On·Call® Sure

Blood Glucose Monitoring System

Evaluation Report

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ACON® Diabetes Care

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1. Introduction

The *On Call® Sure* (Sync) Blood Glucose Monitoring System is a hand-held, battery-operated meter with test strips, control solution, lancet and lancet device used to measure the glucose concentration in whole blood.

The *On Call® Sure (Sync)* Blood Glucose Monitoring System is for use by healthcare professionals and also for diabetic patients self-monitoring at home.

2. Measurement Principle

The *On Call® Sure test strip* is a biosensor which uses the principle of electrochemistry for detection of glucose concentration in blood. The blood sample is automatically drawn into the test strip by capillary action where it mixes with chemical reagents initiating a reaction. A transient electrical current is generated during the reaction which is detected by the meter and directly related to the blood glucose concentration in the sample.

The *On Call® Sure (Sync)* Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm, and/or palm, as well as healthcare professional use with fresh neonatal whole blood samples and fresh venous and arterial whole blood samples.

3. On Call® Sure (Sync) Blood Glucose Monitoring System

Specifications

Feature	Specification
Technology	Biosensor/Electrochemical, Glucose dehydrogenase (FAD-GDH)
Test Time	5 seconds
Sample Size	0.6 µL
Result Calibration	Plasma-equivalent (Complied with IFCC)
Sample Application	Wicking action, End-fill
Sample Type	Fresh whole blood (Capillary, Venous, Arterial and Neonatal)
Primary Sites	Fingertip
Alternate Sites	Forearm & Palm
Hematocrit Range	10 - 70%
Operating Temp Range	5 - 45°C
Operating Humidity Range	10 - 90% (non-condensing)
Storage Temperature Range	2 - 35°C
Calibration Method	Auto coding
Glucose Test Range	0.6 - 33.3 mmol/L (10 - 600 mg/dL)
Strip Shelf Life	24 months
Open Vial Expiration	6 months
Control Solution	3 levels
Test Averaging	7,14,30,60,90-day averages
Battery	Two (2) CR 2032 3.0V Coin Cell Batteries
Battery Life	3,000 measurements for testing (not considering data transfer)
Memory Storage	Up to 1000 records with time and date
Data transfer port	USB
Beep Function	Yes
Automatic Shutoff	2 minutes after last action
Wireless Frequency (On Call Sure Sync Meter)	2.4 GHz Worldwide ISM Band (Instrumentation, Scientific and Medical)
Other Functions	Strip ejector on the meter
	Individually foil wrapped test strips available
	Insufficient sample volume detection
	Five (5) customizable test reminders
	Ketone warning, Hypo and hyper warnings
	2nd sample application allowed
	Auto-setting QC / Sample Model

4. Accuracy Evaluation - Performed By Trained Technicians

4.1 Capillary Whole Blood from Fingertip

4.1.1 Purpose

Studies were conducted to assess the accuracy of the *On Call® Sure (Sync)* Blood Glucose Monitoring System with capillary blood samples.

4.1.2 Procedure

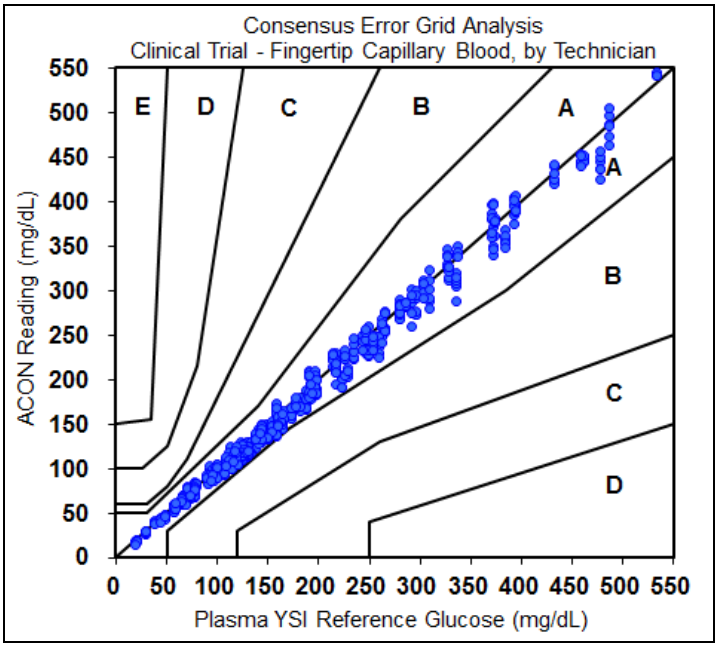
Trained technicians performed capillary finger sticks on study subjects and dosed the test strips. 266 data points, for each lot of test strips, from 111 subjects were collected in the study. The tested range of glucose was from 19.6 to 534 mg/dL. Per EN ISO 15197: 2015, some of the blood samples with very low and very high levels of blood glucose were adjusted by technicians. The hematocrit range tested was 28% to 50%.

