On•Call[®] Sure

Blood Glucose Monitoring System

NEW **ISO** 15197



- GDH-FAD Enzyme
- 10-70% HCT Range
- 0.6μL Capillary/Venous/ Arterial/Neonatal Sample
- No-coding
- 5s Testing Time
- US 510(k) & CE

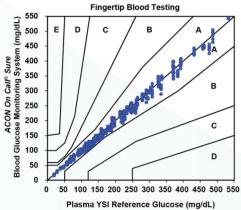


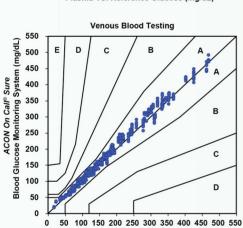




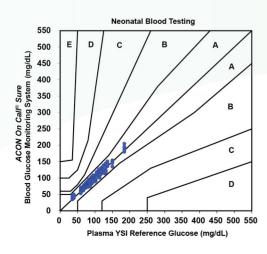
Accurate and Reliable

Extensive clinical studies demonstrate the accuracy of the *On Call® Sure* Blood Glucose Monitoring System with fresh capillary, venous, arterial and neonatal blood samples can comply with **ISO15197:2013/EN ISO 15197:2015.**





Plasma YSI Reference Glucose (mg/dL)



Consensus Error Grid Analysis Clinical Trial - Fingertip Capillary Blood, by Technician Acon On Call® Sure Blood Glucose Monitoring System

710011 Out Out Dioda Clacose Helitering System							
System Accuracy Results for Glucose Concentration ≥100mg/dL							
Within ±5%	Within ±10%	Within ±15%					
335 / 582 (57.6%)	530 / 582 (91.1%)	582 / 582 (100.0%)					
System Accuracy Results for Glucose Concentration <100mg/dL							
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL					
156 / 216 (72.2%)	214 / 216 (99.1%)	216 / 216 (100.0%)					
System Accuracy Results for both Glucose Concentration ≥100mg/dL and <100mg/dl							
Within ±15% or ±15mg/dL							
798 / 798 (100.0%)							
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Consensus Error Grid Analysis Clinical Trial - Venous Blood, by Technician Acon On Call® Sure Blood Glucose Monitoring System

71007 017 047 0470 Bioda Ciacose Homicornig System							
System Accuracy Results for Glucose Concentration ≥100mg/dL							
Within ±5%	Within ±10%	Within ±15%					
253 / 522 (48.5%)	448 / 522 (85.8%)	512 / 522 (98.1%)					
System Accuracy Results for Glucose Concentration <100mg/dL							
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL					
129 / 240 (53.8%)	206 / 240 (85.8%)	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%)							

Consensus Error Grid Analysis Clinical Trial - Neonatal Blood, by Technician Acon On Call® Sure Blood Glucose Monitoring System

System Accuracy Results for Glucose Concentration ≥ 100mg/dL							
Within ±5%	Within ±10%	Within ±15%					
70 / 120 (58.3%)	104 / 120 (86.7%)	120 / 120 (100.0%)					
System Accuracy Results for Glucose Concentration < 100mg/dL							
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL					
134 / 234 (57.3%)	204 / 234 (87.2%)	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%)						







Advanced Features for Diabetes Management









Specifications

Feature	Specification		
Technology	Biosensor/Electrochemical, Glucose dehydrogenase(GDH-FAD)		
Testing Range	10-600mg/dL (0.6-33.3mmol/L)		
Calibration Method	No coding		
Result Calibration	Plasma-equivalent		
Test Time	5 seconds		
Sample Size	0.6µL		
Sample Type	Fresh whole blood(Capillary, Venous, Arterial and Neonatal)		
Test Sites	Fingertip, Forearm, Palm		
Hematocrit Range	10-70%		
Memory Storage	1,000 results with data and time		
Test Averaging	7,14,30,60,90-day averages		
Data Transfer	USB		
Control Solution	3 levels		
Audio Feature	Optional beep for sample detection, error messages		
Automatic Shutoff	2 minutes after last action		
Battery	Two(2) CR 2032 3.0V coin cell batteries		
Battery Life	3,000 measurements		
Operating Conditions	5-45 ℃ and 10-90% relative humidity		
Strip Storage Temperature	2-35℃		
Expiration Date	24 months (18 months after first opening)		
	Automatic detection of insufficient sample		
Other Functions	2nd sample application allowed		
	Sample perturbation detection		

Catalog

Product Name	Catalog No.	Contents			
On Call® Sure Blood Glucose Monitoring System	G115-10U √+	1 Meter 10 Lancets 1 Carrying Case	10 Test Strips 1 Lancing Device 1 Warranty Card	1 Control Solution 1 Manual 1 Quick Reference	
	G115-11U √+	1 Meter 1 Carrying Case	1 Lancing Device 1 Warranty Card	1 Manual 1 Quick Reference	e Guide
On Call® Sure Blood Glucose Meter	G115-12U √+	1 Meter 1 Manual	1 Control Solution1 1 Carrying Case	10 Lancets 1 Warranty Card	1 Lancing Device 1 Quick Reference Guide
	G115-13U √+	1 Meter 1 Carrying Case	1 Control Solution1 1 Warranty Card	1 Manual 1 Quick Reference	e Guide
		25 Test Strips (25/vial) 50 Test Strips (25/vial) 100 Test Strips (25/vial)		1 Package Insert	
				1 Package Insert	
	G135-10U √+			1 Package Insert	
		50 Test Strips (50/vial)		1 Package Insert	
On Call® Sure Test Strips		100 Test Strips (50/vial)		1 Package Insert	
		200 Test Strips (50	,	1 Package Insert	
		25 Test Strips (Ind	lividually Foil Pouch)	1 Package Insert	
	G135-11U √+	1 \	lividually Foil Pouch)	1 Package Insert	
			idividually Foil Pouch)	1 Package Insert	
On Call® Lancets	G124-10A √ +	100 Lancets (25/b	ag)		
On Call® Lancing Device	G124-11A √ +	1 Lancing Device		1 Package Insert	
On Call® Sure Control Solution	G125-12U √ +	1 Control Solution 0		1 Control Solution 2	0
On Call® Diabetes Management Software Kit	G124-13A +	1 USB Data Trans	fer Cable	1 Installation Disk	





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