

FORA[®] Diamond



MINI



Accurate Results Every Time



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

*EN ISO 15197:2015 requires ≥ 99 % in zones A and B.

Mobile. Smart. Accurate.

- New Intuitive Sensing Technology (IST) with clinically validated accuracy
- Bluetooth connectivity for seamless data management
- GDH-FAD test strips for accurate measurements
- Compact design and easy readings with LCD backlight





FORA[®] Diamond **MINI**

Take Control of Your Day.

As clever things can come in surprisingly small packages, the FORA[®] Diamond MINI has been designed to be as portable and efficient as possible. Its compact and discreet design enables the testing of blood sugar on the go. It is fast and accurate, and requires small blood samples.

Your results can be downloaded on the iFORA BG app to assess your blood sugar trends. FORA[®] Diamond MINI helps you to manage and take control of your day!

Mobile. Smart. Accurate.

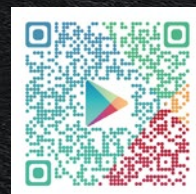
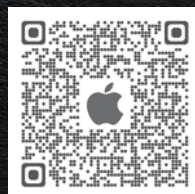
Despite its compact body, the FORA[®] Diamond MINI is packed with a complex technology. The GDH-FAD test strips and the new Intuitive Sensing Technology (IST) guarantee accurate results.

On top of the clinically validated accuracy, the meter is also equipped with Bluetooth that syncs and analyses data together with the iFORA BG app, making the FORA[®] Diamond MINI a Smart choice for a more complete diabetes self-management.





Free Download



Reliable Data Analysis and Communication

Bridge the Gap Between Physician Care and Diabetes Self-Management

Caregivers and patients do not always have matching schedules to arrange face-to-face consultations. With that in mind, ForaCare Suisse AG has developed two platforms, to support the treatment of patients wherever they are: iFORA BG and FORA® Telehealth system.

Bluetooth®

Equipped with Bluetooth, FORA® Diamond MINI allows seamless data sync and analysis with the **iFORA BG** mobile app.

For patients – iFORA BG

The iFORA BG provides detailed and yet careful data management tools to assist patients with their diabetes management. Some of its key features include graphs that show trends. The app also allows communication with a telehealth system, empowering patients to communicate with their caregivers when they require treatment advice.





For caregivers – FORA[®] Telehealth System

ForaCare's Telehealth system was created as a tool to help caregivers care for their patients wherever they are. The software provides a user-friendly interface, while offering a variety of reports including abnormal results review, abnormal measurement frequency review, and strip shortage monitoring.

New Intuitive Sensing Technology (IST)

