WOODLEY
EQUIPMENT COMPANY LTD.

g-Pet PLUS+

Veterinary Glucometer

Accuracy Studies

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Abstract

The gPet PLUS test strips are to be used with the gPet PLUS veterinary glucometer only. The gPet PLUS test strips and meter are designed to use amperometric technology to measure glucose (sugar) in whole blood.

The gPet PLUS test strips for veterinary use only.

The gPet PLUS Blood Glucose Monitoring System is intended for use in the home or in a veterinary professional setting to monitor the blood glucose levels in dogs and cats and horses.

The results of this study confirm the statistical and clinical accuracy of the gPet PLUS veterinary glucometer. The gPet PLUS veterinary glucometer demonstrated good accuracy in both the home and veterinary professional setting when monitoring blood glucose levels in dogs and cats and horses. The gPet PLUS also met the current ISO system accuracy criteria (95% of the individual blood glucose results within ± 15 mg/dL of the results, of the manufacturers measurement procedure at glucose concentration < 100 mg/dL and within ± 15% at glucose concentrations ≥ 100 mg/dL) with 100% of results being acceptable.

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Introduction:

The gPet PLUS test strips are to be used with the gPet PLUS veterinary glucometer only. The gPet PLUS test strips and meter are designed to use amperometric technology to measure glucose (sugar) in whole blood. The gPet PLUS Test Strips are for veterinary use only.

The gPet PLUS veterinary glucometer is intended for use in the home or in a veterinary professional setting to monitor blood glucose levels in dogs and cats and horses. The detailed specification is shown at Table I.

Table I. Specification of gPet PLUS Blood Glucose Monitoring System

Test Principle	Amperometric Biosensor with FAD-Glucose Dehydrogenase
Detecting Range	20 ~ 600 mg/dL
Test Time	5 seconds
Sample Volume	0.7ul
Blood Sample	Venous and Capillary Whole Blood
HCT Range	20% ~60 %
Operating Temperature	10 to 40 ℃ (50-104℉)
Strip Storage Temperature	4 to 30 ℃ (39-86℉)
Operating Humidity	10 to 90%
Average result	7,14 and 30 Days
Memory capacity	500 Test Results
PC download option	USB Interface
Battery Power	Two AAA batteries

Diabetes mellitus is a common disorder of dogs, cats and horses. Monitoring of patient blood glucose levels is an essential element of diabetes management; however, hand-held instruments designed for convenient glucose monitoring in humans are not validated for veterinary use.

The gPet PLUS is a hand-held glucose monitoring device specifically developed for veterinary use. This work represents the study of the performance of the device in the clinical setting.

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Methods and Design

To compare the accuracy of the gPet PLUS and three other hand-held devices against the reference method used by YSI 2300 STAT PLUS (YSI) , for measurement of blood glucose in diabetic and non-diabetic dogs, cats and horses.

- Venous whole blood samples from five cats, five dogs and six horses were investigated in this study.
- Venous whole blood samples were taken and tested immediately on each of three hand-held glucose monitoring devices: gPet PLUS, Accu-Chek® Performa (ROCHE) and AlphaTRAK (Abbott). Each venous blood sample was measured with six tests on the gPet PLUS and one test on both the Performa and AlphaTRAK.
- Plasma samples were prepared according to standard practices and then the plasma glucose level was measured with YSI 2300 STAT PLUS analyser. The use of a YSI 2300 STAT PLUS glucose analyser was directly referred to NCCLS (the National Committee for Clinical Laboratory Standards) in addition to an internal QA scheme. Precision performance is at an inter-assay CV of <2.5% at 3.4mmol/L (62 mg/dL), <1.5% at 8.9mmol/L (160 mg/dL) and <1.6% at 14.4 mmol/L (260 mg/dL) over the 4 months period of analysis.
- All hand-held meter calibration and testing was performed in accordance with the manufacturers instructions.
- Accuracy was determined for each instrument: Bias of results compared to YSI were calculated as follows:

