

Instructions for Use Manual

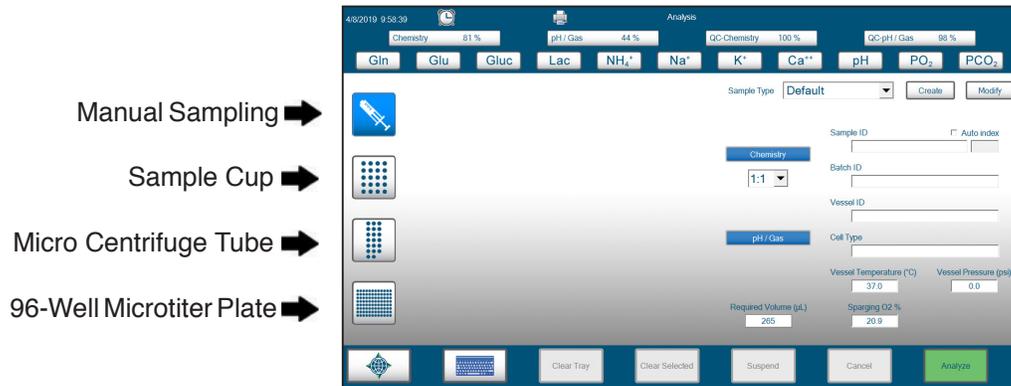


BioProfile® FLEX2 Basic A, B, C
Quick Reference Guide

nova®
biomedical

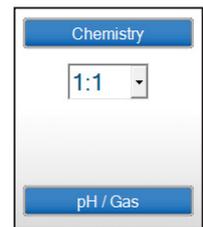
Performing a Sample Analysis

The BioProfile FLEX2 Basic A, B, C analyzers offer four different methods of sampling:



Running a Manual Sample

- Select the Analysis button from the Left Home Screen. 
- Select the Manual Analysis button. 
- Select a pre-configured Sample Type from the dropdown menu or use the Default Sample Type.
- Select or deselect the desired modules by tapping the module buttons. A selected module will turn **BLUE**.
- Configure the Chemistry Module dilution ratio by using the dropdown under the Chemistry button.



NOTE: *After module configuration, the required volume for the sample analysis will appear on the screen.*

- Enter sample information into the open fields.
- Vessel Temperature, Vessel Pressure and Sparging O₂% can be edited by selecting the appropriate field.
- Press  and wait for the probe to appear.
- Once probe is visible, present the sample to the probe and select **Aspirate**.

This image shows the sample information configuration screen. It includes fields for 'Sample ID' (with an 'Auto index' checkbox), 'Batch ID', 'Vessel ID', and 'Cell Type'. Below these are fields for 'Vessel Temperature (°C)' (37.0), 'Vessel Pressure (psi)' (0.0), and 'Sparging O₂ %' (20.9).

Running a Sample Cup or Micro Centrifuge Tube Sample

- Select the Analysis button from the Left Home Screen. 
- Select the Sample Cup or Micro Centrifuge Tube Analysis   button depending on which tray is currently installed.
- Select a cup location by tapping the corresponding cup indicator on the screen.
- Select a pre-configured Sample Type from the dropdown menu or use the Default Sample Type.
- Select or deselect the desired modules by tapping the module buttons. A selected module will turn **BLUE**.
- Configure the Chemistry Module dilution ratio by using the dropdown under the Chemistry button.



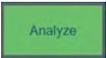
CAUTION: *Nova recommends that Sample Cup and Micro Centrifuge tubes be filled with 400µL to mitigate short sampling. For Sample Cup analysis, use the Bioprofile Sample Cup (PN 58275).*

- Enter the sample information into the open fields.
- Vessel Temperature, Vessel Pressure and Sparging O₂%, can be edited by selecting the appropriate field.
- Press  to start analysis.

Running a 96-Well Microtiter Plate Sample

- Select the Analysis button from the Left Home Screen. 
- Select the 96-Well Microtiter Plate button. 
- Select a tray location by tapping the corresponding position on the screen.
- Select a pre-configured Sample Type from the dropdown menu or use the Default Sample Type.
- Select or deselect the desired modules by tapping the module buttons. A selected module will turn **BLUE**.
- Configure the Chemistry Module dilution ratio by using the dropdown under the Chemistry button.

CAUTION: *Nova recommends that wells be filled with 400µL to mitigate short sampling.*

- Enter the sample information into the open fields.
- Vessel Temperature, Vessel Pressure and Sparging O₂%, can be edited by selecting the appropriate field.
- Press  to start analysis.

Consumable Replacements

Changing a pH/Gas Calibrator Cartridge

- Pull the tab on the left side of the main analyzer door to open the door.
- Remove the existing cartridge by pulling on the white handle on the front of the pack.
- Replace the pH/Gas Calibrator Cartridge by positioning the pack into the pack chamber and pushing it until the pack is flush with the analyzer chassis.
- Close the analyzer door.

NOTE: *The Smart Maintenance feature will automatically detect the new Calibrator Cartridge and will prime and calibrate the module. As this proceeds, the Time to Completion icon will appear in the top right corner of the User Interface.*



Changing a Chemistry Calibrator Cartridge and Reagent Cartridge

The Chemistry module uses two cartridges: the Calibrator Cartridge (small pack) and Reagent Cartridge (large pack). These packs must be changed together. Prior to installing the cartridges, the Calibrator Cartridge must be activated.

- Activate the Calibrator Cartridge by unfastening the clips on the bags and removing them.
- Push the internal cup through the crease created by the clip and close the top flap.
- Vigorously shake the pack back and forth for 2 minutes to activate.
- Pull the tab on the left side of the analyzer to open the door.
- Remove the existing Reagent Cartridge and Calibrator Cartridge.
- Replace the Reagent Cartridge and Calibrator Cartridge by positioning each pack into the appropriate pack chamber and pushing it until the pack is flush with the analyzer chassis.
- Close the main analyzer door.

