

FORA® 6



Multiparameter Handheld Devices

with the level of precision and accuracy according to laboratory analysis



For professional & home use

World's First Multi-parameter Meter

FORA® 6 Series measures blood glucose (BG), hematocrit concentration (HCT), hemoglobin (HB), β -Ketone (KB), uric acid (UA) and total cholesterol (TCH), in a simple, accurate and reliable way.



FORA[®] 6

Multiparameter Handheld Devices with the level of precision and accuracy according to laboratory analysis

The FORA[®] 6 series is the first multi-parameter meter in the world and comes in three models: FORA[®] 6 Connect, FORA[®] 6 Plus, and FORA[®] 6 Smart. For blood glucose measurement, the FORA[®] 6 series simply requires a very small sample size (0,5 µL of blood) and a 5-second reaction time. The reliable test results can help users manage their own or their patients' health conditions and make timely lifestyle changes to avoid hypoglycemia or hyperglycemia.



Connects wirelessly with Bluetooth Smart technology, which can easily be paired with a smartphone / tablet

Strip feed light

Strip ejection design reduces the possibility of cross-infection

3 meal tags : general (Gen), pre-meal (AC), post-meal (PC);
1 QC mode for control solution test

1000 memory capacity with date & time

1 x AAA battery

White backlight, large display and high contrast design. clear, easy to read

Records your test results and includes the time of the measurement

Up ▲, Down ▼ and Main M rubber buttons, easy to use and clean



STRIP FEED
LIGHT



90 DAYS
AVERAGE



1,000
MEMORY SETS



PRE-MEAL /
AFTER-MEAL



4 ALARMS



TELEHEALTH
CLOUD

Models



FORA 6 Connect

FORA 6 Plus

FORA 6 Smart

Multi-parameter blood glucose monitoring systems



Bluetooth Smart V4.0 embedded

All data can be exported via the strip port by the FORA My dongle 2

Blood glucose monitoring system



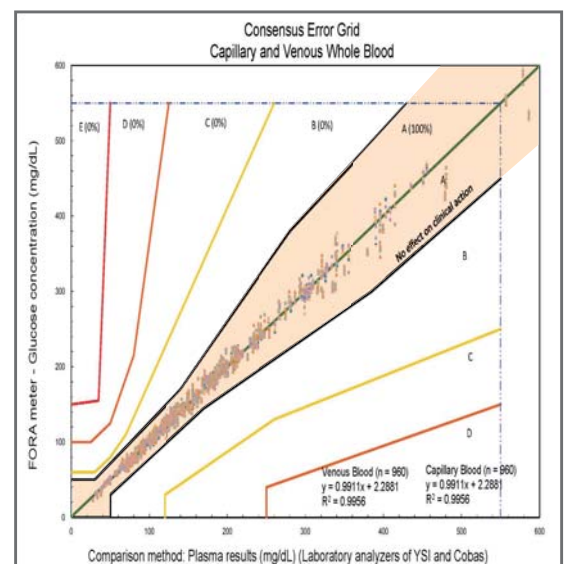
All data can be exported via the strip port by the FORA My dongle 2

BLOOD GLUCOSE TEST STRIPS



- For blood glucose test, NO calibration is needed.
- High level of accuracy which has surpassed the standards of the New ISO15197:2013
- Tiny sample size - 0.5 μ L of blood
- Quick results - 5 Seconds
- 0 ~ 70% Hematocrit Range
- Vial pack with 24 months of shelf-life

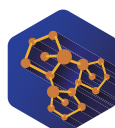
* All FORA® 6 meter kits include the FORA® 6 blood glucose test strips as standard. Other parameters are available and to be purchased separately.



