

FORA® 6

Multi-Functional Monitoring Systems

Handheld Blood Glucose & Multiparameter Meters



For Advanced Diabetes Management

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 handheld 6-parameter meter in the world that enables the measurements of 6 parameters for a faster and more comprehensive testing. 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.



Strip feed light

Strip ejection design
reduces the possibility of
cross-infection

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

1000 memory capacity
with date & time

1 x AAA battery

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

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

Meters



FORA® 6 Connect



FORA® 6 Plus

Multiparameters



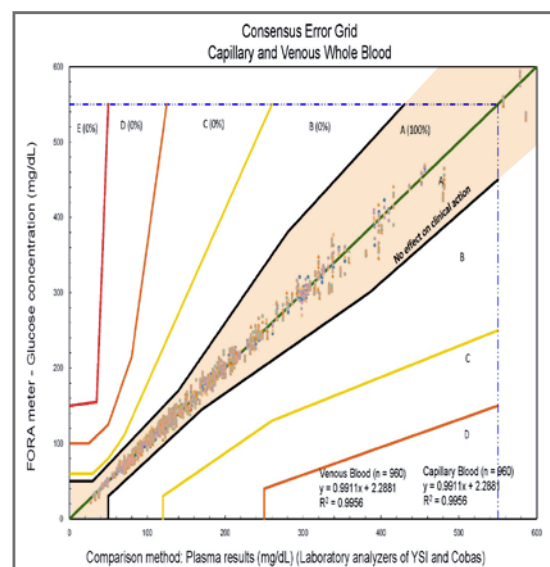
Bluetooth Smart V4.0
embedded

All data can be exported via the strip port
by FORA® My Dongle II

BLOOD GLUCOSE TEST STRIPS



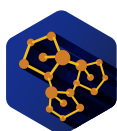
- Tiny sample size - 0.5 μ L of blood
- Quick results - 5 Seconds
- 0 ~ 70% Hematocrit Range
- Application: General Patients (Capillary; Venous; Arterial); Dialysis Patients; Gestational Diabetics; people with cardiovascular diseases or metabolic syndrome
- Neonatal Whole Blood; Alternative-site testing



0.5 μ L SAMPLE
VOLUME



5 SECONDS
REACTION TIME



GDH-FAD
ENZYME



HIGH PRECISION
TEST STRIPS



AST (ALTERNATE
SITE TESTING)



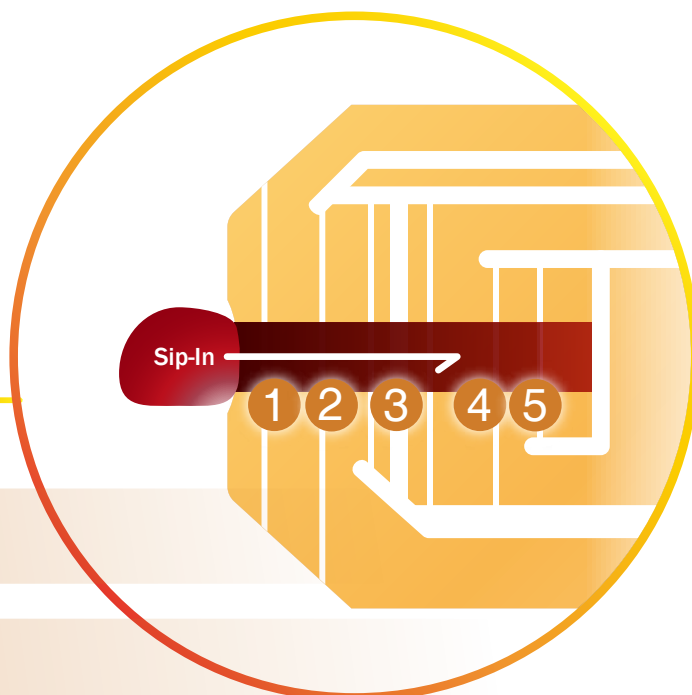
ASSI
TECHNOLOGY



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).

