REF 63438

IVD Rx Only CE

Nova Primary Glucose Analyzer

nova® biomedical

Instructions for Use Manual

Nova Primary Glucose Analyzer Instructions for Use Manual

Ordering Information

The Nova Primary Glucose Analyzer Instructions for Use Manual can be ordered from Nova Biomedical Order Services. Write or call:

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Waltham, MA 02454 U.S.A.

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FAX: 1-800-316-1178 (in the U.S.A.) or
+1-781-891-9718 (outside the U.S.A.)
Website: www.novabiomedical.com

EC REP Authorized Representative

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Technical Assistance

For technical assistance inside the United States and Canada, call Nova Biomedical Technical Services at:

U.S.A.: 1-800-545-NOVA (1-781-894-0800) or FAX: 1-781-894-0585
Canada: 1-800-263-5999

Technical Assistance

For technical assistance outside the United States and Canada, call your local Nova subsidiary or authorized distributor.

Nova Biomedical recommends users report any **serious incidents/adverse events** back to Nova Biomedical or Nova Biomedical's Authorized Representative as well as to their local Competent Authority as required.

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NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD — *In vitro* diagnostic medical device

 Caution

 Consult instructions for use

 Biological risk

REF — Catalog number

 Manufactured by

CONTROL — Control

LEVEL — Level

 Hazard

LOT — Batch code

SN — Serial Number

 Temperature limitation

Use by

 Electronic Waste

EC REP — Authorized Representative in the European Commission

 Laser Radiation - Do Not Stare Into Beam

℞ Only — Prescription Use Only

Revision History

Rev.	Release	Description
A	12-2021	Initial Release
B	06-2023	FDA 510(k) review and IVDR compliance updates
C	09-2024	Updates to include latest software features

Table of Contents

1 INTRODUCTION

This manual provides all necessary instructions for the routine operation and upkeep of the Nova Primary Glucose Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your analyzer.

WARNING: Blood samples and blood products are potential sources of infectious agents. Handle all blood products and flow path components (waste-line, sample probe and adaptor, sensor, membrane cap, etc.) with care. Gloves and protective clothing are recommended. When performing maintenance and troubleshooting procedures, also use protective eyewear.

1.1 ABOUT THIS MANUAL

This manual is for the Nova Primary Glucose Analyzer.

This section introduces the Primary Glucose Analyzer and covers requirements, tests performed, procedural limitations, clinical utility, and sample handling.

Throughout this manual:

NOTE indicates especially important information;

CAUTION indicates information that is critical to avoid instrument damage or incorrect results;

WARNING indicates a possible hazard to the operator.

1.2 SAFETY

Personnel operating this analyzer must be proficient in the operating and replacement procedures of the analyzer. The following safety procedures should be followed.

General Safety

1. Read the safety and operating instructions before operating the analyzer.
2. Retain the safety and operating instructions for future reference.
3. Observe all warnings on the analyzer and in the operating instructions.
4. Follow all operating and use instructions.
5. Do not use the analyzer near water, for example near a sink, etc.
6. Use only with a cart or stand that is recommended by the manufacturer. The analyzer and cart combination should be used with care. Quick stops, excessive force, and uneven surfaces may cause the analyzer and cart combination to overturn.
7. Place the analyzer so that its location or position does not interfere with its proper ventilation.
8. Place the analyzer away from heat sources.
9. Connect the analyzer to a power supply only of the type described in the operating instructions or marked on the analyzer.
10. Do not defeat the safety purpose of the polarized or grounding-type plug.
11. Route power cords so that they are not likely to be walked on or pinched by items placed upon or against them, paying particular attention to cords at plugs, power sockets, and at the point where they exit from the analyzer.
12. The analyzer should be cleaned only as recommended by the manufacturer.
13. Take care not to let objects or liquids fall into the analyzer.
14. The analyzer should be serviced by qualified service personnel.
15. Do not attempt to service the analyzer beyond that described in the operating instructions. All other servicing should be referred to qualified service personnel.

Electrical Safety

1. To reduce the risk of electric shock, do not remove the cover.
2. There are no user-serviceable parts inside the analyzer.
3. Servicing must be done by qualified service personnel.
4. To reduce the risk of fire or electric shock, do not expose the analyzer to water.
5. Use Nova Part Number 64118 external power supply to power up the analyzer.
6. Ensure that the wall outlet receptacle is properly wired and earth grounded.
7. DO NOT use a 3-to-2 wire plug adapter.
8. DO NOT use a 2-wire extension cord or a 2-wire multiple-outlet power strip.

Chemical and Biological Safety

1. Observe all precautionary information printed on the original solution containers.
2. Operate the analyzer in the appropriate environment.
3. Take all necessary precautions when using pathologic or toxic materials to prevent the generation of aerosols.
4. Wear appropriate laboratory personal protective equipment (PPE), e.g., safety glasses, gloves, lab coat, and breathing apparatus, when working with hazardous materials.
5. Dispose of all waste solutions according to standard hospital procedures and local regulations.

Disposal of Used Analyzers for Customers in Europe

This symbol () on the product label indicates that the product should not be treated as household waste.

Device/Accessories: To ensure the product is disposed of properly, clean all analyzer surfaces and components and hand over the product to the applicable collection point for the recycling of electrical and electronic equipment.

1.3 INSTALLATION AND USE

This section covers the installation requirements and assembly procedures for the Nova Primary Analyzer. Before using the analyzer, operators should be familiar with the Operation and Operating Procedures described in this manual.

Federal Communications Commission (FCC) Notice

The Nova Primary Analyzer complies with Part 15 of the FCC Rules: Operation is subject to the following conditions:

1. The Nova Primary may not cause harmful interference.
2. The Nova Primary must accept any interference received, including interference that may cause undesired operation. Changes and Modifications not expressly approved by Nova Biomedical Corporation can void your authority to operate this equipment under the Federal Communications Commission rule.

NOTE: Under the warranty, a Nova factory trained service representative will install this equipment for you.

1.4 REQUIREMENTS

Working Area Requirements (Environmental):

Keep the working area around the system free of dirt, corrosive fumes, vibration, and excessive temperature changes.

Table 1-1 Nova Primary Requirements

Electrical Requirements	
Operating Voltage Range	100 – 240 VAC
Operating Frequency	47 – 63 Hz
Power Consumption	Maximum: 180 W, Typical Load: Less than 100 W
Heat Load	Maximum: 614BTU/hr., Typical: Less than 340 BTU/hr.
Ambient Operating Temperature	15 °C – 32 °C (59°F – 89.6°F)
Operate at Humidity	20 to 85% (noncondensing)
Operate at Altitude	up to 10,000 feet (3050 meters)
Dimensions	
Height	17.2 in (43.8 cm)
Width	11.3 in (28.8 cm)
Depth	17.8 in (45.3 cm)
Weight	
26.5 lb (12.0 kg) without reagent pack	
31.9 lb (14.5 kg) with full reagent pack, power supply and wireless keyboard	

Lifting the Analyzer:

1. One person is needed to lift the analyzer.

CAUTION: Never use the door (open or closed) to assist you in lifting the analyzer. The door cannot support the weight of the analyzer.

2. From the front of the analyzer, place your hands under each side of the analyzer.
3. Lift the analyzer. Remember to bend your knees and lift with your legs and not your back.
4. Place the analyzer on a clean, flat surface.

1.5 CLEANING THE ANALYZER

Nova Biomedical recommends using 70% reagent alcohol (v/v) or isopropyl alcohol (IPA) for cleaning the various analyzer surfaces or components when required. When using alcohol, use a lint-free cloth lightly dampened with the cleaning reagent to wipe down the analyzer surfaces. Never spray or pour reagent directly onto or into the analyzer. Once wiped down, dry all residual fluid with a lint-free cloth.

1.6 INTENDED USE, TESTS PERFORMED, AND CLINICAL UTILITY

Intended Use

The Nova Primary Glucose Analyzer System is indicated for *in vitro* diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of Glucose in lithium heparinized venous whole blood and plasma.

Measured Parameter

Glucose

Clinical Utility

Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

1.7 THE SAMPLE

- Lithium heparin venous whole blood and plasma samples from syringes, blood collection tubes, and small cups.
- The minimum sample size for analysis is 25 µL.

1.7.1 HANDLING REQUIREMENTS

Correct sample handling is critical to ensure that the values obtained accurately reflect the in vivo state. Ensure that all samples have been obtained and stored following consistent, clinically accepted protocols.

Whole Blood

Venous blood samples should be collected with minimal stasis, without the exercise of the arm. Collect blood for analysis in vacuum tubes containing lithium heparin. It is particularly important to ensure that samples are well mixed before introduction into the analyzer. Nova Biomedical recommends that you analyze the sample within 15 minutes for glucose to minimize the clinical impact of glycolysis on the measured glucose result. Measurement delays greater than 15 minutes may impact the clinical accuracy of the whole blood glucose measurement.

Plasma

The Current CLSI Guideline is GP44-A4 Vol. 30 No. 10 (replaces document H18) indicates that plasma should be physically separated from contact with cells as soon as possible to a maximum time limit of 2 hours from the time of collection.

Collect plasma samples with minimal stasis, without the exercise of the arm, in vacuum tubes containing lithium heparin. Obtain plasma by centrifuging heparinized whole blood within 1 hour of collection. Following centrifugation at 1000 RCF for 10 to 15 minutes, remove the cap and use a syringe or bulb pipette to obtain a plasma sample. Take the sample from the area close to the cells. Plasma samples more than 1 hour old should be centrifuged immediately before analysis to remove any fibrin clots. If assays will not be completed within 8 hours, the plasma sample should be stored refrigerated at 2 to 8˚C. If assays will not be completed within 48 hours or if the plasma sample is to be stored beyond 48 hours, the samples are to be stored frozen at -20˚C.

References

1. CLSI Guideline GP44-A4. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline - Fourth Edition.
2. CLSI Guideline GP41, 7th Edition. Collection of Diagnostic Venous Blood Specimens.
3. Jacobs., Kasten, DeMott, and Wolfson, ed. 1990. Laboratory Test Handbook. Lexi-Comp Inc.
4. Tietz, N.W., ed. 1986. Textbook of Clinical Chemistry. W.B. Saunders Co.

1.7.2 Acceptable Anticoagulants

- **Lithium heparin** is the **acceptable anticoagulant** for use with the analyzer.
- EDTA, citrate, oxalate, sodium heparin, and sodium fluoride have not been evaluated for use.
- Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, heparin concentrations of 20 I.U. per mL to over 100 I.U. per mL may result.
- Liquid or dry heparin when present in **excess** of 100 IU/mL may **cause errors.** Ensure blood collection devices are filled per manufacturer's instructions.
- Our experience suggests that lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable.

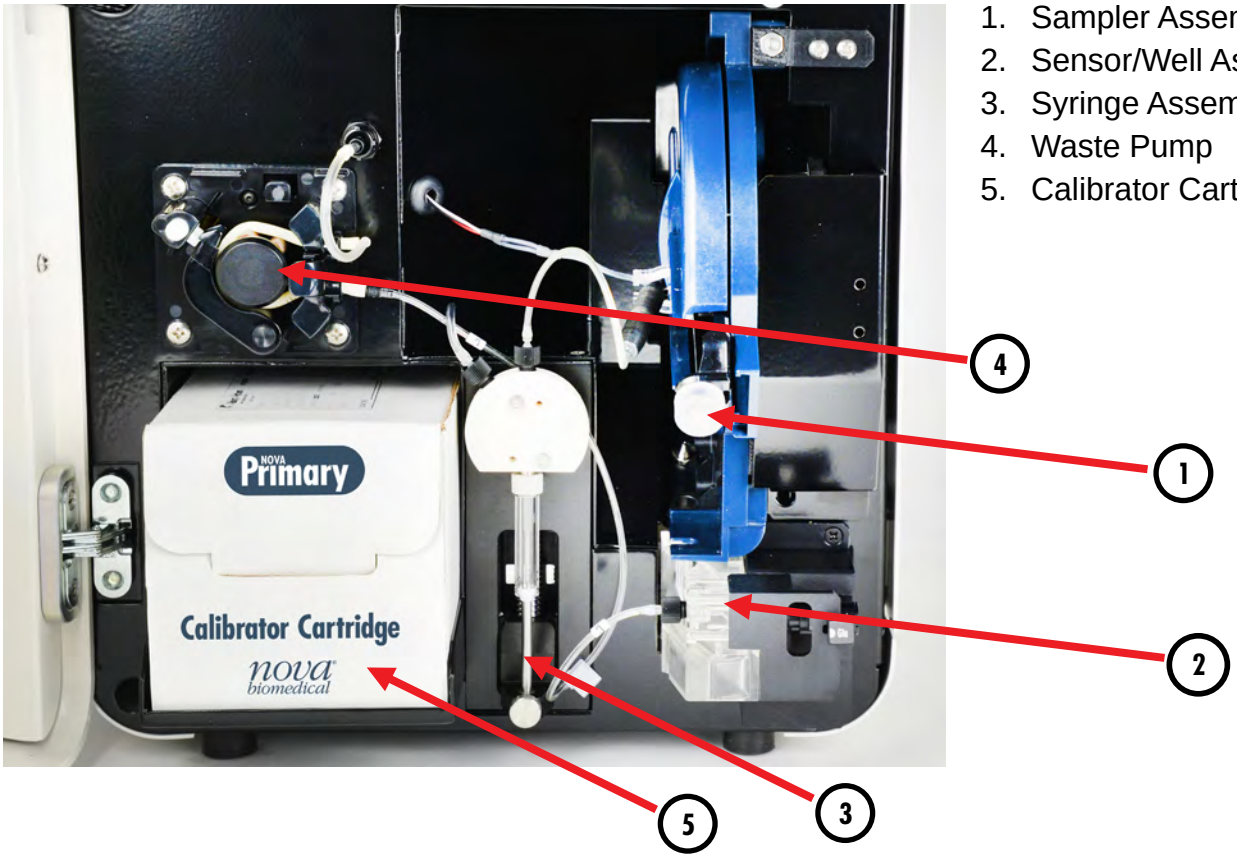
1.8 Warnings and Precautions

- To ensure optimal system performance, the Use By symbol  printed on the glucose membrane, glucose sensor, syringe, sample probe, and pump tubing packaging indicates the last date they should be installed on the analyzer.
- Operators should periodically inspect the sample flowpath for signs of fluid leakage. This includes the syringe, sample probe, waste pump, and all tubing connections to these components. If a potential leak is observed, please contact Nova Technical Support or your authorized Nova distributor for assistance.
- Whole blood samples with Hematocrit values below 17% or above 62% have not been evaluated for use on the system.

2 GETTING STARTED

The Nova Primary Glucose Analyzer is pictured below.

1. Touch-screen Display
2. Printer
3. Sampler
4. Door/Front Panel



1. Sampler Assembly
2. Sensor/Well Assembly
3. Syringe Assembly
4. Waste Pump
5. Calibrator Cartridge

2.1 ANALYZER STARTUP PROCEDURE

The Nova Primary Glucose Analyzer is a semi-automated instrument. When the Nova Primary Analyzer is powered on, it automatically loads the required operating sequences and launches the Graphical User Interface (GUI) on the touch screen display. When the power-up procedure is complete, the User Account Login window will be displayed.

To navigate the User Interface and to enter alphanumeric text, the operator can use a combination of the touchscreen display, a popup keyboard overlay on the display, an external wireless keyboard, and the wireless barcode scanner.

To use the keyboard overlay, press the keyboard icon  when displayed on the screen and use it as you would any keyboard. Use the arrows in each corner to move the keyboard to a desired corner of the screen, or touch and drag the keyboard to the desired location. Press any arrow key to display additional special characters. Press the red X to remove the keyboard from the screen.

NOTE: If the active screen does not support special characters, the additional characters are not shown.

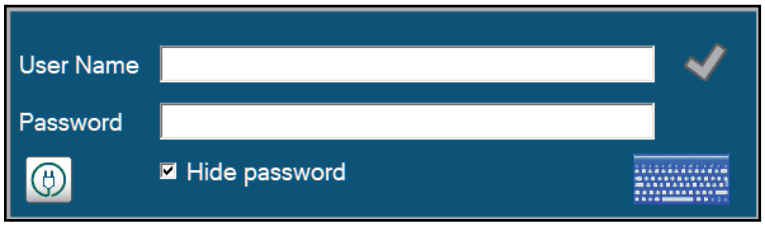
2.2 THE USER INTERFACE

During the initial installation, an Administrator User Account and Password must be created to log into the analyzer's User Interface. This Administrator account is then used to create any additional Administrator or User accounts and passwords required for other operators. User Names must be a minimum of 3 alphanumeric characters and are not case sensitive. User Passwords must be a minimum of 8 and a maximum of 25 alphanumeric characters and must contain at least one capital letter and one number. Passwords are case sensitive and should not include spaces or special characters (!,@,#,$,%,^,&,*,/,<).

The default Administrator account User Name is Flex2admin. The password is Password1. Once logged in, you will be prompted to change the password.

2.2.1 LOG-IN TO THE ANALYZER

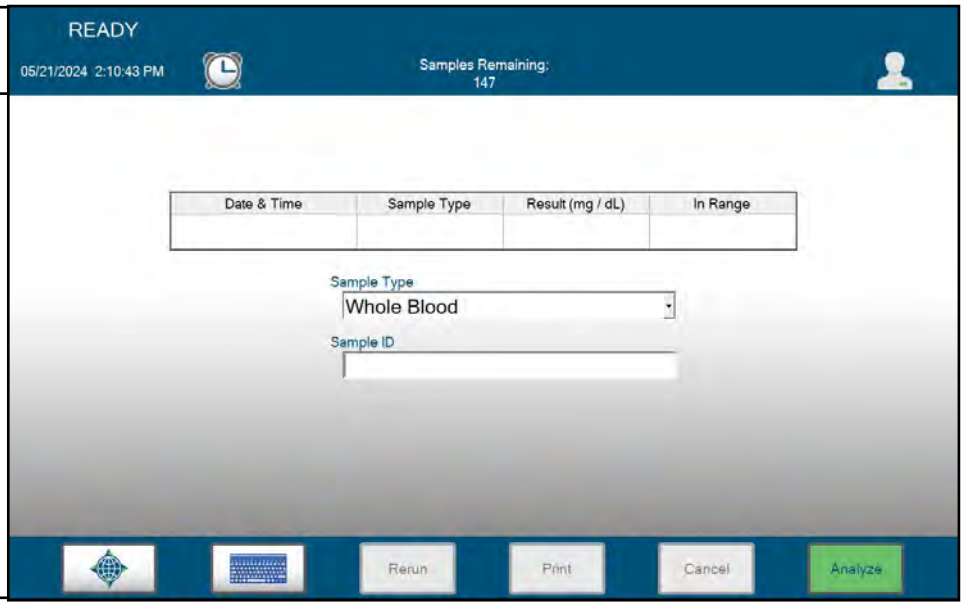
Pressing the Destination Screen button in the lower-left corner of the touchscreen will display the Destinations Overlay used to navigate through the user interface.