0.5 μ L SAMPLE VOLUME



5 SECONDS REACTION TIME



GDH-FAD ENZYME



HIGH PRECISION TEST STRIPS



AST (ALTERNATE SITE TESTING)



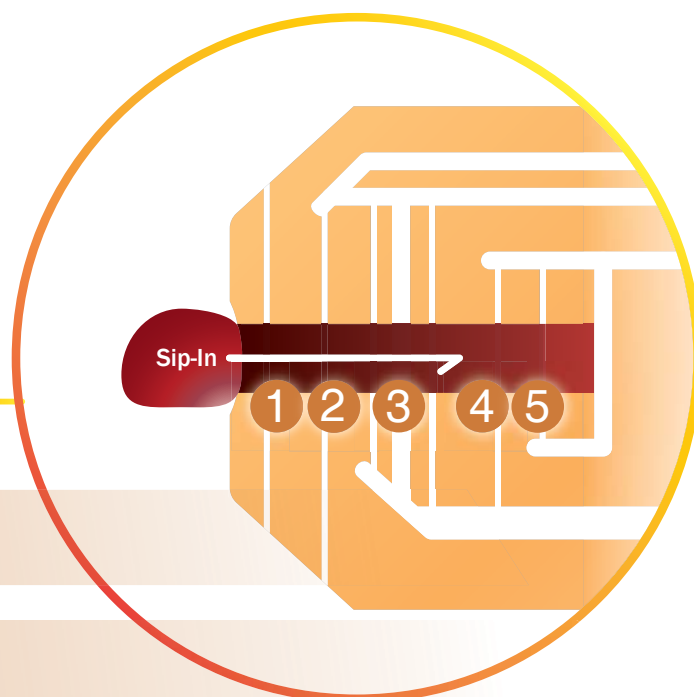
ASSI TECHNOLOGY



NO CODING

Advantages of our Test Strips

- Advanced Superior Sip-in (ASSI) Technology is available on all test strips
- High precision made with gold
- High quality with a long shelf life
- CV < 5%¹
- HCT Range 0%~70%
- Much greater level of accuracy with GDH-FAD Enzyme
- **5-electrode Technology**



- 1 Individual hematocrit level is detected by touch
- 2
- 3 Blood sample is detected and measured
- 4
- 5 A detection point to avoid erroneous reading due to insufficient blood sample volume

Accuracy & Precision



The FORA 6 blood glucose monitoring system fulfills the ISO 15197 criteria².

According to test results, the CVs of repeatability were 2.74% and 2.48% for venous and capillary samples, respectively. 100% of the measured glucose values from venous and capillary (fingertip) blood samples fell within either ± 15 mg/dL (0.83mmol/L) of the average comparison measurement result at glucose concentration <100 mg/dL (5.55 mmol/L) or within $\pm 15\%$ at glucose concentration >100 mg/dL (5.55 mmol/L).

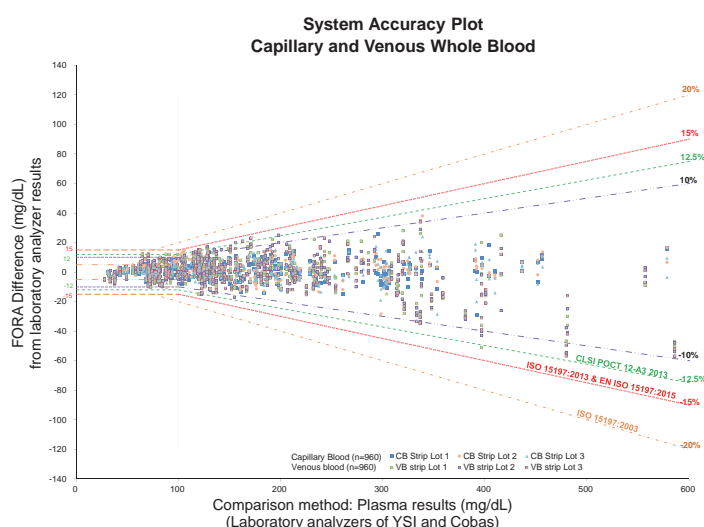


Fig - The test result shows that the FORA 6® Series fulfills the standards of the CLSI³ & ISO 15197 criteria.

Reference:

1. Reliable approval and clinically validated by the AMCR institute (625 West Citracado Parkway, Suite 112, Escondido, CA 92025) in the US during the period of the 15th to the 22nd of April 2015. The reference measurements were performed according to the YSI 2300 STAT PLUS blood glucose analyzer.
2. ISO 15197:2013 & EN ISO 15197:2015 In Vitro Diagnostic Test Systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
3. Clinical and Laboratory Standards Institute (CLSI) 2013 Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities.