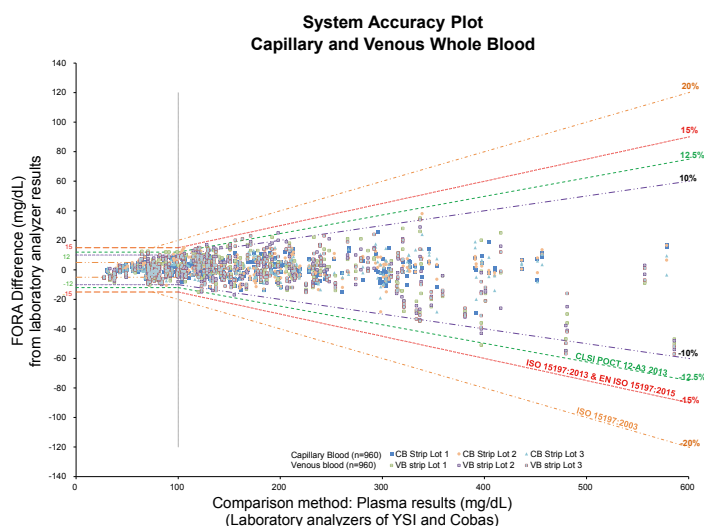


Fig - The test result shows that the FORA 6® Series fulfills the standards of the CLSI³ & ISO 15197 criteria.

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

BLOOD GLUCOSE (BG)



- For blood glucose test, NO calibration is needed.
- High level of accuracy which has surpassed the standards of ISO 15197:2015
- Tiny sample size - 0.5µL of blood
- Quick results - 5 Seconds
- 0~70% Hematocrit Range
- Application: **General Patients (Capillary; Venous; Arterial); Dialysis Patients; Gestational Diabetics**
- **Neonatal Whole Blood; Alternative-site testing**
- Vial pack with 24 months of shelf-life

BG-HCT-HB (3 IN 1)



- 3 parameters in 1: Blood Glucose (BG), Hematocrit (HCT) & Hemoglobin (HB)
- Enzyme: GDH-FAD
- Measurement Ranges:
BG 10~600mg/dL
HCT 0~70%
HB 0~23.8g/dL
- Sample volume - 0.5µL
- Quick results - 5 Seconds
- Application: **General Patients (Capillary; Venous; Arterial); Dialysis Patients; Gestational Diabetics;**
- **Neonatal Whole Blood; Alternative-site testing**
- Individual foil pack with 18 months of shelf-life

β-KETONE (KB)



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

URIC ACID (UA)



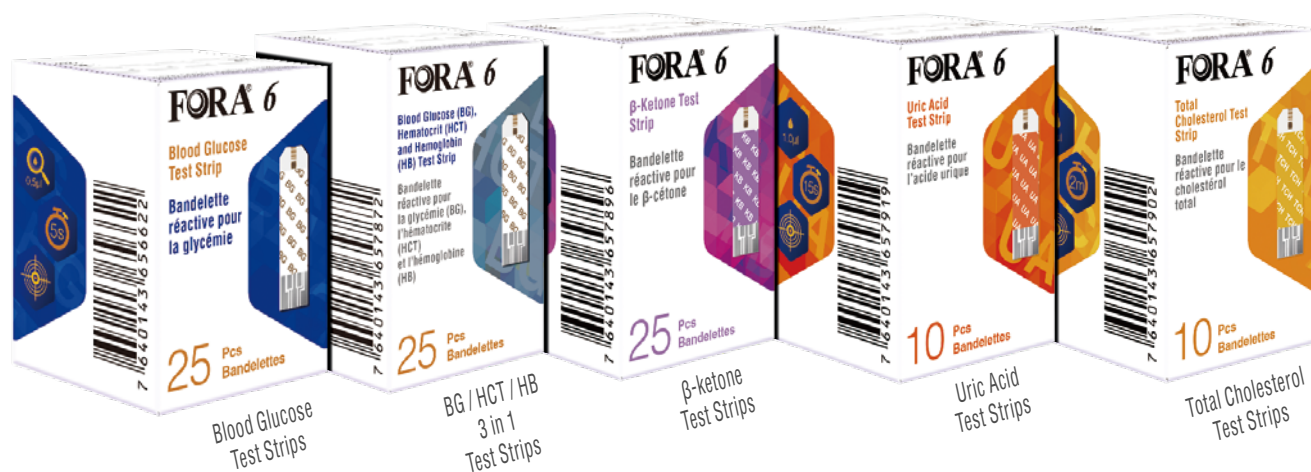
- Designed for patients with diabetes or gout who prefer a self-testing and self-monitoring option.
- Enzyme: Uric acid catalyst
- Tiny sample volume - 1.0µL
- Quick results - 15 Seconds
- Measurement Ranges: 3~20mg/dL
- Individual foil pack with 18 months of shelf-life

