

OKmeter®

Direct

OKmeter® Direct Blood Glucose Monitoring System



CE 0123

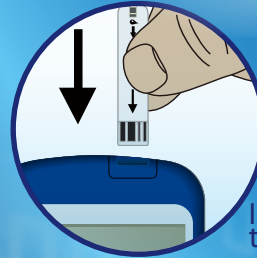
TUV SUD ISO 13485

G.M.P. Medical Device

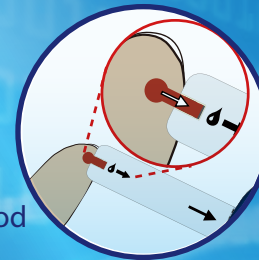


ISO13485

CE 0123



1
Insert test strip to
turn on meter.



2
Apply small blood
sample.



3
Obtain results in 6
seconds.

✓ No Coding ✓ Alternative Site Testing

- Accurate results in 6 seconds
- Very small blood sample, only 0.7 µL
- 180 test memory with date and time
- Risk Indicator and Ketone warning
- PC download

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)
 Helmholtzstrasse 20, D-89081 Ulm / Germany

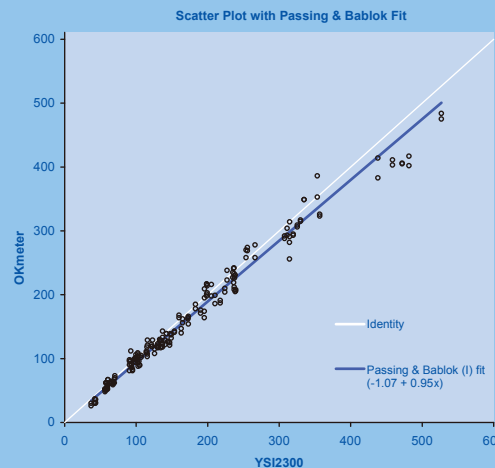
System accuracy results for glucose concentration < 4.2 mmol/L (75 mg/dL)

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)
19 / 40 (48 %)	34 / 40 (85 %)	40 / 40 (100 %)

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

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
64 / 160 (40 %)	118 / 160 (74 %)	154 / 160 (96 %)	159 / 160 (99 %)

The OKmeter blood glucose system complies with the system accuracy requirements of the ISO 15197 Standard. 199 of 200 (99.5%) results meet the requirements.



SPECIFICATIONS

Measurement Range	20~600 mg/dL (1.1~33.3 mmol/L)
Specimen 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 µl
Sensitivity in HCT Range	20-60%
Operating Conditions	10~40°C (50~104°F) / 10~85% R.H. Altitude ≤ 3,402 m (11,161 ft) above the sea level
Storage/Delivery Conditions	4~40°C (39~104°F) / ≤ 10~85% R.H. (strip included) -20~50°C (-4~122°F) / ≤ 90% R.H. (strip excluded)
Memory Capacity	180 test results with date and time
Risk Indicator	☺When test within 70-120 mg/dL (3.9-6.7 mmol/L) ☺When test < 70 mg/dL (3.9 mmol/L) ☺When test > 120 mg/dL (6.7 mmol/L) Ketone warning when test > 240 mg/dL (13.3 mmol/L)
Average Calculation	7, 14, 21 and 28 days
Downloadable	YES (RS-232 port)
Battery Type	1.5V AAA Alkaline Batteries X2
Battery Life	1,000 times of measurements
Meter Dimensions	95mm(L) X 45mm(W) X 18mm(H)
Meter Weight	Approximate 70g (with battery)
Expiration for test strip	Storage: 24 months In-Use: 180 days



Manufacturer

OK Biotech Co., Ltd.

4F-1, No. 83, Sec. 2, Gongdao 5th Rd., 300
 Hsinchu City, Taiwan

TEL: +886-3-5160258 FAX: +886-3-5160028

<http://www.okbiotech.com>

<http://www.glucose-meter-manufacturer.com>

service@okbiotech.com