  Hand-Held Meter Glucose Levels/ YSI Reference Glucose Levels

  Bias = Hand-Held Meter Response – YSI Reference

  %Bias = 100 * (Hand-Held Meter Response –YSI Reference) / YSI Reference

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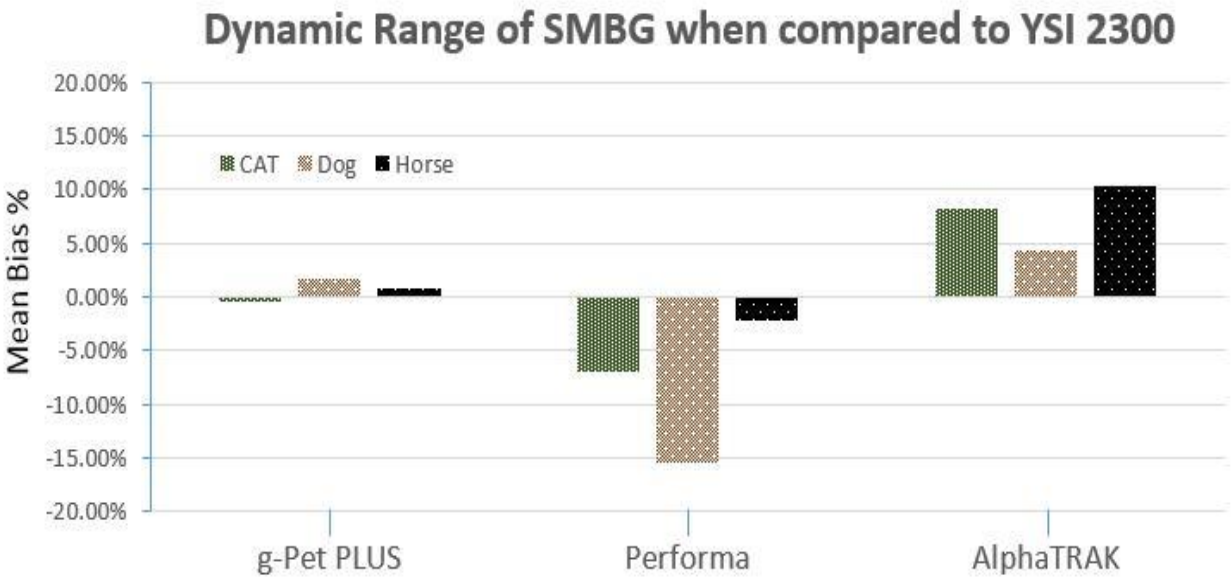
Summary of Bias Results from YSI 2300 STAT PLUS (YSI)

The average Bias results of cat, dog and horse were shown below.



SPECIES	gPet PLUS	Performa	AlphaTRAK
CAT	-0.44%	-7.02%	8.16%
DOG	1.63%	-15.40%	4.34%
HORSE	0.78%	-2.14%	10.40%

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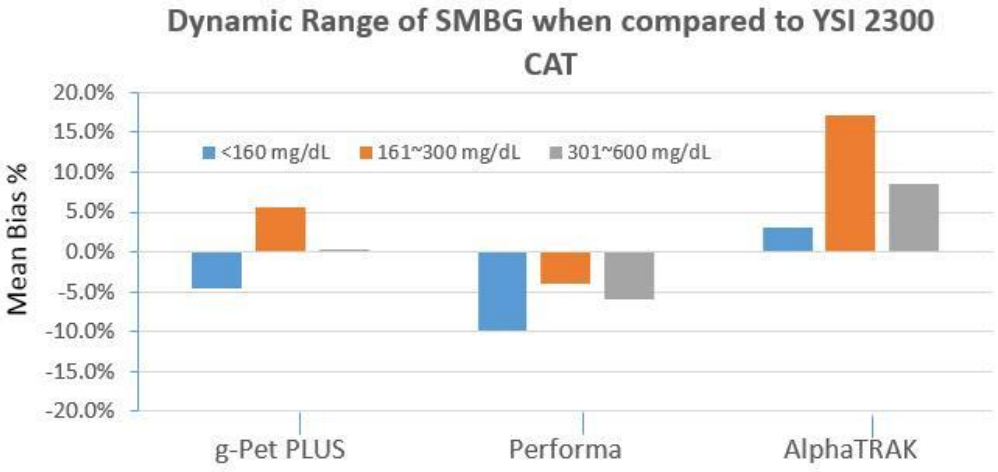