The operator is prompted to enter their Username and Password. The operator can also choose to power down the analyzer by selecting the plug icon in the lower left-hand corner of the log-in window.

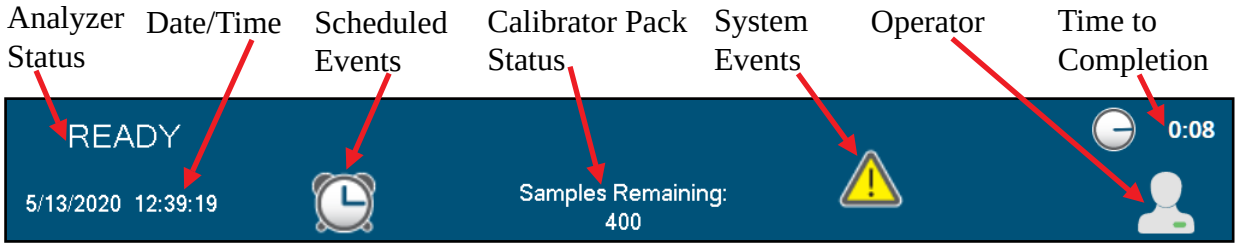
Once a valid Username and Password is entered, the checkmark to the right of the Username will turn green ✓. Press Enter on the keyboard or tap the green check mark to access the User Interface.

When first logging into the analyzer, the Sample Analysis screen is displayed. On this screen, the operator can see the current system status and access the remainder of the user interface features. The display contains two sections, the Status Bar, and the Destination Screen.

Status Bar	
Destination Screen	

2.2.2 THE STATUS BAR

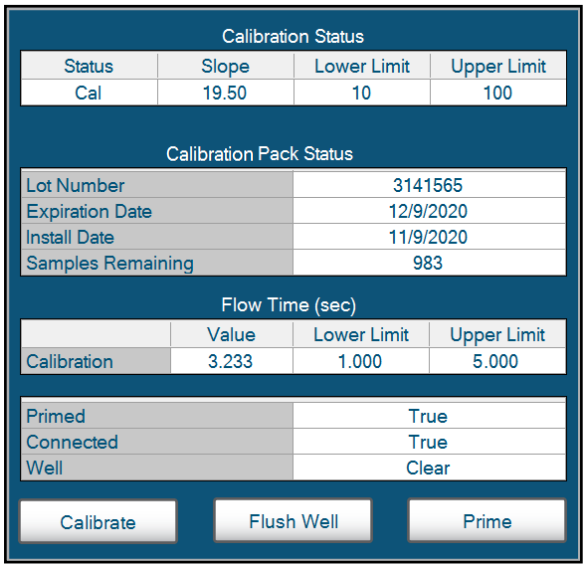
The Status Bar at the top of the screen shows the current Analyzer Status, Date and Time, next Scheduled Event, Calibrator Pack status, System Events, the currently logged in Operator (when login is required), and time to completion.



Analyzer Status – indicates if the analyzer is **Ready** for analysis or **Busy** with a blue background. If the analyzer is **Not Ready** for analysis, **Not Ready** is displayed with a yellow background.

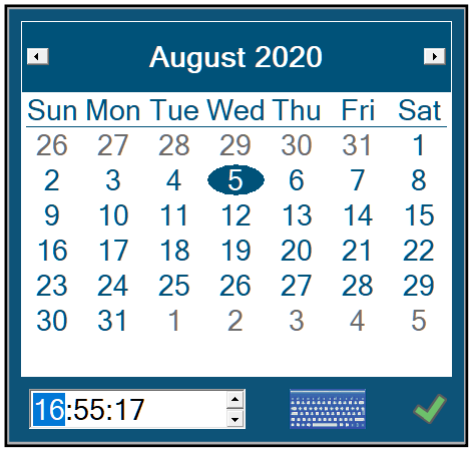
Press on any open area on the Status Bar to display the Analyzer Status Overlay. The overlay provides additional information about the Calibration Status, Calibrator Pack Status, and other system status data.

Operators are also able to Flush the waste well and Prime the Calibrator Pack from the overlay as required.

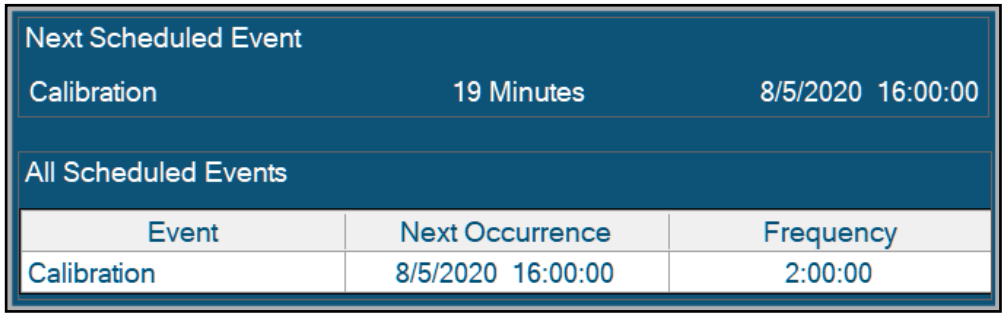


Date/Time – displays the current system date and time.

Press the Date/Time on the status bar to display the Date/Time overlay. Operators can update the current system date and time from the overlay.



Scheduled Events – press the Scheduled Events icon to display the next scheduled event's date and time. If a scheduled calibration is due in less than 5 minutes the icon will be displayed with a yellow background and a countdown timer indicating how much time is left before the calibration will begin.

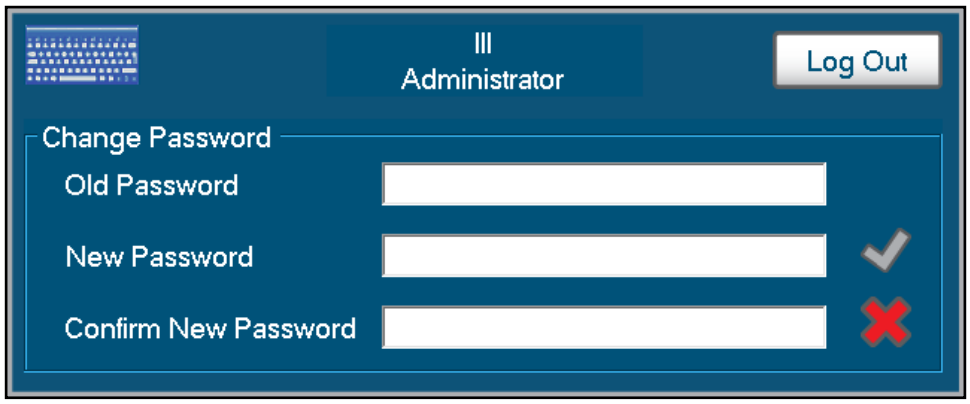


Calibrator Pack Status - displays the estimated number of samples remaining in the Calibrator Pack. When less than 10% of the pack is remaining, **< 10%** is displayed with a yellow background. If the Calibrator Pack is **Empty, Expired,** or **Not Installed**, the status is displayed with a red background.

System Events – press the System Events icon to display the Event overlay. This will provide additional information to help the operator identify any problems with the system. Touch the display to clear the event overlay.

Operator – press the Operator icon to Logout of the User Interface or to update the logged-in user's password.

Operator Logout/Change Password Overlay



Time to Completion – a countdown timer is displayed whenever an active process is running on the analyzer. The timer displays the amount of time left until the process is completed.

2.3 DESTINATION SCREENS

The Destination Screens are accessed to analyze patient and Quality Control samples, review test results, and to configure, maintain, and service the Nova Primary Analyzer. Destination Screens are displayed below the Status Bar on the touchscreen display and change to the selected Destination.

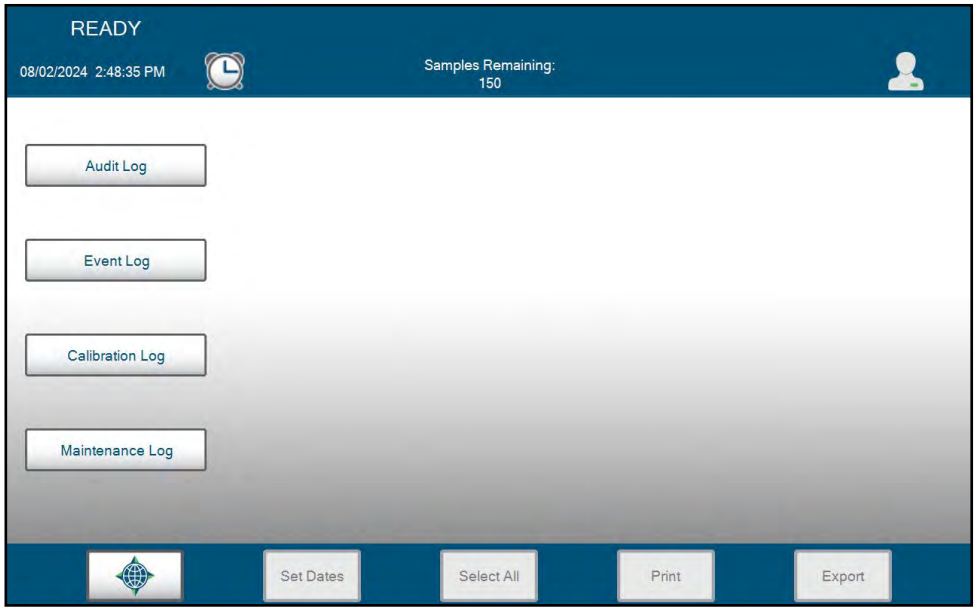
Pressing the Destination Screen button in the lower-left corner of the touchscreen will display the Destinations Overlay used to navigate through the user interface.

Destination screens include:

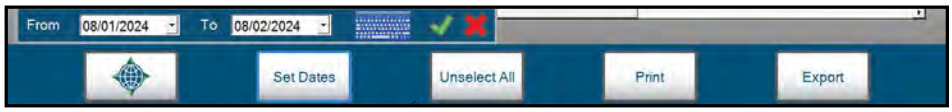
- System **Logs** - Audit Log, Error Log, Calibration Log, and Maintenance Log
- **Calibrate** the system manually.
- **Service** level features
- **QC** configuration and testing menu
- System **Configuration** options
- System **Maintenance** procedures
- Sample **Analysis** testing menu
- Previous **Results History**
- **Shut Down** the analyzer if needed.

2.3.1 LOGS

The Logs screen provides access to the analyzer Audit, Error, Calibration, and Maintenance Logs. Select the button of the log to display to show any entries for the current date.



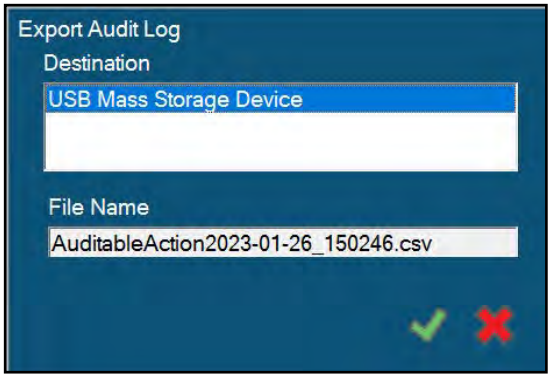
The **Set Dates** button on the bottom of each log screen allows the operator to enter a date range of the log entries to display.



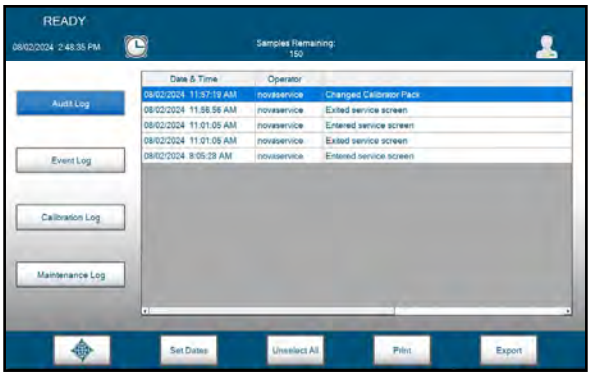
To Print reports, use the **Select All** button or select individual entries in the displayed list, then press the **Print** button.

To Export log entries as a comma separated values (.csv) file, insert a compatible USB drive in the USB port on the back of the analyzer. Use the **Select All** button or select individual entries in the displayed list, then press the **Export** button.

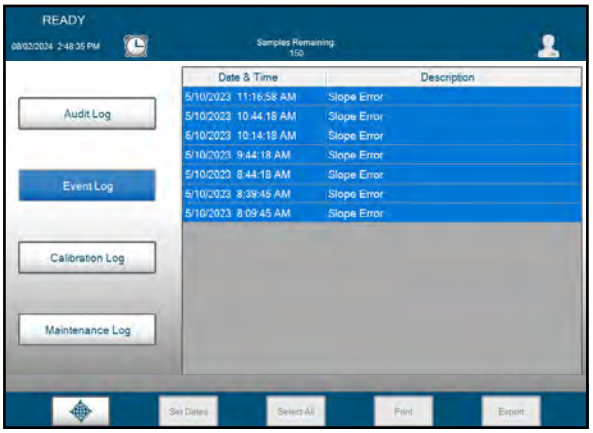
The analyzer will create a file name based on the log being displayed and current date and time. Select the green checkmark to copy the file to the USB drive, or press the red **X** to cancel.



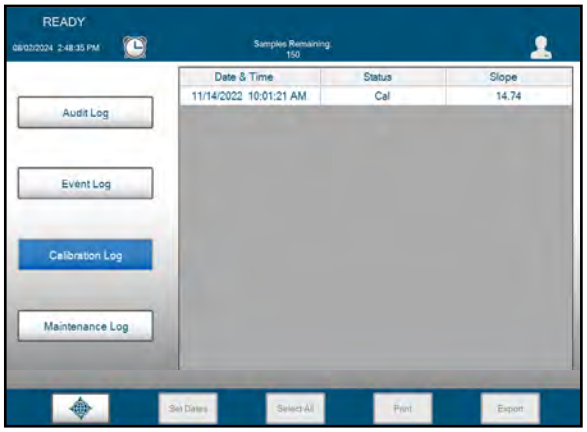
Audit Log – the Audit Log contains the date and time and the operator ID that an auditable action was performed. For a list of recorded activities, see *Section 7.6 Auditable Actions*.



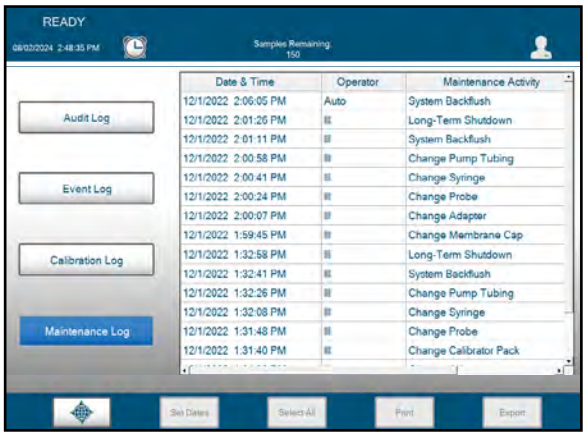
Event Log - The Event Log will display the date and time an event occurs and a brief description of the event. Refer to Chapter 6 Troubleshooting for more information on system events. Operators cannot delete or modify the Event Log.



Calibration Log - The Calibration Log displays the date and time of each system calibration, the calibration status, and the slope of the glucose sensor.



Maintenance Log - The Maintenance Log displays the date and time each maintenance activity was performed, the operator that performed the maintenance, and the maintenance activity performed.



2.3.2 CALIBRATE

Press the Calibrate button to initiate a 2-point calibration of the Glucose sensor/membrane and air detectors.

2.3.3 SERVICE

The Service screen contains advanced user and service only functions. Please refer to *Chapter 7 Advanced User Functions*.

Install Software – used by your local Nova Service representative to update analyzer software when a new release is made available.

Flowpath Service – provides manual control of the analyzer's electromechanical components for use in troubleshooting system errors.

Clear Data – provides a means of permanently clearing patient and QC data as well as selected log files from the analyzer's database.

System Backflush – used to clear any obstructions within the sensor/dilution well assembly.

Long Term Shutdown – used to shutdown the analyzer for extended periods of time.

Resource Issues – contains additional information on errors logged by the analyzer. Used by Technical Support and Service representatives for troubleshooting purposes.

Clear Print Queue – tool to purge any queued printer files if needed.

Tools – used by your local Nova Service representative as a troubleshooting aid.

Auto Log – provides a means of downloading analyzer log files for review by Nova's software development team if needed.

PSoC's – (Programmable System on Chip) Displays the status and software version of the analyzer Controller and Sensor Well assemblies.

2.3.4 QUALITY CONTROL (QC)

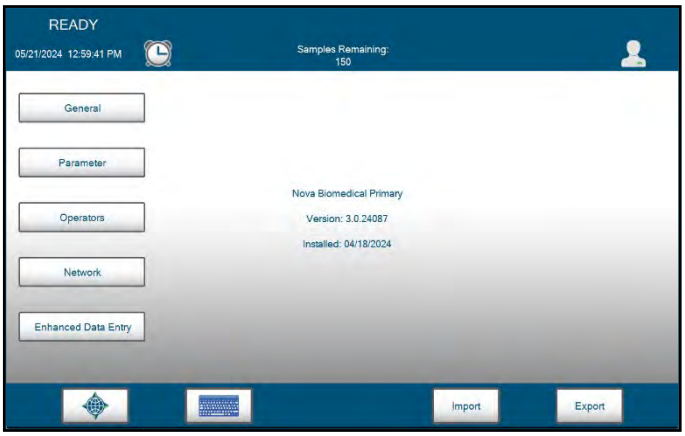
The QC screen provides the ability to configure and analyze Quality Control (QC) samples on the analyzer.

