

FORA[®] Diamond PRIMA



Accurate Results Every Time



**100% of results in
Zone A of Consensus
Error Grid (CEG)***

*EN ISO 15197:2015 requires $\geq 99\%$ in zones A and B.

Diabetes Management Made Simple

- New Intuitive Sensing Technology (IST) with clinically validated accuracy
- Streamlined design for the fashionable lifestyle
- GDH-FAD test strips for accurate measurements
- USB connection for convenient data transmission
- LCD backlight screen for clear and easy readings

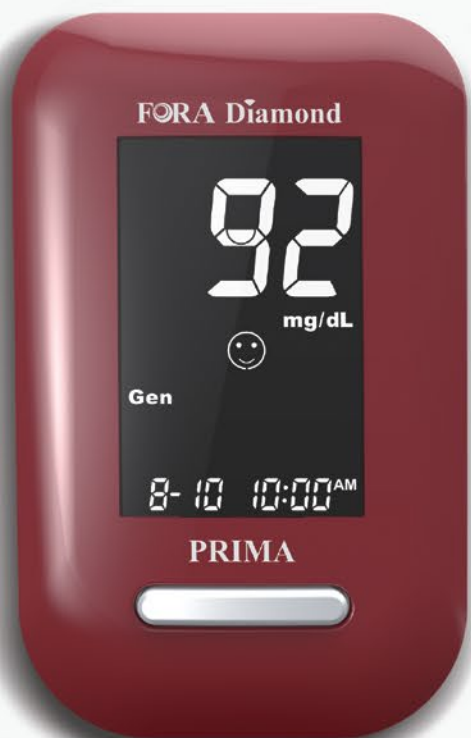




FORA[®] Diamond PRIMA

Fulfills Your Life Aesthetics.

The fashionable elegant design on FORA[®] Diamond PRIMA fulfills your life aesthetics of never making a compromise for pursuing the beauties even to a small blood glucose meter.



Innovation at the palm of your hands

A beautiful appearance is never equal to slick performance to FORA[®] Diamond PRIMA.

Extreme accuracy is established by several merits such as the **New Intuitive Sensing Technology (IST)**, which constantly ensures the stability of testing results, and GDH-FAD test strips for the least interfering testing result.

USB Connection

FORA[®] Diamond PRIMA can export your blood glucose records to your computer and trace your health status through USB connection.



FORA® Lancing Device

- Depth indicator with six different settings
- Cocking control and release button to improve sampling control
- Lancet ejector

FORA® Diamond PRIMA

- Interference-free measurements with New Intuitive Sensing Technology (IST)
- Easy-to-use with intuitive operation
- Fast and accurate results in 5 seconds
- Strip ejection design reduces the risk of cross-infection

FORA® Diamond Test Strips

- High accuracy and precision with GDH-FAD enzyme
- Improved blood sampling with Advanced Sip-in (ASSI) technology
- No-coding



Intuitive Sensing Technology (IST)