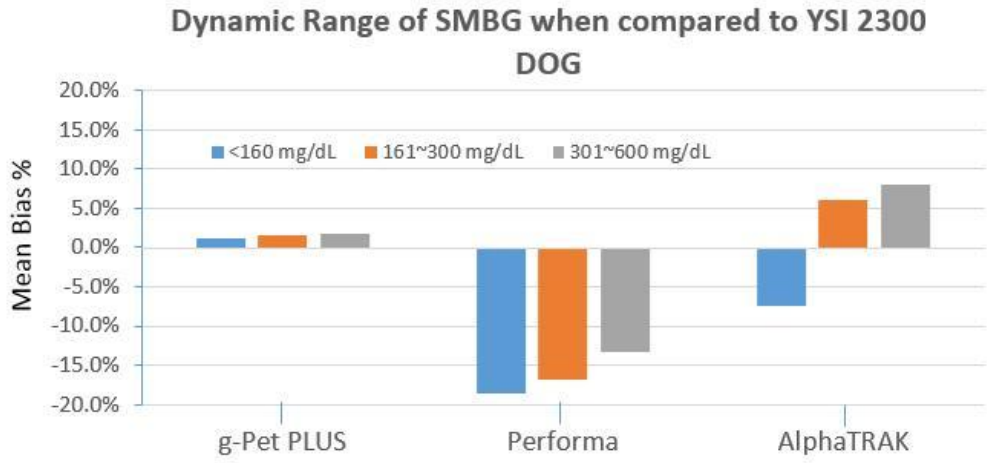

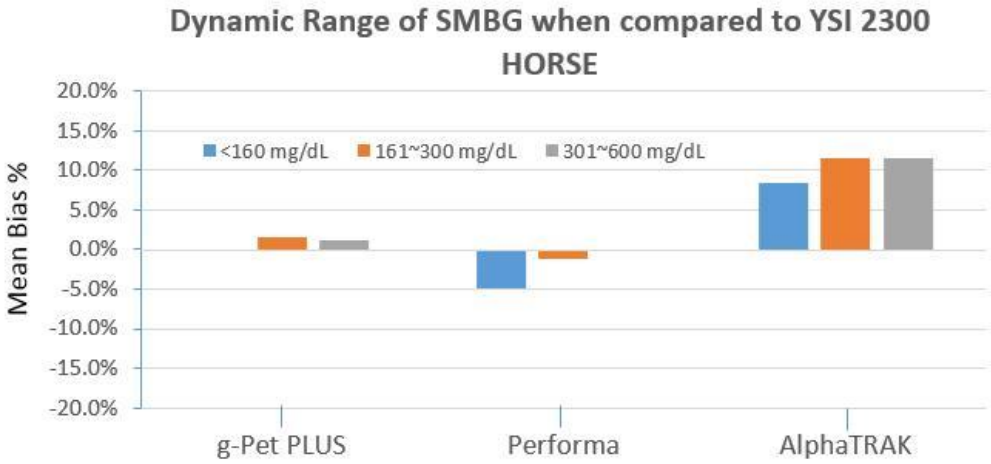

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CAT

YSI 2300	gPet PLUS	Performa	AlphaTRAK
<160 mg/dL	-4.5%	-9.8%	3.1%
161~300 mg/dL	5.6%	-4.1%	17.2%
301~600 mg/dL	0.4%	-6.0%	8.6%

DOG

YSI 2300	gPet PLUS	Performa	AlphaTRAK
<160 mg/dL	1.2%	-18.6%	-7.5%
161~300 mg/dL	1.6%	-16.8%	6.1%
301~600 mg/dL	1.8%	-13.3%	8.0%

HORSE

YSI 2300	gPet PLUS	Performa	AlphaTRAK
<160 mg/dL	-0.2%	-4.9%	8.4%
161~300 mg/dL	1.6%	-1.1%	11.5%
301~600 mg/dL	1.1%	-0.2%	11.6%

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Summary of Accuracy Results of Hand-Held Meters:

Hand-Held Meter	Glucose Reference (mg/dL)	*Tests (n)	Mean % Bias	% Relative to YSI
gPet PLUS	YSI 2300 STAT PLUS	Cat (102)	-0.44	99.56
		Dog (60)	1.63	101.63
		Horse (150)	0.78	100.78
Performa	YSI 2300 STAT PLUS	Cat (17)	-7.02	92.98
		Dog (10)	-15.40	84.60
		Horse (25)	-2.14	97.86
AlphaTRAK	YSI 2300 STAT PLUS	Cat (17)	8.16	108.16
		Dog (10)	4.34	104.34
		Horse (25)	10.40	110.40

*Each venous blood sample were measured with six tests for gPet PLUS and one test for Performa and AlphaTRAK respectively.

The accuracy studies of all the BG monitoring system were summarized in Table I

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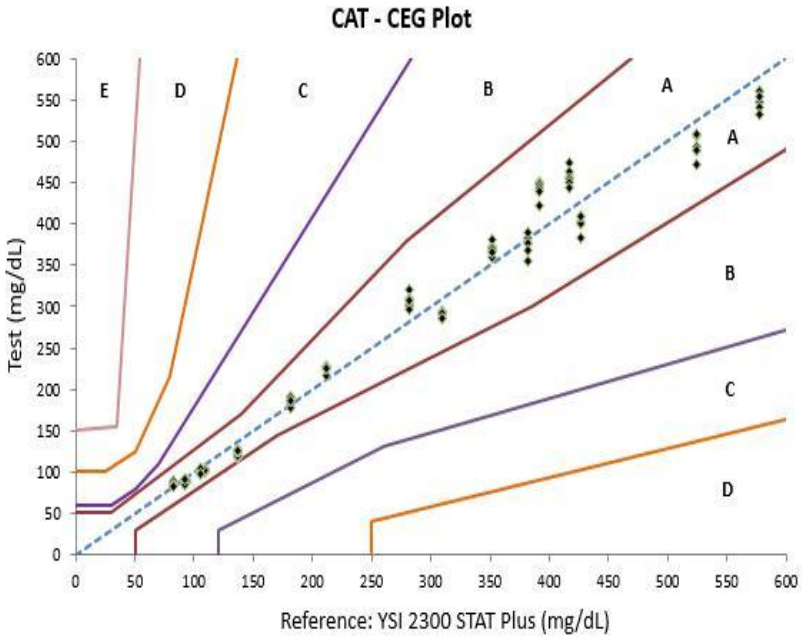
TABLE I. BLOOD GLUCOSE MONITORING SYSTEM ACCURACY RESULTS

SPECIES		New ISO 15197	BG concentration <100mg/dL			BG concentration ≥100mg/dL			
		Percentage	±5 mg/dL	±10 mg/dL	±15 mg/dL	±5%	±10%	±15%	MARE
CAT	g-Pet PLUS	99.0% (101/102)	83.3% (15/18)	100.0% (18/18)	100.0% (18/18)	32.1% (27/84)	84.5% (71/84)	98.8% (83/84)	6.04%
	Performa	94.1% (16/17)	0.0% (0/3)	0.0% (0/3)	100.0% (3/3)	50.0% (7/14)	71.4% (10/14)	92.9% (13/14)	7.89%
	AlphaTRAK	58.8% (10/17)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	35.7% (5/14)	42.9% (6/14)	50.0% (7/14)	12.28%
DOG	g-Pet PLUS	100.0% (60/60)	75.0% (9/12)	100.0% (12/12)	100.0% (12/12)	10.4% (5/48)	79.2% (38/48)	100.0% (48/48)	7.15%
	Performa	60.0% (6/10)	0.0% (0/2)	0.0% (0/2)	100.0% (2/2)	0.0% (0/8)	12.5% (1/8)	50.0% (4/8)	15.40%
	AlphaTRAK	90.0% (9/10)	50.0% (1/2)	100.0% (2/2)	100.0% (2/2)	37.5% (3/8)	50.0% (4/8)	87.5% (7/8)	8.85%
HORSE	g-Pet PLUS	100.0% (150/150)	80.6% (29/36)	97.2% (35/36)	100.0% (36/36)	70.2% (80/114)	92.1% (105/114)	100.0% (114/114)	3.93%
	PERFORMA	100.0% (25/25)	83.3% (5/6)	100.0% (6/6)	100.0% (6/6)	84.2% (16/19)	100.0% (19/19)	100.0% (19/19)	3.46%
	AlphaTRAK	68.0% (17/25)	50.0% (3/6)	66.7% (4/6)	83.3% (5/6)	31.6% (6/19)	57.9% (11/19)	63.2% (12/19)	11.43%

