NOVA Primary™

Whole Blood Glucose Reference Analyzer

Nova Primary addresses the needs of glucose device manufacturers and researchers for an accurate, easy-to-use, blood glucose reference analyzer to replace the discontinued YSI STAT PLUS 2300. The Nova Primary glucose reference analyzer state-of-the-art features include:

An accurate Nova glucose sensor

25 µL whole blood sample

Automatic hematocrit measurement and correction for plasma equivalent glucose results

Simple, color touchscreen operation

Comprehensive data storage and connectivity

FDA Cleared

nova® biomedical

NOVA Primary™

Whole blood glucose reference analyzer

Nova Primary is a modern, accurate, easy-to-use, laboratory blood glucose reference analyzer that uses a 25 µl sample of whole blood or plasma. Nova Primary fills the need for a new glucose reference analyzer to replace the YSI STAT PLUS 2300 Glucose and L-Lactate analyzer (YSI, Inc., Yellow Springs, OH). Manufacturers of blood glucose measuring devices and clinical diabetes researchers need a reference and correlation analyzer. The Nova Primary analyzer fills that need with rapid, accurate glucose oxidase measuring technology, reduced maintenance, and a simple, three-step touchscreen operation.

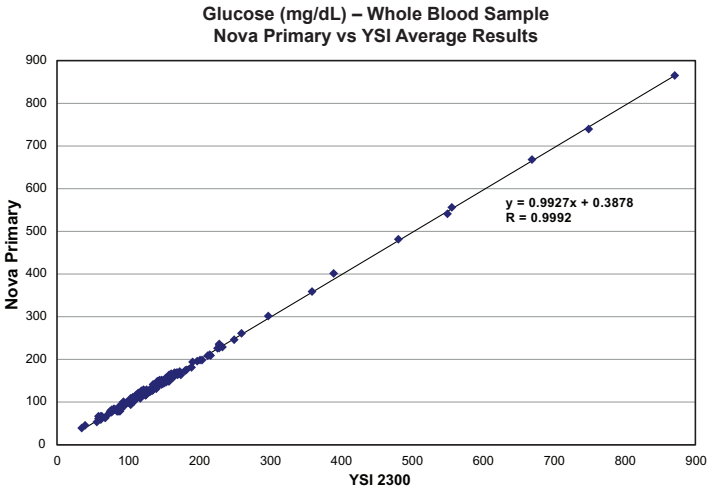
Accurate biosensor technology

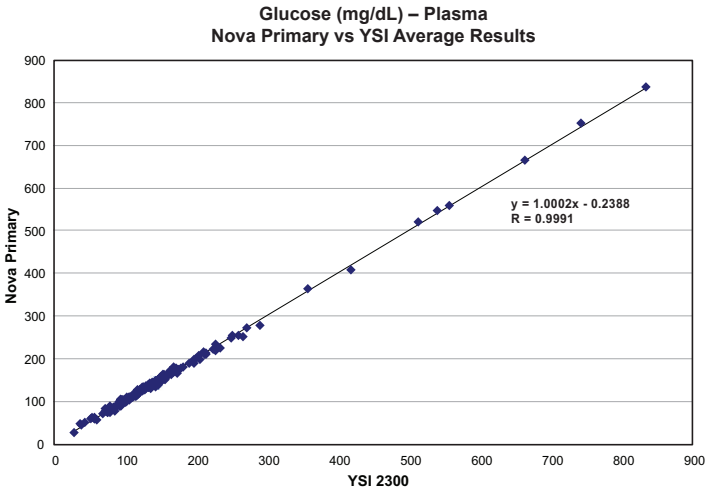
Nova Primary glucose biosensor

Nova Primary uses a glucose oxidase electrochemistry sensor to measure glucose in whole blood and plasma. Nova's Stat Profile critical care analyzers have used this technology for over 20 years. It is accurate, reliable, and proven over time. Glucose in the sample is rapidly oxidized by the biosensor's glucose oxidase membrane cap, producing hydrogen peroxide. The hydrogen peroxide is oxidized at the electrode base (platinum anode), producing a current directly proportional to the concentration of glucose in the sample. Snap-in, glucose oxidase membrane caps are easily replaced in seconds and have a use-life of up to 3 weeks. The electrode base has a use-life of up to one year.

Excellent correlation to the YSI 2300

The Nova Primary provides excellent correlation of whole blood and plasma samples to the YSI 2300 across a wide measurement range of 20-900 mg/dL. Calibrators and controls are traceable to National Institute of Standards and Technology (NIST) Standard SRM-917, assuring excellent lot-to-lot consistency and glucose testing accuracy.



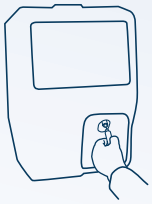



READY
Samples Remaining:
400
Date & Time
Results (mg / dL)
In Range
12/2/2022 12:27:09
95
Sample ID
123456789
Print
Cancel
Analyze
NOVA
Primary

Touchscreen operation

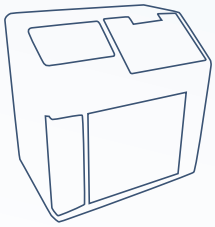
Nova Primary uses a large (10.1”) modern color touchscreen interface. It can be operated with minimal training and all functions are performed simply. For example, performing a whole blood glucose test requires only 3 steps, versus 8 steps for the YSI 2300.