Test Strips

FORA® 6 Series offers a simple solution for your testing needs which include 6 parameters: Blood Glucose (BG), Hematocrit (HCT), Hemoglobin (HB), β -Ketone (KB), Uric Acid (UA), Total Cholesterol (TCH).

BG-HCT-HB (3 IN 1)



- 3 parameters in 1: Blood Glucose (BG), Hematocrit (HCT) & Hemoglobin (HB)
- Enzyme: GDH-FAD
- Measurement Ranges:
BG - 10 ~ 600 mg/dL
HCT - 0 ~ 70 %
HB - 0 ~ 23.8 g/dL
- Sample volume - 0.5 μ L
- Individual foil pack with 18 months of shelf-life

B-KETONE (KB)



- Designed for diabetics who prefer a self-testing option
- Enzyme: Hydroxybutyrate Dehydrogenase
- Tiny sample volume - 0.8 μ L
- Quick result - 10 Seconds
- Measurement Ranges: 0.1~8.0 mmol/L
- Individual foil pack with 18 months of shelf-life

URIC ACID (UA)



- Designed for patients with diabetes or gout who prefer a self-testing and self-monitoring option.
- Enzyme: Uric Acid Catalyst
- Tiny sample volume - 2.0 μ L
- Quick result - 15 Seconds
- Measurement Ranges: 3~20 mg/dL
- Individual foil pack with 18 months of shelf-life



TOTAL CHOLESTROL (TCH)

- Designed for people with diabetes or cardiovascular disease who prefer a self-monitoring option.
- Enzyme: Cholesterol esterase / Cholesterol oxidase
- Tiny sample volume -3.0 μ L
- Quick result - 120 Seconds
- Measurement Ranges: 100~400 mg/dL
- Individual foil pack with 18 months of shelf-life



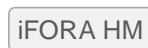
*All FORA® 6 Test Strips Series can be purchased separately.

Connectivity

FOR PROFESSIONAL & HOME USE



*Smart life
from now on.*



FORACARE TELHEALTH SYSTEM

ForaCare not only offers various medical devices and unique APPs for patients, but also provides a telehealth system for professional caregivers.

ForaCare Telehealth System can help users consolidate their measurements.



White Paper

Objective

The goal of the study was to assess the accuracy and reliability of seven blood glucose monitoring systems (BGMS) in clinical studies in accordance with the “Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use Guidance for Industry and Food and Drug Administration Staff” criteria and more stringent guidelines.

Methods

The study sample was collected from 353 subjects. The capillary blood specimens were collected via fingertip stick used on participants from the AMCRI Institute (625 West Citracado Parkway, Suite 112, Escondido, CA 92025) and tested on three different lots of test strips.

The study sample was collected from 372 subjects. The venous blood specimens were collected from participants at the AMCRI Institute (625 West Citracado Parkway, Suite 112, Escondido, CA 92025) and tested on three different lots of test strips.

Results

The **FORA® GoldAdvance Plus (FORA® 6 Connect)* BGMS** has met the requirements of the “Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use Guidance for Industry and Food and Drug Administration Staff” from all three lots of test strips tested.

Reagent system lot	Sample Type	Within $\pm 10\text{mg/dL}$ & $\pm 10\%$ (Within $\pm 0.5\text{ mmol/l}$ & $\pm 10\%$)	Within $\pm 12\text{mg/dL}$ & $\pm 12\%$ (Within $\pm 0.67\text{ mmol/l}$ & $\pm 15\%$)	Within $\pm 15\text{mg/dL}$ & $\pm 15\%$ (Within $\pm 0.83\text{ mmol/l}$ & $\pm 20\%$)
TD16J215CEE	Capillary	680 / 706 (96.3%)	693 / 706 (98.2%)	703 / 706 (99.6%)
	Venous	728 / 744 (97.8%)	736 / 744 (98.9%)	744 / 744 (100%)
TD16J222CEE	Capillary	678 / 706 (96.0%)	695 / 706 (98.4%)	704 / 706 (99.7%)
	Venous	725 / 744 (97.4%)	740 / 744 (99.5%)	743 / 744 (99.9%)
TD16J212CEE	Capillary	677 / 706 (95.9%)	689 / 706 (97.6%)	697 / 706 (98.7%)
	Venous	727 / 744 (97.7%)	737 / 744 (99.1%)	743 / 744 (99.9%)

Conclusion

This study showed that when compared with the test results with a laboratory reference, the **FORA® GoldAdvance Plus (FORA® 6 Connect)*** blood glucose monitoring system met the current accuracy standard in accordance with the “Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use Guidance for Industry and Food and Drug Administration Staff”.