Analysis – select the Analysis button then select the desired QC, Linearity, or Proficiency Level to analyze.

Results – select the Results button to review past QC sample results.

Configuration – select the Configuration button to add new QC, Linearity, or Proficiency lot numbers and expected ranges.

2.3.5 CONFIGURATION



The Configuration screen provides a way to customize the analyzer for the location where it will be used.

General – select the General button to enter an analyzer ID and location and select from several options to customize the analyzer as desired.

Parameter – select the Parameter button to choose the unit of measure, measurement resolution, and modify the reportable analytical measurement range.

Operators – select the Operators button to add new or edit existing operators.

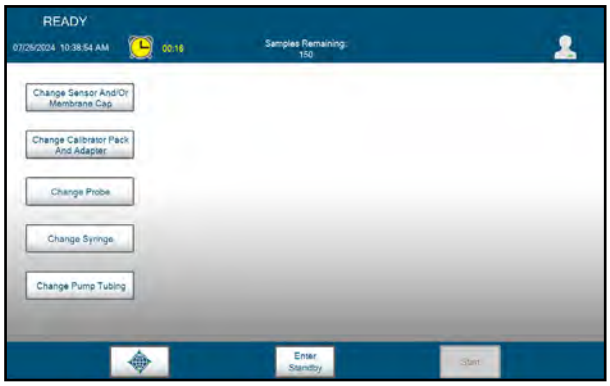
Network – for future connectivity options.

Enhanced Data Entry - displayed when enabled in the General Configuration menu. Allows custom text or list fields to be added by the end user.

Import – import an analyzer configuration file from a USB device.

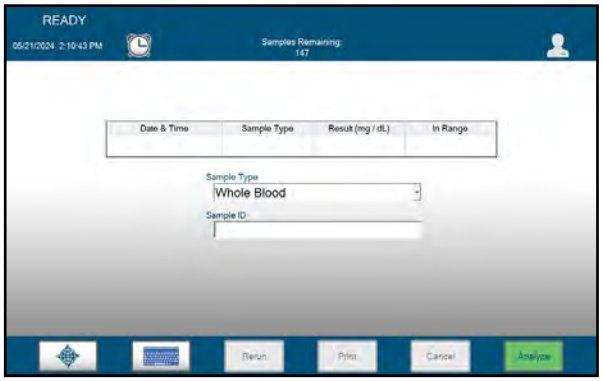
Export – export the current analyzer configuration file to a USB device.

2.3.6 MAINTENANCE



The Maintenance screen provides a means of replacing the consumables used on the analyzer, flushing the system if necessary, placing the analyzer in Standby, and taking it out of Standby. Step-by-step instructions for these maintenance procedures can be found in Chapter 4.

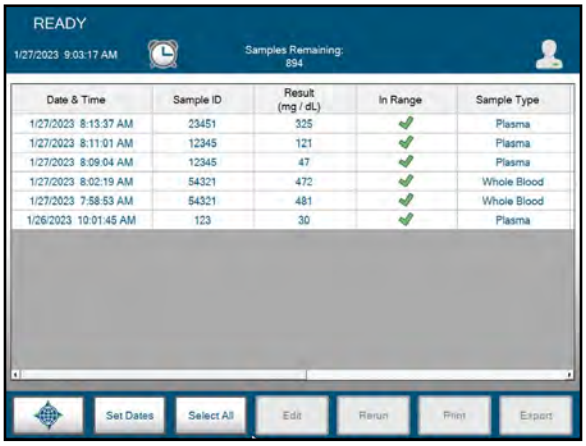
2.3.7 ANALYSIS



The Analysis screen is displayed when preparing to run patient samples. The operator selects the Sample Type if necessary, enters a sample ID, and presses Analyze to begin the sample analysis. Results are posted as soon as they are available.

2.3.8 RESULTS HISTORY

The Results History screen displays all samples for the current date. The date range can be modified to show additional samples. Selected samples can be printed or exported to a USB device.



2.3.9 SHUT DOWN

Press Shut Down to shut down the analyzer. An "Are You Sure?" popup will be displayed, select **Yes** to shut down the analyzer. Select **No** to cancel the shut down process.

2.4 SYSTEM CALIBRATION

The Nova Primary performs a 2-point calibration of the glucose sensor and membrane and the system's air detectors every two hours to maintain optimal sensor performance. A 1-point calibration is run during each whole blood sample analysis to confirm the current sensor/membrane calibration has not changed. Due to differences in the sample matrix, a 1-point calibration is run on Plasma samples every 30 minutes or after every 10 samples, whichever occurs first.

2-Point calibrations also occur more frequently after a sensor or membrane is changed. For the first two hours, calibrations are run every 30 minutes. For the next two hours, calibrations occur every hour. After four hours, the analyzer returns to its normal 2-hour calibration frequency.

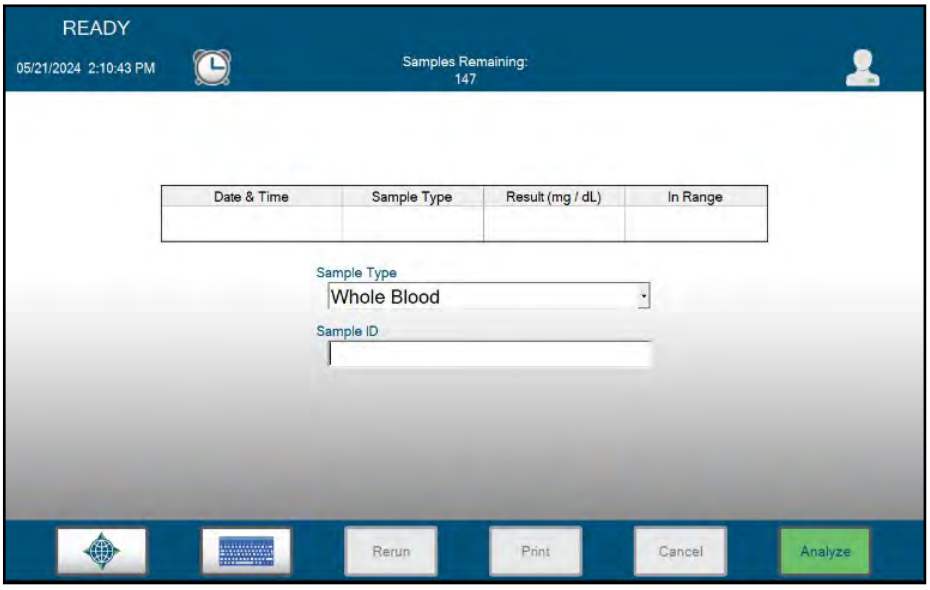
3 SAMPLE ANALYSIS

The Nova Primary Glucose Analyzer System was designed for *in vitro* diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of Glucose in lithium heparinized venous whole blood and plasma samples.

3.1 ANALYZING A WHOLE BLOOD OR PLASMA SAMPLE

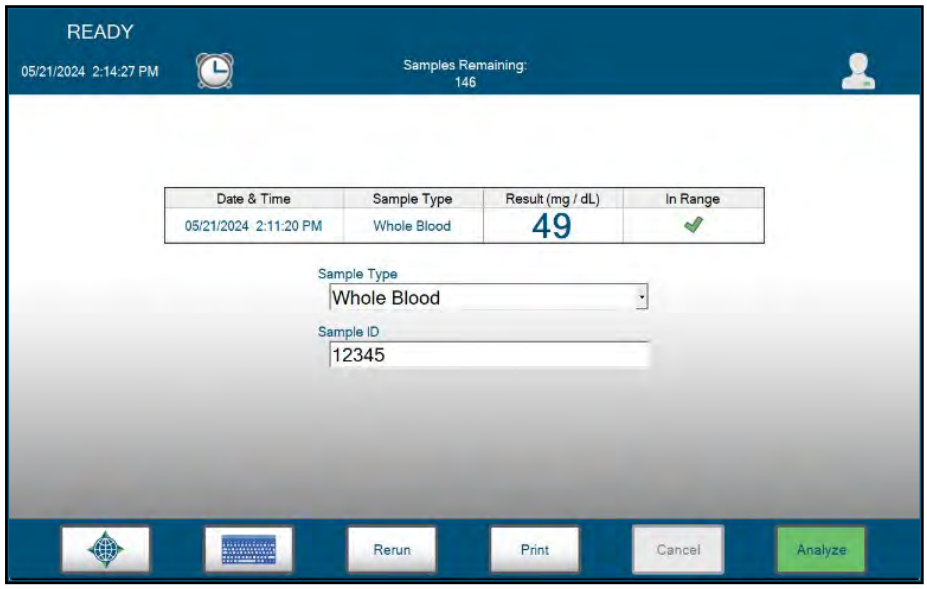
To analyze a whole blood or plasma sample:

1. Verify the analyzer is **READY** to analyze the sample.
2. If necessary, press the **Destinations** button then select **Analysis** to display the Sample Analysis screen.
3. Select Sample Type, Whole Blood or Plasma, if necessary. The default Sample Type is displayed automatically.
4. Enter a Sample ID of up to 40 alpha-numeric characters, if desired.
5. Press **Analyze** to extend the sample probe.



6. Position the sample container so the sample probe is immersed in the sample, then press **Aspirate**.
7. The analyzer aspirates the sample into the flowpath, the sample probe retracts, and the analysis starts. If desired, press **Cancel** to terminate the analysis.

8. The analyzer displays the sample results on the screen. If enabled, the on-board thermal printer prints the results. If not enabled, press the **Print** button to print the results, if desired.
9. Results within the expected normal range are displayed with a green checkmark ✓. Results below the expected range are displayed with a red down-arrow ↓, results above the expected range are displayed with a red up-arrow ↑.



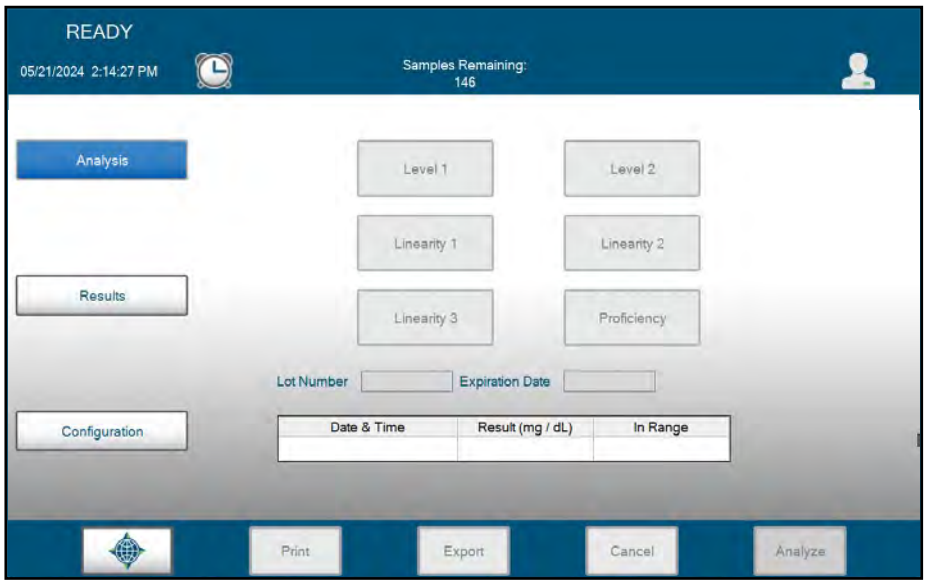
NOTE: ***Sample IDs, and any additional sample information fields, are blank when the Analysis screen is first accessed from the Destinations button. After the initial sample analysis, these fields are left filled in to minimize reentry of sample information when repeating an analysis on the same sample multiple times. The fields are editable if any changes are needed.***

NOTE: ***If desired, press the Rerun button to display a free text entry popup to describe the reason the sample was rerun. Press the green checkmark to save the entry and close the popup window, or press the red X to discard any changes and close the window.***

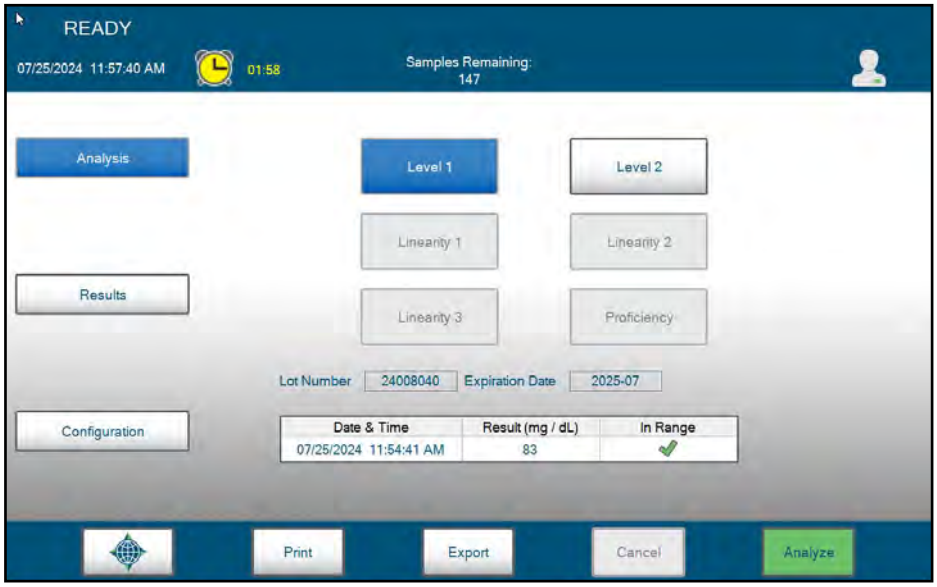
3.2 ANALYZING A QC SAMPLE

To analyze a Quality Control sample:

1. Verify that the analyzer is **READY** for a QC sample analysis.
2. If necessary, press the **Destinations** button then, select **QC** to display the QC screen.
3. Select **Analysis**, then select the button for the desired QC, Linearity, or Proficiency sample.
4. Press **Analyze** to extend the sample probe.
5. Position the QC vial so the sample probe is immersed in the sample, then press **Aspirate**.
6. The analyzer aspirates the sample into the flowpath, the sample probe retracts, and the analysis starts. If desired, press Cancel to terminate the analysis.
7. The analyzer displays the sample results on the screen. If enabled, the on-board thermal printer prints the results.



8. Results within the expected range are displayed with a green checkmark ✓. Results below the expected range are displayed with a red down-arrow ↓, results above the expected range are displayed with a red up-arrow ↑.



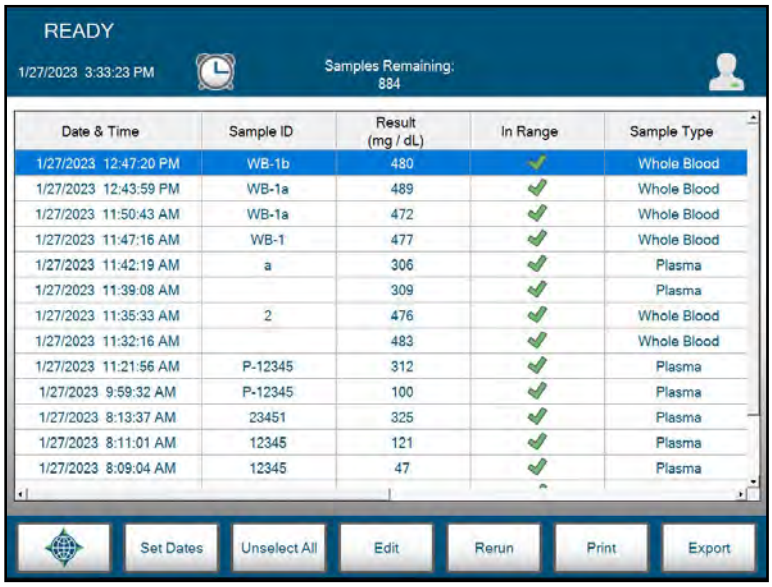
3.3 RECALLING SAMPLE RESULTS

Previously analyzed sample results are retained indefinitely in the analyzers database. These samples can be recalled for review, printed, and exported to a USB device as a .csv file for use in an offline spreadsheet. Samples can also be rerun by first selecting a sample, then pressing the Rerun button. The sample analysis screen is displayed with the sample information from the selected sample entered.

NOTE: Use the left/right and up/down scrollbars to view additional sample details.

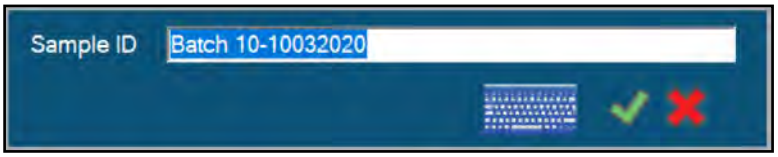
To recall sample results:

1. If necessary, press the **Destinations** button, then select **Results History** to display the Results History screen. Samples analyzed on the current date are shown automatically.



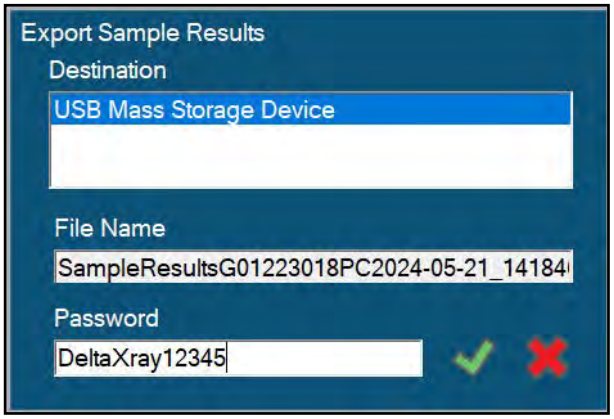
2. To expand the date range of the displayed samples, press the **Set Dates** button and enter the starting and ending date range for samples to be displayed. Press the green checkmark to display the results or press the red X to cancel.