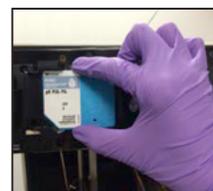
NOTE: *The Smart Maintenance feature will automatically detect the new Cartridge and will prime and calibrate the module. As this proceeds, the Time to Completion icon will appear in the top right corner of the User Interface.*



Changing a MicroSensor Card™

- Pull the tab on the left side of the main analyzer door to open the door.
- Open the pH/Gas or Chemistry sensor module by gently pulling on the black cover.
- Remove the existing card and replace by positioning the new MicroSensor Card into the holder.
- Close the sensor module door and close the analyzer door.

NOTE: *The Smart Maintenance feature will automatically detect the new MicroSensor Card and will install, prime, and hydrate the card. As this proceeds, the Time to Completion icon will appear in the top right corner of the User Interface.*



Additional training can be found here: <http://www.brainshark.com/novabio/FLEX2>

NOTE: *The Brain Shark Training videos are modeled using the FLEX2 analyzer. Although some procedures and screens differ, many of the applications and maintenance procedures are still applicable to the FLEX2 Basic A, B, C analyzers.*

BioProfile® FLEX2 Basic A, B, C Instructions for Use Manual

Order and Download Information

The *BioProfile® FLEX2 Basic A, B, C Instructions for Use Manual* can be ordered from Nova Biomedical Order Services or downloaded from Nova Biomedical's product documentation website.

Contact Nova Biomedical Order Services:

Nova Biomedical	Telephone: 1-800-822-0911
200 Prospect Street	Email: novaorders@novabio.com
Waltham, MA 02454-9141	Nova-OrdersSupport@novabio.com
U.S.A.	Website: www.novabiomedical.com

Download PDF from Nova Biomedical's Product Documentation Website:

www.novabiomedicaldocs.com

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

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

Trademarks

BioProfile® is a registered trademark of Nova Biomedical.

Copyright

Printed in the U.S.A. Copyright 2025, Nova Biomedical, Waltham, MA 02454-9141.

Table of Contents

1	Introduction	1-1
1.1	About This Manual.....	1-1
1.2	Safety	1-1
1.3	Installation and Use.....	1-2
1.4	System Requirements	1-3
1.5	Intended Use and Tests Performed.....	1-4
1.6	The Sample.....	1-4
	1.6.1 Handling Requirements.....	1-4
	1.6.2 Test Menu and Analytical Ranges	1-4
	1.6.3 Alternate Units of Measure.....	1-6
1.7	Interfering Substances	1-6
2	Getting Started	2-1
2.1	Power Up Procedure.....	2-1
2.2	Operational Overview	2-2
	2.2.1 System Log-In	2-2
	2.2.2 Home Screens	2-2
	2.2.3 Status Bar	2-3
	2.2.4 Destinations Icon.....	2-10
	2.2.5 Analysis Menus	2-10
	2.2.6 Historical Results Menu	2-12
	2.2.7 Calibration Menu	2-14
	2.2.8 QC Menu	2-14
	2.2.9 User Menu.....	2-15
	2.2.10 Maintenance Menu	2-15
	2.2.11 Settings Menu	2-16
	2.2.12 Logs Menu	2-16
	2.2.13 Database Menu	2-16
	2.2.14 Service Menu	2-17
	2.2.14.1 Customer Service.....	2-17
	2.2.14.2 Nova Service	2-18
	2.2.15 Standby Menu	2-19
	2.2.16 Shut Down	2-19
2.3	System Calibration	2-19
	2.3.1 Automatic Module Calibration	2-19
	2.3.2 Smart Maintenance Functionality.....	2-19
	2.3.3 pH/Gas Module Calibration	2-20
	2.3.4 Chemistry Module Calibration	2-20
	2.3.5 pH/Gas & Chemistry Combined	2-21
	2.3.6 Warranty Support	2-21

3	Operation	3-1
3.1	Keyboard, Mouse, and Scanner (Optional)	3-1
3.2	Analytical Unit	3-1
3.2.1	pH/Gas Module	3-1
3.2.1.1	pH/Gas Calibrator Cartridge	3-1
3.2.1.2	pH/Gas MicroSensor Card	3-2
3.2.1.3	pH/Gas Reference Sensor	3-2
3.2.1.4	pH/Gas Pump Tubing Harness	3-2
3.2.2	Chemistry Module	3-3
3.2.2.1	Chemistry Calibrator and Reagent Cartridges	3-3
3.2.2.2	Chemistry MicroSensor Card	3-3
3.2.2.3	Chemistry Reference Sensor	3-4
3.2.2.4	Chemistry Pump Tubing Harness	3-4
3.3	Onboard Quality Control	3-4
3.3.1	QC Lockout Feature	3-7
3.4	Analyzer Settings	3-8
3.4.1	General Settings	3-9
3.4.1.1	Analyzer ID	3-9
3.4.1.2	Analyzer Location	3-9
3.4.1.3	Enable/Disable Auto Logoff	3-9
3.4.1.4	Enable/Disable Sample Results Auto Export	3-10
3.4.1.5	Exported Data Directly to USB through Bridge Computer	3-12
3.4.1.6	Enable/Disable Onscreen Keyboard	3-12
3.4.1.7	Date Format Configuration	3-12
3.4.1.8	Date Separator Configuration	3-13
3.4.1.9	Hour Time Configuration	3-13
3.4.1.10	Numeric Format Configuration	3-13
3.4.1.11	Enable Onboard QC	3-13
3.4.1.12	Use Network Login	3-14
3.4.2	Create/Edit Users	3-14
3.4.2.1	Creating A User Account	3-14
3.4.2.2	Changing a User Account	3-15
3.4.2.3	Importing & Exporting User Accounts	3-16
3.4.2.4	User Account Privilege Levels	3-16
3.4.3	Parameters Settings	3-18
3.4.3.1	Configuring Units of Measure	3-18
3.4.3.2	Test Suppression	3-19
3.4.4	Scheduling Automatic QC & Maintenance	3-19
3.4.4.1	Onboard QC Scheduling	3-20
3.4.4.2	Chemistry/Gas Calibration Time Scheduling	3-20
3.4.4.3	Depro Wells Scheduling	3-20
3.4.4.4	Database Backup Scheduling	3-21
3.4.5	OPC	3-21
3.4.6	Active Directory	3-21
3.4.7	Sample Information List Management	3-22
3.4.7.1	Deleting Sample List Entries	3-22
3.4.7.2	Sample ID Auto-Indexing Configuration	3-22
3.5	Running an Analysis	3-23
3.5.1	Select Sample Type	3-25
3.5.2	Select Parameter Panel	3-27
3.5.3	Enter Sample Information	3-27
3.5.4	Module Configuration & Analysis	3-28