* The BGMS of FORA GoldAdvanced Plus is called the FORA 6 Connect in the European Market.

Reference

- 2013 International Diabetes Federation, the global burden. <http://www.idf.org/diabetesatlas/5e/the-global-burden>
- Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use Guidance for Industry and Food and Drug Administration Staff
- In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013.
- Parkes JL, Slatin SL, Pardo S, Ginsberg BH: A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. Diabetes Care 2000; 23:1143-1148.
- Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986; 1:307-10.
- Passing H, Bablok. A new biometrical procedure for testing the equality of measurements from two different analytical methods. Application of linear regression procedures for method comparison studies in clinical chemistry, Part I. J Clin Chem Clin Biochem 1983; 21:709-20.
- AMCRI Institute. System accuracy evaluation of Seven Blood Glucose Monitoring Systems versus YSI 2300 STAT Plus™ glucose analyzer following “Blood Glucose Monitoring Test Systems for prescription Point-of-Care Use Guidance for Industry and Food and Drug Administration Staff”. Mar 13th ~ Apr 20th 2015. Project no.: 120816-02.

Fig-1. Consensus Error Grid for FORA GoldAdvance Plus (FORA 6 Connect) with three reagent system lots (Capillary Blood)

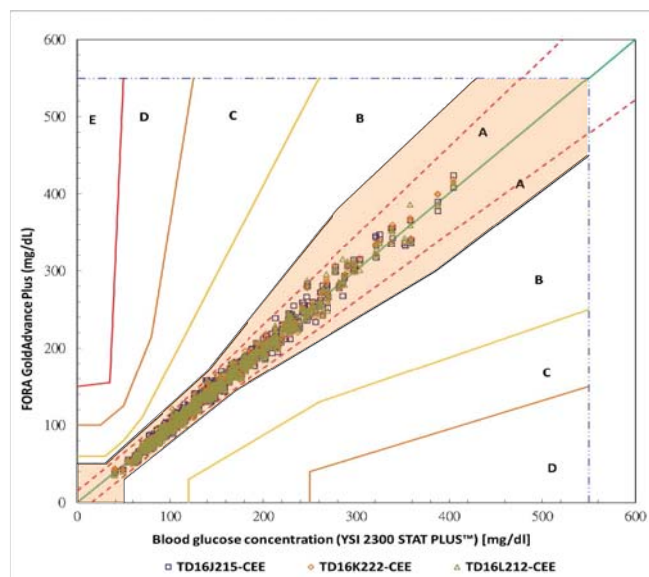
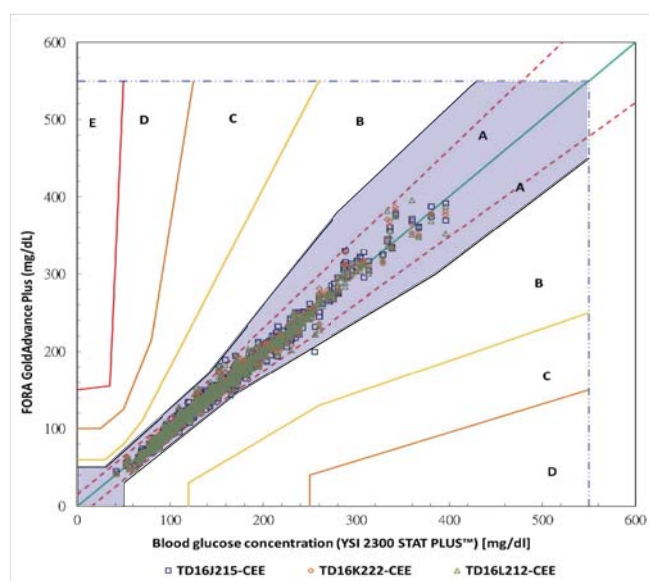


