







C E 0123





- Accurate results in 6 seconds
- Very small blood sample, only 0.7 μL
- 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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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 ± 0.56 mmol/L	Within ± 0.83 mmol/L
(Within ± 5 mg/dL)	(Within ±10 mg/dL)	(Within ± 15 mg/dL)
7 / 40 (18 %)	19 / 40 (48 %)	33 / 40 (83 %)

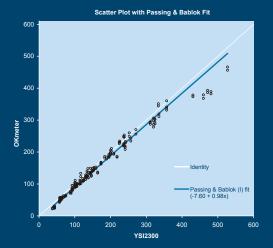
System accuracy results for glucose concentration > = 4.2 mmol/L (75 mg/dL)

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	Within ± 0.56 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
& ± 10 %	& ± 10 %	& ± 15 %	& ± 20 %
(Within ± 5 mg/dL & ± 10 %)	(Within ± 10 mg/dL & ± 10 %)	(Within ± 10 mg/dL & ± 15 %)	(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

Capillary Whole Blood

Measurement Range 20-600 mg/dL (1.1-33.3 mmol/L)

Sample Type

Alternative Site Testing

YES (palm, forearm, upper arm, calf,

and thigh)

Calibration Against

Test Time

Sample Volume

Sample Application

Operating Condition

Storage Condition

Memory Capacity

Risk Indicator

Plasma-Equivalent

6 seconds

0.7 µL

Capillary Effect

10-40 °C (50-104°F), 10-85% R.H.

4-40 °C (39-104°F), 10-85% R.H.

250 tests with time and date

⊕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)

7, 15 and 30 days

RS-232

Downloadable

Battery Type

Average

Battery Life

Meter Dimensions

Meter Weight

Expiration for test strips

3V Li-Battery (CR 2032) X1

1,000 tests

93 X 53 X 15 mm

50g (including battery)

Storage: 24 months

In use: 180 days