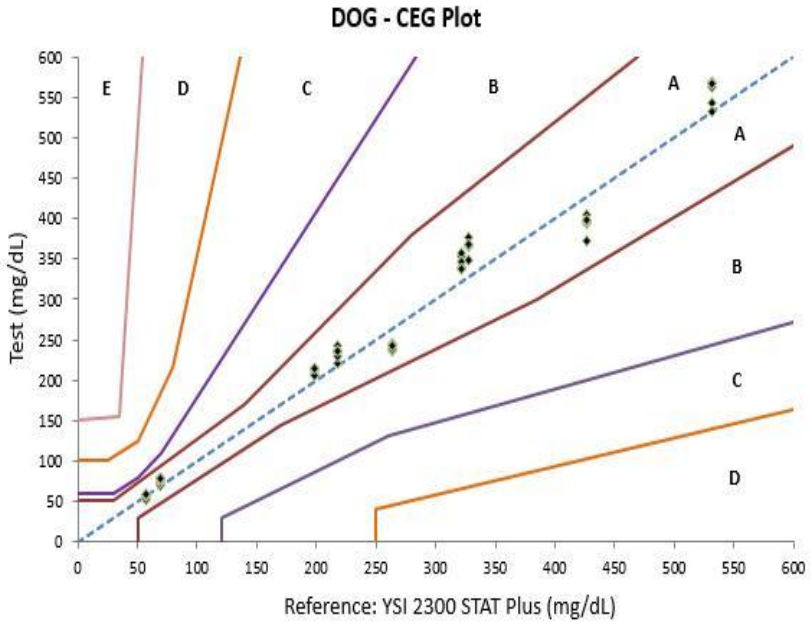
Values are percentages (valid n/total n). Values ≧ 95% are in bold type; remaining values are < 95%.

The Consensus Error Grid (CEG) plot measured by gPet PLUS device are shown as below.



Consensus Error Grid- CAT

Total	Region	A+B	A	B	C	D	E
102	Points	102	102	0	0	0	0
	CEG (%)	100.0%	100.0%	0.0%	0.0%	0.0%	0.0%



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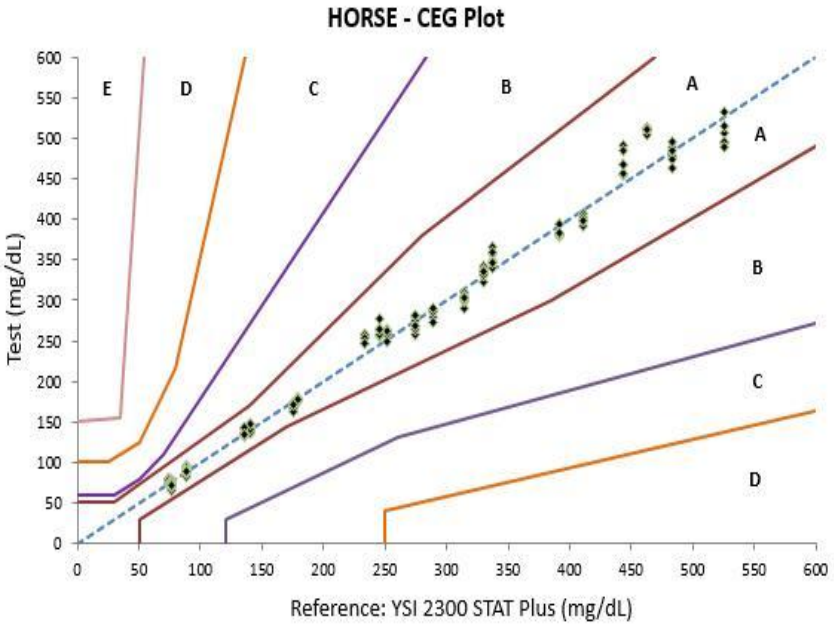
Consensus Error Grid- DOG