The ages of the study subjects ranged from 23 to over 88. All the study subjects were well informed about the study and learned instructions for proper of use of the system. Capillary blood samples from all study subjects' fingertips were collected into a microtainer tube (with heparin anticoagulant) and then plasma of each sample was tested in duplicate on the YSI reference instrument (YSI Model 2300 STAT PLUS Glucose Analyzer). The plasma YSI value from fingertip capillary blood sample for each study subject was used for comparison.

4.1.3 Results

System accuracy results of capillary whole blood testing from fingertips are shown in ***Figure 1***.

Figure 1



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Finger Sample Site Tested by Technician			
System Accuracy Results for Glucose Concentration <5.55 mmol/L (<100 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)	
156 / 216 (72.2%)	214 / 216 (99.1%)	216 / 216 (100.0%)	
System Accuracy Results for Glucose Concentration ≥5.55 mmol/L (≥100 mg/dL)			
Within ±5%	Within ±10%	Within ±12%	Within ±15%
335 / 582 (57.6%)	530 / 582 (91.1%)	566 / 582 (97.3%)	582 / 582 (100.0%)
System Accuracy Results for Glucose Concentrations Between 1.09mmol/L (19.6mg/dL) and 29.6mmol/L (533.5mg/dL)			
Within ±0.83mmol/L (±15mg/dL) or ±15%			
798 / 798 (100%)			
Within ±0.56mmol/L (±10mg/dL) or ±12%			
780 / 798 (97.7%)			

4.1.4 Conclusions

The data displayed above show equivalent correlation to the reference method, demonstrating that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides high accurate results with capillary blood samples from fingertip.

4.2 Venous Whole Blood

4.2.1 Purpose

Studies were conducted to assess the accuracy of the *On Call® Sure (Sync)* Blood Glucose Monitoring System with venous whole blood samples.

4.2.2 Procedure

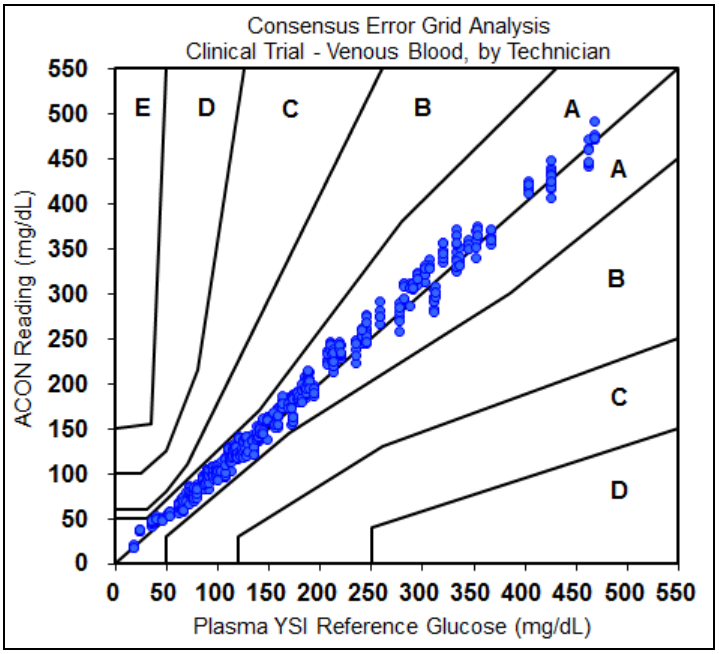
Trained technicians performed the venous blood sample on study subjects and dosed the test strips. 254 data points, for each lot of test strips, from 103 subjects were collected in the study. The tested range of glucose was from 17.4 to 561 mg/dL. Per EN ISO 15197: 2015, some of the blood samples with very low and very high levels of blood glucose were adjusted by technicians. The hematocrit range tested was 28% to 56%.

