



CareSens® Expert+

Blood Glucose & β -Ketone Monitoring System for Hospital



POCT
SALES GUIDEBOOK

Specification

> Analyzer

Dimension / Weight	161X74X25 mm / 213 g
Display	4" color LCD (touchscreen)
Memory	5,000 test results memory
Battery	3.7V Li-ion polymer rechargeable battery
Data transfer	Ethernet, USB cable, Wi-Fi

> Test Strip

	Blood glucose	Blood β -Ketone
Sample Volume	0,4 μ L	0,5 μ L
Measurement time	5 seconds	8 seconds
Test range	20–600 mg/dL (1.1–33.3 mmol/L)	0.1–8.0 mmol/L
Hematocrit	15–65%	30–60%
Measurement temperature	5–45°C (41–113°F)	15–30°C (59–86°F)

Advantage

Meet ISO 15197:2013 (EN ISO 15197:2015)	Available various sample types (Fresh capillary / Venous whole blood)
Auto identification of blood glucose and blood β -Ketone strip	Remarkable readability with intuitive UI and high resolution color screen
Simple maintenance and automatic software update	Easy data access through CareSens® DataManger; web based data manager



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Clinical Performance

> Precision

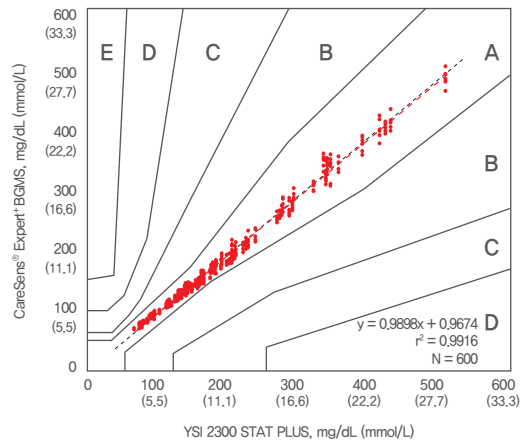
Evaluated according to ISO 15197:2013 (EN ISO 15197:2015) repeatability evaluation protocol. All three lots met the acceptance criteria of the repeatability test in all concentration interval

Concentration	Acceptance criteria*	Lot 1 : MA09CAH2P			Lot 2 : MA09CAE3Q			Lot 3 : MA09CAE9M			Pooled SD or CV
		Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)	
30–50 mg/dL	SD <5 mg/dL	44.2	2.5	–	45.3	2.2	–	45.3	2.2	–	2.3 mg/dL
51–110 mg/dL	SD <5 mg/dL or CV <5%	77.1	3.0	–	75.9	3.0	–	76.7	3.1	–	3.0 mg/dL
111–150 mg/dL	CV <5%	124.0	4.4	3.5	123.0	5.0	4.1	126.0	6.0	4.7	4.2%
151–250 mg/dL	CV <5%	186.0	7.0	3.8	182	5.9	3.3	187	5.3	2.8	3.3%
251–400 mg/dL	CV <5%	289.0	9.7	3.4	294	8.9	3.0	295	8.0	2.7	3.0%

*The precision evaluation was conducted according to ISO 15197:2013 / EN ISO 15197:2015 and the acceptance criteria shown in the table are established by the manufacturer

> Accuracy

Evaluated according to ISO 15197:2013 (EN ISO 15197:2015) system accuracy evaluation protocol.



CareSens® DataManager

Available of real time data transfer via Wi-Fi, Ethernet, USB cable and provides multiple protocols; POCT1–A, IHE(HL7)

