

FORA[®]



ADVANCED pro GD40

Multi-Functional Monitoring System



Dual Parameters:
Blood Glucose & β -Ketone



Free Self-care App
iFORA HM



A Professional Diabetes Device

- Wide HCT range for BG and β -Ketone Tests
- Strip ejection mechanism
- Bluetooth connectivity (GD40h)



FORA[®] ADVANCED pro

Multi-Functional Monitoring System

FORA[®] ADVANCED pro series is a **dual-parameter** handheld device which measures both **blood glucose and β -Ketone** levels. The HCT range (0% ~ 70%) covers all possible applications: **advanced diabetes care at home, primary care, neonatal care, gestational diabetes care, elderly care, and dialysis care.**



Strip Ejection
reduces the possibility of cross-infection

Bluetooth Connectivity (GD40h)

5 Tags: Gen/AC/PC/QC/KETONE

Extra Large Display, Screen Backlit,
and Large Digits

1,000 memory capacity
with date & time

One-button Design

Strip Feed Light



Tiny Sample Volume

- 0.8 μ L for Blood Glucose Test
- 1.0 μ L for β -Ketone Test



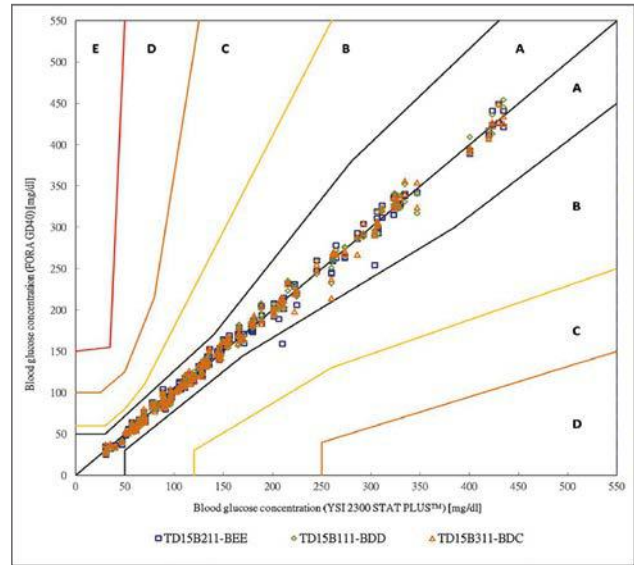
Quick Results

- 5 Seconds for Blood Glucose Test
- 10 Seconds for β -Ketone Test

Clinical Validation - BG Test Strips^[1]

A clinical study in April 2015 was conducted by the AMCR Institute (625 West Citracado Parkway, Suite 112, Escondido, CA92025). **The study demonstrated that the FORA® GD40 Blood Glucose Monitoring System has met the accuracy requirements of the ISO 15197:2013 standard.** The report showed that 100% of the results from the samples < 100mg/dL (5.55mmol/L) fell within the ±15 mg/dL (±0.83 mmol/L) criteria while 98% from the samples > 100 mg/dL (5.55 mmol/L) fell within the ±15% criteria.

Consensus Error Grid for FORA GD40 with three reagent system lots

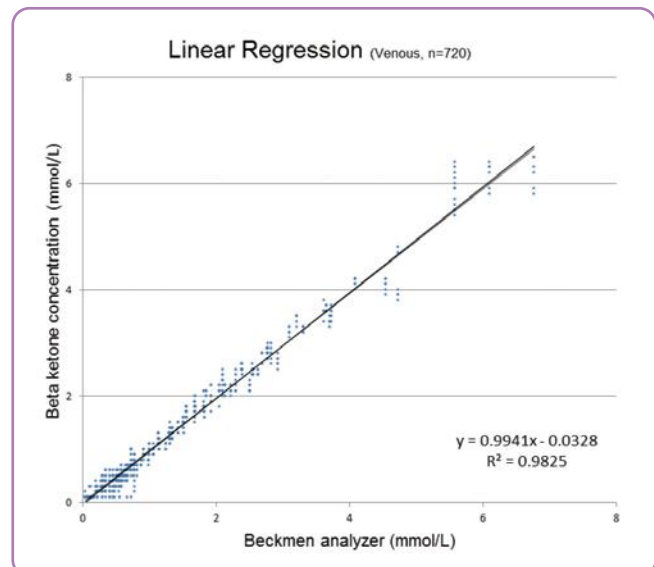
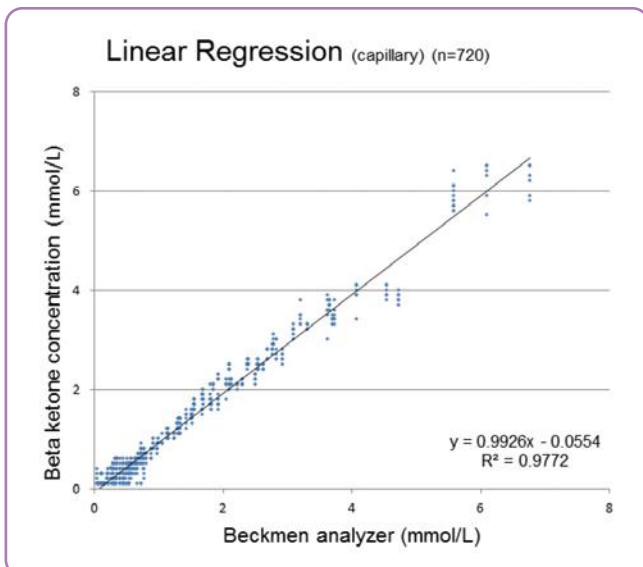