A trained technician performed testing with each study subject's venous blood samples on the studied system. The testing was performed using the same method provided in the instructions for use for the studied system. Venous blood samples from all study subjects were collected into a microtainer tube (with heparin anticoagulant) and then plasma of each sample was tested in duplicate on the YSI reference instrument (YSI Model 2300 STAT PLUS Glucose Analyzer) for comparison.

4.2.3 Results

System accuracy results of venous whole blood testing are shown in ***Figure 2***.

Figure 2



Venous Sample Tested by Technician			
System Accuracy Results for Glucose Concentration ≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
253 / 522 (48.5%)	448 / 522 (85.8%)	512 / 522 (98.1%)	522 / 522 (100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
129 / 240 (53.8%)	206 / 240 (85.8%)	240 / 240 (100.0%)	240 / 240 (100.0%)
System Accuracy Results for both Glucose Concentration ≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
752 / 762 (98.7%)			

4.2.4 Conclusions

The data displayed above show equivalent correlation to the reference method, demonstrating that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides high accurate results with venous blood samples.

4.3 Arterial Whole Blood

4.3.1 Purpose

Studies were conducted to assess the accuracy of the *On Call® Sure (Sync)* Blood Glucose Monitoring System with arterial whole blood samples.

4.3.2 Procedure

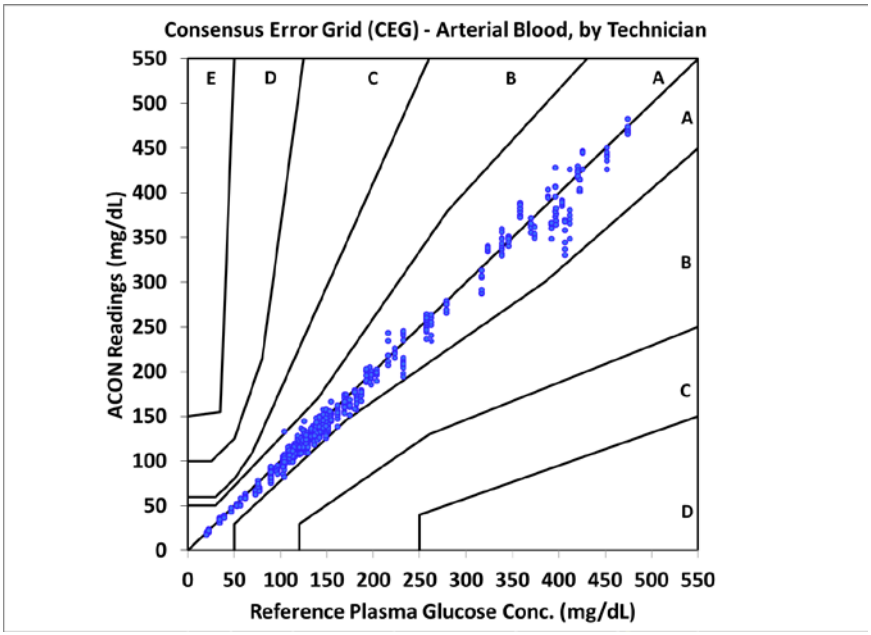
Medical nurses collected the arterial blood sample from study subjects and dosed the test strips. The arterial blood samples are also measured in a GEM 4000 Premier Blood Gas Analyzer, as a reference instrument, for the following data: %HCT, pO_2 level, blood glucose concentration. The tested range of glucose was from 20.1 to 475 mg/dL. The hematocrit range tested was 20% to 56%.

Additionally, 10 venous blood samples were contrived by blood gas tonometry to raise the pO_2 to the level of arterial blood samples, to mimic arterial blood samples with very low and very high levels of blood glucose by incubating the contrived samples or by supplementing additional glucose to the contrived samples.

4.3.3 Results

System accuracy results of arterial whole blood testing are shown in ***Figure 3***.

Figure 3



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Arterial Sample Tested by Technician		
System Accuracy Results for Glucose Conc. <5.55 mmol/L (<100 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)
60 / 96 (62.5%)	88 / 96 (91.7%)	95 / 96 (99.0%)
System Accuracy Results for Glucose Conc. ≥5.55 mmol/L (≥100 mg/dL)		
Within ±5%	Within ±10%	Within ±15%
345 / 633 (54.5%)	567 / 633 (89.6%)	622 / 633 (98.3%)
System Accuracy Results for Glucose Concentrations		
Within ±0.83mmol/L (±15mg/dL) or ±15%		
717 / 729 (98.4%)		

4.3.4 Conclusions

The data displayed above show equivalent correlation to the reference method, demonstrating that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides high accurate results with arterial blood samples.

