Premier α
Blood Glucose Monitoring System
Accuracy and Precision Test Report

Introduction

Premier α Blood Glucose Monitoring System (BGMS) is an *in-vitro* diagnostic medical device that provides reliable blood glucose test results for diabetic and pre-diabetic patients. By using the BGMS the blood glucose levels can be monitored at the real time. For diabetic patients and healthcare physicians, knowing the blood glucose levels helps to take appropriate actions for the food intake, level of exercise, and the insulin dose adjustment during insulin therapy; therefore, hypo- and hyperglycemia can be prevented. The use of BGMS also helps to manage lifestyle choices as it enables users to observe the fluctuation of the blood glucose levels with various activities.

Premier α satisfies the latest ISO standard for Blood Glucose Monitoring Systems. Premier α BGMS measures the blood glucose concentration with a minimum volume of 0.4μL within 5 seconds, for hematocrit range of 15 ~ 65%, within the measurement range 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L).

This document presents the performance characteristics of Premier α BGMS that are fully compliant with the EN ISO 15197:2015 standard.

System Accuracy

Materials & Method

The system accuracy evaluation was conducted according to the guideline EN ISO 15197: 2015. One hundred subjects enrolled for this study to evaluate the performance of three test strip lots of Premier α BGMS, where the subjects obtained capillary blood samples after washing, drying and pricking the finger of their choice. The blood glucose result obtained from Premier α BGMS was compared against the reference equipment result, where an extra volume of capillary blood sample was required to measure the YSI 2300 STAT PLUS glucose analyzer, as well as for hematocrit measurement.

Acceptance criteria

- ✓ 95% of the individual glucose results shall fall within ±15 mg/dL of the reference results at glucose concentrations less than 100 mg/dL and within 15% at glucose concentrations greater than or equal to 100 mg/dL.
- ✓ 99% of all results are required to be in zones A and B of the Consensus Error Grid.

Results

The hematocrit range of the samples in this study was 27 ~ 50%, and the range of glucose concentrations was 38.1 ~ 531.7 mg/dL (2.1 ~ 29.5mmol/L). Figure 1 shows the system accuracy data of three strip lots(N=600).

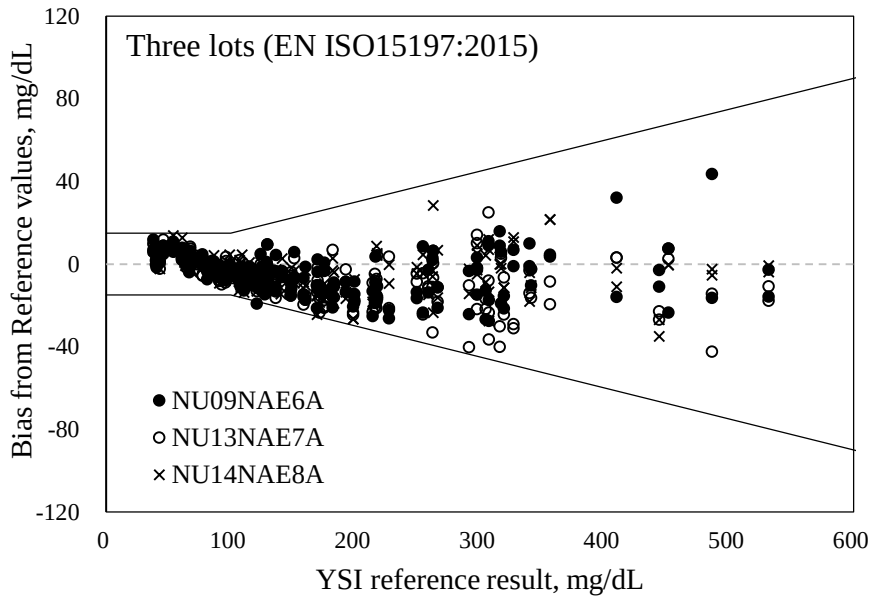

Figure 1. Premier α BGMS System Accuracy Plot with Capillary Whole Blood (EN ISO 15197:2015)

Table 1, 2 and 3 demonstrates the percentage of samples within the acceptance criteria for three lots combined. As seen in the tables, 100% of the data for glucose concentrations < 100 mg/dL (5.56 mmol/L), and 99.8% of the data for glucose concentrations ≥100 mg/dL (5.56 mmol/L) were within the acceptance criteria. Therefore in total, 99.8% of the data was within the system accuracy requirement of EN ISO 15197:2015.