Region	Number	Percent
A	599	99.83%
B	1	0.17%
C	0	0.00%
D	0	0.00%
E	0	0.00%

Reagent System Lot	Within ± 5 mg/dL & ± 5% (Within ± 0.28 mmol/L & ± 5%)	Within ± 10 mg/dL & ± 10% (Within ± 0.56 mmol/L & ± 10%)	Within ± 15 mg/dL & ± 15% (Within ± 0.83 mmol/L & ± 15%)
TD15B211-BEE	147 / 200 (73.5%)	192 / 200 (96.0%)	197 / 200 (98.5%)
TD15B211-BDD	151 / 200 (75.5%)	194 / 200 (97.0%)	200 / 200 (100%)
TD15B311-BDC	143 / 200 (71.5%)	193 / 200 (96.5%)	199 / 200 (99.5%)

Clinical Study - β-Ketone Test Strips^[2]

A clinical evaluation of the β-Ketone monitoring system was carried out by comparing FORA test strip results to the Beckmen Analyzer results. Three reagent lots of FORA test strips were tested to ensure that representative performance would be obtained. Good correlation was found between FORA® β-Ketone test strip results and the comparative method results ($r^2 = 0.97$; $r^2 = 0.98$). This has shown that **the FORA® β-Ketone monitoring system delivers great results and achieves advanced performance of both capillary and venous blood tests.**



Reference:

- AMCR Institute (2015, April 15th - 22th). *System accuracy evaluation of FORA GD40 Blood Glucose Monitoring System versus YSI 2300 STAT PLUS™ glucose analyzer following ISO 15197:2013.* Project No.: 031015-01.
- ForaCare Laboratory (2016, January 5th). *Clinical Study Report for the β-Ketone Monitoring System.* Document No.: FC03-005422.

Specifications



Meter	GD40g	GD40h
Connectivity	RS232 (4 pin) to USB cable	Bluetooth V4.0
Power Source	2 x 1.5V AAA batteries	
Memory Capacity	1,000 records	
Dimension	110 (L) x 57 (W) x 25 (H) mm	
Weight	71g (without battery)	
System Operating Condition	10°C to 40°C, below 85% R.H.	
Meter Storage Condition	-20°C to 60°C, below 95% R.H.	



Test Strip	Blood Glucose Test Strips	β -Ketone Test Strips
Enzyme Type	GDH-FAD	β -Hydroxybutyrate Dehydrogenase
Blood Volume/ Reaction Time	0.8 μ L / 5 seconds	1.0 μ L / 10 seconds
Measurement Range	10 ~ 600 mg/dL (0.5 ~ 33.3mmol/L)	0.1 ~ 8.0 mmol/L
Hematocrit Range	0 ~ 70%	10 ~ 70%
Accuracy	\pm 15mg/dL for reading < 100 mg/dL; \pm 15% for reading \geq 100 mg/dL	
Precision	SD < 5 mg/dL for reading < 100 mg/dL; CV < 5% for reading \geq 100 mg/dL	SD < 0.1 mmol/L for reading < 1 mmol/L; CV < 7.5% for reading \geq 1 mmol/L
Calibration	No Code	Code Card
Strip Storage Condition	2°C to 30°C, below 85% R.H.	2°C to 30°C, below 85% R.H.

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