3. An individual result's Sample ID can be edited by first selecting the sample ID to edit, then pressing **Edit**. The Sample ID is displayed and can be updated by the user. Press the green checkmark to save any changes or press the red X to cancel without saving.



4. To print a sample result, first select the sample to print then press the **Print** button. Select multiple samples or select all samples, then press **Print** to print the selected sample results. If the Print button is inactive (greyed out) no results have been selected.

5. To export samples to a USB drive,
   a. Insert a USB drive in the USB connector on the back of the analyzer.
   b. Select the sample data to export. Use the **Set Dates** button to recall data from a specific time frame then select the data to export.
   c. Press the **Export** button to display the destination drive and timestamped file name that will be created. If the Export button is inactive (greyed out) no results have been selected.



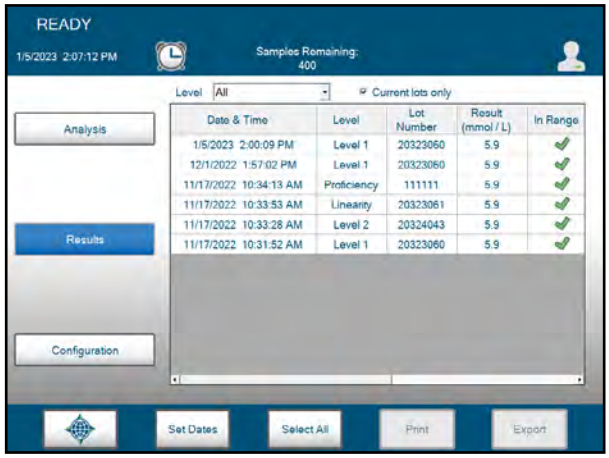
   d. If file encryption has been enabled in the Configuration Menu, a blank Password field is displayed. Enter a case sensitive password that will be required to open the file.
   e. Press the green checkmark to export the file or press the red X to cancel. If the destination is blank and the checkbox remains grey, a USB drive was not found.

3.4 RECALLING QC RESULTS

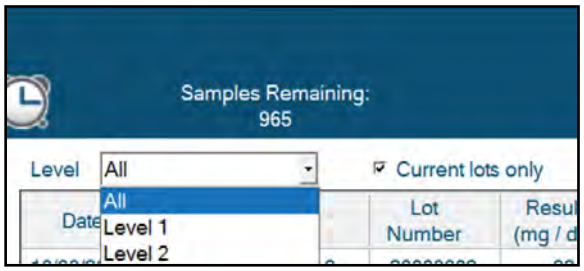
Previously analyzed QC results are retained indefinitely in the analyzers database. These samples can be recalled for review, printed, and exported to a USB device as a .csv file for use in an offline spreadsheet.

To recall QC results:

1. If necessary, press the **Destinations** button, then select **QC** to display the QC Analysis screen.
2. Select the **Results** button. All QC samples analyzed on the current date are shown automatically.

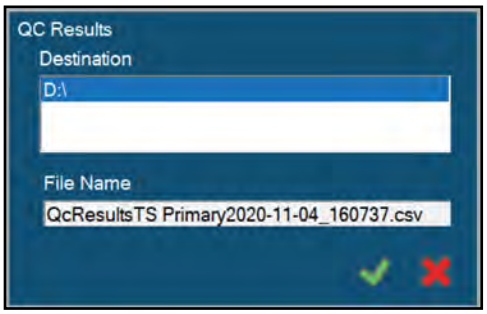


3. To narrow the list of displayed results, select the **Level** dropdown list and select the desired level to display. Deselect the **Current lots only** checkbox to include inactive lots of QC.



4. To expand the date range of the displayed samples, press the **Set Dates** button and enter the starting and ending date range for samples to be displayed. Press the green checkmark to display the results or press the red X to cancel.

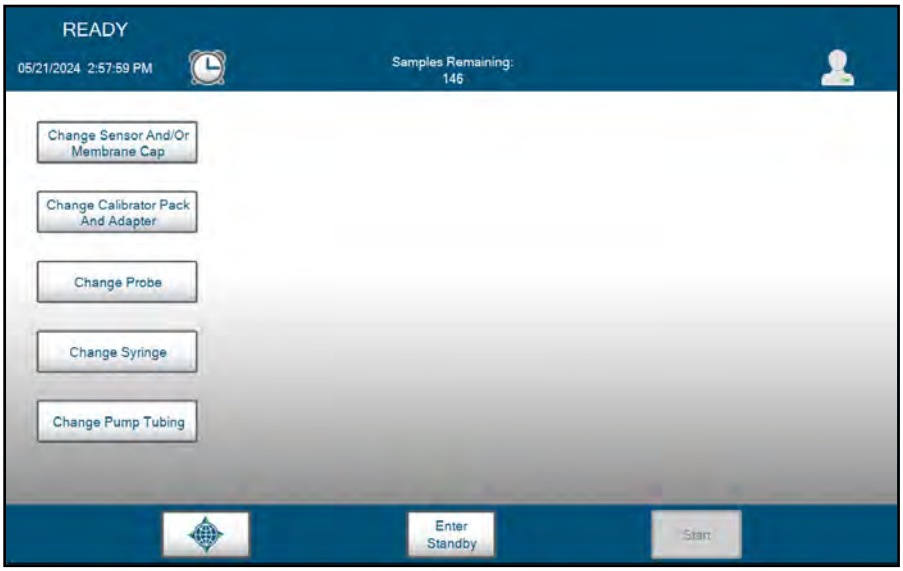
5. To print a sample result, first select the sample or samples to print then press the **Print** button. Select multiple samples or select all samples, then press **Print** to print the selected sample results.
6. To export samples to a USB drive:
   a. Insert a USB drive in the USB connector on the back of the analyzer.
   b. Select the sample data to export. Use the **Set Dates** button to recall data from a specific time frame then select the data to export.
   c. Press the **Export** button to display the destination drive and timestamped file name that will be created. If the Export button is inactive (greyed out) no results have been selected.
   d. Press the green checkmark to export the results or press the red X to cancel.



4 MAINTENANCE

The following section provides detailed information and directions for maintaining the Nova Primary Analyzer. To access the maintenance functions from the Destinations overlay, press the **Maintenance** button to display the available system maintenance functions.

From the Maintenance Menu, the operator can change the Glucose membrane cap and sensor, Calibrator Pack, Sample Probe, Syringe Assembly, and Pump Tubing. The system can also be placed in a Standby state to conserve fluids when not in use and taken out of Standby when ready for use.

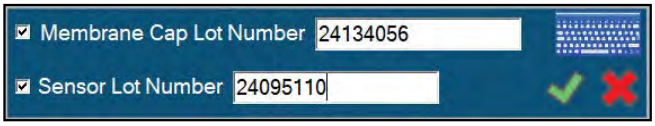


4.1 CHANGE SENSOR AND/OR MEMBRANE CAP

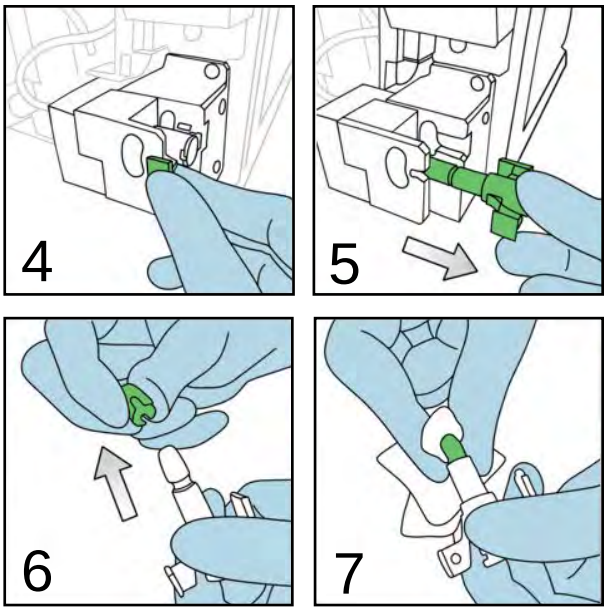
WARNING: Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP). Gloves and protective clothing are recommended.

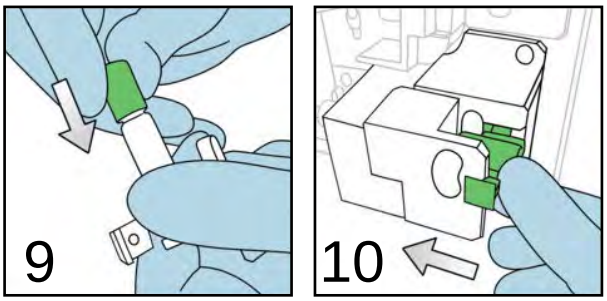
To replace the Glucose sensor or Membrane Cap

1. From the Destinations overlay, select **Maintenance**, then select **Change Sensor and/or Membrane Cap**.
2. Press **Start** to display the Lot Number overlay.
3. If desired, enter the Lot Number of the sensor or membrane. If changing the glucose sensor, first select the **Sensor Lot Number** checkbox, then enter the Lot Number. Press the green checkmark ✔ to continue. The pump will run briefly to remove fluid from the flowpath.



4. Unlock the Glucose sensor from the chamber.
5. Remove the sensor from the chamber.
6. Remove the old membrane cap and discard it.
7. Wipe the tip of the glucose sensor with a lintless tissue dampened with deionized water to remove any residue from the old membrane cap, then dry the sensor with a lintless tissue.
8. Press the **Install Sensor** [Install Sensor] button in the upper right hand corner of the screen.
9. Install a new Glucose membrane cap onto the sensor.
10. Install the sensor into the sensor chamber.





11. Press **Continue** [Continue] to prime the flowpath and recalibrate the sensor.

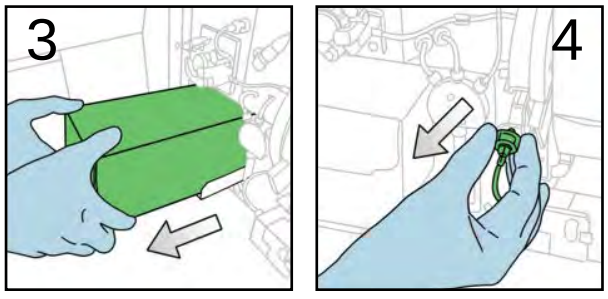
4.2 CHANGE CALIBRATOR PACK

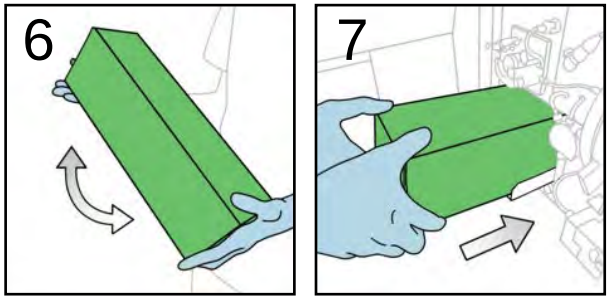
WARNING: Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP). Gloves and protective clothing are recommended.

To replace the Calibration Pack

1. From the Destinations overlay, select **Maintenance** then select **Change Calibrator Pack and Adapter.**
2. Press **Start.**

   The Sample Probe will reposition itself so the adapter can be accessed.
3. Remove the old Calibrator Pack.
4. Remove the old adapter and install the new adapter.
5. Press **Install Calibrator Pack** [Install Calibrator Pack].
6. Mix the new calibrator pack by gentle inversion for 10 seconds.
7. Install the new Calibrator Pack in the analyzers fluid bay.





8. Press **Continue** [Continue] to prime the Calibrator pack and calibrate the analyzer.

4.3 CHANGE PROBE

WARNING: Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP). Gloves and protective clothing are recommended.

To change the Sample Probe

1. From the Destinations overlay, select **Maintenance** then select **Change Sample Probe**.
2. Press **Start** to display the Lot Number overlay.
3. If desired, enter the Lot Number of the Sample Probe being installed. Press the green checkmark ✓ to continue.

The Sample Probe will be repositioned for replacement.

4. Remove the adapter from the sampler assembly.
5. Disconnect the sample line connecting the sample probe to the syringe assembly.
6. Disconnect the Air Detector cable from the chassis.
7. Pinch the probe tabs to release the probe from the sampler assembly, then gently pull the probe to the left to remove it.
8. Press **Install Probe** 

.
9. Slide the new Probe onto the sampler assembly, ensuring the locking tabs click into place securely.
10. Install the adaptor by sliding it over the probe and onto the sampler assembly.
11. Connect the air detector cable to the chassis.
12. Attach the sample line to the syringe assembly. Confirm all connections are secure, then press **Continue** 

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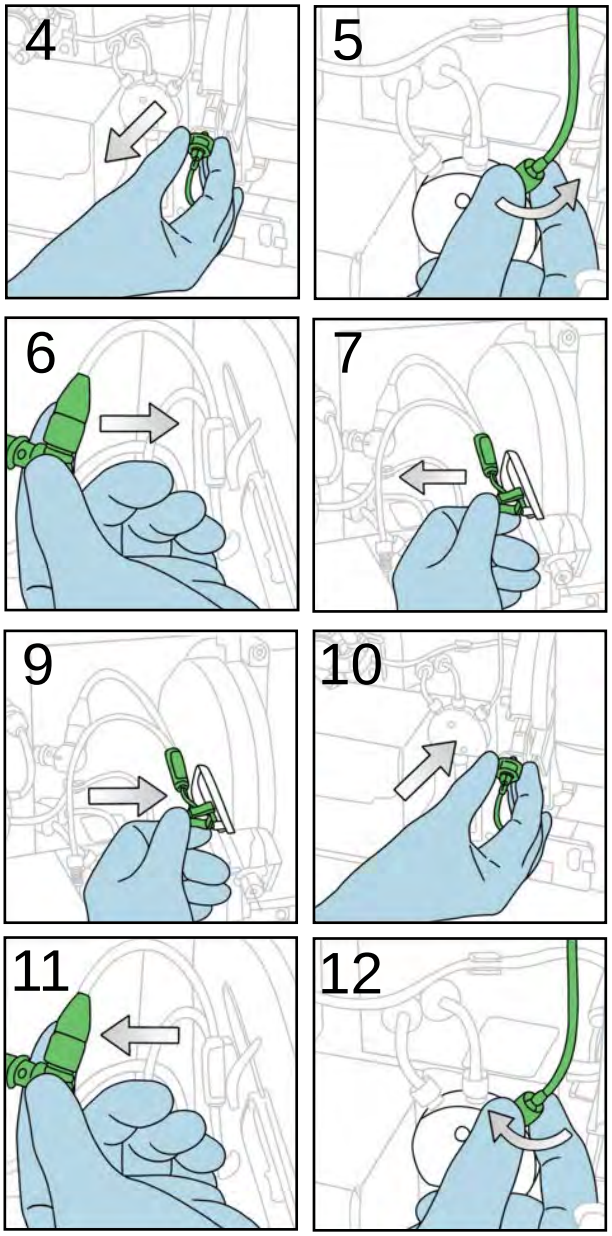


4.4 CHANGE SYRINGE

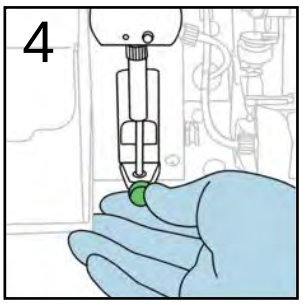
WARNING: Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP). Gloves and protective clothing are recommended.

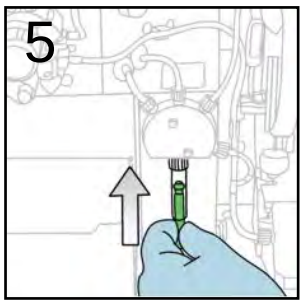
To change the Syringe

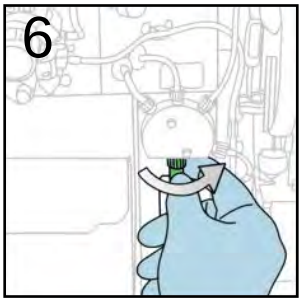
1. From the Destinations overlay, select **Maintenance** then select **Change Syringe**.
2. Press **Start** to display the Lot Number overlay.
3. If desired, enter the Lot Number of the Syringe being installed. Press the green checkmark ✓ to continue.

The syringe will retract.

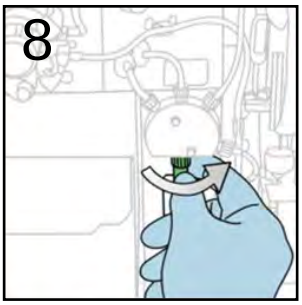
4. After the syringe fully retracts, loosen the plunger thumbscrew.
5. Push the plunger up into the syringe.
6. Unscrew the syringe by turning the barrel counterclockwise.

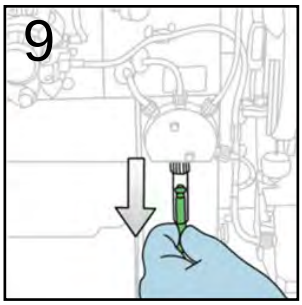


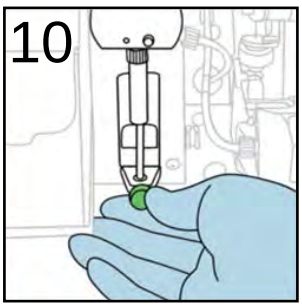




7. Press **Install Syringe** Install Syringe.
8. Attach the syringe barrel by turning the barrel clockwise.
9. Extend the syringe plunger
10. Tighten the thumbscrew.







11. Press **Continue** Continue.

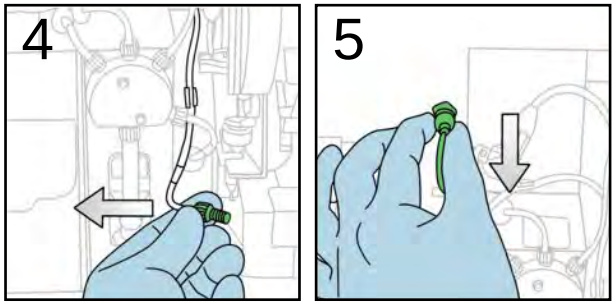
4.5 CHANGE PUMP TUBING

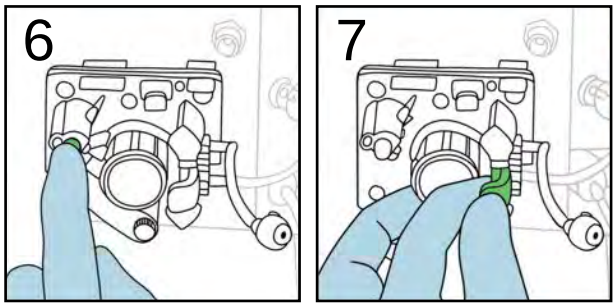
WARNING: Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP). Gloves and protective clothing are recommended.