Table 1. System Accuracy Results for Glucose Concentrations < 100 mg/dL (5.6mmol/L)

Accuracy Criteria	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Percent (n/n) within criteria	117/186 (62.9%)	181/186 (97.3%)	186/186 (100%)

Table 2. System Accuracy Results for Glucose Concentrations ≥ 100 mg/dL (5.6mmol/L)

Accuracy Criteria	within ± 5 %	within ± 10 %	within ± 15 %
Percent (n/n) within criteria	207/414 (50.0%)	375/414 (90.6%)	413/414 (99.8%)

Table3. Premier α BGMS System Accuracy Results for all concentration range tested

Accuracy Criteria	within ± 5 mg/dL or 5%	within ± 10 mg/dL or 10%	within ± 15 mg/dL or 15%
Percent (n/n) within criteria	324/600 (54.0%)	556/600 (92.7%)	599/600 (99.8%)

The Consensus Error Grid (CEG) plot shows the three strip lots' results (N=600) obtained from the System accuracy evaluation of Premier α BGMS (Figure 2).

All of the data points were located within zone A of CEG, demonstrating that the Premier α BGMS poses no risk to the diabetic patient from giving altered clinical action.

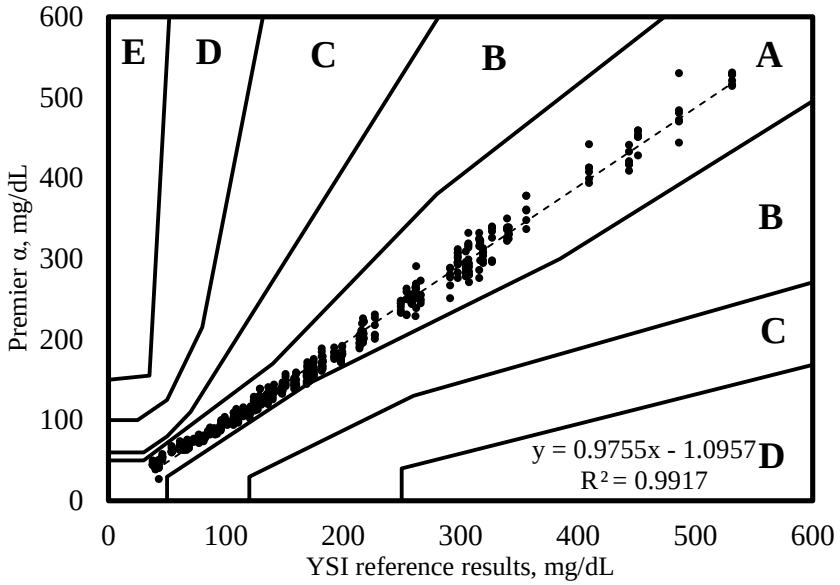

Figure 2. Consensus Error Grid of Premier α BGMS values plotted against the reference values (EN ISO 15197:2015)

Precision

Materials & Method

Precision evaluation as proposed by the EN ISO 15197:2015 comprises repeatability and intermediate precision studies. Repeatability study was conducted by a single operator within a day using venous blood samples adjusted to five glucose concentration intervals. The intermediate precision test was conducted using three levels of control solutions representing the hyperglycemic, euglycemic and hypoglycemic ranges respectively. The study was conducted by multiple numbers of operators for 10 days. For both studies, 10 meters and three test strip lots were used.

Repeatability Test Results

For each venous blood sample, BGMS measurement of three strip lots were obtained. 100 BGMS values of each concentration interval per strip lot were obtained. The averages of three strip lot results are shown in Table 4. For low and low-mid venous blood samples, the pooled SDs were 2.0 and 2.5 mg/dL, while for mid, mid-high and high venous blood samples, the pooled CVs were 3.1, 3.7 and 2.8% respectively.

Table 4. Repeatability Results of Premier α BGMS

Glucose level	Low (30–50 mg/dL)	Low-Mid (51–110 mg/dL)	Mid (111–150 mg/dL)	Mid-High (151–250 mg/dL)	High (251-400 mg/dL)
Mean, mg/dL	39.4	77.1	131	207	324
Pooled SD, mg/dL	2.0	2.5	4.0	7.7	9.1
Pooled CV, %	-	-	3.1	3.7	2.8

Intermediate Precision Test Results

For each control solution, BGMS measurement of three strip lots were collected. 100 BGMS values of each concentration interval per strip lot per day were obtained over the fora ten-day period. The averages of three strip lot results are shown in Table 5. For low glucose concentration, the pooled SD was 1.0 mg/dL, while for low-mid and mid control solutions, the pooled CVs were 2.7 and 2.6% respectively.