TOTAL CHOLESTEROL (TCH)



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

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



System Accuracy Evaluation

FORA® 6 Connect versus Cobas Integra® 400 plus

System Accuracy: Section 6.3.3

ISO 15197:2013^[1] / EN ISO 15197:2015^[2]

The system shall meet both of the following minimum criteria for acceptable system accuracy.

- 95% of the measured glucose values shall fall within either $\pm 0,83$ mmol/l (± 15 mg/dl) of the average measured values of the reference measurement procedure at glucose concentrations $< 5,55$ mmol/l (<100 mg/dl) or within $\pm 15\%$ at glucose concentrations $\geq 5,55$ mmol/l (≥ 100 mg/dl).
- 99% of individual glucose measured values shall fall within zones A and B of the Consensus Error Grid (CEG) for type 1 diabetes.

Introduction and Scope

The study was conducted by Institut für Diabetes-Technologie Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm with Project No. IDT-1739(2)-FS^[3] in between 30 November 2017 and 19 December 2017. The capillary whole blood samples taken from 113 different subjects with 600 glucose values were obtained (200 from each of 3 reagent system lots).

Test Results

System accuracy result for glucose concentrations < 100 mg/dL (5.55 mmol/L)

| Reagent System Lot | Within ± 5 mg/dL (Within ± 0.28 mmol/L) | Within ± 10 mg/dL (Within ± 0.56 mmol/L) | Within ± 15 mg/dL (Within ± 0.83 mmol/L) |
|--------------------|--|---|---|
| WG17H104-CEE | 17 / 52 (32.7%) | 35 / 52 (67.3%) | 51 / 52 (98.1%) |
| WG17H604-CEE | 23 / 52 (44.2%) | 44 / 52 (84.6%) | 52 / 52 (100%) |
| WG17H904-CEE | 12 / 52 (23.1%) | 36 / 52 (69.2%) | 51 / 52 (98.1%) |

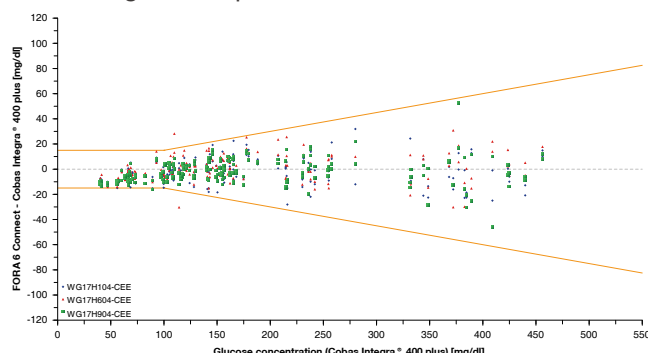
System accuracy result for glucose concentrations ≥ 100 mg/dL (5.55 mmol/L)

| Reagent System Lot | Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ |
|--------------------|-------------------|-------------------|-------------------|
| WG17H104-CEE | 104 / 148 (70.3%) | 137 / 148 (92.6%) | 148 / 148 (100%) |
| WG17H604-CEE | 100 / 148 (67.6%) | 136 / 148 (91.9%) | 146 / 148 (98.6%) |
| WG17H904-CEE | 103 / 148 (69.6%) | 144 / 148 (97.3%) | 148 / 148 (100%) |