Nova Primary sample analysis



1. Press Analyze
2. Position Sample
3. Press Aspirate

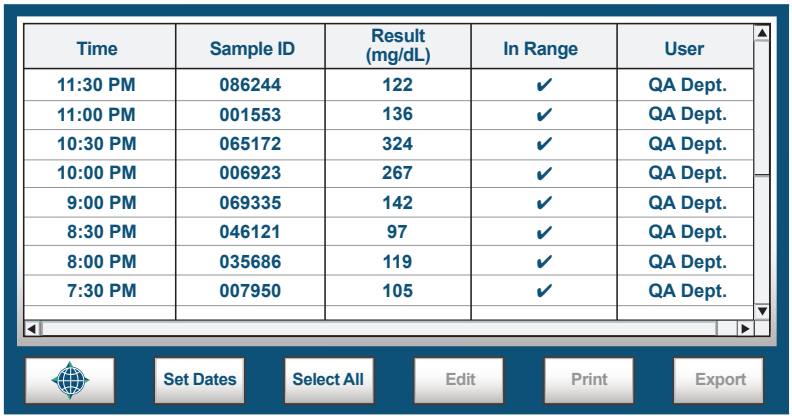
YSI 2300 sample analysis



1. Measure Hematocrit
2. Press “Run”
3. Press “Sample”
4. Enter Hct digit 1
5. Enter Hct digit 2
6. Press “Enter”
7. Position “Sample”
8. Press “Sample”

Comprehensive data storage and export

Nova Primary has on-board storage for thousands of test results and QC samples. Test data is exported through the USB port using comma delimited (csv) format for easy data capture, review, analysis, and sorting.



Time	Sample ID	Result (mg/dL)	In Range	User
11:30 PM	086244	122	✔	QA Dept.
11:00 PM	001553	136	✔	QA Dept.
10:30 PM	065172	324	✔	QA Dept.
10:00 PM	006923	267	✔	QA Dept.
9:00 PM	069335	142	✔	QA Dept.
8:30 PM	046121	97	✔	QA Dept.
8:00 PM	035686	119	✔	QA Dept.
7:30 PM	007950	105	✔	QA Dept.

Automates the analysis of plasma equivalent whole blood glucose

Nova Primary measures the hematocrit levels of whole blood samples and uses them to calculate an accurate plasma equivalent whole blood glucose. This eliminates the need for a separate hematocrit assay and manual entry of hematocrit values for each glucose sample.

Single calibrator cartridge simplifies reagent maintenance

Nova uses a single, plug-in, reagent cartridge instead of separate calibrator, buffer, and waste bottles. The Primary cartridge contains ready-to-use, pre-made calibrators and buffers, plus a built-in waste receptacle for easy maintenance. Cartridge replacement takes less than 2 minutes.

Nova Primary plug-in calibrator cartridge

Other cartridge benefits:

- Multiple cartridge sizes accommodate variable sample workloads
- RFID technology reports the cartridge expiration date and number of samples remaining
- Eliminates daily checking of individual calibration, buffer, and waste bottle levels, and separate replacement schedules
- Eliminates weekly or daily manual preparation of buffer solutions
- Eliminates maintenance to the waste receptacle, a potential biohazard

Eliminates peristaltic pump maintenance

The YSI 2300 used two peristaltic pumps and a magnetic mixer to perform sample and calibrator dilutions and mixing. Peristaltic pump tubing degrades with time and becomes loose at the fittings, affecting dilution accuracy and requiring replacement. Nova Primary uses a highly accurate, maintenance-free syringe pump to perform sample dilutions and mixing.

Syringe Pump benefits:

- Eliminates the need for periodic replacement of sample and calibrator peristaltic pump tubing
- Eliminates monthly cleaning of calibrant pumping system
- Provides consistently accurate sample dilution and mixing

Cybersecurity protection

Nova Primary has extensive safeguards to protect the system from outside cybersecurity attacks. The main operating system is an embedded, light version of Windows® with Windows Defender anti-virus firewall.

Nova Primary specifications

Glucose Measurement Range: 20 - 900 mg/dL

Acceptable Samples: Whole blood (heparinized) and plasma

Sample Volume: 25 µL

Glucose Measurement Time:
Single analysis: 1.5 minutes
Throughput: 35 samples per hour

Operating Temperature Range: 15°C - 32°C (59°F - 89.6°F)

Electrical Power Requirement: 180 Watts

Printer: On-board Thermal Printer

Certifications:
Universal: EN ISO 13485:2016

EU: EN 61010-1:2010/AMD1:2019; EN 61010-2-101:2017; EN 61326-2-6:2013; EN 55011:2016

US: IEC 61010-1:2010/AMD1:2016; IEC 61010-2-101:2018; IEC 60601-1-2:2014

Calibration: Fully automatic two-point calibration; user selectable single-point calibration or with each sample. Manual calibration initiated at any time.

Communication Protocols:
ASTM, HL7, or POCT1-A2 connectivity formats.

Physical Specifications: 26.5 lb (12.0 kg) without reagent pack; 31.9 lb (14.5 kg) with full reagent pack, power supply and wireless keyboard. It can be operated benchtop or on a mobile cart with battery backup.

Compact Size

Weight:
26.5 lb (12 kg) without reagent pack

Optional Mobile Cart with Power Supply

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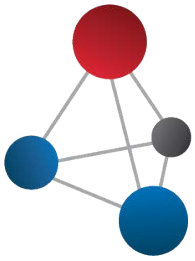
Specifications current as of revision date. 533C V1 US/INT 7/10/23

Notes:



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