4.4 Neonatal Whole Blood

4.4.1 Purpose

Neonatal whole blood samples from a total of 59 newborns were tested for the neonatal blood sample accuracy clinical study for the *On Call® Sure (Sync)* Blood Glucose Monitoring System.

4.4.2 Procedure

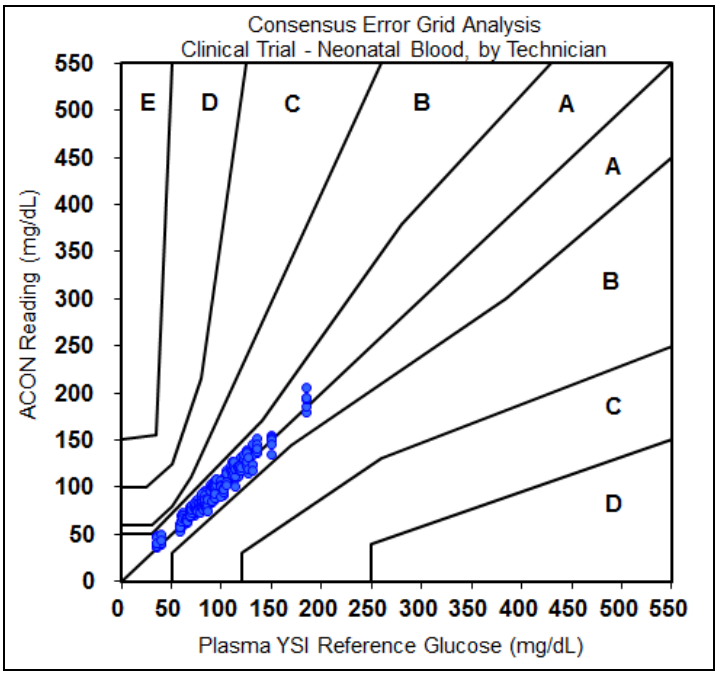
Trained technicians performed neonatal blood sample and dosed the test strips. 118 data points, for each lot of test strips, from 59 subjects were collected in the study. The tested range of glucose was from 35.3 to 184.3 mg/dL. The hematocrit range tested was 27% to 63%.

The trained technician obtained neonatal whole blood from each subject and performed the testing in duplicate. Then the trained technician collected appropriate volume of neonatal whole blood sample into blood collection tube with Heparin anticoagulant. The neonatal whole blood sample was tested in duplicate on the YSI Model 2300 STAT PLUS Glucose Analyzer (a well-characterized laboratory method) for comparison.

4.4.3 Results

System accuracy results of neonatal whole blood testing are shown in ***Figure 4***.

Figure 4



Neonatal Sample Tested by Technician			
System Accuracy Results for Glucose Concentration ≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
70 / 120 (58.3%)	104 / 120 (86.7%)	120 / 120 (100.0%)	120 / 120 (100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
134 / 234 (57.3%)	204 / 234 (87.2%)	234 / 234 (100.0%)	234 / 234 (100.0%)
System Accuracy Results for both Glucose Concentration ≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
354 / 354 (100.0%)			

4.4.4 Conclusions

The data displayed above show equivalent correlation to the reference method, demonstrating that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides high accurate results with neonatal whole blood samples.

4.5 Alternative Site Testing (AST)

4.5.1 Purpose

To test the results of testing samples from alternative sites using the *On Call® Sure (Sync)* Blood

4.5.2 Procedure

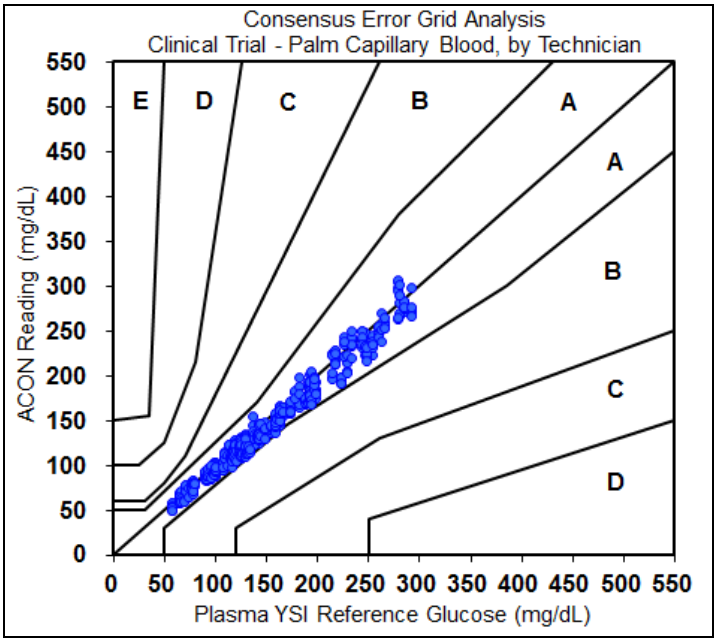
There 111 participants whose forearm blood sample and palm blood sample were tested by technicians. Before or after the strip testing, the blood samples from the fingertips of the same participants were tested on YSI Model 2300 STAT Plus Glucose Analyzer by technicians for comparison. The plasma YSI value range was from 57.0 to 384 mg/dL for fingertip. The hematocrit range tested was 28% to 50%.