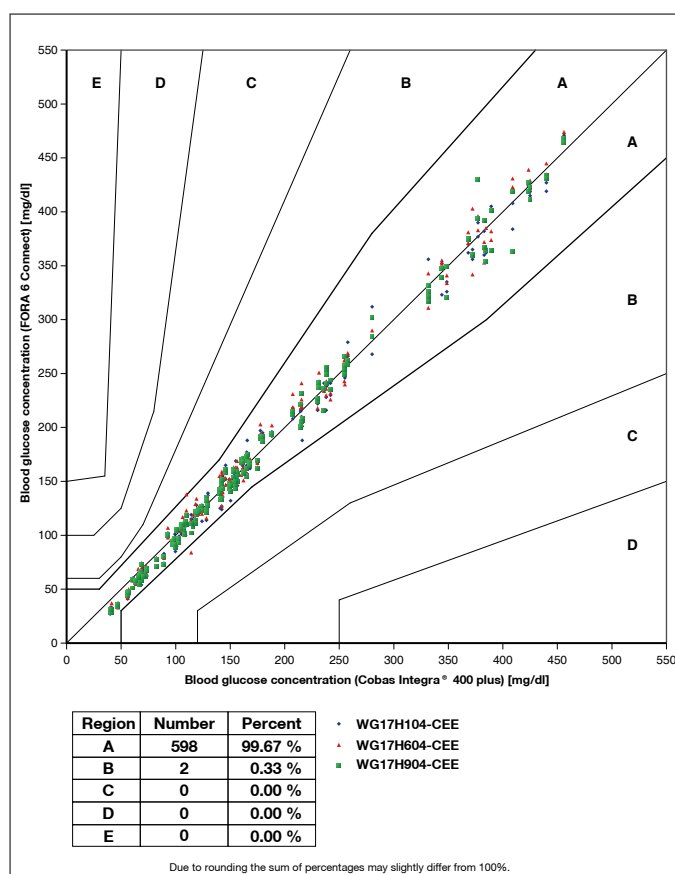
System accuracy result for glucose concentrations between 40 mg/dL (2.22 mmol/L) and 456 mg/dL (25.3 mmol/L)

| Reagent System Lot | Within ± 5 mg/dL & $\pm 5\%$ (Within ± 0.28 mmol/L & $\pm 5\%$) | Within ± 10 mg/dL & $\pm 10\%$ (Within ± 0.56 mmol/L & $\pm 10\%$) | Within ± 15 mg/dL & $\pm 15\%$ (Within ± 0.83 mmol/L & $\pm 15\%$) |
|--------------------|---|--|--|
| WG17H104-CEE | 121 / 200 (60.5 %) | 172 / 200 (86 %) | 199 / 200 (99.5 %) |
| WG17H604-CEE | 123 / 200 (61.5 %) | 136 / 148 (91.9%) | 198 / 200 (99.0 %) |
| WG17H904-CEE | 115 / 200 (57.5 %) | 180 / 200 (90 %) | 199 / 200 (99.5 %) |

Absolute differences between FORA 6 Connect and Cobas Integra® 400 plus



Consensus Error Grid for FORA 6 Connect with three reagent system lots



Conclusion

This study shows that the FORA 6 Connect Multi-functional Monitoring System is in compliance with ISO 15197:2013 / EN ISO 15197:2015 when comparing the test results to a laboratory reference. In addition, 100% of individual glucose values measured fall within zones A and B of the Consensus Error Grid (CEG).