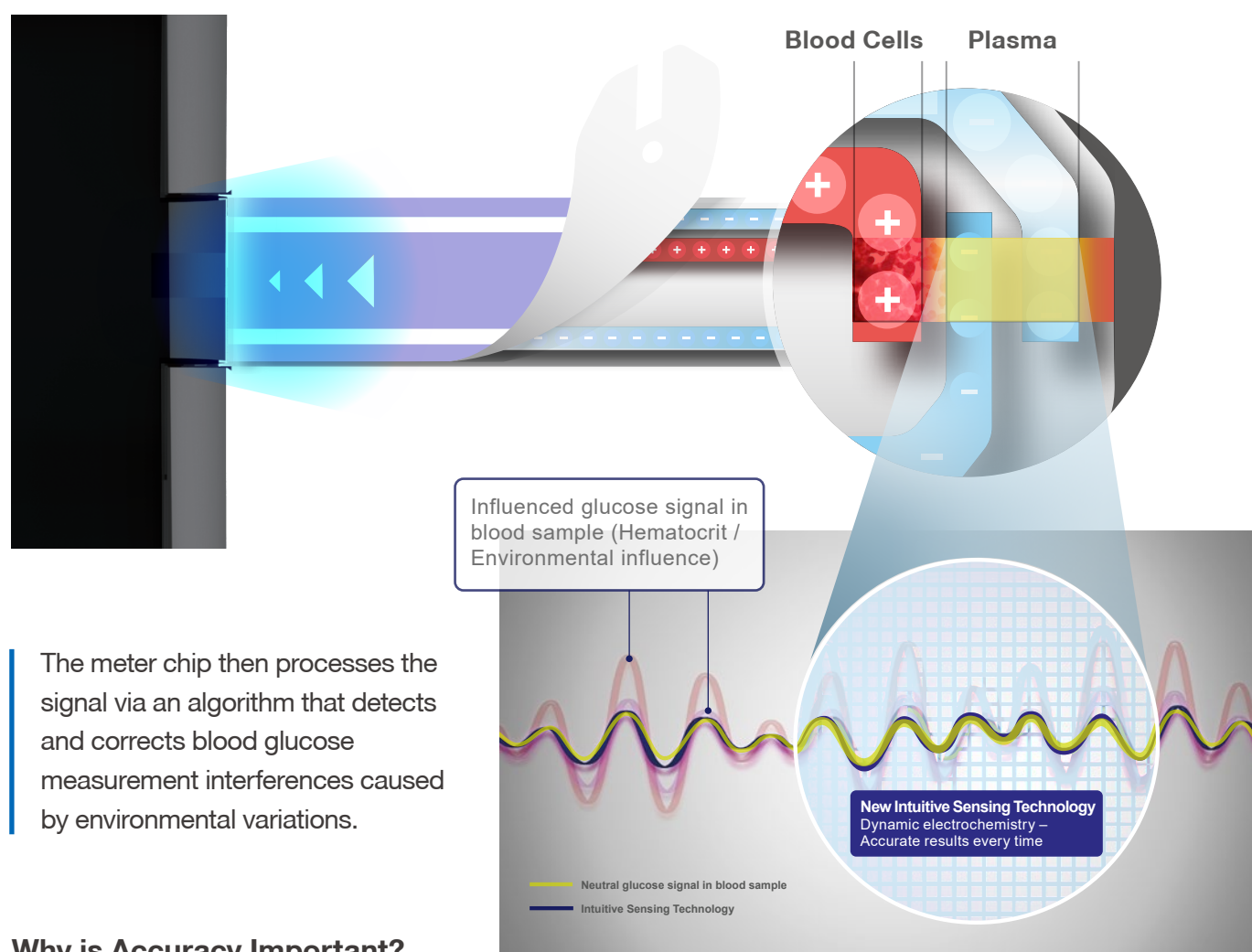


What is New Intuitive Sensing Technology (IST)?

The New 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 MINI uses the **New 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.



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

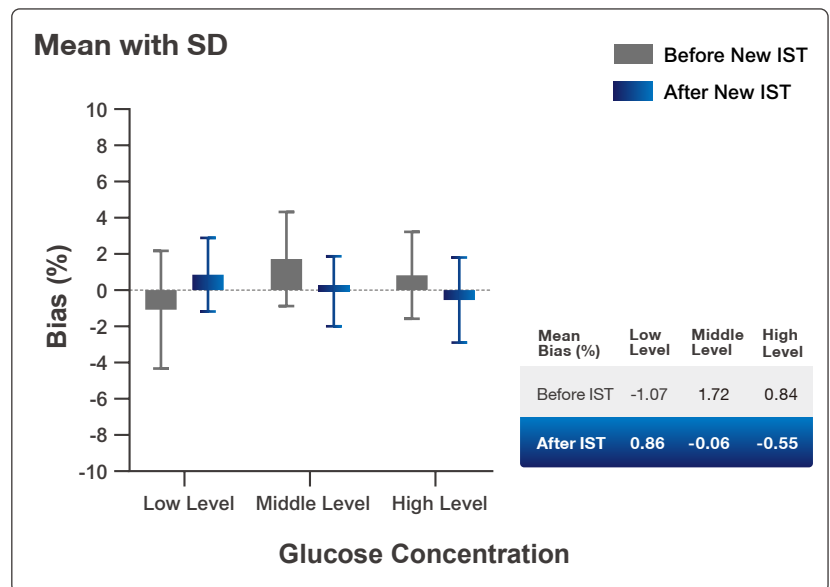
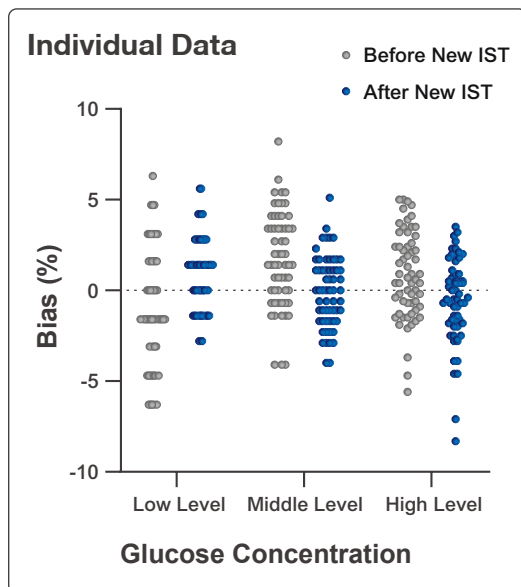
This report is intended to compare the performance of glucose measurement function for FORA® Diamond BGMS before and after the New IST based on the analysis from the existing data.

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 New IST | Mean | 63.3 | 149.5 | 540.5 |
| | SD | 2.07 | 3.82 | 12.87 |
| | CV | 3.27% | 2.55% | 2.38% |
| After New 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 New 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 MINI Meter

| | |
|-----------------------|--|
| Model No. | DM30b |
| Unique Features | Bluetooth Connectivity IST Technology |
| Dimensions | 93.0 (H) X 26.0 (W) X 15.5 (D) cm |
| Weight | 31.4 g (without Battery) |
| Ketone Warning | No. if ≥ 240 mg/dL (13.3 mmol/L) |
| Meal Tag / Mode | Yes. Pre-meal (AC) / Post-meal (PC) / QC |
| Daily Alarm | 4 Alarms |
| Strip Indicator Light | No |
| Strip Ejection | No |
| Connectivity | Bluetooth (V4.0) |
| 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 | Rechargeable lithium-polymer 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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