Patient selection criteria insured that subjects were tested at least 2 hours after or before a meal. All the study subjects were well informed about the study and learned the instructions for proper of use of the system.

4.5.3 Results

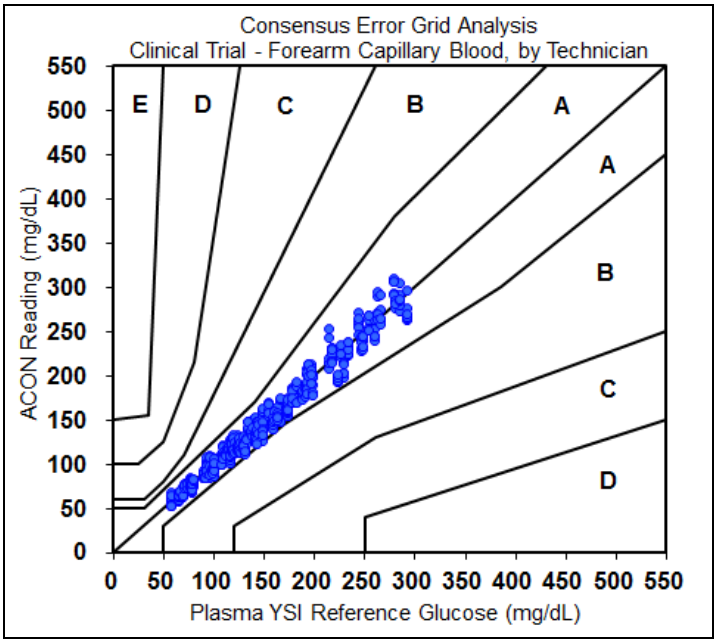
System accuracy results for alternative site tests are as follows:

Figure 5



Palm Sample Site Tested by Technician			
System Accuracy Results for Glucose Concentration ≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
246 / 516 (47.7%)	447 / 516 (86.6%)	514 / 516 (99.6%)	516 / 516 (100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
95 / 150 (63.3%)	146 / 150 (97.3%)	150 / 150 (100.0%)	150 / 150 (100.0%)
System Accuracy Results for both Glucose Concentration ≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
664 / 666 (99.7%)			

Figure 6



Forearm Sample Site Tested by Technician			
System Accuracy Results for Glucose Concentration ≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
297 / 516 (57.6%)	469 / 516 (90.9%)	513 / 516 (99.4%)	516 / 516 (100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
99 / 150 (66.0%)	141 / 150 (94.0%)	150 / 150 (100.0%)	150 / 150 (100.0%)
System Accuracy Results for both Glucose Concentration ≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
663 / 666 (99.5%)			

4.5.4 Conclusions

The data above indicate equivalent correlation to the reference method, demonstrating that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides high accurate results with capillary whole blood samples from alternate sites such as the palm and forearm.

5. Accuracy Evaluation for Capillary Whole Blood - Performed by Patients

5.1 Purpose

To test the results from capillary whole blood performed by patients with the *On Call® Sure (Sync)* Blood Glucose Monitoring System.

