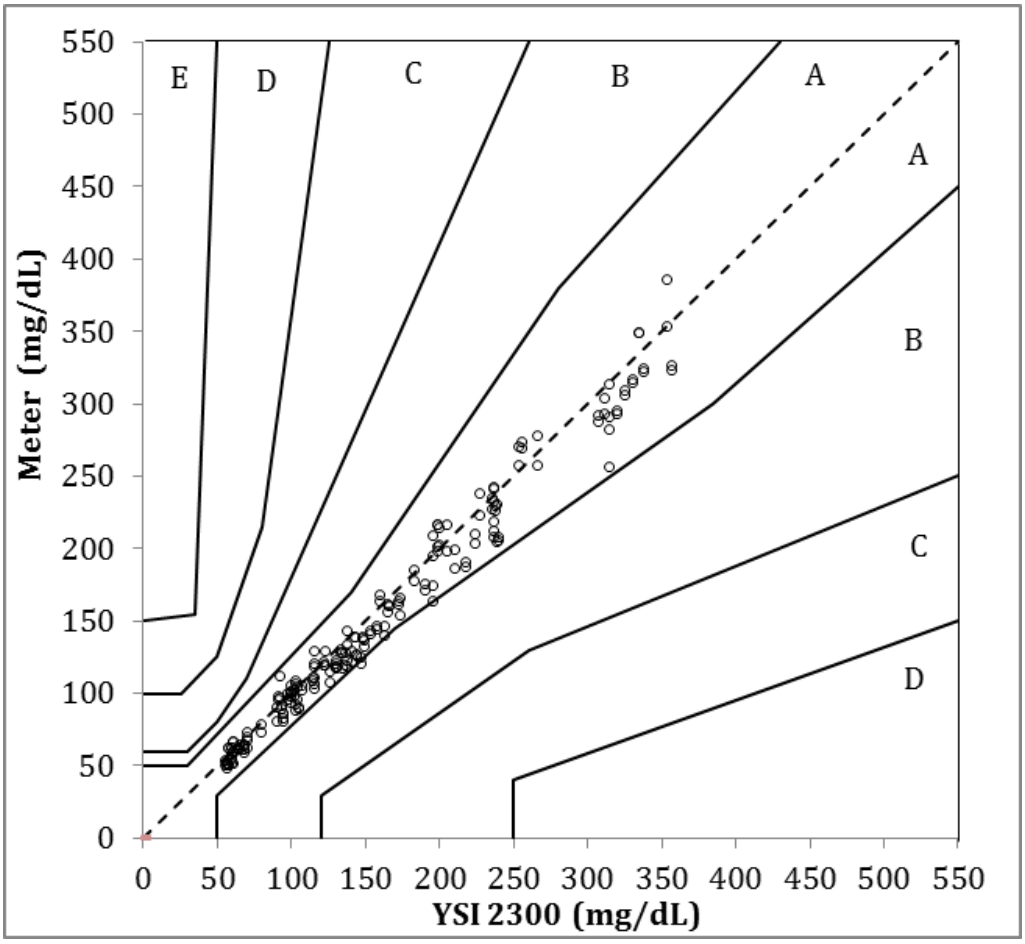

Fig. 2 Consensus error grid analysis of the measurements of OKmeter AcePlus Blood Glucose Monitoring System versus Glucose Analyzer YSI 2300.

➢ Summary and Conclusions

- Accuracy evaluation according to EN ISO 15197 was performed for OKmeter AcePlus (OK-A) from OK Biotech
- Reference method: Glucose oxidase / YSI 2300 STAT PLUS
- Minimum acceptable accuracy according to EN ISO 15197:2013
  ≥ 95% of the individual results shall fall within ± 15 mg/dL of the reference measurement at glucose concentrations < 100 mg/dL and within ± 15% at glucose concentrations ≥ 100 mg/dL.
- In the current evaluation
  - 97.4 % of results with OKmeter AcePlus (C) fell within the limits for system accuracy defined by EN ISO 15197:2013.
- In summary
  - OKmeter AcePlus complies with the system accuracy criteria of EN ISO 15197:2013.