3.6	Audit Log Notation	3-29
3.7	Error Log Notation	3-32
3.8	Calibration Log	3-32
3.9	Maintenance Log	3-33
3.10	Warranty Log	3-33
3.11	Diagnostic Logs	3-34
3.12	Database	3-34
	3.12.1 Backing Up the Database	3-34
	3.12.2 Restoring the Database	3-35
4	Maintenance	4-1
4.1	System Maintenance Screen	4-1
	4.1.1 Module DePro	4-1
	4.1.2 DePro Wells	4-2
	4.1.3 Change Syringe	4-2
	4.1.4 Change Probe	4-3
	4.1.5 Change Pump Tubing	4-3
	4.1.6 Long-Term Shutdown	4-5
4.2	pH/Gas Module	4-6
	4.2.1 Installing pH/Gas Calibrator Cartridge	4-6
	4.2.2 Installing pH/Gas Sensor Card.....	4-7
	4.2.3 Installing the pH/Gas Reference Sensor.....	4-7
4.3	Chemistry Module	4-8
	4.3.1 Installing Chemistry Calibrator Cartridge	4-8
	4.3.2 Installing Chemistry MicroSensor Card.....	4-10
	4.3.3 Installing the Chemistry Reference Sensor.....	4-11
4.4	Service Menu	4-12
	4.4.1 RFID Test	4-12
	4.4.2 Resource Issues	4-13
	4.4.3 Auto Log.....	4-13
	4.4.4 PSoCs Test	4-13
4.5	Cleaning FLEX2 Basic A, B, C Surfaces	4-13
	4.5.1 Flowpath Service.....	4-14
	4.5.1.1 Gas Sensor Module.....	4-14
	4.5.1.2 Chemistry Sensor Module	4-18
	4.5.1.3 Additional Flowpath Service Controls	4-20
5	Troubleshooting	5-1
5.1	Troubleshooting Procedures	5-1
5.2	Error Codes	5-1
5.3	Troubleshooting Steps for Flowpath Service	5-35
	5.3.1 Waste Well Blocked	5-35
	5.3.2 No Sample Acquired Error	5-36
	5.3.3 pH Gas No Standard A, No Standard B, or no Flush Error	5-39
	5.3.4 Chemistry Well Blocked	5-40
	5.3.5 Chemistry No Standard D1, No Standard D2, and No DFlush Error	5-42

A	Instrument Specifications	A-1
A.1	Instrument Specifications	A-1
A.2	BioProfile FLEX2 Basic A, B, C Spare Parts & Supplies List	A-4
B	Theory	B-1
B.1	pH/Gas and Chemistry Sensor Calibration	B-1
B.1.1	Two-Point Calibration	B-1
B.1.2	One-Point Calibration	B-1
B.2	Principle of Measurement	B-1
B.2.1	Sodium, Potassium, Ionized Calcium, and Ammonium	B-1
B.2.2	pH Measurement	B-1
B.2.3	Partial Pressure of Carbon Dioxide (<i>PCO</i> ₂)	B-2
B.2.4	Partial Pressure of Oxygen (<i>PO</i> ₂)	B-2
B.2.5	Glucose	B-2
B.2.6	Lactate	B-2
B.2.7	Glutamine and Glutamate	B-2
B.3	Calculated Values	B-3
B.3.1	Temperature Correction for Measured Values	B-3
B.3.2	Calculated Parameters	B-3
B.4	Warranty	B-5

1 INTRODUCTION

This manual provides all necessary instructions for the routine operation and upkeep of the BioProfile FLEX2 Basic A, B, C Analyzers. Please read this manual carefully. It has been prepared to help you attain optimum performance from your analyzer.

WARNING: *Cell culture samples are potential sources of infectious agents. Handle all sample and flow path components (sensor cards, reagent packs, pump tubing, etc.) with care. Gloves and personal protective clothing are recommended.*



This section introduces the BioProfile FLEX2 Basic A, B, C Analyzers and covers requirements, tests performed, procedural limitations, and sample handling.

NOTE: *Under the BioProfile Warranty, a Qualified Nova service representative will install this equipment for you.*

1.1 ABOUT THIS MANUAL

This manual is for the Nova Biomedical BioProfile FLEX2 Basic A, B, C Chemistry Analyzers. Throughout this manual:

NOTE: *Indicates especially important information.*

CAUTION: *Indicates information that is critical to avoid instrument damage or incorrect results.*

WARNING: *Indicates possible hazard to the operator.*

1.2 SAFETY

Personnel operating the BioProfile FLEX2 Basic A, B, C must be proficient in the operation and replacement procedures of the analyzer. The following safety procedures must 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 on a bench or stand that is recommended by the manufacturer.
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 only 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.
16. Do not attempt to override the door latch safety mechanism unless instructed by a trained Nova Representative.

Electrical Safety

1. To reduce the risk of electric shock, do not remove the analyzer cover.
2. There are no operator serviceable parts inside the analyzer.
3. Servicing must be done only by qualified service personnel.
4. Before changing the fuses, unplug the power cord.
5. Replace the fuses with only the same type and rating.
6. To reduce the risk of fire or electric shock, do not expose the analyzer to water.
7. The analyzer is supplied with a main, non-rewireable plug for the intended country.
8. Ensure that the wall outlet receptacle is properly wired and earth grounded.
9. DO NOT use a 3 to 2 wire plug adaptor.
10. 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 toxic materials to prevent the generation of aerosols.
4. Wear appropriate laboratory attire, *e.g.*, *safety glasses, gloves, lab coat, and breathing apparatus*, when working with hazardous materials.
5. Dispose of all waste solutions according to company standard operating procedures.
6. Some BioProfile FLEX2 Basic A, B, C reagent packs contain a waste bag/pouch where biological material will be collected. This is considered a biohazard and should be disposed of according to company and/or state or local procedures.