5.2 Procedure

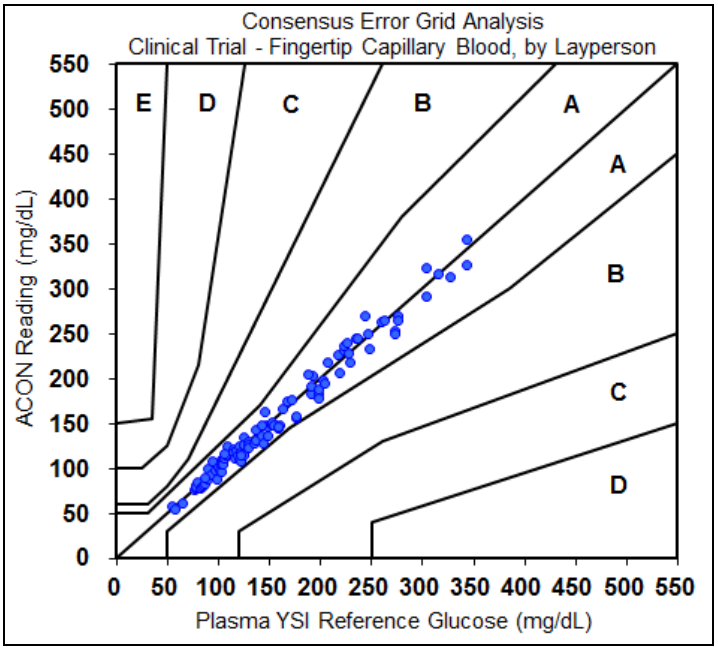
The capillary blood samples from subjects were tested by each subject on the *On Call® Sure (Sync)* Blood Glucose Monitoring System. All the study subjects were well informed about the study and learned the instructions for proper of use of the system. The user study included the testing of capillary blood samples from fingertip, palm and forearm sites from each study subject. The plasma YSI range was from 55 to 344 mg/dL for fingertip. The hematocrit range tested was 32% to 56%.

Fingertip capillary blood samples from each subject were also collected and tested on the YSI reference instrument (YSI Model 2300 STAT Plus Glucose Analyzer) by technicians for comparison. Three different test strip lots were used during the study. ***Figure 7*** demonstrates the test results from the capillary blood samples collected from the fingertips using three lots of the test strips.

5.3 Results

System accuracy results for fingertip capillary whole blood tests performed by patients are as follows:

Figure 7



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Fingertip Sample Site Tested by Layperson			
System Accuracy Results for Glucose Concentration ≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
44 / 80 (55.0%)	72 / 80 (90.0%)	80 / 80 (100.0%)	80 / 80 (100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	Within ±20mg/dL
9 / 20 (45.0%)	18 / 20 (90.0%)	20 / 20 (100.0%)	20 / 20 (100.0%)
System Accuracy Results for both Glucose Concentration ≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
100 / 100 (100.0%)			

5.4 Conclusions

The results indicate that a layperson can obtain accurate results when testing with capillary whole blood.

6. Repeatability Precision

6.1 Purpose

The purpose of this study was to validate the repeatability precision for the *On Call® Sure (Sync)* Blood Glucose Monitoring System.

6.2 Procedure

For this study, technicians obtained venous whole blood samples in vacutainer tubes containing heparin anticoagulant. The blood sample hematocrit level was prepared to 42% ± 2%, and then the three blood glucose concentrations shown in the **Table 1** were prepared and tested by YSI Model 2300 STAT Plus Glucose Analyzer.

Generally, a minimum of 3 lots containing10 meters and 500pcs test strips each are needed for repeatability precision evaluations. Blood samples are then tested using 10 test strips on 10 separate meters (10 strips per meter) at each concentration level.

Table 1 - Glucose Concentration Levels for Repeatability Precision Evaluation

Level	Glucose Concentration Level (mg/dL)
1	30 – 50 mg/dL
2	51 – 110 mg/dL
3	111 – 150 mg/dL
4	151 – 250 mg/dL
5	251 – 400 mg/dL

6.3 Results

Table 2 shows the results of precision testing of venous blood for glucose strip testing. Results having values lower than 100 mg/dL must have standard deviations (SD) ≤5 mg/dL per glucose concentration level. For results greater than 100 mg/dL, accepted values must have a coefficient of variance (CV) less than 5%.

Table 2 - Repeatability Precision with Whole Blood

MEAN	42.6 mg/dL	82.2 mg/dL	133.3 mg/dL	205.1 mg/dL	334.6 mg/dL
Standard Deviation (mg/dL) or Coefficient of Variation (%)	1.24 mg/dL	2.28 mg/dL	2.5%	2.5%	2.6%

6.4 Conclusions

The study results indicate that the precision estimates fall within the acceptance criteria. In fact, the CV is calculated to be ≤3.0%, sustaining that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides precise results with whole blood.

7. Intermediate Precision

7.1 Purpose

The purpose of this study was to validate the intermediate precision for the *On Call® Sure (Sync)* Blood Glucose Monitoring System.