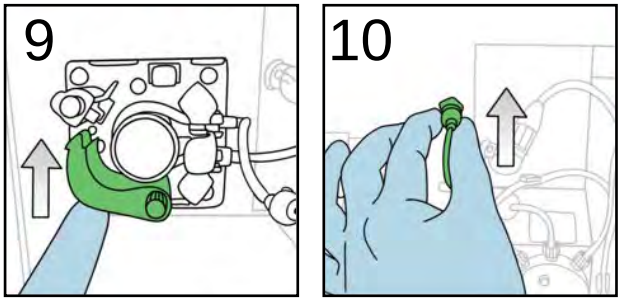
To change the Pump Tubing

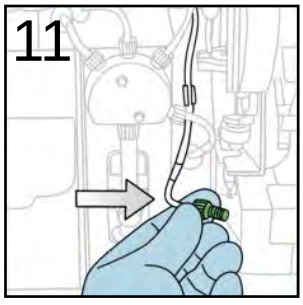
1. From the Destinations overlay, select **Maintenance** then select **Change Pump Tubing**.
2. Press **Start** to display the Lot Number overlay.
3. If desired, enter the Lot Number of the Pump Tubing being installed. Press the green checkmark ✔ to continue.

4. Disconnect the waste tubing from the well assembly.
5. Disconnect the waste tubing line connected to the analyzer chassis.
6. Press the pump pressure plate release button and lower the pressure plate.
7. Slide the old pump tubing off the pump rollers.
8. Press **Install Tubing** [Install Tubing].
9. Slide the new pump tubing onto the pump roller cage and close the pump pressure plate. Ensure the plate clicks into place securely.
10. Connect the waste line to the chassis.
11. Connect the waste tubing to the well assembly.









12. Press **Continue** [Continue].

5 CONFIGURATION AND SETUP

The Nova Primary configuration and setup options are used to customize the analyzer's User Interface to meet each location's operating requirements. This section explains the available options and their function.

5.1 GENERAL

General configuration settings include the following options:

- **Language** – select the desired display language from the drop-down list of available languages.
- **Analyzer ID** – enter an analyzer ID of up to 25 alpha-numeric characters.
- **Location** – enter a location for the analyzer of up to 50 alpha-numeric characters.
- **Use Network Time** – when selected, the analyzer will synchronize with the network time server when connected to the local network. When not selected, the analyzer will use its internal clock.
- **Default Sample Type** – select the default sample type used on the analyzer. The sample type is shown on the analysis screen and can be changed there if needed.
- **24 Hour/12 Hour Time Format** – select the time format to use. Choose 24 hour (0 to 24) or 12 hour (0 to 12 AM/PM).
- **Date Separator** – select the date separator to use. Choose backslash (/), dash (–) or decimal (.) from the drop-down list.
- **Date Format** – select the date format to use. Choose MM DD YYYY, DD MM YYYY, or YYYY MM DD from the drop-down list.
- **Enable Standby** – when enabled, the analyzer will go into Standby mode at the Enter time and exit Standby mode at the Exit time. Standby mode conserves calibrator fluids by pausing the normal calibration cycle and running a brief maintenance sequence occasionally to prevent any blockages in the sample flowpath.
- **Enable Auto Logoff** – if Users are configured in the system, enabling Auto Logoff will log off the currently logged in user after the entered number of minutes.
- **Enable QC Lockout** – when enabled, the analyzer will not report a sample result if a Quality Control result is outside the expected range. QC lockout can be cleared by running a QC sample that recovers a value within the expected range.
- **Enable Auto Print** – when selected, sample results are automatically printed on the local printer.
- **Require Login** – when individual Users are configured in the system, enabling Require Login prevents use of the analyzer unless a valid User has logged into the analyzer.
- **Encrypt Exported Sample Results** – when enabled, sample results uploaded to an external drive are encrypted. If not selected, results are sent as an unencrypted .csv file.
- **Display Sample ID** – when enabled, a sample ID field is displayed
- **Enable Enhanced Data Entry** – when enabled, operators have access to a configurable, enhanced data entry menu.
- **Numeric Format** – Select either a decimal point or a comma numeric separator.

NOTE: ***Use this feature when a regular Standby schedule is expected. The analyzer can be put into and brought out of Standby mode at any time if desired.***

5.2 PARAMETER

Parameter settings include the following options:

- **Lower Limit** – enter the lower limit of expected values. Results that fall below this limit are flagged with a red down arrow.
- **Upper Limit** – enter the upper limit of expected values. Results that fall above this limit are flagged with a red up arrow.
- **Units of Measure** – select the desired unit of measure from the available options.
- **Decimal Places** – select no decimal (X.) or 1 decimal place (X.x) for results less than 100 mg/dL.

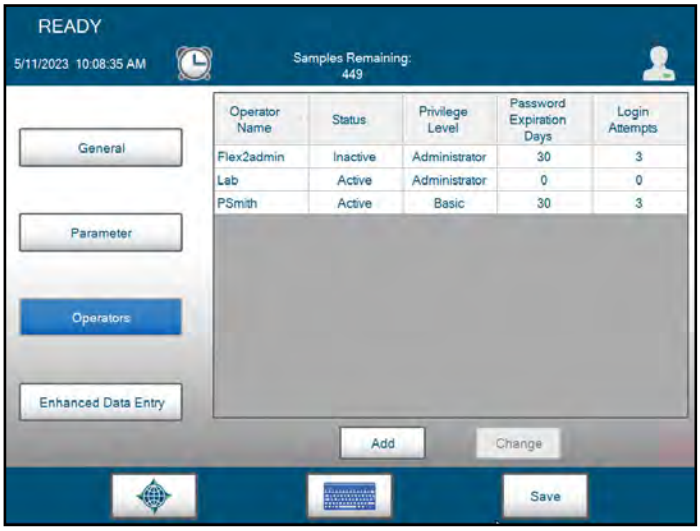
Press **Save** to save any changes.

5.3 OPERATORS

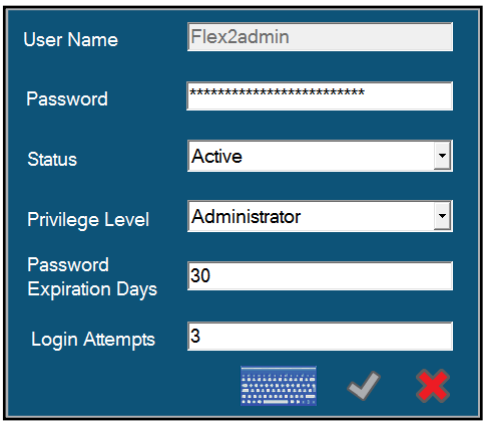
The Nova Primary allows an operator with Administrator privileges to create and edit Operator Accounts for other system operators. Each Operator Account must have a unique User Name and an associated Password. Once an Operator Account is created, it can be activated or deactivated, but it cannot be deleted or removed from the system database. Operator Accounts are assigned a specific privilege level (Basic, Intermediate, or Administrator) based on the desired level of system access. A system administrator can set a password expiration date for individual Operator Accounts and can also set a limit for the number of failed log-in attempts for each operator.

To add a new operator or change the configuration of an existing user:

1. Select **Operators**, then press **Add** to add a new operator or highlight an existing operator and press **Change** to update the configuration of an existing operator.

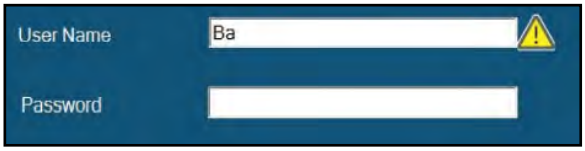


2. Enter an Operator Name in the box provided. User Names must be 3-25 alphanumeric characters and are not case-sensitive. User names can include dashes (-) and underscores (_) but no spaces or special characters (!,@,#,$,%,^,&,*,/,<).



3. Enter a Password for the User Account. Passwords must be 8-25 alphanumeric characters and are case-sensitive. The password must include at least 1 capital letter, 1 lowercase letter, and 1 number. Passwords can include dashes (-) and underscores (_) but no spaces and no special characters (!,@,#,$,%,^,&,*,/,<).

NOTE: ***The alert icon will appear and flash next to the User Name and Password entry boxes when entering in these items. The alert icon will be visible until the User Name and Password criteria have been met. When adding a new User Account, the system will not let the operator enter any information into the next section until the criteria for the previous section have been met.***



4. Select the Status for the User Account (Active or Inactive). Only active User Accounts can login to the system. If a User Account has been made inactive or has been deactivated as a result of too many failed login attempts, the account must be made active again by a system administrator.

5. Select the Privilege Level for the User Account (Basic, Intermediate, or Administrator). Refer to the chart below for detailed user functionality.

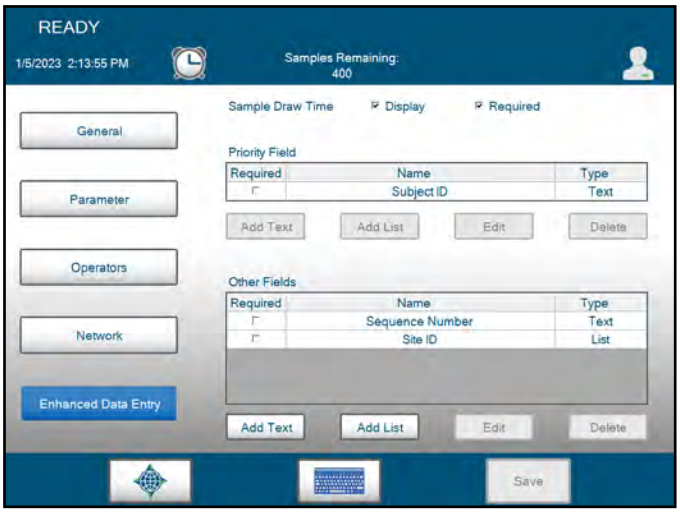
Analysis Menu	**Basic**	**Interm.**	**Admin**
Run Sample Analysis	X	X	X
Cancel Sample Analysis	X	X	X
Enter Sample ID	X	X	X
Historical Results Menu	**Basic**	**Interm.**	**Admin**
Export/Print Historical Results	X	X	X
QC Menu	**Basic**	**Interm.**	**Admin**
Run External QC	X	X	X
Export/Print QC Results	X	X	X
View QC Results	X	X	X
Cancel QC Analysis	X	X	X
Configure QC	X	X	X
User Menu	**Basic**	**Interm.**	**Admin**
Change Password	X	X	X
Log Out Current User	X	X	X
Maintenance Menu	**Basic**	**Interm.**	**Admin**
Change Sensor/ Membrane Cap	X	X	X
Change Syringe	X	X	X
Change Probe	X	X	X
Change Pump Tubing	X	X	X
Calibrate Air Detectors	X	X	X
Service Menu	**Basic**	**Interm.**	**Admin**
Install Software			X
Flowpath Service			X
System Backflush			X
Archive Data			X
Long Term Shutdown	X	X	X
Resource Issues			X
Clear Print Queue	X	X	X

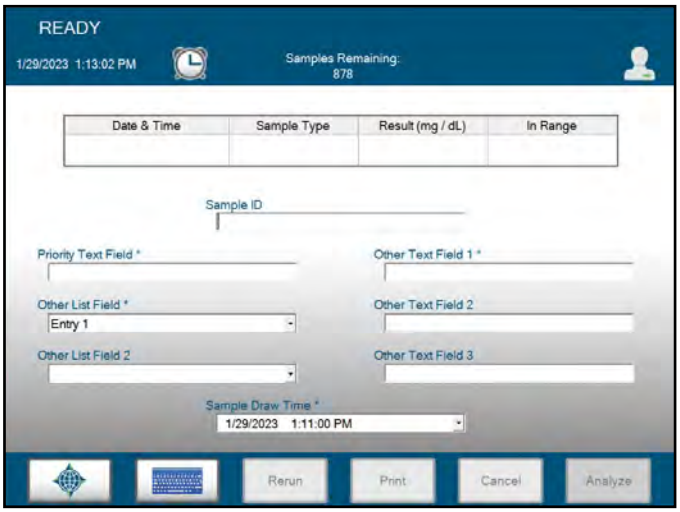
Configuration	**Basic**	**Interm.**	**Admin**
Modify General Settings			X
Create/Edit Users			X
Modify Parameters			X
Modify Network Settings			X
Logs Menu	**Basic**	**Interm.**	**Admin**
View Audit Logs	X	X	X
Export Audit Logs	X	X	X
View Error Logs	X	X	X
Export Error Logs	X	X	X
View Calibration Logs	X	X	X
Export Calibration Logs	X	X	X
View Maintenance Logs	X	X	X
Export Maintenance Logs	X	X	X
Shutdown Button	**Basic**	**Interm.**	**Admin**
Shutdown Analyzer	X	X	X
Status Window	**Basic**	**Interm.**	**Admin**
Run Calibration	X	X	X
Run Flush Wells	X	X	X
Run Prime	X	X	X
Time/Date Window	**Basic**	**Interm.**	**Admin**
Change Date/Time		X	X

6. Set the number of days after which the password will expire. For example, if this number is set to 30 days, the password will expire every 30 days. The end user will be required to create a new password every 30 days upon logging in to the system. The same password cannot be used twice. If this number is set to 0, the password will have no expiration for this User Account.
7. Set the failed Login Attempts number. For example, if this number is set to 3, the User Account will be made inactive after 3 failed login attempts by the end user. A system administrator would then need to make the User Account active again. If this number is set to 0, the User Account will have no limit to the number of failed login attempts.
8. When all User Account information is correctly entered, select the green checkmark to add the User Account to the system database. Selecting the red X will cancel the process.

5.4 ENHANCED DATA ENTRY

When enabled in General settings, Enhanced Data Entry allows the end user to customize default data fields as required or optional and to create up to 6 additional free text entry fields or drop-down lists. The Priority Field can be either a text or a list field and will be displayed as the first field on the sample analysis screen.

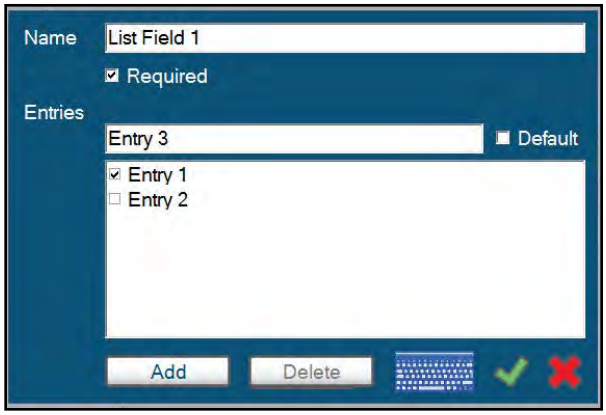




To configure the Priority and Other Fields:

1. Select the field type to add, either **Add Text** or **Add List**.
2. When adding a Text field, a popup window is displayed to add a field Name of up to 20 alphanumeric characters including space, dash -, and underscore _. If Required is selected, a sample analysis cannot begin until the field has a valid entry.
3. If the name contains illegal characters or is too long, a red exclamation icon is displayed at the end of the field. Hover over the icon to see a description of the problem. Select to save the field name or click X to cancel and discard any changes.

4. When adding a List field, a popup window is displayed to add a field Name of up to 20 alphanumeric characters including space, dash -, and underscore _. If Required is selected, a sample analysis cannot begin until the field has a valid entry. If the name contains illegal characters or is too long, a red exclamation icon is displayed. Hover over the icon to see a description of the problem.
5. Next, add entries to select in the dropdown list. Entries names can be up to 20 alphanumeric characters including space, dash -, and underscore _. One entry can be selected as a default entry by checking the Default checkbox.
6. Press **Add** to add the current Entry to the list.
7. When all Entries have been completed select ✓ to save the list field or click **X** to cancel and discard any changes.
8. Remember to press **Save** Save before exiting the Enhanced Data Entry screen to save any changes that were made.



5.5 QUALITY CONTROL CONFIGURATION

The Nova Primary has 2 levels of external Quality Control material for monitoring. Results that exceed the entered ranges are flagged for easy identification. There are additional selections for Linearity and Proficiency testing materials.

To configure a lot of QC material:

1. From the Destinations Overlay, select the **QC** button to display the QC screen.
2. Select **Configuration** then select the desired QC **Level 1** or **Level 2**.
3. Enter the Lot Number of the QC material.
4. Enter the Expiration Date. Select the Year and Month from the dropdown list.
5. Enter the Lower Limit and Upper Limit for the selected level of Quality Control, Linearity, or Proficiency material. Test results lower than the Lower Limit are flagged with a red down arrow; results above the upper limit are flagged with a red up arrow. Results within the entered range are displayed with a green checkmark.
6. Press **Save** to save the QC lot entries.

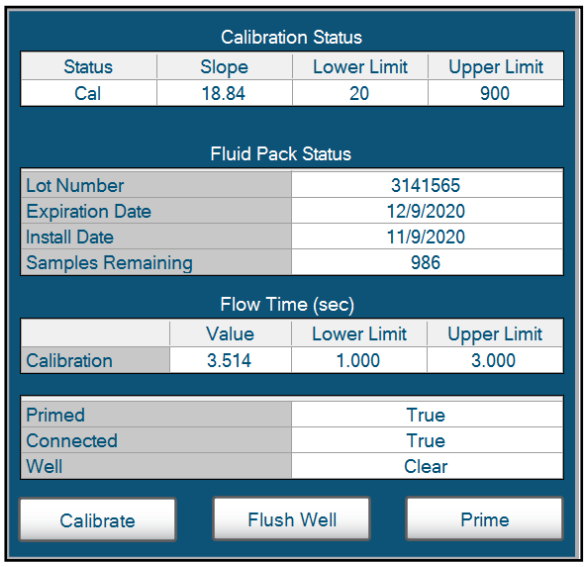
6 TROUBLESHOOTING

The Nova Primary continuously monitors the status of all electromechanical components, consumables, and software processes to ensure the analyzer is operating correctly. In the event an error condition is identified, the analyzer will display a system event icon ⚠ in the Header Bar to notify the user of the problem. This section explains the meaning of each event code and lists troubleshooting steps that you can take to resolve the problem.

