



Blood Glucose Monitoring System

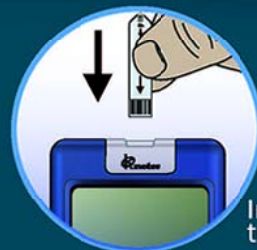


FDA
FDA510(K)-K063026

CE0123

No Coding

Alternative Site Testing



1

Insert test strip to turn on meter.

2

Apply small blood sample.



3

Obtain results in 6 seconds.

- Accurate results in 6 seconds
- Very small blood sample, only 0.7uL
- 250 test memory with date and time
- Risk Indicators for lower than 70 mg/dL or higher than 180 mg/dL
- PC download



Manufacturer

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OK-1C-EN-120516

SYSTEM ACCURACY (ISO 15197)

Test system: OKmeter

Reference system: YSI2300

Sample: Whole blood (capillary)

Investigative Site:

Institut für Diabetes-Technologie GmbH an der
Universität Ulm (IDT)

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System accuracy results for glucose concentration < 4.2 mmol/L (75 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)
7 / 40 (18 %)	19 / 40 (48 %)	33 / 40 (83 %)

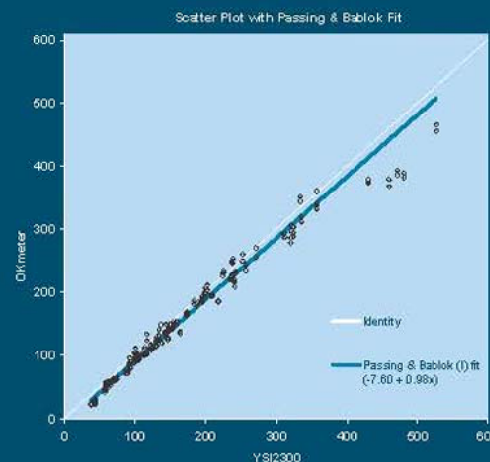
System accuracy results for glucose concentration ≥ 4.2 mmol/L (75 mg/dL)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
54 / 160 (34 %)	112 / 160 (70 %)	147 / 160 (92 %)	158 / 160 (99 %)

Combined system accuracy results (absolute and relative deviations)

Within ± 0.28 mmol/L ± 10 % (Within ± 5 mg/dl, ± 10 %)	Within ± 0.56 mmol/L ± 10 % (Within ± 10 mg/dl, ± 10 %)	Within ± 0.83 mmol/L ± 15 % (Within ± 15 mg/dl, ± 15 %)	Within ± 0.83 mmol/L ± 20 % (Within ± 15 mg/dl, ± 20 %)
119 / 200 (59.5 %)	131 / 200 (65.5 %)	166 / 200 (83 %)	191 / 200 (95.5 %)

The OKmeter blood glucose system complies with the
system accuracy requirements of the ISO 15197 Standard.
191 of 200 (95.5%) results meet the requirements.



SPECIFICATIONS

Measurement Range	20-600 mg/dL (1.1-33.3 mmol/L)
Sample Type	Capillary Whole Blood
Alternative Site Testing	YES (palm, forearm, upper arm, calf, and thigh)
Calibration Against	Plasma-Equivalent
Test Time	6 seconds
Sample Volume	0.7 μ L
Sample Application	Capillary Effect
Operating Condition	10-40 $^{\circ}$ C (50-104 $^{\circ}$ F), 10-85% R.H.
Storage Condition	4-40 $^{\circ}$ C (39-104 $^{\circ}$ F), 10-85% R.H.
Memory Capacity	250 tests with time and date
Risk Indicator	⊕ When test within 70-120 mg/dL (3.9-6.7 mmol/L) ⊕ When test < 70 mg/dL (3.9 mmol/L) or > 180 mg/dL (10 mmol/L)
Average	7, 15 and 30 days
Downloadable	RS-232
Battery Type	3V Li-Battery (CR 2032) X1
Battery Life	1,000 tests
Meter Dimensions	93 X 53 X 15 mm
Meter Weight	50g (including battery)
Expiration for test strips	Storage: 24 months In use: 180 days