7.2 Procedure

For this study, ten replicate assays drawn from 3 test strip lots were performed on 10 meters each day, for a total of 10 days.

7.3 Results

Table 3 below shows the results of intermediate precision for glucose strip testing.

Table 3 - Intermediate Precision with Glucose Control Solution

#	Mean (mg/dL)	Standard Deviation (mg/dL) or Coefficient of Variation (%)
Strip lot 1	36.0 mg/dL	0.91 mg/dL
	115.3 mg/dL	2.3%
	321.0 mg/dL	2.1%
Strip lot 2	35.8 mg/dL	1.09 mg/dL
	115.3 mg/dL	2.3%
	320.9 mg/dL	2.0%
Strip lot 3	36.0 mg/dL	1.05 mg/dL
	114.7 mg/dL	2.7%
	319.9 mg/dL	1.6%

7.4 Conclusions

Accepted performance for results lower than 100 mg/dL is a standard deviation (SD) ≤5 mg/dL per glucose concentration level. For results greater than 100 mg/dL coefficient of variance (CV) less than 5% is required. The study results indicate that the precision estimates meet the acceptance criteria. In fact, the CV is less than or equal to 3.0%, suggesting that the *On Call® Sure (Sync)* Blood Glucose Monitoring System provides precise results with control solutions.

8. Effect of Hematocrit

8.1 Purpose

Hematocrit influence was assessed through testing of venous blood samples with heparin anticoagulant.

8.2 Procedure

Ten tests were done on meters at each hematocrit level, and for each glucose concentration, using 3 test strip lots. The average reading was then compared with the plasma glucose value from YSI Model 2300 STAT Plus Glucose Analyzer.

8.3 Results

Table 4 below shows the average bias of results from one test strip lot at 3 blood glucose concentrations, and 5 different hematocrit levels.

Table 4 - Bias at different level of blood glucose concentrations with different Hematocrit

Glucose level (mg/dL)	40	130	325
Bias with Hct 10%	-6.8 mg/dL	1.2 %	-3.7 %
Bias with Hct 25%	-1.3 mg/dL	4.7 %	2.2 %
Bias with Hct 42%	0.7 mg/dl	4.3 %	-0.6 %
Bias with Hct 55%	3.2 mg/dL	-0.4 %	-0.3 %
Bias with Hct 70%	7.3 mg/dL	-2.7 %	-7.4 %

Hct = Hematocrit

8.4 Conclusions

The results show that the acceptance criteria are met for the hematocrit effect study: average %Bias (average strip reading vs. plasma YSI value) is ≤±10% when glucose concentration is ≥100 mg/dL, and average Bias (average strip reading vs. plasma YSI value) is <±10 mg/dL when glucose concentration is <100 mg/dL. The test results also show that accurate reading can be obtained for *On Call® Sure (Sync)* Blood Glucose Monitoring System when testing within the hematocrit range of 10%–70%.

9. Effect of Interfering Substances

9.1 Purpose

The purpose of this study was to validate the interference effect of various substances for the *On Call® Sure (Sync)* Blood Glucose Monitoring System.

9.2 Procedure

For this study, technicians obtained venous whole blood samples in vacutainer tubes containing heparin anticoagulant. The blood sample hematocrit level was prepared to 42% ± 2%, and then the three blood glucose concentrations shown in the **Table 5** were prepared and tested by YSI Model 2300 STAT Plus Glucose Analyzer.

Table 5 - Glucose Concentration Levels for Interference Effect

Level	Glucose Concentration Level (mg/dL)
1	50 – 70 mg/dL
2	110 – 130 mg/dL
3	250 – 270 mg/dL

Blood samples containing each interfering substance from the table below were prepared at the low test concentration and high test concentration for each glucose concentration level above. Control blood samples were prepared at different glucose concentrations without the substance.

Ten test strips from each of three strip lots were tested on meters for each interfering substance test level at each glucose concentration level.

9.3 Results

The results of glucose strip testing are shown in **Summary Table 1**.

