FORA® 6 GTel

Cellular Multi-Parameter Monitoring System

Greater Accuracy According to EN ISO 15197:2015

Built-in SIM card
3G/4G Data Transmission

Multiple Parameters
Blood Glucose, Hematocrit, Hemoglobin, β-Ketone, Total Cholesterol and Uric Acid

Touch Panel
Color Display and Easy-to-use

A Comprehensive
Diabetes Management Device

- Data seamlessly uploaded directly to the cloud
- Trends and graphs generated automatically
- Service button for direct assistance

Designed by FORA

FORA® 6 GTel

Cellular Multi-Parameter Monitoring System

FORA®6 GTel is a SIM embedded multi-parameter handheld device which can measure blood glucose, hematocrit, hemoglobin, β-ketone, total cholesterol and uric acid for a more comprehensive diabetes management.

The built-in SIM card allows data to be seamlessly uploaded directly to the cloud, reducing the time spent in pairing and syncing with a smartphone, simplifying the communication between patients and healthcare professionals.

1. **Service Button**
   for when assistance is needed
2. **Strip Feed Light**
3. **3g/4g Signal Indicator**
4. **Rechargeable Battery**
5. **Strip Ejection**
   reduces the possibility of cross-infection
6. **Color & Touch Screen**
   intuitive operation, user-friendly design
7. **Digital Logbook**
   check your measuring results anytime anywhere
8. **Two-way Message**
   instant communcation between patients and healthcare professionals
9. **Sync data to Telehealth**
10. **Talking Function**
    English / Español / Français

Built-in SIM card
3G/4G Data Transmission

System Accuracy Evaluation

FORA® 6 GTel versus YSI Analyzer

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.

a) 95% of the measured glucose values shall fall within either ± 15mg/dL (± 0.83 mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations < 100 mg/dL (5.5 mmol/L) or within ± 15% at glucose concentrations ≥ 100mg/dL (≥ 5.55 mmol/L).

b) 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 ForaCare Suisse AG with Project No. FC03-0004135[3] in 2015.

Capillary and Venous blood samples were taken from 160 different subjects. The evaluation of the system accuracy consisted of testing the capillary and venous blood from each subject with Blood Glucose Test Strips. To ensure that representative performance would be obtained, the test was performed with three reagent lots for each Capillary and Venous blood samples.

Test Result

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

Sample Type	Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.55 mmol/L)	Within ±15 mg/dL (Within ±0.83 mmol/L)
Capillary Blood	175 / 246 (71.1%)	233 / 246 (94.7%)	246 / 246 (100%)
Venous Blood	144 / 234 (61.5%)	217 / 234 (92.7%)	234 / 234 (100%)

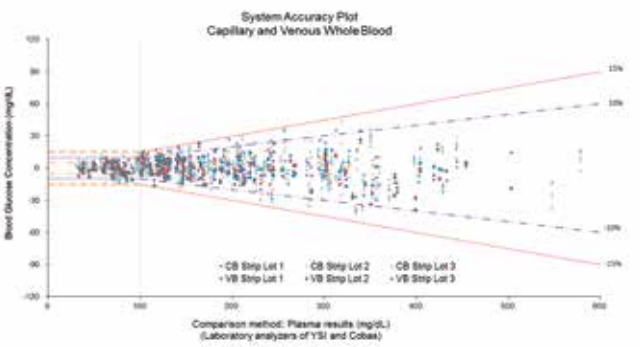
System accuracy result for glucose concentrations ≥ 100 mg/dL (5.55 mmol/L)

Sample Type	Within ±5%	Within ±10%	Within ±15%
Capillary Blood	455 / 714 (63.9%)	652 / 714 (91.3%)	714 / 714 (100%)
Venous Blood	458 / 726 (63.1%)	664 / 726 (91.5%)	726 / 726 (100%)