1.3 INSTALLATION AND USE

This section covers the installation requirements and assembly procedures for the BioProfile FLEX2 Basic A, B, C analyzers. Prior to use of the analyzer, operators should be familiar with the operation and operating procedures of the system.

Federal Communications Commission (FCC) Notice

The BioProfile FLEX2 Basic A, B, C analyzers comply with Part 15 of the FCC Rules: Operation is subject to the following conditions:

1. The BioProfile FLEX2 Basic A, B, C may not cause harmful interference
2. The BioProfile FLEX2 Basic A, B, C 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 Federal Communications Commission rules.

1.4 SYSTEM REQUIREMENTS

Working Area Requirements (Environmental):

The BioProfile FLEX2 Basic A, B, C should be operated indoors. Keep the working area around the system free of dirt & debris, corrosive fumes, vibration, and excessive temperature changes.

CAUTION: *The analyzers should not be installed on the same bench top or within close proximity to any high speed centrifuge systems. Since these systems often create a significant amount of vibration, placement of the BioProfile FLEX2 Basic A, B, C analyzers near or on the same bench top may impact sample results.*

- Installation Category (II)
- Pollution Degree (2)

Electrical Requirements

- Operating Voltage Range: 100–240 VAC
- Operating Frequency: 50–60 Hz
- Power Consumption: 480 Watts
- Fuses (2): SB 8A or T8A/250V

Ambient Operating Temperature

- 15°C – 30°C (59°F – 86°F)

Operate at Humidity

- 20–85% without condensation

Dimensions	Measurement
Height	23.5in (59.69cm)
Width	16.75in (42.55cm)
Depth	25.0in (63.50cm)

Weight

- Less than 125lb (56.7kg) with installed reagent packs

Lifting the Analyzer

1. Two people are needed to lift the analyzer.

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

2. From the left side, Person #1 places right-hand and left-hand fingertips under the lower frame of the analyzer.
3. Tilt the analyzer so that both hands (one at a time) can grip under the analyzer (approximately 4 centimeters in from the front and back).
4. From the right side, Person #2 places right hand on the back of the machine to steady it as Person #1 tilts the analyzer backward.
5. Person #2 can now grip under the analyzer (approximately 4 centimeters in from the front) with the left hand. Then remove right hand from the back and grip under the analyzer (approximately 4 centimeters in from the back).
6. The analyzer now can be lifted from floor or bench and moved to a new location. If on the floor, position the analyzer to lift with your legs and not your back.
7. Place the analyzer onto a clean and flat surface.
8. Reverse the directions to place the analyzer back down.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

NOTE: The analyzer should always be re-calibrated after it has been lifted or moved. If the analyzer has been validated for use in a GMP setting, it is the responsibility of the End User to determine if re-validation is necessary if the system has been moved from one location to another.

1.5 INTENDED USE AND TESTS PERFORMED

Intended Use

The BioProfile FLEX2 Basic A, B, C are intended for the quantitative determination of pH, PO_2 , PCO_2 , glutamine (**Gln**), glutamate (**Glu**), glucose (**Gluc**), lactate (**Lac**), ammonium (**NH₄⁺**), sodium (**Na⁺**), potassium (**K⁺**), and calcium (**Ca⁺⁺**).

From the directly measured results and temperature entered by operator, the BioProfile FLEX2 Basic A, B, C offer the following calculated parameters:

- Temperature Corrected pH (for entered values other than 37°C)
- Temperature Corrected PO_2 (for entered values other than 37°C)
- Temperature Corrected PCO_2 (for entered values other than 37°C)
- Air Saturation
- CO_2 Saturation
- HCO_3^- (Bicarbonate) Concentration

1.6 THE SAMPLE

The sample material appropriate for testing on the BioProfile FLEX2 Basic A, B, C analyzers is cell culture samples and media.

This section covers sample requirements and reference values for the BioProfile FLEX2 Basic A, B, C.

1.6.1 HANDLING REQUIREMENTS

Ensure that all samples have been obtained and stored following accepted protocols. It is particularly important to ensure that samples are well mixed before introduction into the analyzer. Nova Biomedical recommends that you analyze the sample immediately to prevent changes in results due to cell metabolism and gas equilibration. Storing samples on ice is not recommended. Using iced samples may elevate the PO_2 results.

1.6.2 TEST MENU AND ANALYTICAL RANGES

Chemistry Module

FLEX2 Basic A

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gln	mmol/L	0.10	6.00	Dil. Ratio = 1:1
		0.20	12.00	Dil. Ratio = 1:2
		0.40	24.00	Dil. Ratio = 1:4
Glu	mmol/L	0.10	6.00	Dil. Ratio = 1:1
		0.20	12.00	Dil. Ratio = 1:2
		0.40	24.00	Dil. Ratio = 1:4
Gluc	g/L	0.10	15.00	Dil. Ratio = 1:1
		0.20	30.00	Dil. Ratio = 1:2
		0.40	60.00	Dil. Ratio = 1:4

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Lac	g/L	0.10	6.00	Dil. Ratio = 1:1
		0.20	12.00	Dil. Ratio = 1:2
		0.40	24.00	Dil. Ratio = 1:4
NH ₄ ⁺	mmol/L	0.20	25.00	Dil. Ratio = 1:1
		0.40	50.00	Dil. Ratio = 1:2
		0.80	100.00	Dil. Ratio = 1:4
Na ⁺	mmol/L	40.0	300.0	Dil. Ratio = 1:1
		80.0	600.0	Dil. Ratio = 1:2
		160.0	1200.0	Dil. Ratio = 1:4
K ⁺	mmol/L	1.00	100.00	Dil. Ratio = 1:1
		2.00	200.00	Dil. Ratio = 1:2
		4.00	400.00	Dil. Ratio = 1:4
Ca ⁺⁺	mmol/L	0.10	10.00	Dil. Ratio = 1:1
		0.20	20.00	Dil. Ratio = 1:2
		0.40	40.00	Dil. Ratio = 1:4

Range depends on selected dilution ratio.