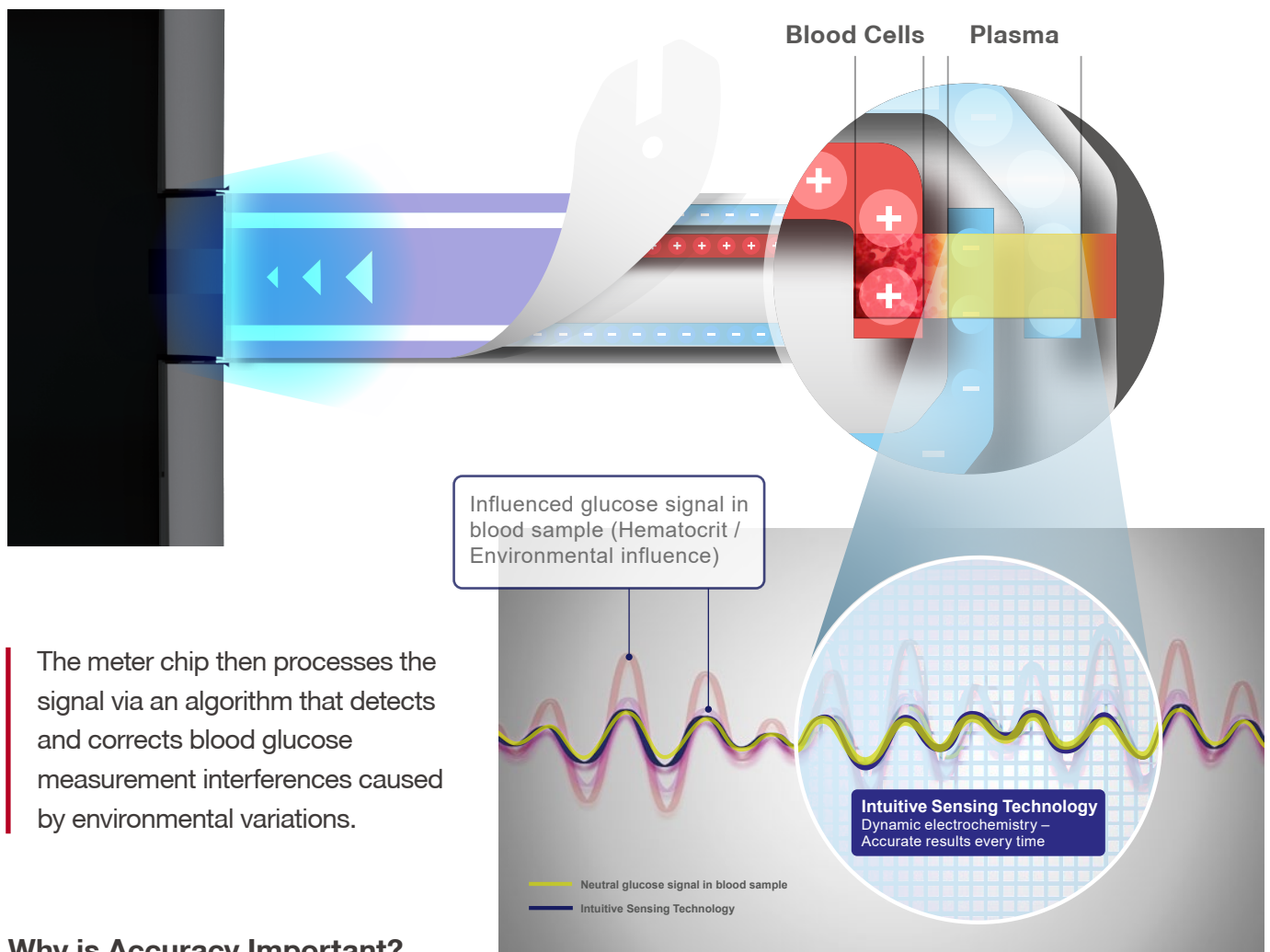


What is Intuitive Sensing Technology (IST)?

The Diamond IST is the second generation of Diamond blood glucose monitoring systems. Detecting common sources of interference in the blood sample is crucial for accurate blood glucose measurement results. FORA® Diamond GD50 uses the **Intuitive Sensing Technology (IST)**, an innovative technology included in all Diamond meters. The meter applies Dynamic Electrochemistry in blood glucose measurements to identify sources of interference, providing accurate and precise results.

How Intuitive Sensing Technology (IST) Works?

The meter detects the blood sample and sends advanced signals into the test strip. The electrically charged signals polarize the blood into blood cells and plasma, detecting distortions caused by the hematocrit. This allows the meter to provide accurate results, free from variation interference from the sample.



The meter chip then processes the signal via an algorithm that detects and corrects blood glucose measurement interferences caused by environmental variations.

Why is Accuracy Important?

Blood glucose meter accuracy is important for several reasons:

- Improved reliability in your data and trust in your current diabetes management plan.
- Helps you understand and/or anticipate potential lab results when going for your A1c checkup.
- Accurate meters are able to detect episodes of hypo- or hyperglycemia.
- Can help with decision-making surrounding medication dosages.

The electrochemistry is essentially utilized to correct the hematocrit levels that could lead to wrongful blood glucose meters in the blood. A POC device displaying inaccurate blood glucose levels can potentially lead to incorrect diets, or worse, incorrect medication dosages which could be fatal.

Outstanding Accuracy



FORA® Diamond's innovative technologies are backed up by strong evidence. What was great, just got better.