Fig-2. Consensus Error Grid for FORA GoldAdvance Plus (FORA 6 Connect) with three reagent system lots (Venous Blood)



Specifications



FORA® 6 Connect



FORA® 6 Plus



FORA® 6 Smart

Meters

Benefits	Multi-parameter blood glucose monitoring systems, available for Blood glucose, 3-in-1(BG/HCT/HB), Ketone, Uric Acid and Total Cholesterol testing		Blood glucose monitoring system, specialized for blood glucose measurement
Measuring Range (BG test)	10 ~ 600mg/dL (0.55 ~ 33.3mmol/L)		10 ~ 600mg/dL (0.55 ~ 33.3mmol/L)
Beep Sound	Yes, ON / OFF / Universal Tone®		Yes, ON / OFF / Universal Tone®
Ketone Warning	Yes, if the value higher than 240mg/dL		Yes, if the value higher than 240mg/dL
Meal tag / mode	AutoQC mode; GEN / AC / PC		AutoQC mode; AC / PC
LCD Backlight	✓	✓	✓
Strip Indication Light	✓	✓	✓
Strip Ejection	✓	✓	✓
Connectivity	Bluetooth Smart V4.0	Strip Port Comm	Strip Port Comm
Power Source	1 AAA battery		1 AAA battery
Battery life	At least 1,000 times		At least 1,000 times
Memory Capacity	1,000 memory sets		1,000 memory sets
Dimension	89.8 (L) x 54.9 (W) x 18.0 (H) mm		96.4 (L) x 34.5 (W) x 18.2 (H) mm
Weight	64.1g (without Battery)		29.4g (without Battery)
Operating Condition	8°C (46.4°F) ~ 45°C (113°F)		8°C (46.4°F) ~ 45°C (113°F)

Test Strips

*All FORA® 6 Test Strips Series can be purchased separately.

Model	Blood Glucose	BG-HCT-HB	β-Ketone (KB)	Uric Acid (UA)	Total Cholesterol (TCH)
Enzyme Type	GDH-FAD		Hydroxybutyrate Dehydrogenase	Uric Acid Catalyst	Cholesterol esterase Cholesterol oxidase
Blood Sample Requirement	0.5 µL		0.8 µL	2.0 µL	3.0 µL
Reaction Time	5 Seconds		10 Seconds	15 Seconds	2 Minutes
Measurement Range	10 ~ 600 mg/dL (0.55 ~ 33.3mmol/L)	BG : 10 ~ 600 mg/dL HB : 0 ~ 23.8 g/dL	0.1 ~ 8.0 mmol/L	3 ~ 20 mg/dL	100 ~ 400 mg/dL
Haematocrit Range	0 ~ 70%		10 ~ 70%	20 ~ 60%	10 ~ 70%
Precision	SD < 5 mg/dL (0.278 mmol/L) if < 100 mg/dL (5.55 mmol/L); CV < 5% if ≥ 100 mg/dL (5.55 mmol/L)		≤ 1 mmol/L, SD < 0.1mM; > 1 mmol/L, CV < 7.5%	CV < 7.5%	CV < 7.5%
Accuracy	±15mg/dL if < 100mg/dl ; ±15% if ≥ 100mg/dL		--	--	--
Alternative Site Testing	Yes. (Fingertips, Palm, Upper arm or Forearm)		Not Applicable	Not Applicable	Not Applicable
Applicable Sample Type	Capillary; Venous		Capillary; Venous	Capillary; Venous	Capillary; Venous
Storage Condition	2°C (35.6°F) ~ 30°C (86.0°F) ; RH < 90%		2°C (35.6°F) ~ 30°C (86.0°F) ; RH<85%	2°C (35.6°F) ~ 30°C (86.0°F) ; RH<85%	2°C (35.6°F) ~ 30°C (86.0°F) ; RH<85%
Strip Pack	Vial / Individual Pack	Vial / Individual Pack	Vial / Individual Pack	Vial / Individual Pack	Vial / Individual Pack
Shelf Life Time	24M / 18M	18M	18M	18M	18M

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