FLEX2 Basic B

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gln	mmol/L	0.10	6.00	Dil. Ratio = 1:1
Glu	mmol/L	0.10	6.00	Dil. Ratio = 1:1
Gluc	g/L	0.10	15.00	Dil. Ratio = 1:1
Lac	g/L	0.10	6.00	Dil. Ratio = 1:1
NH ₄ ⁺	mmol/L	0.20	25.00	Dil. Ratio = 1:1
Na ⁺	mmol/L	40.0	300.0	Dil. Ratio = 1:1
K ⁺	mmol/L	1.00	100.00	Dil. Ratio = 1:1
Ca ⁺⁺	mmol/L	0.10	10.00	Dil. Ratio = 1:1

FLEX2 Basic C

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gluc	g/L	0.10	15.00	Dil. Ratio = 1:1
Lac	g/L	0.10	6.00	Dil. Ratio = 1:1
Na ⁺	mmol/L	40.0	300.0	Dil. Ratio = 1:1
K ⁺	mmol/L	1.00	100.00	Dil. Ratio = 1:1
Ca ⁺⁺	mmol/L	0.10	10.00	Dil. Ratio = 1:1

pH/Gas Module

Parameter	Units	Linear Range Low End	Linear Range High End
pH	-	5.000	8.000
PO ₂	mmHg	3.0	500.0
PCO ₂	mmHg	3.0	300.0

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

1.6.3 ALTERNATE UNITS OF MEASURE

The BioProfile FLEX2 Basic A, B, C support the following alternate, user-selectable units of measure:

Unit	PO2	PCO2	Gln	Glu	Gluc	Lac	NH4+
Default	mmHg	mmHg	mmol/L	mmol/L	g/L	g/L	mmol/L
Alternate	kPa	kPa	g/L	g/L	mmol/L	mmol/L	g/L

1.7 INTERFERING SUBSTANCES

Consider the list of known interfering substances when interpreting abnormally high Glucose results.

- Mannose (10 g/L) has been shown to increase Glucose concentration by approximately 0.20 g/L.
- Acetaminophen (10 mg/dL) has been shown to increase the Glucose concentration by approximately 15 mg/dL.

NOTE: *Galactose, Lactose, and Maltose have no effect on Glucose concentration. Ascorbic Acid (50 mg/dL) and Uric Acid (40 mg/dL) have no effect on Glucose concentration.*

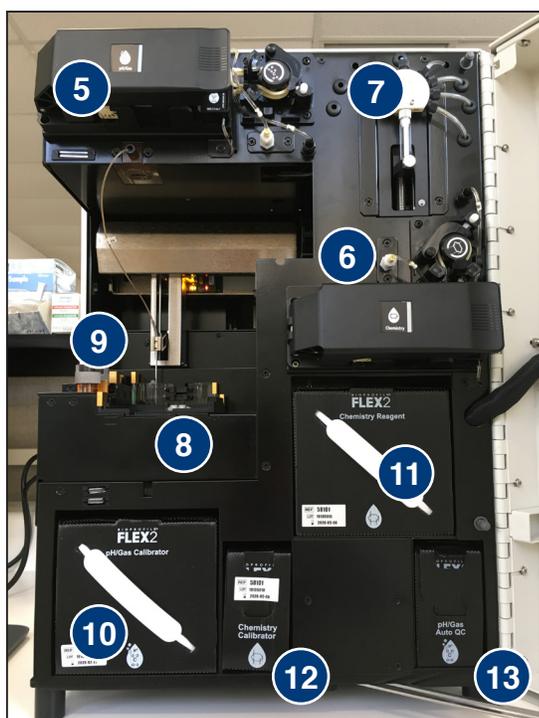
2 GETTING STARTED

The BioProfile FLEX2 Basic A, B, C Analyzer is pictured here.

- 1 User Interface
- 2 Manual Sampling Port
- 3 External USB Port
- 4 Analyzer Door
- 5 pH/gas Sensor Module



GETTING STARTED
2



- 6 Chemistry Sensor Module
- 7 Syringe Pump
- 8 User Domain
- 9 Onboard Chem QC Cartridge
- 10 pH/gas Calibrator Cartridge
- 11 Chemistry Reagent Cartridge
- 12 Chemistry Calibrator Cartridge
- 13 pH/gas Auto QC Cartridge

2.1 POWER UP PROCEDURE

The BioProfile FLEX2 Basic A, B, C analyzers are powered on using the switch on the rear of the system. When the system is powered on, it will automatically load the required operating sequences and launch 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.

CAUTION: To avoid system damage, always power the system off with the Shut Down buttons located within the Graphical User Interface. DO NOT power the BioProfile FLEX2 Basic A, B, C Analyzer off by flipping the power switch on the back of the analyzer. Once the analyzer has been completely shut down using the GUI buttons, the switch on the back of the analyzer can be moved to the OFF position.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

2.2 OPERATIONAL OVERVIEW

2.2.1 SYSTEM LOG-IN

At the time of installation, an Administrator User Account and Password must be created in order for the system administrator to log into the FLEX2 Basic A, B, C User Interface. Once the Administrator account is created, the administrator can then create and edit additional User Accounts and Passwords.

When the BioProfile FLEX2 Basic A, B, or C analyzer is powered on, the operator is presented with the account log-in window:



2.1 User Name & Password Log-in Window

The operator is prompted to enter a User Name 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. The User Name must be a minimum of 3 alpha-numeric characters and is not case sensitive. 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 should not include spaces or special characters (!, @, #, \$, %, ^, &, *). The operator should use the keyboard provided with the analyzer to enter the User Name and Password.

Once an acceptable User Name and Password are entered, the check mark  to the right of the User Name box will turn green. The operator can then press Enter on the keyboard or tap the check mark to access the User Interface.

2.2.2 HOME SCREENS

Upon login, the operator is presented with the Left Home Screen. The Left Home Screen displays the Analysis, Historical Results, Calibration, QC, User and Maintenance icons.



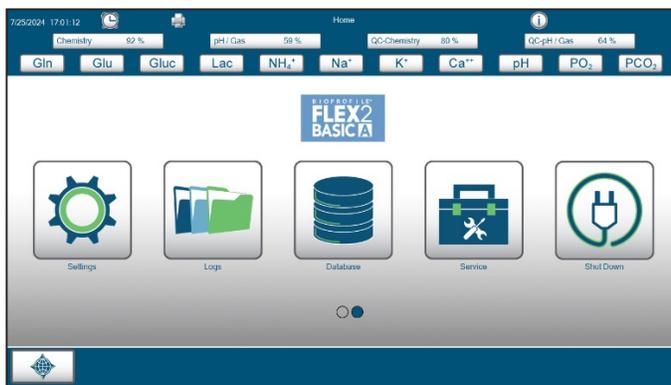
2.2 FLEX2 Basic A Left Home Screen

To display the Right Home screen, the operator can touch the display and drag it or swipe to the left.