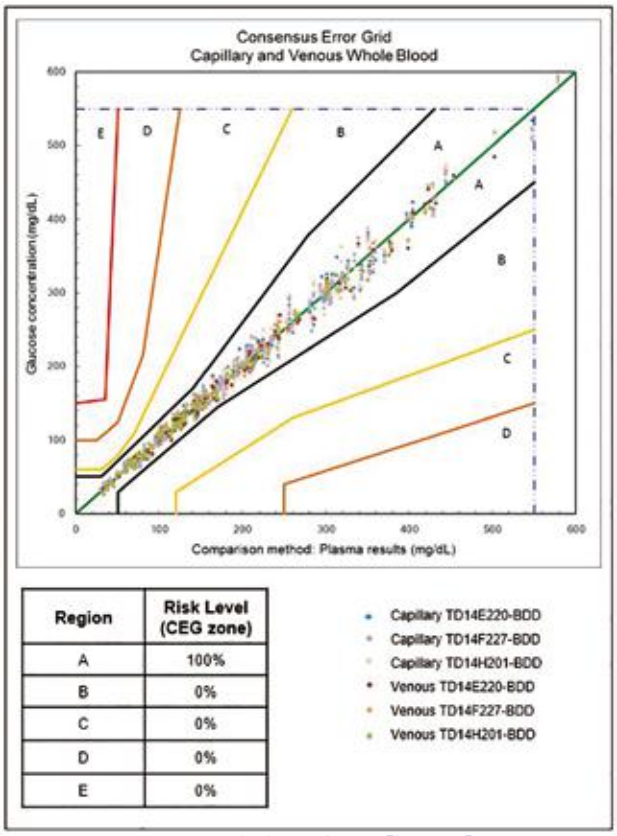
System accuracy result for glucose concentrations in Capillary and Venous Samples

Sample Type	Glucose Concentration Range	Within ±15mg/dL or ±15% (Within ±0.83mmol/L or ± 15%)
Capillary Blood	30.3 – 578.5 mg/dL (1.68 – 32.14 mmol/L)	960 / 960 (100%)
Venous Blood	33.6 – 630.0 mg/dL (1.87 – 35.00 mmol/L)	960 / 960 (100%)

Absolute differences between FORA 6 Gtel and YSI Analyzer



Consensus Error Grid - capillary and venous samples



Region	Risk Level (CEG zone)
A	100%
B	0%
C	0%
D	0%
E	0%

Capillary TD14E220-BDD
Capillary TD14F227-BDD
Capillary TD14H201-BDD
Venous TD14E220-BDD
Venous TD14F227-BDD
Venous TD14H201-BDD

Conclusion

This study shows that the FORA® 6 GTel 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

1. 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.
2. European Committee for Standardization. In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. EN ISO 15197:2015.
3. ForaCare Suisse AG (2017). *Clinical Study Report: FORA 6 GTel Multi-Functional Monitoring System on Blood Glucose Monitoring System.* Project no. FC03-0004135.

Specifications

Meters

FORA® 6 GTel

FORA® 6 Connect

FORA® 6 Plus

Parameters	Multi-functional Monitoring Systems Blood Glucose, 3-in-1(BG/HCT/HB), β-Ketone, Uric Acid and Total Cholesterol		
Unique Features	Talking Guidance (English / Spanish / French) Two Way Message Encouraging reminder Service Button Trends, Graphs and 7, 14, 21, 28, 60, 90-Day Average	Universal Tone® 7, 14, 21, 28, 60, 90-Day Average	Universal Tone® 7, 14, 21, 28, 60, 90-Day Average
Ketone Warning	Yes, if ≧ 240mg/dL	Yes, if ≧ 240mg/dL	Yes, if ≧ 240mg/dL
Meal Tag	Before Meal / After Meal / No Tag	AutoQC mode; GEN / AC / PC	AutoQC mode; GEN / AC / PC
Display	Color Touch Screen	LCD Backlight	LCD Backlight
Daily Alarm	4 Alarms	4 Alarms	4 Alarms
Strip Indication Light	Yes	Yes	Yes
Strip Ejection	Yes	Yes	Yes
Connectivity	Cellular Data (3G/4G)	Bluetooth	Strip Port Comm (via FORA® My Dongle II)
Power Source	Rechargeable LI-Polymer battery	1 AAA battery	1 AAA battery
Memory Capacity	1,000 memory sets	1,000 memory sets	1,000 memory sets

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 µL		0.8 µL	1.0 µL	3.0 µL
Reaction Time	5 Seconds		10 Seconds	15 Seconds	60 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%	20 ~ 60%
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	24M / 18M	18M	18M	18M

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