6.1 STATUS OVERLAY

The Status Overlay provides a quick summary of the overall status of the analyzer. To display the Status Overlay, touch an open section of the blue header bar at the top of the screen. To clear the Status Overlay, touch the screen a second time.

The Status Overlay contains the:



Calibration Status of the glucose sensor. Calibrated (Cal) or Uncalibrated (UnCal), the glucose sensor slope, and the programmed analytical measurement range (Lower and Upper Limits).

Calibrator Pack Status shows the lot number of the installed calibrator pack, the expiration date, the date the pack was installed, and the estimated number of samples remaining in the pack.

Flow Time displays the measured flowtime from the last calibration sequence and the expected flowtime range programmed into the analyzer.

Primed indicates if the analyzer is primed with the required reagent. The analyzer must be primed to be available for sampling. If the module is primed, the prime status will read True. If the module is not primed, the status will read False.

Connected indicates if the analyzer is connected to the internal onboard computer. The analyzer must be connected to be available for sampling. If the analyzer is connected, the connected status will read True. If the analyzer is not connected, the status will read False.

Well shows the status (Blocked or Clear) of the sample dilution well. This well must be clear for the analyzer to be available for sampling. If the well status indicates that is blocked, additional troubleshooting is required.

Three functions are available on the bottom of the overlay for use as a first step to correct specific problems. If these do not correct the issue, additional troubleshooting procedures are detailed later in this section.

Calibrate will initiate a 2-point calibration for the glucose sensor and air detectors to address an UnCal status.

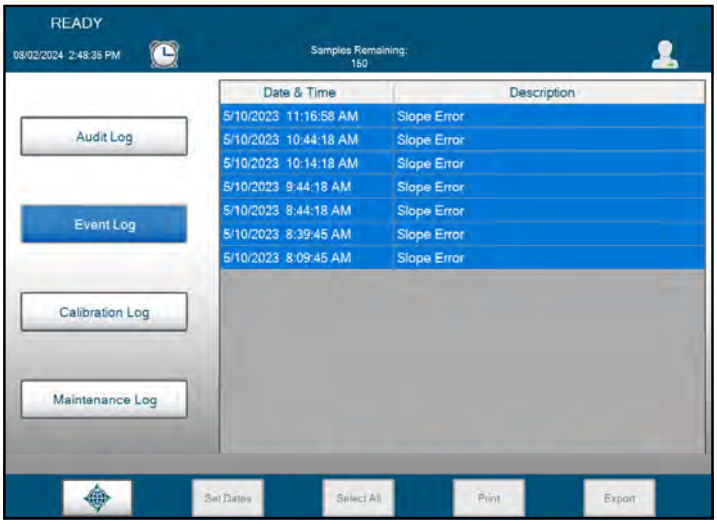
Flush Well will initiate an automated process that will attempt to clear any blockages that may exist in the dilution well.

Prime will initiate a system priming sequence to address flow issues that may exist when the Primed status is False.

6.2 EVENT LOG

All system events that have occurred are recorded in the analyzer's Event Log. To access the event log:

1. Press the **Destinations** button then select the **Logs** button.
2. Press the **Event** button to display the Events screen.
3. Any system events that occurred on the current date are displayed with the Date/Time the event occurred and a Description of the event. Refer to Section 6.3 Troubleshooting Procedures.



4. To expand the date range of the displayed events, press the **Set Dates** button and enter the starting and ending date range for events to be displayed. Press the green checkmark to display the events or press the red **X** to cancel.

To Print reports:

1. Use the **Select All** button or select individual entries in the displayed list.
2. Press the **Print** button.

To Export log entries as a comma separated values (.csv) file:

1. Insert a compatible USB drive in the USB port on the back of the analyzer.
2. Use the **Select All** button or select individual entries in the displayed list.
3. Press the **Export** button.

   The analyzer will create a file name based on the log being displayed and current date and time. Select the green checkmark to copy the file to the USB drive, or press the red **X** to cancel.

6.3 TROUBLESHOOTING PROCEDURES

These troubleshooting procedures use the most logical and direct steps to resolve an event code. The solutions are set up in a block format that lists steps to perform to restore correct operation. These steps are also organized to prevent unnecessary consumable replacement.

If the recommendations given here do not resolve the problem, contact Nova Technical Services for troubleshooting assistance.

FOR TECHNICAL ASSISTANCE CALL:

USA: 1-800-545-NOVA

CANADA: 1-800-263-5999

OTHER COUNTRIES: Contact the local Nova Biomedical Sales Office or authorized Nova Biomedical Distributor.

6.3.1 EVENT CODES

Slope Error

The sensor slope is calculated during each calibration sequence. A Slope Error is generated when the calculated slope is lower than the slope low limit or above the slope high limit.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Install a new Glucose Membrane Cap.
3. Install a new Glucose Sensor.
4. Contact Nova Biomedical Technical Support.

Slope Drift Error

A slope drift check is performed during each calibration sequence. A Slope Drift Error is generated when the difference between the current sensor slope and the previous slope exceeds software limits.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Install a new Glucose Membrane Cap.
3. Install a new Glucose Sensor.
4. Contact Nova Biomedical Technical Support.

Background Error

A background check is performed during each calibration sequence. A Background Error is generated when the difference between sensor readings of the Diluent and the Standard A calibrator exceed software limits.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Install a new Glucose Membrane Cap.
3. Install a new Glucose Sensor.
4. Contact Nova Biomedical Technical Support.

Sensor Error

A Standard A to Diluent ratio check is performed in the calibration sequence before the slope is calculated. A Sensor Error is generated when the ratio of the Standard A sensor reading to the Diluent sensor reading exceeds software limits.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Install a new Glucose Membrane Cap.
3. Install a new Glucose Sensor.
4. Contact Nova Biomedical Technical Support.

Flow Slow

Fluid flow through the dilution well is checked during the calibration and analysis sequence. Fluid in the dilution well is pulled through the assembly by the peristaltic pump. If there is still fluid in front of the well air detector when the pump stops, a Flow Slow error is displayed, and the sequence is terminated.

Recommended Solutions:

1. Repeat the analysis.
2. Backflush the dilution well. Refer to Section 7.3, System Backflush.
3. Replace the Pump Tubing. Refer to Section 4.5, Change Pump Tubing.
4. Contact Nova Biomedical Technical Support.

Flow Fast

During an analysis sequence, if the measured flow time is faster than expected, a Flow Fast error is displayed, and the analysis sequence is terminated.

Recommended Solutions:

1. If the calibrator pack indicates <10% fluid remaining, replace the calibrator pack.
2. Backflush the dilution well. Refer to Section 7.3, System Backflush.
3. Contact Nova Biomedical Technical Support.

Temperature Drift

At the start of an analysis sequence if the current temperature of the dilution well assembly is greater than 4˚C from the temperature at the time the last calibration was run, a Temperature Drift error is displayed, and the sequence is terminated.

Recommended Solutions:

1. Recalibrate the analyzer.
2. If the Temperature Drift error reoccurs, contact Nova Biomedical Technical Support.

Waste Well Not Available

The Dilution Well is monitored by the system to determine a ready/not ready status. If the well is not ready, a Waste Well Not Available error is displayed, and the sequence is terminated.

Recommended Solutions:

1. Calibrate the analyzer.
2. Contact Nova Biomedical Technical Support.

No Sample

During an analysis sequence when sample is aspirated, if no sample is detected or the volume aspirated exceeds software limits, a No Sample error is displayed, and the sequence terminates.

Recommended Solutions:

1. Repeat the analysis.
2. If the problem persists, flush the sample probe with DI water using the flushing kit.
3. Confirm the sample probe air detector is connected to the analyzer.
4. Replace the sample probe.
5. Contact Nova Biomedical Technical Support.

System Probe Not Available

At the start of an analysis sequence, the state of the system (Sample) probe air detector is verified. If the air detector is not available, a System Probe Not Available error is displayed, and the sequence terminates.

Recommended Solutions:

1. Confirm the sample probe air detector is connected to the analyzer.
2. Recalibrate the analyzer.
3. Replace the sample probe.
4. Contact Nova Biomedical Technical Support.

Sensor Not Primed

At the start of an analysis sequence, if the sensor (system) is not primed, a System Not Primed error is displayed, and the sequence terminates.

Recommended Solutions:

1. From the Calibration Status window, Prime the system.
2. Recalibrate the analyzer.
3. Contact Nova Biomedical Technical Support.

Pack Not Primed

At the start of an analysis sequence, the state of the calibrator pack is confirmed. If the pack is not primed, a Pack Not Primed error is displayed, and the sequence terminates.

Recommended Solutions:

1. From the Calibration Status window, Prime the system.
2. Recalibrate the analyzer.
3. Contact Nova Biomedical Technical Support.

Well Air Detector Not Calibrated

At the start of an analysis sequence, the state of the well air detector is confirmed. If the air detector is not calibrated, a Well Air Detector Not Calibrated error is displayed, and the sequence terminates.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Contact Nova Biomedical Technical Support.

Probe Air Detector Calibration Failed

If the sample probe air detector calibration fails, a Probe Air Detector Calibration Failed error is displayed and the analysis terminates.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Verify the sample probe air detector is connected to the analyzer.
3. Replace the sample probe assembly.
4. Contact Nova Biomedical Technical Support.

Probe Error

If the Hct sensor calibration fails, a Probe Error is displayed, and the analysis terminates.

Recommended Solutions:

1. Recalibrate the analyzer.
2. Verify the sample probe air detector is connected to the analyzer.
3. Replace the sample probe assembly.
4. Contact Nova Biomedical Technical Support.

7 ADVANCED USER FUNCTIONS

Advanced user functions are available in the Service menu for use as needed. These include software updates, advanced troubleshooting resources and an extended shutdown procedure if the analyzer will be unused for an extended period of time.

7.1 INSTALLING SOFTWARE

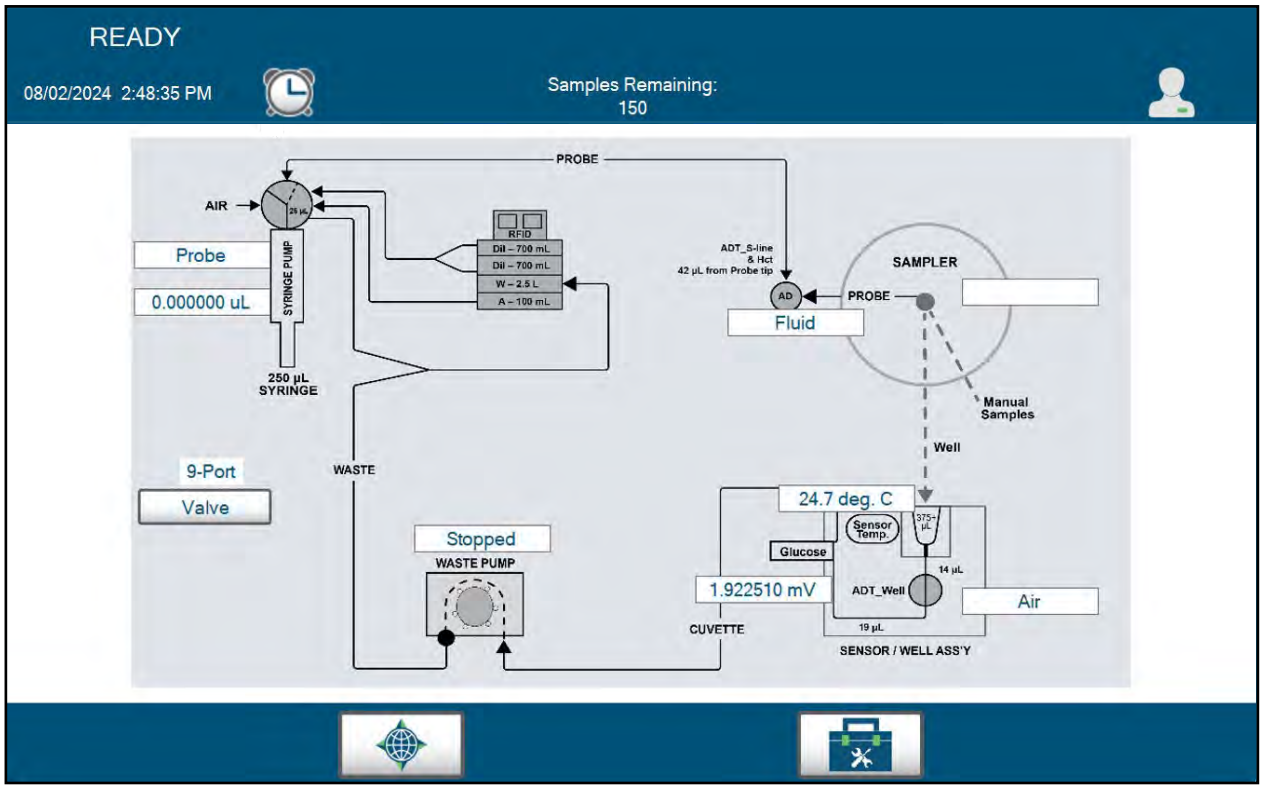
This function is intended for use by authorized Nova service representatives to update the analyzer's analytical software.

7.2 FLOWPATH SERVICE

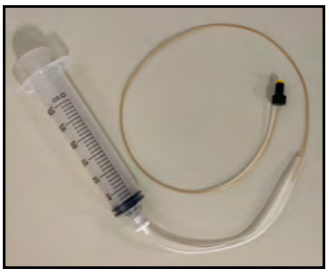
The Flowpath Service screen is primarily for use by trained Nova service representatives to test and evaluate the analyzer's electromechanical components.

Select the white box next to a component to display additional information about that component and, where applicable, allow the component to be exercised to test functionality.

Press the toolbox icon to return to the service page.



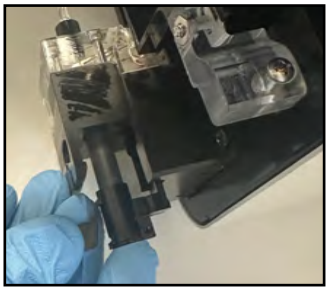
7.3 SYSTEM BACKFLUSH



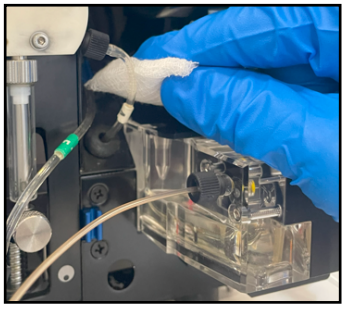
System Backflush positions the sample probe to allow easy access to the dilution well. The backflush tool (syringe with tubing and threaded adapter) can be connected to the dilution well waste outlet port to backflush the dilution well assembly in the event it becomes blocked.

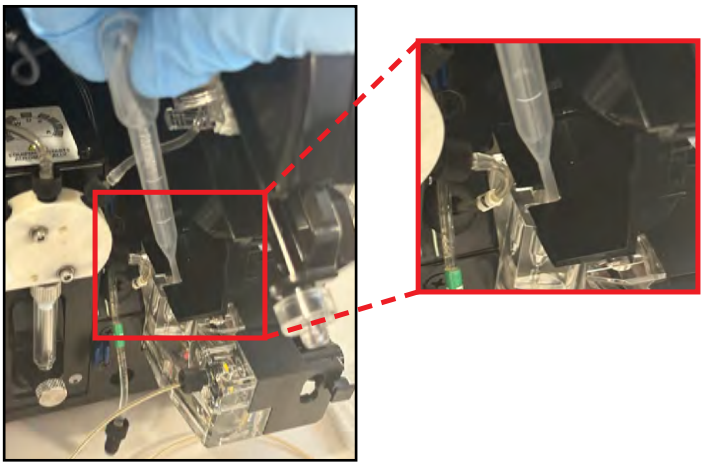
To backflush the dilution well:

- From the Service page press the **System Backflush** button to reposition the sample probe away from the dilution well.
- Remove the glucose sensor and insert the sensor blank.
- Disconnect the waste line from the dilution well assembly.
- Attach the backflush syringe tubing to the dilution well assembly.



- Fill the syringe with air, deionized water, or a dilute (10%) bleach solution.
- Hold gauze or similar absorbent material over the dilution well to catch any overflow.
- Press the syringe to backflush the well assembly and clear any obstruction that may be present.
- Use a disposable pipette to remove any remaining fluid from the dilution well.





- Remove the syringe tubing from the dilution well assembly and reattach the waste line.
- Remove the sensor blank and reinstall the glucose sensor.

NOTE: ***In most cases, it is advisable to replace the sensor membrane cap. Refer to Section 4.1 Change Sensor and/or Membrane Cap.***

CAUTION: ***When flushing with a bleach solution, flush a second time with deionized water.***

- When done, press **Continue** to prime the system.

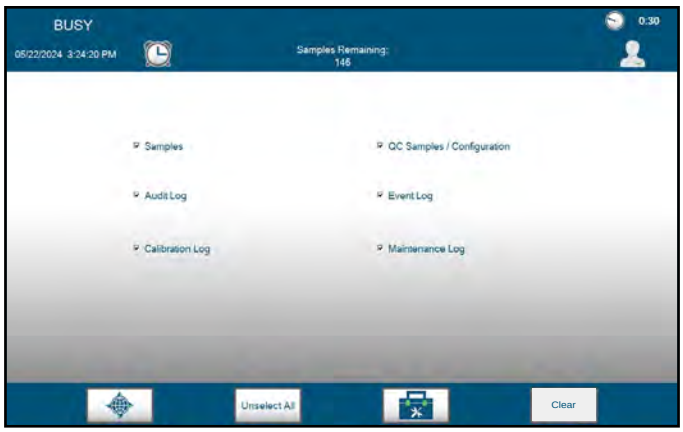
7.4 CLEAR DATA

Data can be cleared from the analyzer's database if desired. Please note that the Clear Data function DOES NOT save a copy of the data before permanently deleting it from the analyzer. Export any Patient data, QC data, and logs you wish to save before clearing the data.