2.3 Swipe/Drag Left

Swiping or dragging the screen to the left will display the Right Home Screen. The Right Home Screen displays the Settings, Logs, Database, Service, Standby, and Shut Down icons.



2.4 FLEX2 Basic A Right Home Screen

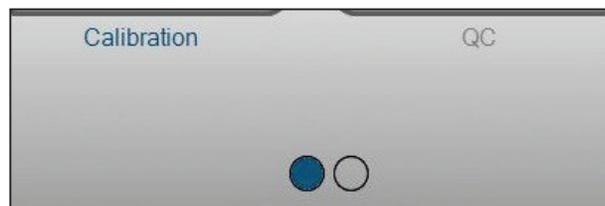
Swiping or dragging to the right on the User Interface will display the Left Home Screen again.

In addition to swiping or dragging right or left to view the two Home Screens, there are 2 dots located near the bottom center of either Home Screen displays. An operator can switch between the Left and Right Home Screens by selecting the left or right dot with the keyboard mouse, or simply by touching the left or right dot on the display.



2.5 Swipe/Drag Right

If the left dot is filled in, the system is currently displaying the Left Home Screen. If the right dot is filled in, the system is currently displaying the Right Home Screen.



2.6 Left/Right Home Screen Dots

2.2.3 STATUS BAR

The Status Bar is always visible in the display as the operator navigates through the User Interface. The Status Bar provides the following information:

- Current Date & Time
- Current Screen in Display
- Next Scheduled Event Icon
- Module Status & Remaining Reagent Volume
- Parameter Status
- Analysis and Sequence Countdown Timer (when running)
- Alert Icon (if any)
- Printer Icon
- Warranty Alert Icon (if any)



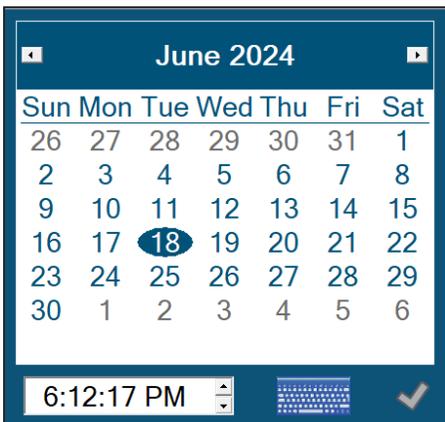
2.7 Status Bar

Date & Time

The current date and time are displayed at the top left of the Status Bar.

6/18/2024 3:02:25 PM

2.8 Date/Time



2.9 Date/Time Change Window

If an operator with the appropriate privilege level taps on the Date/Time indicator, this will open up the Date & Time Change window and the operator can adjust the date and time as needed.

Current Screen in Display

At the top center of the Status Bar, the Current Screen in Display is provided. *Examples include Home, Analysis, Historical Results, Maintenance, etc.*

Next Scheduled Event Icon

The Next Scheduled Event icon is located to the right of the date & time in the Status Bar.

When scheduled maintenance is imminent, the icon changes color as an alert.

Selecting **Next Scheduled Event** will display the Next Scheduled Event window. This window will show what scheduled event is due to occur. The window also provides a list of all scheduled events that are programmed to occur automatically, the date & time they will occur, and the frequency at which they are set to occur.

Next Scheduled Event		
Calibration	56 Minutes	6/18/2024 7:10:00 PM
All Scheduled Events		
Event	Next Occurrence	Frequency
Calibration	6/18/2024 7:10:00 PM	2:00:00
Adjust Intensity	6/21/2024 4:45:16 AM	Weekly
Depro Wells	6/19/2024 4:31:00 PM	Daily
ESM Depro	6/19/2024 2:56:00 PM	Daily
Database Backup	6/19/2024 1:00:00 AM	Daily

2.10 Next Scheduled Event Window

Module Status & Remaining Reagent Volume Icons

The middle of the Status Bar displays icons for each of the installed modules, their current status, and the remaining reagent volume (%) for the reagent cartridge(s) required by that module. The possible module and remaining reagent volume icons for the FLEX2 Basic A, B, C are as follows:



2.11 Module Status and Remaining Reagent Volume Icons

When the reagent cartridge(s) for a specific module are installed, the reagent volume remaining for that module will reset to 100%. The percent remaining volume will then count down until the cartridge reaches less than 10%. At that point the status icon will read **<10%** and the text will change to yellow, alerting the operator that the reagent cartridge will need to be replaced soon. The remaining volume status does not count lower than <10%.

The other messages and alerts that will be provided in these icons are as follows:

- **Not Installed:** Red text indicates that the reagent cartridge(s) for a particular module are not installed or that the analyzer is not detecting the presence of the cartridge's RFID tag.
- **Empty:** Red text indicates that the reagent cartridge(s) currently installed for that module have no remaining reagent and a new reagent cartridge will need to be installed for the module to be made available.
- **Expired:** Red text indicates that the reagent cartridge(s) currently installed for that particular module have reached the use-life from time of installation or they have surpassed the shelf-life expiration date indicated on the reagent packaging.

Module Information

Selecting any of the **Module Status** icons displays the Module Status window for that particular module. The Module Status window provides important information about the module. Selecting a **Chemistry Module** parameter displays the Chemistry Module Status window.

