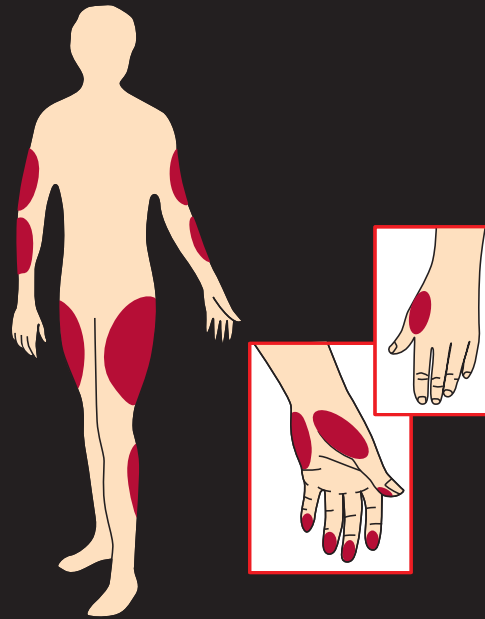


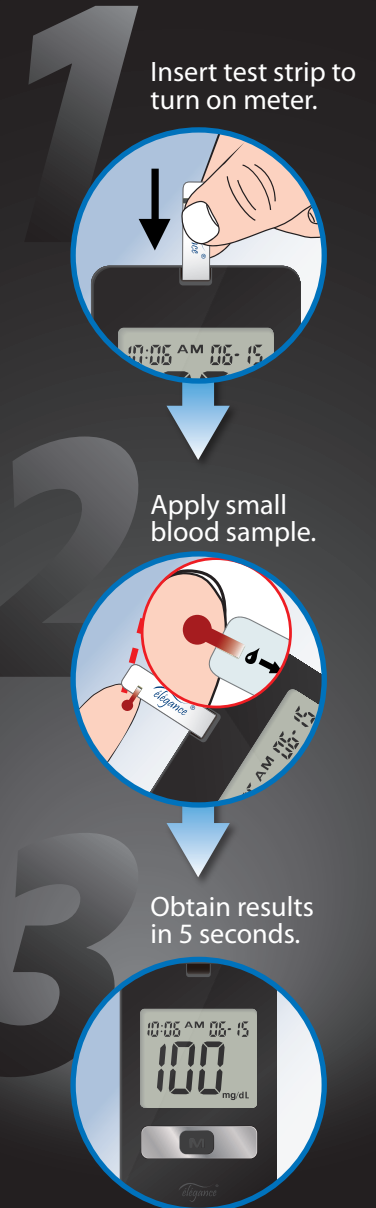
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BLOOD GLUCOSE MONITORING SYSTEM



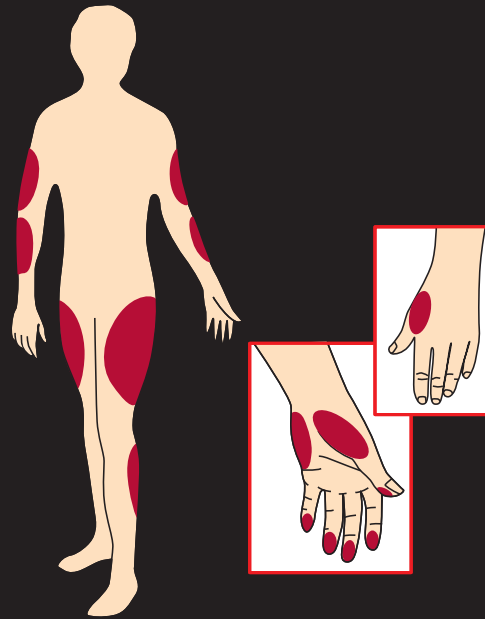
- Amperometric Biosensor
- 0.5 μ L Blood
- 5 Seconds Result
- AST Testing
- Diabetes Monitoring Software

STEPS



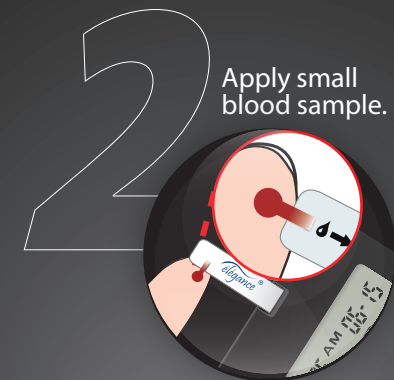
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BLOOD GLUCOSE MONITORING SYSTEM



- Amperometric Biosensor
- 0.5 μ L Blood
- 5 Seconds Result
- AST Testing
- Diabetes Monitoring Software

STEPS



SYSTEM ACCURACY (ISO 15197)