NOTE: The analyzer will shut down and restart to complete the archiving process.

To Clear data:

- From the Service Page, select **Clear Data** to display Clear Data page.
- All data categories are selected by default when entering the page. Deselect (uncheck) any data category(s) you wish to retain in the database.
- Press **Clear** to clear the selected data.



7.5 LONG TERM SHUTDOWN

Long Term Shutdown flushes the analyzer's internal tubing and analytical flowpath to prepare it for long term shut down. This will clear the pathway of any fluids that may dry up and block it if the analyzer is shut down for an extended period of time. You will need the following tools:

- Nova Primary Flushing Adapter (PN 66021).
- A small beaker filled with deionized or distilled water.
- An empty beaker to collect the waste fluids.

Follow the steps below to flush the analyzer prior to long term shutdown.

1. Remove the calibrator cartridge and insert the flushing adapter in its place.
2. Place the ends of the three (3) unmarked reagent lines into the beaker of water.
3. Place the Waste line (labeled with a W) into the empty beaker.
4. From the Service page, press the **Long Term Shutdown** button, then press **Start**. The analyzer will flush the internal tubing and sample flowpath with the water in the beaker.
5. When the pump and syringe stop, the flowpath has been flushed but still contains water. Remove the three reagent lines from the beaker of water leaving the waste line in its beaker.
6. Press **Continue** to flush the flowpath of any remaining fluids.
7. When the pump and syringe stop, open the pump pressure plate, then remove the waste line from the pump roller cage.
8. From the Destinations page press **Shut Down** to turn off the analyzer.

7.6 AUDITABLE ACTIONS

The following are the actions recorded in the Primary's Audit Log:

General Activity

System Started	System Calibrations	System Prime Sequences
Flush Well Sequences	Sample Analysis Sequence	QC Sample Analysis Sequence
Export System Configuration	Import System Configuration	Operator Logging In
Operator Logging Out	Maximum Login Attempts Exceeded	System Shut Down

Sample Results History

Change Sample ID	Change Priority Field	Change Other Field
Export Sample Results	Printing Sample Results	

QC Results History

Export QC Result	Print QC Result

Analyzer Configuration

Change Analyzer ID	Change Location	Change Language
Change Use Network Time	Change Time Format	Change Date Format
Change Date Separator	Change Numeric Format	Change Auto Logoff
Change Require Login	Change Auto Print	Change Require Login
Change Display Sample ID	Change Encrypt Exported Results	Change Enhanced Data Entry
Change Default Sample Type	Change System Date	Change System Time

Parameter Configuration

Change Upper Limit	Change Lower Limit	Change Units of Measure
Change Decimal Places		

Operator Configuration

Change Operator's Password	Change Operator's Status	Change Operator's Privilege
Change Operator's Password Expiration Days	Change Operator's Login Attempts	

Enhanced Data Entry

Change Display Sample Draw Time	Change Sample Draw Time Required	Change Priority Field Name
Change Priority Field Required	Delete Priority Field	Change Priority Field List Item
Delete Priority Field List Item	Changed Other Field Name	Change Other Field Required
Delete Other Field		

Maintenance Actions

Change Sample Probe	Change Calibrator Pack	Change Sensor and Membrane
Change Syringe	Change Pump Tubing	Enter Standby Mode
Exit Standby Mode		

Service Actions

Enter Service Screen	Install New Software	Perform Flowpath Service
Perform System Backflush	Perform Long Term Shutdown	Clear Print Queue
Exit Service Screen		

7.7 RESOURCE ISSUES

Resource Issues may provide additional information to Technical Support and Service representatives on the status of the analyzer's electronic and electromechanical components. Press the toolbox icon to return to the service page.

7.8 INSTALLING 3RD PARTY SOFTWARE

Please contact Nova Technical Support for information on installing 3rd party software on the analyzer. The analyzer software contains numerous built in cybersecurity precautions and additional software may not be required.

A APPENDIX

Appendix A includes analyzer specifications, performance data, solutions and reagents, consumable lists, reference information, and warranty for the Nova Primary Glucose Analyzer.

A.1 SPECIFICATIONS

Glucose Operating Range	20 – 900 mg/dL 1.1 – 50 mmol/L
Glucose Measurement Resolution	1 mg/dL
Sample Type	Lithium heparin whole blood and plasma
Sample Volume	25 µL
Limit of Blank	1.0 mg/dL
Limit of Detection	4.0 mg/dL
Limit of Quantification	4.0 mg/dL

A.2 QUALITY CONTROL

Healthcare facilities should follow federal, state, and local guidelines for testing quality control materials. At a minimum, Nova Biomedical recommends that each laboratory performs the following minimum QC procedures (External Ampule QC) on each analyzer:

During every 24 hours of testing, analyze one normal and one abnormal level of control.

After performing system maintenance, follow good laboratory practice guidelines for performing quality control analysis.

CAUTION: Sensor performance may be affected by the use of controls or linearity material other than those offered for sale by Nova Biomedical. Contact Nova Biomedical for additional information.

A.3 ANALYTICAL SPECIFICITY

Interference testing was performed according to the Interference Testing in Clinical Chemistry; Approved Guideline - Third Edition: CLSI EP07-A3. Testing was done using lithium heparinized venous whole blood and plasma collected from consenting donors.

No significant interference (<10%) was observed up to the following concentration levels:

Table A-1

Interfering Substances Causing No Clinically Significant Effect on Test Results (Whole Blood)

Acetaminophen	20 mg/dL	Hydroxyurea	0.8 mg/dL
Acetoacetate	2 mmol/L	Ibuprofen	2.4 mmol/L
Acetylsalicylic Acid	3.62 mmol/L	Intralipid	1.0% solution
Ammonium Chloride	107 µmol/L	Lactate	6.6 mmol/L
Ascorbic Acid	50 mg/dL	Low Hematocrit	17%
Bilirubin	342 µmol/L	Maltose	13 mmol/L
Benzalkonium Chloride	10 mg /L	Mannose	1 mmol/L
B-hydroxybutyrate	2 mmol/L	Pyruvate	309 µmol/L
Dobutamine	2 mg/dL	Salycylic Acid	4.34 mmol/L
Dopamine Hydrochloride	5.87 µmol/L	Sodium Citrate	12 mmol/L
Ethanol	86.8 mmol/L	Sodium Oxalate	500 mg/dL
Fluoride	105 µmol/L	Thiocyanate	6.8 mmol/L
D-Galactose	1.0 mmol/L	Xylose	25 mg/dL
Glucosamine	30 µmol/L	N-Acetylcysteine	10.2 mmol/L
Glycolic Acid	1 mmol/L	Glutathione	3 mmol/L
Hemoglobin	2 g/L	Creatinine	15 mg/dL
Heparin	100 IU/mL	Cholesterol	500 mg/dL
High Hematocrit	62%	Methyl-DOPA	2 mg/dL

Table A-2			
Interfering Substances Causing No Clinically Significant Effect on Test Results (Plasma)			
Acetaminophen	20 mg/dL	Hydroxyurea	0.8 mg/dL
Acetoacetate	2 mmol/L	Ibuprofen	2.4 mmol/L
Acetylsalicylic Acid	3.62 mmol/L	Intralipid	1.0% solution
Ammonium Chloride	107 µmol/L	Lactate	6.6 mmol/L
Ascorbic Acid	50 mg/dL	Maltose	13 mmol/L
Bilirubin	342 µmol/L	Mannose	1 mmol/L
Benzalkonium Chloride	10 mg /L	Pyruvate	309 µmol/L
B-hydroxybutyrate	2 mmol/L	Salycylic Acid	4.34 mmol/L
Dobutamine	2 mg/dL	Sodium Citrate	12 mmol/L
Dopamine Hydrochloride	5.87 µmol/L	Sodium Oxalate	500 mg/dL
Ethanol	86.8 mmol/L	Thiocyanate	6.8 mmol/L
Fluoride	105 µmol/L	Xylose	25 mg/dL
D-Galactose	1.0 mmol/L	N-Acetylcysteine	10.2 mmol/L
Glucosamine	30 µmol/L	Glutathione	3 mmol/L
Glycolic Acid	1 mmol/L	Creatinine	15 mg/dL
Hemoglobin	2 g/L	Cholesterol	500 mg/dL
Heparin	100 IU/mL	Methyl-DOPA	2 mg/dL

A.4 ANALYTICAL PERFORMANCE STUDIES

A.4.1 METHOD COMPARISON

Nova Biomedical conducted a method comparison study in a clinical laboratory setting comparing three Nova Primary Glucose Analyzers to two YSI 2300 Analyzers. The protocol was based upon methods described in Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition, CLSI EP09-A3. Discarded lithium heparinized venous whole blood and plasma samples from consenting donors were evaluated. Samples were spiked or diluted to cover the analytical measurement range. Each sample was tested in a singlet on the 3 test analyzers and the 2 reference analyzers. The singlet result was compared to the average of the test results from the reference analyzers.

Table A-3

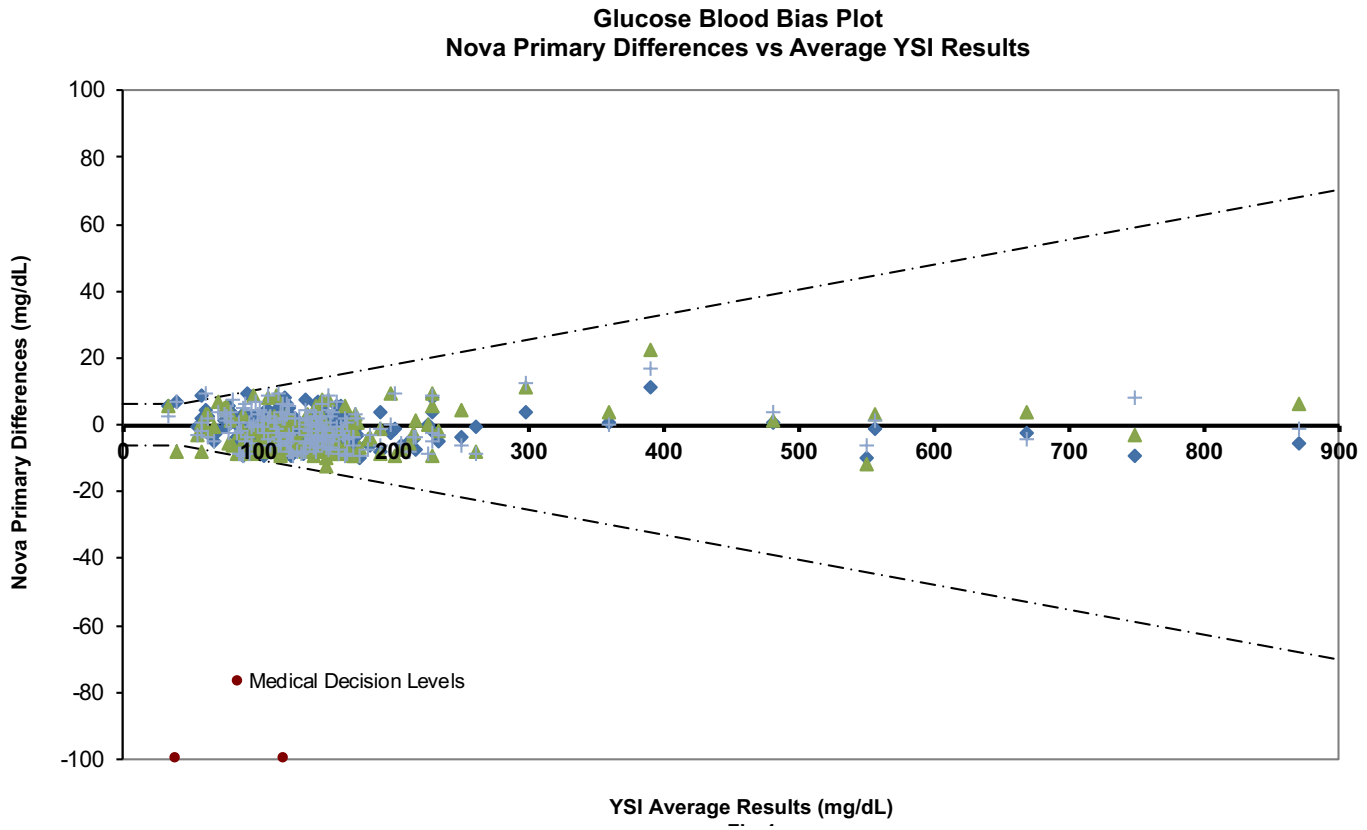
Whole Blood Method Comparison Nova Primary vs YSI 2300

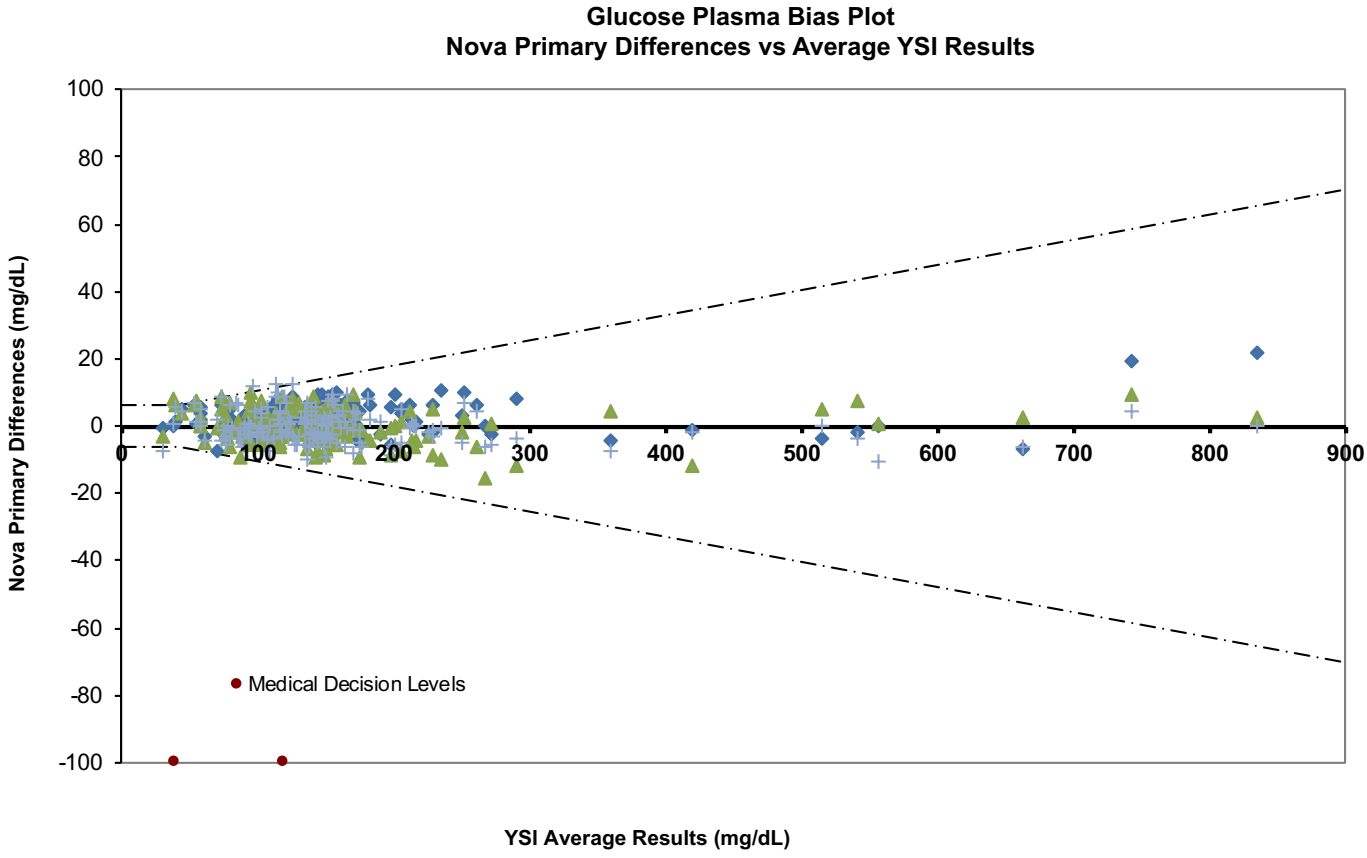
Nova Primary Analyzer	N	# altered samples	range	Slope	Intercept	r
GP01	174	15	34-871	0.9927	0.3878	0.9992
GP02	174	15	34-871	1.0017	-1.5404	0.9990
GP03	174	15	34-871	1.0083	-3.7425	0.9989

Table A-4

Plasma Method Comparison Nova Primary vs YSI 2300

Nova Primary Analyzer	N	# altered samples	range	Slope	Intercept	r
GP01	170	15	30-835	1.0088	1.1364	0.9992
GP02	170	15	30-835	0.9935	1.0018	0.9991
GP03	170	15	30-835	1.0002	-0.2388	0.9991


Glucose Blood Bias Plot
Nova Primary Differences vs Average YSI Results
Nova Primary Differences (mg/dL)
100
80
60
40
20
0
-20
-40
-60
-80
-100
0
100
200
300
400
500
600
700
800
900
Medical Decision Levels
YSI Average Results (mg/dL)


Glucose Plasma Bias Plot
Nova Primary Differences vs Average YSI Results
Nova Primary Differences (mg/dL)
100
80
60
40
20
0
-20
-40
-60
-80
-100
0
100
200
300
400
500
600
700
800
900
Medical Decision Levels
YSI Average Results (mg/dL)

A.4.2 PRECISION

A.4.2.1 WITHIN-RUN PRECISION PERFORMANCE

Within-run precision was assessed for aqueous (QC/Linearity), whole blood, and plasma specimens by measuring 20 replicates of targeted sample concentrations on three analyzers. The average, SD, and CV% for each analyzer for each sample type and level were calculated. The pooled average, SD, and CV% from all 3 analyzers for each QC level were calculated. The venous whole blood and plasma samples were manipulated to increase the glucose levels.