The Chemistry Module Status window provides the following information:

Calibration Status					Chemistry Cartridge	
Parameter	Status	Slope	Lower Limit	Upper Limit	Lot Number	Expiration Date
Gln	C	36.56	5.00	100.00	24171033	8/7/2024
Glu	C	63.81	5.00	100.00	7/24/2024	250
Gluc	C	72.44	5.00	150.00	Chemistry Sensor Card	
Lac	C	56.44	5.00	100.00	Lot Number	24172006
NH4+	C	11.44	8.50	12.50	Expiration Date	8/7/2024
Na+	C	10.23	8.50	12.50	Install Date	7/24/2024
K+	C	10.77	8.50	12.50	Samples Remaining	545
Ca++	C	10.66	8.50	12.50	Hydrated	True

Well Status		DePro Fluid Remaining	
Well	Status	Primed	Connected
Chemistry	Clear	True	True
Waste	Clear	DePro Fluid Remaining 94%	

Flow Times (sec)			
	Flow Time	Lower Limit	Upper Limit
Calibration	1.796	1.000	3.000
Analysis		4.000	11.000

2.12 Chemistry Module Status Window

- **Calibration Status:** Shows the status (C = Calibrated, UC = Uncalibrated, W=Warranty, QC=QC Lockout) for each of the parameters of the Chemistry Module. This section also provides the slope value for each parameter from the most recent module calibration as well as the Lower and Upper slope limits.
- **Well Status:** The Well Status section shows the current status (**Blocked** or **Clear**) of the wells utilized by the Chemistry module. These wells must be clear in order for the module to be available for sampling. If the well status indicates that the Chemistry or Waste Wells are blocked, additional troubleshooting is required.
- **Flow Times (sec):** This section provides the flow times in seconds for the last Chemistry Module calibration and the most recent Chemistry Module analysis. The flow time Lower and Upper limits are also displayed.
- **Chemistry Cartridge:** This section provides all of the information for the currently installed Chemistry module reagent cartridges including the Lot Number, Expiration Date, the installation date of the cartridges, and the number of sample tests remaining.
- **Primed Status:** This section indicates if the module is primed with the required reagent. The module 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 Status:** This section indicates if the module is properly connected to the internal controller. The module must be connected to be available for sampling. If the module is connected, the connected status will read **True**. If the module is not connected, the status will read **False**.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

- **Chemistry Sensor Card:** This section provides all of the information for the currently installed Chemistry Module MicroSensor Card including the Lot Number, Expiration Date, the Installation Date, the number of samples remaining for the card, and the hydration status (**True** or **False**).
- **DePro Fluid Remaining:** This field displays the estimated percent of DePro cleaning solution remaining in the chemistry cartridge. When this percentage reaches zero, you will no longer be able to execute module depro and depro wells sequences but the pack will not be marked as empty as long as there are samples remaining in the chemistry cartridge.

From the Chemistry Module Status window, an operator with the applicable privileges can also:

- Calibrate the Chemistry Module
- Run a Clear Wells sequence
- Run a Prime sequence

pH/Gas Module

Selecting a **pH/Gas Module** parameter displays the pH/Gas Module Status Window.

Calibration Status					Gas Cartridge	
Parameter	Status	Slope	Lower Limit	Upper Limit	Lot Number	24031021
pH	C	10.39	8.50	12.00	Expiration Date	8/4/2024
PO2	C	7.84	1.50	25.00	Install Date	7/10/2024
PCO2	C	12.25	6.50	15.00	Samples Remaining	250
Primed					True	
Connected					True	
Flow Times (sec)						
	Flow Time	Lower Limit	Upper Limit			
Calibration	3.038	2.000	5.000			
Analysis		3.000	5.000			
					Gas Sensor Card	
					Lot Number	24151055
					Expiration Date	7/31/2024
					Install Date	7/10/2024
					Samples Remaining	395
					Hydrated	True
					Well Status	
					Well	Status
					Waste	Clear
					Calibrate	Prime

2.13 pH/Gas Module Status Window

The pH/Gas Module Status window provides the following information:

- **Calibration Status:** Shows the status (**C** = Calibrated, **UC** = Uncalibrated, **W**=Warranty, **QC**=QC Lockout) for each of the parameters of the pH/Gas Module. This section also provides the slope value for each parameter from the most recent module calibration as well as the Lower and Upper slope limits.
- **Primed Status:** This section indicates if the module is primed with the required reagent. The module 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 Status:** This section indicates if the module is properly connected to the internal onboard computer. The module must be connected to be available for sampling. If the module is connected, the connected status will read **True**. If the module is not connected, the status will read **False**.
- **Well Status:** The Well Status section shows the current status (**Blocked** or **Clear**) of the Waste Well. This well must be clear in order for the module to be available for sampling. If the well status indicates that the Waste Well is blocked, additional troubleshooting is required.
- **Flow Times (sec):** This section provides the flow times in seconds for the pH/Gas Module calibration and the last pH/Gas Module analysis. The flow time Lower and Upper limits are also displayed.

- **pH/Gas Cartridge:** This section provides all of the information for the currently installed pH/Gas module reagent cartridge including the Lot Number, Expiration Date, the Installation Date of the cartridge, and the remaining samples for the cartridge.
- **pH/Gas Sensor Card:** This section provides all of the information for the currently installed pH/Gas Module MicroSensor Card including the Lot Number, Expiration Date, the Installation Date, the number of samples remaining for the card, and the hydration status (**True** or **False**).

From within the pH/Gas Module Status window, an operator with the applicable privileges can also:

- Calibrate the pH/Gas Module
- Run a Prime sequence

Chemistry QC

Selecting **QC-Chemistry** from the Status bar opens the Chemistry QC cartridge status window.

The Chemistry QC Cartridge Status window provides the following information for the onboard Chemistry QC:

Chemistry QC Cartridge	
Lot Number	24142055
Expiration Date	8/2/2024
Install Date	7/19/2024
Samples Remaining	46

2.14 Chemistry QC Cartridge Status Window

- **Lot Number:** The lot number of the onboard Chemistry QC cartridge.
- **Expiration Date:** The date the QC cartridge expires. This is the post-install expiry. The shelf life expiry can be found on the cartridge or on the cartridge packaging.
- **Install Date:** The date the QC cartridge was installed on the analyzer.
- **Samples Remaining:** The number of samples remaining based on the amount of Chemistry QC remaining in the installed cartridge.

pH/Gas QC

By selecting **QC-pH/Gas** in the Status bar, the pH/Gas QC cartridge status window appears.