Total	Region	A+B	A	B	C	D	E
60	Points	60	54	6	0	0	0
	CEG (%)	100.0%	90.0%	10.0%	0.0%	0.0%	0.0%



Consensus Error Grid- HORSE

Total	Region	A+B	A	B	C	D	E
150	Points	150	150	0	0	0	0
	CEG (%)	100.0%	100.0%	0.0%	0.0%	0.0%	0.0%

For the gPet PLUS hand-held meter, the mean % bias, for cat, dog and horse blood samples are not significantly different from zero at the 5% significance level. This provides strong evidence that the gPet PLUS results are statistically equivalent to the YSI results.

For the Performa and AlphaTRAK hand-held meters, the mean % biases for each of the cat, dog and horse blood samples are slightly different from the YSI reference results. For Performa, the hand-held meter for humans, the results are lower than YSI 2300 STAT PLUS. For the AlphaTRAK, the hand-held meter for veterinary use, the results are higher than YSI 2300 STAT PLUS.

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The accuracy of gPet PLUS meter shows that 99%~100% of individual difference are falling within ±15mg/dL at glucose concentration for samples <100mg/dL and within ±15% at glucose concentrations ≧100 mg/dL. Each meter met the ISO 15197 requirement of 95% of individual glucose results falling within ±15mg/dL at glucose concentration for samples <100mg/dL and within ±15% at glucose concentrations ≧100 mg/dL.

Regression:

Regression analysis was performed and intercepts, slopes and correlation coefficients (r2) were calculated for each hand-held instrument versus the YSI reference results.

Summary of Regression Statistics

Hand-Held Meter	Animal	Slope	Intercept (mg/dL)	r2	n
gPet PLUS	Cat	0.99	3.17	0.9783	102
	Dog	0.96	14.68	0.9765	60
	Horse	1.02	-1.03	0.9892	150
Performa	Cat	0.92	3.57	0.9843	17
	Dog	0.85	-0.11	0.9919	10
	Horse	1.02	-6.72	0.9967	25
AlphaTRAK	Cat	1.06	6.90	0.9481	17
	Dog	1.04	4.35	0.9861	10
	Horse	1.13	-4.87	0.9740	25

For the gPet PLUS hand-held meter, the intercept and slope for cat, dog and horse blood samples are not significantly different from the line of equivalency (intercept: 0, slope: 1). This provides strong evidence that gPet PLUS results are statistically equivalent to the YSI results, at all glucose values.

Conclusions

The results of this study confirm the statistical and clinical accuracy of the gPet PLUS veterinary glucometer. The gPet PLUS veterinary glucomater demonstrated good accuracy in both the home and veterinary professional setting to monitor blood glucose levels in dogs and cats and horses.

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The gPet PLUS met the current ISO system accuracy criteria (95% of the individual blood glucose results within ± 15 mg/dL of the results, of the manufacturer' s measurement procedure at glucose concentration < 100 mg/dL and within ± 15% at glucose concentrations ≥ 100 mg/dL) with 100% of results being acceptable.

The accuracy of the gPet PLUS was shown to be superior to that of Performa and AlphaTRAK. On average, the gPet PLUS results were within -0.44% of YSI results in a population of diabetic and non-diabetic cats compared to a range of -7.02% ~ 8.16% for comparative devices. In a population of diabetic and non-diabetic dogs, the gPet PLUS results were on average within 1.63% of YSI results, compared to a range of -15.40% ~ 4.34% for comparative devices. In a population of diabetic and non-diabetic horse, the gPet PLUS results were on average within 0.78% of YSI results, compared to a range of -2.14% ~ 10.40% for comparative devices.

References:

1. United States Food and Drug Administration, Division of Clinical Laboratory Devices, Rockville, Maryland USA, "Review Criteria for Assessment of Portable Invasive Blood Glucose Monitoring In Vitro Diagnostic Devices which use Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology," March 1998.
2. International Organization for Standardization, "In vitro diagnostics test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus" ISO 15197 : 2013