System Accuracy Evaluation

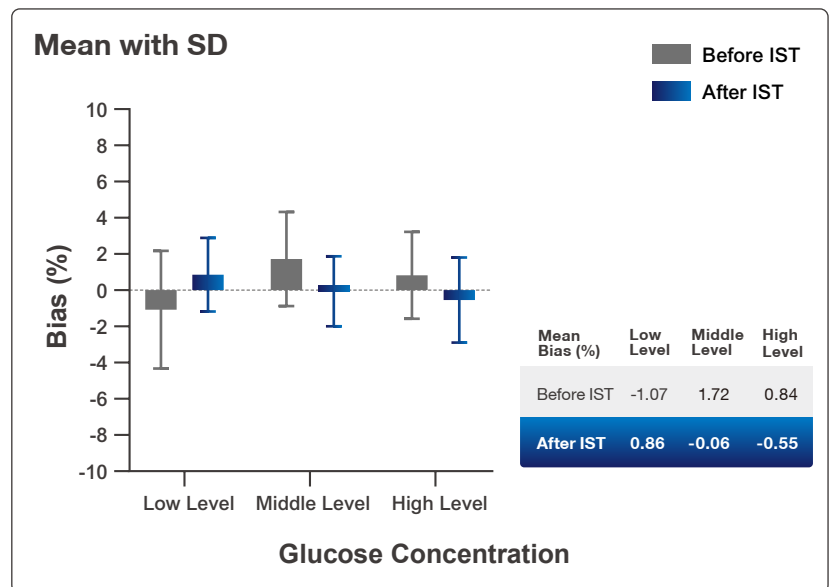
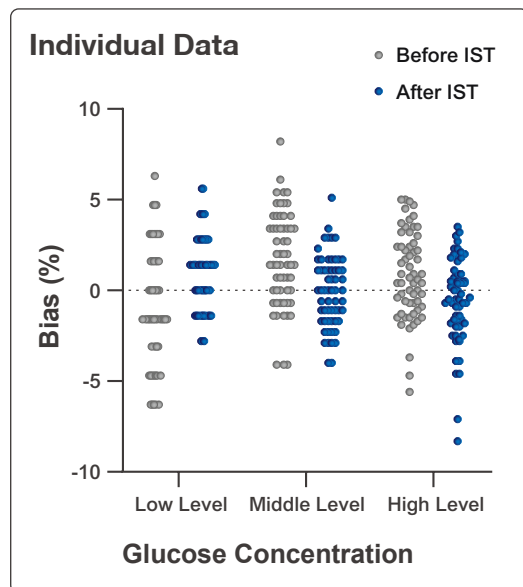
This report is intended to compare the performance of glucose measurement function for FORA® Diamond BGMS before and after IST based on the analysis from the existing data.

Sample Distribution

The glucose concentration intervals were determined with YSI-2300 and adjusted by supplementing the venous blood sample with dextrose solution. Three samples were prepared with glucose concentrations in the intervals: 1) Low (<100 mg/dL), 2) Middle (100~200 mg/dL), 3) High (>500 mg/dL).

Data Analysis

Accuracy: Bias (%) of individual result compared to the value of the reference method (YSI-2300) is calculated. The results are presented by graphs for individual values or their mean with SD.



Precision: for each glucose interval, the test results obtained from Diamond BGMS were calculated to determine its Mean, Standard Deviation (SD), and Coefficient of Variation (CV%)

		Low Level (<100mg/dL)	Middle Level (100~200mg/dL)	High Level (>500mg/dL)
Before IST	Mean	63.3	149.5	540.5
	SD	2.07	3.82	12.87
	CV	3.27%	2.55%	2.38%
After IST	Mean	72.6	174.9	560.9
	SD	1.45	3.39	13.23
	CV	2.00%	1.94%	2.36%

Conclusion

This study shows that the FORA® Diamond Blood Glucose Monitoring System with the IST upgrade has superior performance for accuracy and precision.

For accuracy, the Mean Bias (%) has shown to be lower across all blood glucose levels.

For precision, the new device has a lower SD at low levels. At middle and high levels, it has a considerably smaller CV.

Reference

1. ForaCare Laboratory (2014). *Test Plan Report*. Document No. FC-800-4281100-001-C06.
2. ForaCare Laboratory (2019). *Test Plan Report*. Document No. FC03-0006315.

Specifications



*The product image is in real size.



FORA® Diamond PRIMA Meter

Model No.	DM10
Unique Features	Universal Tone® IST Technology
Dimensions	86 (H) X 53.6 (W) X 19.5 (D) mm
Weight	52.4g (without Battery)
Ketone Warning	Yes. if ≥ 240 mg/dL (13.3 mmol/L)
Meal Tag	Yes. General / Pre-meal (AC) / Post-meal (PC)
Daily Alarm	4 Alarms
Strip Indicator Light	Yes
Strip Ejection	Yes
Connectivity	Cable Link (Micro USB to USB)
Memory Capacity	450 Memory Sets
Operating Condition	+10°C ~ +40°C
Storage Condition	-20°C ~ +60°C
Precision	CV < 5%
Day Average	7-, 14-, 21-, 28-, 60-, 90-Day
Power source	1 AAA Battery
Clinically Validated	Meet EN ISO 15197:2015 Standard

FORA® Diamond Test Strips

Model No.	ACS044
Technology	ASSI Technology
Enzyme Type	GDH-FAD
Coding Type	No-Coding
Blood Sample Volume	0.5 μ L
Reaction Time	5 Seconds
Measuring Range	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
HCT Range	20% ~ 60%
Applicable Sample Type	Capillary; Venous
Application	Dialysis; General Patient; Gestational

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