

On-Call[®] Sure

Blood Glucose Monitoring System

NEW
ISO
15197



Be Sure with On-Call[®] Sure!

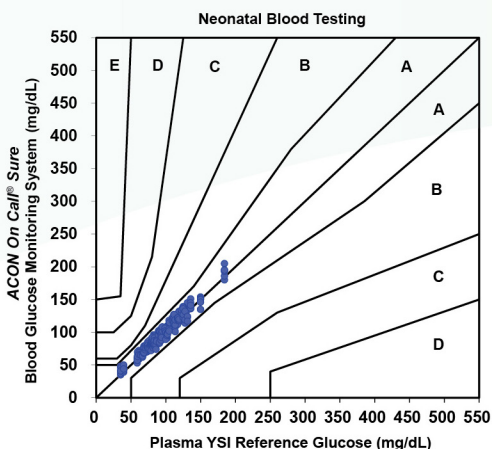
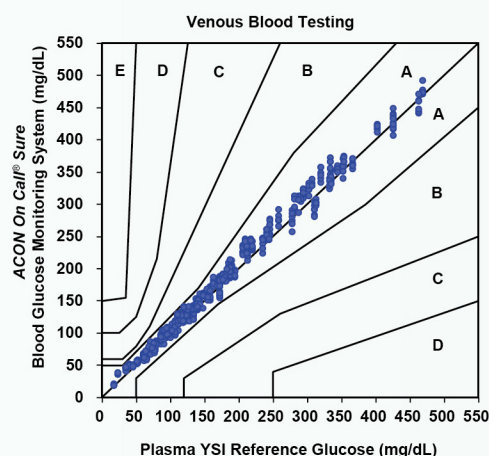
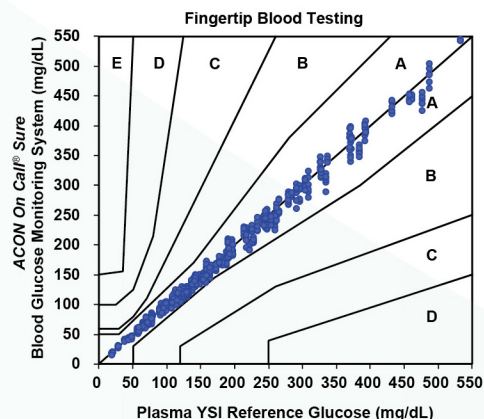
- GDH-FAD Enzyme
- 10-70% HCT Range
- 0.6µL Capillary/Venous/Arterial/Neonatal Sample
- No-coding
- 5s Testing Time
- US 510(k) & CE

ACON[®]
Diabetes Care



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**.



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

System Accuracy Results for Glucose Concentration $\geq 100\text{mg/dL}$		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
335 / 582 (57.6%)	530 / 582 (91.1%)	582 / 582 (100.0%)
System Accuracy Results for Glucose Concentration $< 100\text{mg/dL}$		
Within $\pm 5\text{mg/dL}$	Within $\pm 10\text{mg/dL}$	Within $\pm 15\text{mg/dL}$
156 / 216 (72.2%)	214 / 216 (99.1%)	216 / 216 (100.0%)
System Accuracy Results for both Glucose Concentration $\geq 100\text{mg/dL}$ and $< 100\text{mg/dL}$		
Within $\pm 15\%$ or $\pm 15\text{mg/dL}$		
798 / 798 (100.0%)		

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

System Accuracy Results for Glucose Concentration $\geq 100\text{mg/dL}$		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
253 / 522 (48.5%)	448 / 522 (85.8%)	512 / 522 (98.1%)
System Accuracy Results for Glucose Concentration $< 100\text{mg/dL}$		
Within $\pm 5\text{mg/dL}$	Within $\pm 10\text{mg/dL}$	Within $\pm 15\text{mg/dL}$
129 / 240 (53.8%)	206 / 240 (85.8%)	240 / 240 (100.0%)
System Accuracy Results for both Glucose Concentration $\geq 100\text{mg/dL}$ and $< 100\text{mg/dL}$		
Within $\pm 15\%$ or $\pm 15\text{mg/dL}$		
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 $\geq 100\text{mg/dL}$		
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
70 / 120 (58.3%)	104 / 120 (86.7%)	120 / 120 (100.0%)
System Accuracy Results for Glucose Concentration $< 100\text{mg/dL}$		
Within $\pm 5\text{mg/dL}$	Within $\pm 10\text{mg/dL}$	Within $\pm 15\text{mg/dL}$
134 / 234 (57.3%)	204 / 234 (87.2%)	234 / 234 (100.0%)
System Accuracy Results for both Glucose Concentration $\geq 100\text{mg/dL}$ and $< 100\text{mg/dL}$		
Within $\pm 15\%$ or $\pm 15\text{mg/dL}$		
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 °C and 10-90% relative humidity
Strip Storage Temperature	2-35 °C
Expiration Date	24 months (18 months after first opening)
Other Functions	Automatic detection of insufficient sample
	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 Test Strips 1 Control Solution1 10 Lancets 1 Lancing Device 1 Manual 1 Carrying Case 1 Warranty Card 1 Quick Reference Guide
On Call® Sure Blood Glucose Meter	G115-11U ✓ +	1 Meter 1 Lancing Device 1 Manual 1 Carrying Case 1 Warranty Card 1 Quick Reference Guide
	G115-12U ✓ +	1 Meter 1 Control Solution1 10 Lancets 1 Lancing Device 1 Manual 1 Carrying Case 1 Warranty Card 1 Quick Reference Guide
	G115-13U ✓ +	1 Meter 1 Control Solution1 1 Manual 1 Carrying Case 1 Warranty Card 1 Quick Reference Guide
On Call® Sure Test Strips	G135-10U ✓ +	25 Test Strips (25/vial) 1 Package Insert 50 Test Strips (25/vial) 1 Package Insert 100 Test Strips (25/vial) 1 Package Insert 50 Test Strips (50/vial) 1 Package Insert 100 Test Strips (50/vial) 1 Package Insert 200 Test Strips (50/vial) 1 Package Insert
		25 Test Strips (Individually Foil Pouch) 1 Package Insert 50 Test Strips (Individually Foil Pouch) 1 Package Insert 100 Test Strips (Individually Foil Pouch) 1 Package Insert
	G135-11U ✓ +	100 Test Strips (25/bag)
	G124-10A ✓ +	100 Lancets (25/bag)
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 1 1 Control Solution 2 1 Package Insert
On Call® Diabetes Management Software Kit	G124-13A +	1 USB Data Transfer Cable 1 Installation Disk

✓ CE Marked for sale in the European Community



+ US 510(k) Cleared and CLIA Waived