Table 5. Intermediate Precision Results of Premier α BGMS

Glucose level	Low	Low-Mid	Mid
Mean, mg/dL	39.9	116	346
Pooled SD, mg/dL	1.0	3.1	8.9
Pooled CV, %	-	2.7	2.6

Effect of Hematocrit

Materials & Method

The effect of hematocrit on the performance of the Premier α BGMS was evaluated based on EN ISO 15197: 2015; using blood samples of 3 glucose concentrations and 7 hematocrit levels for 3 test strip lots. From a pool of blood sample at each glucose concentration interval, the hematocrit was adjusted by mixing proportions of the packed cells and the plasma into 15, 20, 30, 42 (control), 50, 60, and 65%. The difference between the average measured value at each packed cell volume level and the average measured value at the mid-level packed cell volume were calculated.

Results

Table 6 shows mean differences in bias at various hematocrit levels. The differences throughout all hematocrit levels were within the acceptance criteria for packed cell volume evaluation in EN ISO 15197:2015; ≤ 10 mg/dL at low glucose concentrations (< 100 mg/dL) and ≤ 10% at higher glucose concentrations (≥ 100 mg/dL). The hematocrit evaluation result is also shown graphically in figure 3.

Table 6. Effect of Hematocrit (Hct)

Mean YSI Reference Value	Mean Difference in Bias from Control (42% Hct.)						
	15%Hct.	20%Hct.	30%Hct.	42%Hct.	50%Hct.	60%Hct.	65%Hct.
42.9	6.4	4.3	3.7	0.0	-0.8	-2.9	-4.8
130	4.6	6.0	2.9	0.0	-3.0	-5.7	-7.9
375	5.9	3.8	3.5	0.0	-4.3	-6.8	-8.9

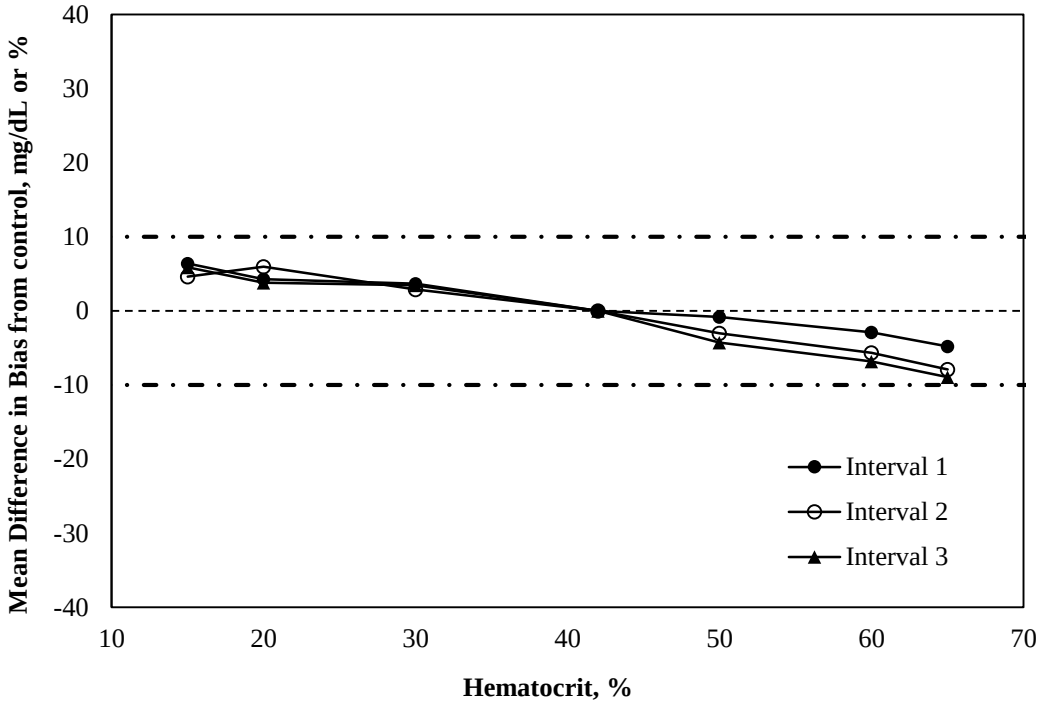

Figure 3. Mean Difference Graph of Premier S BGMS form 42% Hematocrit Value (EN ISO 15197:2015)

Interference

Materials & Method

The Interference Test was conducted in reference to the guidelines in EN ISO 15197:2015 and CLSI EP07-A2. 24 potentially interfering substances (reducing substances, common medications, and non-glucose sugars) were evaluated in paired-sample experimental design, using venous blood samples at two glucose concentration intervals (50 ~ 100 mg/dL and 250 ~ 350 mg/dL) using 3 test strip lots. The average difference between the test sample and the control sample was calculated to evaluate the effect of the interfering substances.