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

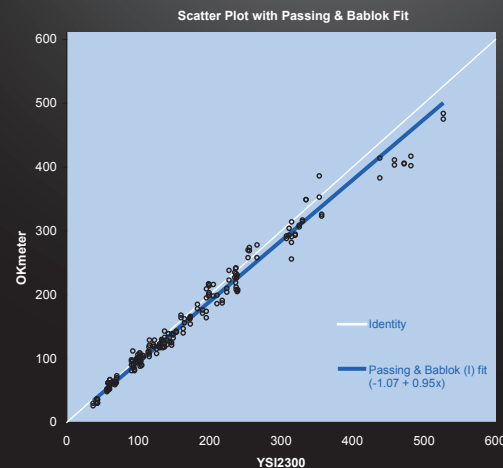
System accuracy results for glucose concentration
< 4.2 mmol/L (75 mg/dL)

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



SPECIFICATIONS

Model Name	CT-X11
Assay Method	Electrochemical biosensor
Test Sample	Capillary Whole Blood
Test Result	Referenced to plasma glucose value
Alternative Site Testing	YES (palm, forearm, upper arm, calf, and thigh)
Sample Size	0.5 µL
Measuring Time	5 seconds
Measuring Range	20 – 600 mg/dL (1.1 – 33.3 mmol/L)
Acceptable HCT Range	20~60%
Operating Condition	5°C~45°C (41~113°F) / 10~85% R.H. Altitude ≤ 3,402 m (11,158 ft) above the sea level
Storage/Transportation Condition	4~45°C (39~113°F) / ≤ 10~85% R.H. (strip excluded)
Memory Capacity	120 test results with time and date
Average Capacity	7, 14, and 28 days
Power Supply	One 3-volt Lithium Battery (battery type CR2032)
Battery Life	Approximately 1,000 tests
Dimensions	97 mm(L) × 58 mm(W) × 19 mm(H)
Weight	38 g



ISO 14001

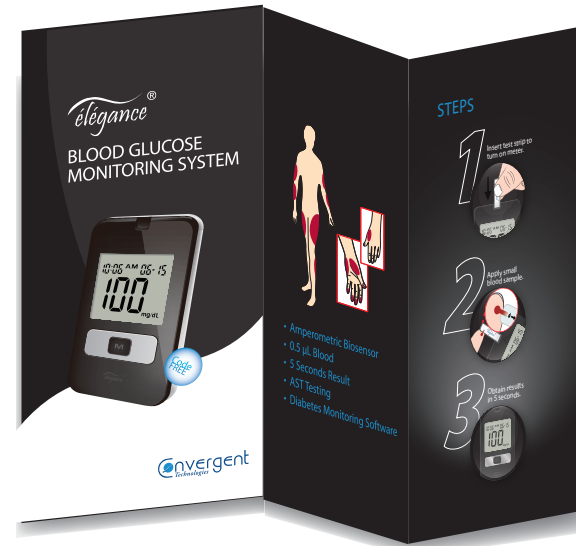
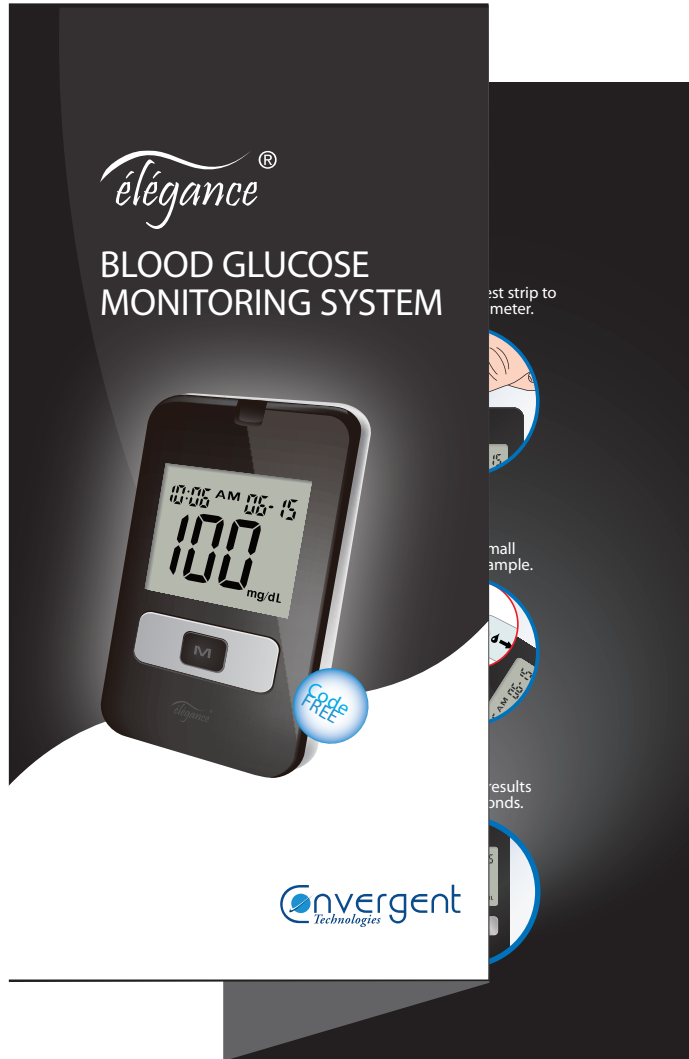
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Letter Z Fold



A side

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