Nova Primary
QC and Linearity Within Run Precision

Quality Control Level 1				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	76	73	75	74
SD	1.6	1.9	1.2	1.9
CV%	2.1	2.5	1.6	2.6

Quality Control Level 2				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	180	181	178	180
SD	1.7	1.4	1.8	2.1
CV%	0.9	0.8	1.0	1.2

Linearity Level 1				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	524	528	521	525
SD	2.7	3.6	2.3	4.2
CV%	0.5	0.7	0.4	0.8

Linearity Level 2				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	869	862	868	866
SD	13.3	10.6	11.1	11.9
CV%	1.5	1.2	1.3	1.4

Nova Primary Whole Blood Within Run Precision				
Whole Blood Level 1				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	35	34	34	34
SD	1.0	1.4	1.0	1.4
CV%	2.9	4.0	2.9	4.0
Whole Blood Level 2				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	75	74	78	76
SD	1.6	1.2	2.1	2.5
CV%	2.1	1.7	2.7	3.3
Whole Blood Level 3				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	181	181	178	180
SD	2.7	2.8	2.9	3.1
CV%	1.5	1.5	1.6	1.7
Whole Blood Level 4				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	309	308	308	308
SD	3.7	2.5	3.2	3.2
CV%	1.2	0.8	1.0	1.0
Whole Blood Level 5				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	507	510	512	510
SD	8.3	8.4	7.3	8.2
CV%	1.6	1.6	1.4	1.6
Whole Blood Level 6				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	677	680	675	677
SD	8.5	7.6	12.4	9.7
CV%	1.3	1.1	1.8	1.4
Whole Blood Level 7				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	761	763	762	762
SD	13.0	11.3	14.2	12.7
CV%	1.7	1.5	1.9	1.7

Nova Primary Plasma Within Run Precision				
Plasma Level 1				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	37	36	36	36
SD	0.5	0.6	0.7	0.7
CV%	1.4	1.7	1.9	1.9
Plasma Level 2				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	121	120	122	121
SD	1.7	1.0	1.5	1.5
CV%	1.4	0.8	1.2	1.2
Plasma Level 3				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	186	187	183	185
SD	1.7	1.3	1.2	2.5
CV%	0.9	0.7	0.7	1.4
Plasma Level 4				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	398	404	400	401
SD	2.0	3.1	1.8	3.4
CV%	0.5	0.8	0.4	0.8
Plasma Level 5				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	558	556	558	557
SD	4.1	3.7	4.5	4.2
CV%	0.7	0.7	0.8	0.7
Plasma Level 6				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	696	698	692	695
SD	6.0	5.4	6.4	6.4
CV%	0.9	0.8	0.9	0.9
Plasma Level 7				
n = 20	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	846	845	841	844
SD	3.7	8.4	6.6	6.8
CV%	0.4	1.0	0.8	0.8

A.4.2.2 WHOLE BLOOD RUN-TO-RUN PRECISION PERFORMANCE

To simulate total run-to-run precision for whole blood, samples of targeted concentrations were run in triplicate in ten separate runs during a single day. Each analyzer was calibrated between triplicate runs. The average SD and CV% for each analyzer for each level were calculated. The venous whole blood samples were manipulated to increase the glucose levels.

Nova Primary Whole Blood Run-to-Run Precision				
Whole Blood Level 1				
n = 30	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	37	38	37	37
SD	1.2	1.5	1.7	1.5
CV%	3.3	3.9	4.6	4.1
Whole Blood Level 2				
n = 30	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	80	81	82	81
SD	1.6	2.1	1.9	2.1
CV%	2.0	2.6	2.3	2.5
Whole Blood Level 3				
n = 30	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	190	192	196	193
SD	3.1	3.6	2.8	4.1
CV%	1.6	1.9	1.4	2.1
Whole Blood Level 4				
n = 30	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	370	373	375	373
SD	7.2	6.6	6.3	6.9
CV%	1.9	1.8	1.7	1.9
Whole Blood Level 5				
n = 30	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	547	551	553	550
SD	14.2	6.1	12.9	11.8
CV%	2.6	1.1	2.3	2.1
Whole Blood Level 6				
n = 30	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	656	658	660	658
SD	13.3	10.3	11.0	11.6
CV%	2.0	1.6	1.7	1.8

A.4.2.3 QUALITY CONTROL AND PLASMA RUN-TO-RUN PRECISION PERFORMANCE

Estimates of the run-to-run precision were determined for each level of Quality Control and plasma. Statistical analysis included individual and pooled analyzer imprecision from 3 analyzers. The plasma samples were altered to decrease or increase the glucose levels.

Nova Primary Quality Control Run-to-Run Precision				
Quality Control Level 1				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	74	74	74	74
SD	2.3	1.9	1.7	2.0
CV%	3.1	2.6	2.2	2.7

Quality Control Level 2				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	198	195	202	198
SD	3.9	1.9	2.5	3.9
CV%	1.9	1.0	1.2	2.0

Nova Primary Plasma Run-to-Run Precision				
Plasma Level 1				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	39	40	41	40
SD	1.7	1.3	0.9	1.4
CV%	4.2	3.2	2.3	3.5

Plasma Level 2				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	99	93	95	96
SD	2.9	2.9	2.6	3.5
CV%	2.9	3.1	2.8	3.7

Plasma Level 3				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	201	198	199	199
SD	5.6	6.1	4.7	5.6
CV%	2.8	3.1	2.4	2.8

Plasma Level 4				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	405	408	413	409
SD	12.2	13.4	13.4	13.4
CV%	3.0	3.3	3.2	3.3

Plasma Level 5				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	560	576	579	572
SD	11.7	19.2	14.0	17.4
CV%	2.1	3.3	2.4	3.1

Plasma Level 6				
n = 80	**Analyzer GP01**	**Analyzer GP02**	**Analyzer GP03**	**Pooled**
Mean (mg/dL)	740	781	789	770
SD	15.1	26.2	22.4	30.5
CV%	2.0	3.4	2.8	4.0

A.5 CALIBRATOR PACK

In addition to the calibrators and solutions, the Calibrator Pack has a self-contained waste bag for safe disposal of waste.

WARNING: Exposure to Blood Borne Pathogens.

A.6 TRACEABILITY OF CALIBRATORS, CONTROLS, AND STANDARDS

The Glucose Calibrators, Controls, and Standards are traceable to National Institute of Standards and Technology (NIST) Standard SRM-917.

A.7 REFERENCE VALUES

Each laboratory should establish and maintain its reference values. The values shown below should be used only as a guide.

Analyte	Default (U.S.) Units of Measure
Glucose (Serum, Fasting, Adult)[1]	**74 - 100 mg/dL**

Reference

1. Burtis, Carl A. and Bruns, David E., ed. 2015. Tietz Fundamentals of Clinical Chemistry, Saunders St. Louis, MO.

A.8 CYBERSECURITY

A.8.1 CYBERSECURITY PROTECTION OVERVIEW

The Nova Primary system includes extensive safeguards to protect the system from outside cybersecurity attacks. In the following sections, you will find a summary of the safeguards. Professional laboratory and Information Technology users that require extensive information and details may contact Nova Biomedical Technical Support at 1-800-545-6682 in North America. Outside of the USA, contact your authorized Nova Primary distributor.

A.8.2 SOFTWARE UPDATES

Healthcare facilities will be notified by Nova Biomedical Technical Support or a local dealer when a software update becomes available. Customer communication is through a Customer Information Bulletin that is forwarded to primary contacts within each healthcare facility. Nova factory-trained Field Support Specialists perform Nova Primary software updates. The software update image is not made public or left at healthcare facility sites. All valid software updates are password protected and contain an embedded SHA-512 cryptographic digest. The Nova Primary Analyzer will not execute a software update if it cannot verify the SHA-512 digest from the update image. Installation of a Nova software update can be scheduled through Nova Technical Support or your local distributor.

A.8.3 OPERATING SYSTEM PATCHES

The Nova Primary Analyzer main operating system is an embedded version of Windows® that has been “trimmed” to contain only applications and drivers that are pertinent to the functionality of the analyzer. Each new Nova Primary software version contains the latest Microsoft Operating System patches available at the time of software release by Nova Biomedical. In addition, healthcare facilities should apply Windows Operating System updates on a schedule consistent with their IT department security policy.

For network-connected analyzers, you may download operating system patches directly from Microsoft®. This requires a time-limited password that changes daily and is available only after contacting Nova Biomedical Technical Support or your local distributor. Outgoing ports from the firewall become temporarily enabled for the duration of the download. The SH-2 signature from Microsoft protects the download image. If the signature cannot be verified, Windows will not install the patch.

Operating system patches may also be performed off-line via a USB drive. This requires a time-limited password that changes daily and is available only after contacting Nova Biomedical Technical Support or your local distributor. The USB device must be explicitly identified and enabled by a factory trained service representative. The SH-2 signature from Microsoft protects the patch image. If the signature cannot be verified, Windows will not install the patch.

Installation of Windows Operating System patches can be scheduled through Nova Technical Support or your local distributor.

A.8.4 ANTI-MALWARE UPDATES

The Nova Primary Analyzer runs the Windows Defender anti-malware platform. Microsoft publishes regular updates of virus and malware definitions to identify new threats as they are discovered in the field. Healthcare facilities should apply Windows Defender updates on a schedule consistent with their IT department security policy. Windows Defender updates are initiated from the Network Configuration screen and can be performed by IT department users with administrative level accounts.

For network-connected analyzers, operating malware definition updates may be downloaded directly from Microsoft. This requires a time-limited password that changes daily and is available only after contacting Nova Biomedical Technical Support or your local distributor. Outgoing ports from the firewall are temporarily enabled for the duration of the download. The SH-2 signature from Microsoft protects the download image. If the signature cannot be verified, Windows will not install the update.

Malware definition updates may also be performed offline via a USB drive. This requires a time-limited password that changes daily and is available only after contacting Nova Biomedical Technical Support or your local distributor. The USB device must be explicitly identified and enabled by a factory-trained service representative. The SH-2 signature from Microsoft protects the updated image. If the signature cannot be verified, Windows will not install the update.

Installation of a Windows defender update can be scheduled through Nova Technical Support or your local distributor.

A.8.4.1 MALWARE CONTROL

The Nova Primary software update image is created following a strict factory procedure that defines the process steps required to ensure that software is free of viruses, malware, and other non-intended consequences. And the system continually runs Windows Defender in the background to scan for viruses and malware.

A.8.5 CREATION OF SOFTWARE FOR RELEASE

Nova Primary software is built on a virtual computer-controlled and physically accessed only by Nova Biomedical Information Technology resources. The virtual computer is scanned for viruses daily. The introduction of malware is not possible through physical access. The virtual computer is exclusively utilized to create Nova Primary software.

A.8.6 SECURITY RISKS RELATED TO ETHERNET CONNECTIVITY

The Nova Primary Analyzer has one RJ-45 Ethernet port. As shipped, the port is physically secured behind an access plate. If access to the port is required for data export or software updates, the access plate must be removed.

Ethernet communication is further protected by the Windows Firewall. In normal operation, all incoming and outgoing ports except for DHCP and NTP are blocked.

Outgoing ports required for operating system security updates may be explicitly enabled by a logged-in user.

Incoming ports for diagnostic purposes are accessible only to factory trained service representatives and requires a time-limited password that changes daily and is available only after contacting Nova Biomedical Technical Support or your local distributor.

A.8.7 SECURITY RISKS RELATED TO USB PORTS

There are many potential risks associated with USB devices. The simplest threats are when a common USB storage device is infected with files containing a virus or malware. More sophisticated threats include normal-looking storage devices that conceal other types of USB devices.

A hidden HID device may attempt to compromise the system by injecting operating system commands to install a virus or malware. A hidden network device may attempt to redirect communication to or from malicious sites.

A.8.8 PHYSICAL PROTECTION

The Nova Primary Analyzer contains one external USB port. As shipped, the port is physically secured behind an access plate. If access to the port is required for data export or software updates, remove the access plate.

A.8.9 DRIVER LEVEL PROTECTION

As further protection, any devices plugged into the USB port are immediately disabled at the device driver level. Before a device can be used, it must be explicitly identified and enabled through the Nova Primary GUI by a logged-in user. Only USB Storage devices may be enabled in this way. Other device types such as HID or Ethernet devices remain disabled at the driver level.

A.8.9.1 DATA IMPORT

Data import operations on USB Storage devices are limited to software and security updates as detailed above. "Autorun" is disabled at the operating system level. Transferring malware or a virus from the storage device would require operating system access. This is protected by a time-limited password that changes daily and is available only after contacting Nova Biomedical Technical Support or your local distributor.

A.8.9.2 DATA EXPORT

Data and log files can be exported to a USB storage device. First, the device must be explicitly identified and enabled by a logged-in user. Exported files can be encrypted.

A.8.10 FIREWALL SETUP AND MAINTENANCE

As shipped to end user facilities, the Nova Primary firewall is configured with all inbound ports disabled, except for port 68 for DHCP. Default outbound ports are limited to DHCP, NTP, and those required for Microsoft Defender updates. Outbound ports for external LIS systems can be configured via the Network Configuration display in the Nova Primary GUI. The Nova Primary does not support other alterations to the firewall configuration.

The Nova Primary automatically scans the firewall state every 30 minutes. Detected differences from the configured state are logged in the database, and the configuration is re-asserted.

A.9 EMISSION AND IMMUNITY TESTING

EMC testing on the Nova Primary Glucose System was conducted to IEC 60601-1-2-2014 standard. The Nova Primary Glucose Analyzer System met the Basic Safety and Essential Performance. Essential Performance was defined as follows: the Nova Primary Glucose Analyzer may reset when power is interrupted and/or the display may jitter on multiple ESD events during testing, allowing for an immediate return to an operational state. This minimizes the risk associated with delayed test results. The analyzer must not experience a non-recoverable ESD event that prevents the analyzer from returning to an immediate operational state.

Testing met the following standards:

Test	Result	Customer Specified Criterion
IEC 61000-4-2	Pass	Basic Safety and Essential Performance
IEC 61000-4-3	Pass	Basic Safety and Essential Performance
IEC 61000-4-4	Pass	Basic Safety and Essential Performance
IEC 61000-4-5	Pass	Basic Safety and Essential Performance
IEC 61000-4-6	Pass	Basic Safety and Essential Performance
IEC 61000-4-8	Pass	Basic Safety and Essential Performance
IEC 61000-4-11	Pass	Basic Safety and Essential Performance

Testing demonstrated that when used in clinical laboratory settings, the Nova Primary Glucose System met Basic Safety and Essential Performance. The system has not been evaluated for use in Point-of-Care settings, or healthcare settings in close proximity to patient-connected devices.

A.10 ORDERING INFORMATION

Description	Reference Number
Calibrator Cartridges	
Nova Primary Calibrator Cartridge 450 Sample	63162
Nova Primary Calibrator Cartridge 150 Sample	63167
Sensors and Membranes	
Nova Primary Glucose Sensor	63231
Nova Primary Glucose Membrane	63230
QC and Linearity	
Nova Primary Ampuled Control	63164
Nova Primary Linearity Level 1	63165
Nova Primary Linearity Level 2	63166
Other	
Assembly Pump Tubing Harness Nova Primary	63568
Replacement Probe/S-Line Nova Primary	63679
Replacement Syringe, 500 µL Nova Primary	63772
Replacement Power Supply Nova Primary	64118
Thermal (Printer) Paper	49200
Backflush Kit	63933
Barcode Scanner	63524
Flushing Adapter	66021

B THEORY

This section explains the instrument theory of the Nova Primary Glucose Analyzer.

B.1 TWO-POINT CALIBRATION

The analyzer uses a 2-point calibration to set the glucose sensor slope and verify sensor performance. The Calibrator Pack contains the standards that are used for this purpose. Calibration can be initiated manually by pressing CALIBRATE from the Destinations overlay and will also occur automatically at regular intervals.

B.2 ONE-POINT CALIBRATION

The determination of the activity for an unknown sample is dependent on both the electrode potential generated by the unknown and that generated by the standard. Sensor drift is the slow variation in sensor response over time. To monitor and minimize the effect of sensor drift on the analytical results, the analyzer uses a 1-point calibration during sample analysis. A drift error will occur when the 1-point calibration is beyond the validated acceptable drift limits and the result will not be reported.

B.3 PRINCIPLE OF MEASUREMENT

Measuring Technology: Measures blood glucose utilizing a discrete glucose sensor and membrane/cap assembly, that are user-replaceable, and based on the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme.

B.3.1 GLUCOSE

Glucose measurement is based on the level of H_2O_2 produced during the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the glucose concentration of the sample.

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose Oxidase}} \text{Gluconic acid} + H_2O_2$$

At a constant potential of 0.70 volts, electroactive H_2O_2 is oxidized at the surface of the platinum anode as follows:

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

The current generated by the flow of electrons at the surface of the platinum sensor is proportional to the glucose concentration of the sample.

B.4 WARRANTY

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C)Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. All parts replaced under the original warranty will be war-ranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure. Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. All requests for service outside Nova's principal hours of operation will be rendered at the prevailing weekend/holiday rates after receipt of an authorized purchase order. Contact Nova for specific information. The following exceptions apply:

1. The The glucose membrane is warranted as stated on the insert that is shipped with the membrane, provided they are stored as stated on the packaging and placed into service prior to the expiration date on the packaging. This warranty is invalid under the conditions specified after item 4.
2. Consumable items, including the calibrator cartridges and reagent packs, pump tubing, and external and internal standards are warranted to be free of defects at time of installation. The item must be placed into service prior to the expiration date printed on the packaging. All defects must be promptly reported to Nova Biomedical in writing. This warranty is invalid under the conditions specified after item 4.
3. Freight is paid by the customer.

The above warranties are invalid if:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranties on sensor cards, tubing, probe, or other parts if these parts are used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts. Reagent formulations not manufactured by Nova Biomedical may contain acids, concentrated salt solutions, and artificial preservatives that have been shown to cause problems such as shortened sensor life, electrode drift, erratic analytical results, and inaccurate instrument performance.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

IN ORDER FOR THE WARRANTY TO BE EFFECTIVE, THE WARRANTY CARD MUST BE SENT TO NOVA BIOMEDICAL, 200 PROSPECT STREET, WALTHAM, MASSACHUSETTS, 02453, USA.