Summary Table 1

Interfering Substances	**Therapeutic / Physiological Levels**	**Test Concentration**		***On Call® Sure (Sync)* System**
		Low	**High**	
Acetaminophen	1.0-3.0 mg/dL	4 mg/dL	20 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call® Sure (Sync)* System
		Low	High	
Ascorbic Acid	0.4-2.0 mg/dL	3 mg/dL	6 mg/dL	INTERFERENCE at abnormally high concentration NO INTERFERENCE at therapeutic levels and levels ≤ 3.0 mg/dL
Cholesterol	114-300 mg/dL	250 mg/dL	500 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Conjugated-Bilirubin	<0.4 mg/dL	34 mg/dL	50 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Creatinine	0.6-1.3 mg/dL	1.5 mg/dL	5 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Dopamine	0.03 mg/dL	0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
EDTA	/	100 mg/dL	200 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Ephedrine	0.001 mg/dL	0.1 mg/dL	0.5 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Ethanol	100-200 mg/dL	200 mg/dL	400 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Fructose	1-6 mg/dL	30 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Galactitol	/	0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at high test concentration
Galactose	4-80 mg/dL	78 mg/dL	100 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call® Sure (Sync)* System
		Low	High	
Gentisic acid	0.2-0.6 mg/dL	6 mg/dL	10 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Glutathione (Reduced)	47-100 mg/dL (Intracellular)	1 mg/dL	92 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Hemoglobin	100-200 mg/dL	200 mg/dL	500 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Heparin Sodium	350-1000 u/L	3000 u/L	80000 u/L	NO INTERFERENCE at therapeutic levels up to high test concentration
Ibuprofen	1.0-7.0 mg/dL	7 mg/dL	50 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Lactitol	/	0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at high test concentration
Lactose	0.5 mg/dL	5 mg/dL	25 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
L-Dopa (Levo-Dopa)	0.02-0.3 mg/dL	0.3 mg/dL	3 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Maltitol	/	0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at high test concentration
Maltose	100 mg/dL	100 mg/dL	1000 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Mannitol	0.0128 mg/dL	300 mg/dL	600 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Methyl Dopa	0.1-0.75 mg/dL	0.75 mg/dL	1.5 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Paralidoxime Idodine (PAM)	5 mg/dL	25 mg/dL	80 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call® Sure (Sync)* System
		Low	High	
Salicylic Acid	10-30 mg/dL	30 mg/dL	60 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Sorbitol	0.044mg/dL	30 mg/dL	70 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Tetracycline	0.2-0.5 mg/dL	0.5 mg/dL	1.5 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Tolazamide	2.0-2.5 mg/dL	5 mg/dL	10 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Tolbutamide	5.4-10.8 mg/dL	11 mg/dL	64 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Triglycerides	150-500 mg/dL	1500 mg/dL	3000 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Unconjugated-Bilirubin	0.3-1.3 mg/dL	20 mg/dL	40 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Urea	6.6-85.8 mg/dL	260 mg/dL	600 mg/dL	NO INTERFERENCE at therapeutic levels up to high test concentration
Uric Acid	2.5-8.0 mg/dL	8 mg/dL	23.5 mg/dL	NO INTERFERENCE at physiological levels up to high test concentration
Xylitol	/	0.03 mg/dL	0.09 mg/dL	NO INTERFERENCE at high test concentration
Xylose	20-40 mg/dL	90 mg/dL	200 mg/dL	INTERFERENCE at levels of 90 mg/dL and 200 mg/dL; NO INTERFERENCE at levels ≤ 6 mg/dL
Anticoagulant	**Manufacturer Part #**	**Test Concentration**		
Sodium Heparin	BD Vacutainer REF 367871	68 USP units (4.0 mL)		NO INTERFERENCE Recommended

Interfering Substances	Therapeutic / Physiological Levels	Test Concentration		*On Call® Sure (Sync)* System
		Low	High	
Lithium Heparin	BD Vacutainer REF 367884	75 USP units (4.0 mL)		NO INTERFERENCE Recommended
EDTA.K2	BD Vacutainer REF 367841	3.6 mg (2.0 mL)		NO INTERFERENCE Recommended
Sodium Citrate	BD Vacutainer REF 363095	9NC 0.109M (2.7 mL)		NO INTERFERENCE Recommended
Sodium Fluoride	BD Vacutainer REF 367921	5 mg/4mg (2mL)		Significant effect, Not Recommended

9.4 Conclusions

The results show that there is no significant interference effect for these substances to *On Call® Sure (Sync)* Blood Glucose Monitoring System except at abnormally high concentration of Ascorbic acid (Vitamin C). And the results also show that there is significant interference effect for Xylose at its normal and high test concentration levels. Sodium Fluoride has a significant effect and is not recommended.

For more detailed information about evaluation reports on the *On Call*® *Sure (Sync)* Blood Glucose Monitoring System, please contact ***ACON*** Laboratories, Inc.

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