Reference

- International Organization for Standardization. In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013.
- International Organization for Standardization. In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. EN ISO 15197:2015.
- Institut für Diabetes Technologie (2018, January 16). System accuracy evaluation of FORA 6 Connect Multi-functional Monitoring System based on ISO 15197:2013 & EN ISO 15197:2015. Project no.: IDT-1739(2)-FS
- ForaCare Suisse AG. Clinical Validation List. www.foracare.ch/validations.html.

Connectivity

FOR PROFESSIONAL & HOME USE



Test Simply.
Live Better.

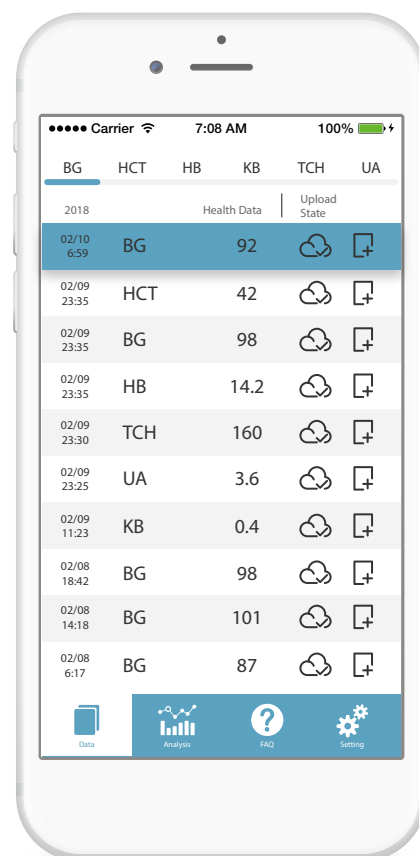


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App Store

GET IT ON
Google Play

 Bluetooth®

iFORA HM



FORACARE TELEHEALTH 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. Discover more:

www.foracare.ch/telehealth-solution



Specifications



FORA® 6 Connect



FORA® 6 Plus

Meters

| | | |
|---------------------------|--|---|
| Benefits | Multi-functional Monitoring Systems, for Blood glucose, 3-in-1(BG/HCT/HB), β -Ketone, Uric Acid and Total Cholesterol testing | |
| Measuring Range (BG test) | 10 ~ 600mg/dL (0.55 ~ 33.3mmol/L) | |
| Beep Sound | Yes, ON / OFF / Universal Tone® | |
| Ketone Warning | Yes, if the value higher than 240mg/dL | |
| Meal Tag | AutoQC mode; GEN / AC / PC | |
| LCD Backlight | Yes | |
| Strip Indication Light | Yes | |
| Strip Ejection | Yes | |
| Connectivity | Bluetooth Smart V4.0 | Strip Port Comm (via FORA® My Dongle II) |
| Power Source | 1 AAA battery | |
| Battery life | At least 1,000 times | |
| Memory Capacity | 1,000 memory sets | |
| Dimension | 89.8 (L) x 54.9 (W) x 18.0 (H) mm | |
| Weight | 64.1g (without Battery) | |
| Operating Condition | 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 | | β -Hydroxybutyrate Dehydrogenase | Uric Acid Catalyst | Cholesterol esterase Cholesterol oxidase |
| Blood Sample Requirement | 0.5 μ L | | 0.8 μ L | 1.0 μ L | 3.0 μ L |
| Reaction Time | 5 Seconds | | 10 Seconds | 15 Seconds | 120 Seconds |
| 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 \geq 100 mg/dL (5.55 mmol/L) | | \leq 1 mmol/L, SD < 0.1mM; > 1 mmol/L, CV < 7.5% | CV < 7.5% | CV < 7.5% |
| Accuracy | \pm 15mg/dL if < 100mg/dl ; \pm 15% if \geq 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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