*The CareSens PRO BGMS test results are presented in this paper. The reagent formulation of the CareSens PRO test strip is the same as that of Premier α.

Results

Results for each test strip lot were shown in Table 7. Most of the substances under evaluation had no effects greater than the acceptance criteria stated in EN ISO 15197: 2015; ≤ 10 mg/dL for glucose concentration < 100 mg/dL and ≤ 10% for glucose concentrations > 100 mg/dL, except for xylose. Xylose underwent a separate dose-response test whereby the maximum xylose concentration without affecting the blood glucose measurement by the BGMS was demonstrated to be 9.69 mg/dL.

Table 7. Effect of Interfering Substances on the Response of the BGMS

Substance	Test Concentration	Mean Difference in Bias from Control	
		Low (Mean YSI =50~100mg/dL)	High (Mean YSI =250~350mg/dL)
Acetaminophen	20 mg/dL	-0.9 mg/dL	2.7%
Ascorbic acid	3 mg/dL	-2.3 mg/dL	0.0%
Bilirubin	20 mg/dL	1.1 mg/dL	1.3%
Cholesterol	500 mg/dL	0.7mg/dL	-0.3%
Creatinine	30 mg/dL	0.2 mg/dL	-1.9%
Dopamine	13 mg/dL	0.4 mg/dL	-0.3%
EDTA	180 mg/dL	1.6mg/dL	1.4%
Galactose	60 mg/dL	-2.4 mg/dL	-0.2%
Gentisic acid	50 mg/dL	0.8 mg/dL	2.7%
Glutathione(Red)	17 mg/dL	-1.0 mg/dL	-0.8%
Hemoglobin	500 mg/dL	-5.6 mg/dL	-2.8%
Heparin	8000 U/dL	-0.8 mg/dL	-0.8%
Ibuprofen	40 mg/dL	1.7 mg/dL	-0.9%
Icodextrin	1094 mg/dL	-2.8 mg/dL	-0.4%
L-Dopa	5 mg/dL	-2.4 mg/dL	0.0%
Maltose	1000 mg/dL	-2.1 mg/dL	-1.4%
Methyldopa	1.5 mg/dL	-0.9 mg/dL	-1.4%
Pralidoxime Iodide	25 mg/dL	-1.8 mg/dL	1.6%
Salicylate	70 mg/dL	1.0 mg/dL	3.7%
Tolazamide	100 mg/dL	-0.3 mg/dL	0.5%
Tolbutamide	100 mg/dL	1.8 mg/dL	3.5%
Triglycerides	3000 mg/dL	-0.5 mg/dL	0.5%
Uric acid	20 mg/dL	-0.5 mg/dL	-0.6%
Xylose	25 mg/dL	33.8 mg/dL	8.9%

At 25 mg/dL of blood xylose concentration, the difference of blood glucose measurement between the test and control samples was above 10 mg/dL at low glucose concentration. Dose-response test was conducted for xylose, and the highest blood xylose concentration at which no interference was observed for blood glucose measurement is 9.69 mg/dL (Table 8).

Table 8. Dose-Response Test Result

Substance	Maximum Interfering Substances Concentration in low glucose concentration
Xylose	9.69 mg/dL

Conclusion

The Premier α BGMS' performance was evaluated with the System Accuracy, Precision, Effect of Hematocrit, and Interference evaluations.

The test results demonstrated that Premier α BGMS provides accurate and reliable blood glucose measurement results that comply with the EN ISO 15197: 2015 standards, with its precision under 5 mg/dL SD at glucose concentrations < 100 mg/dL and within 5% CV at glucose concentrations ≥100 mg/dL. The BGMS is safe to use within the hematocrit range of 15 ~ 65%, and the system is under no influence from the 24 common interfering substances, except for xylose that exhibits interference at > 9.69 mg/dL.

References

1. EN ISO 15197:2015 In vitro Diagnostic Test Systems -Requirements for Blood-Glucose Monitoring Systems for Self-Testing In Managing Diabetes Mellitus.
2. CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline-2nd Edition
3. CareSens PRO BGMS, Interference Test Report (BGM-031A-R007_1).