The pH/Gas QC Cartridge Status window provides the following information for the onboard pH/Gas QC:

Gas QC Cartridge	
Lot Number	24129047
Expiration Date	8/14/2024
Install Date	7/10/2024
Samples Remaining	93
Primed	True
<input type="button" value="Prime"/>	

2.15 pH/Gas QC Cartridge Status Window

- **Lot Number:** The lot number of the onboard pH/Gas QC cartridge.
- **Expiration Date:** The date the QC cartridge expires. This is the post-install expiry. The shelf life expiry can be found on the cartridge or cartridge packaging.
- **Samples Remaining:** The number of samples remaining based on the amount of pH/Gas QC remaining in the installed cartridge.
- **Install Date:** The date the pack was installed on the analyzer.
- **Primed Status:** The pH/Gas QC cartridge has lines leading to the two septa, and it is important these lines stay primed. The status window will read True if they are primed, and False if not. From within the pH/Gas QC Cartridge Status window, an operator can also prime the pH/Gas QC Cartridge.

Time to Completion Timer

The Time to Completion Timer Icon appears in the upper right-hand corner of the Status Bar whenever a sequence (*Calibration, Analysis, or Maintenance*) is running. The estimated remaining time of the sequence is also shown to the right of the timer icon.

When the Time to Completion Icon is present, the operator can tap or select it to view what sequence is currently running.

pH / Gas Calibration	2:19
Chemistry Calibration	2:19

2.16 Current Sequence Running Window

Door Open Icon

Whenever the main analyzer door is open, the Door Open Icon will appear in the Status Bar. If the analyzer door is open and the Door Open Icon is present, the sample probe assembly cannot move about the analytical unit.

Parameter Status Icons

At the bottom of the Status Bar, the parameter status icons for each available parameter are displayed. The User Interface will only display those parameters for the various modules installed on the system.

When a parameter is ready and available for sampling, the parameter icon will have a white background like the one shown here.



When a parameter is in alert status, the icon will have a yellow background like the one shown here.



A parameter may be in alert for the following reasons:

- For the pH/Gas and Chemistry, the parameter icons will turn yellow when the reagent cartridge or MicroSensor card is within $\leq 10\%$ samples remaining. When applicable, the reagent cartridge status text will also change to yellow within these criteria.
- Parameters in alert status are still available for testing and will produce results. These color changes act as a warning to alert the user that consumable replacement will soon be required. Selecting a yellow status icon will show more detail about the impending consumable expiration.

When a parameter is not ready and is unavailable for sampling, the parameter icon will have a red background like the one shown here.



A parameter may be unavailable for the following reasons:

- The parameter is uncalibrated.
- The reagent cartridge(s) required by that parameter are empty, expired, or not installed.
- The MicroSensor Card for the parameter is expired, has reached the use-life date, or is not installed.
- The wells required by the parameter for successful sampling are blocked.
- The module for the parameter is not primed with the required reagents.
- The module for the parameter is not connected to the internal computer.
- The parameter is unavailable due to a dependency on another unavailable parameter.
- System maintenance is required.
- Warranty Claim - The warranty has been redeemed for the parameter or MicroSensor card.

NOTE: *Selecting any Parameter Status Icon will also display the applicable Module Status Window.*

Alert Icon 

When a system error or alert occurs, the Alert Icon will appear near the upper right corner of the Status Bar.



2.17 Alert Icon Text Information

Selecting the Alert Icon will open up a dialog box providing the text information for the error or alert.

NOTE: *The alert icon appears when viewing a historical result that has errors associated with it.*

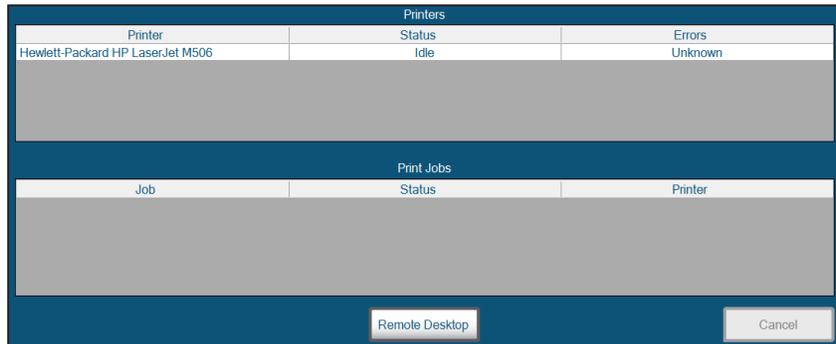
Warranty Alert Icon 

If a Parameter fails to calibrate 3 consecutive times, the option to claim warranty credit toward a new MicroSensor card is made available. More information about consumable warranties can be found in Section 2.3.5.

Print Icon 

The Print functionality allows for direct printing of reports to local and network printers in addition to creating an electronic PDF report.

Selecting the Print Icon will display the printers available to the FLEX2 Basic A, B, C Bridge Computer and any current Print Jobs. Additionally, selecting the Print Icon will allow users with administrator privilege level to access the Bridge Computer via Remote Desktop.



2.18 Print Queue

Selecting the icon will show a list of printers available on the Bridge PC and their print queue.

For accurate printer status and print job reporting, Nova Biomedical recommends Enterprise type printers with Web-based Enterprise Management (**WBEM**) capabilities. To install printer drivers and troubleshoot printer errors, select the **Remote Desktop** icon and log in to the Bridge PC. The default Bridge PC account is **Username:** FlexII **Password:** FlexII and can be changed to meet company policy.

NOTE: *Only users with Administrator privilege level have access to the Remote Desktop icon.*

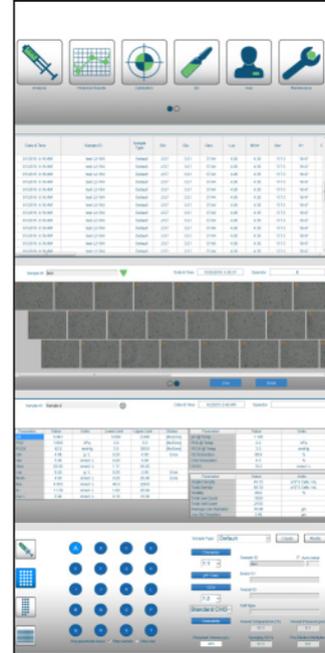
BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

2.2.4 DESTINATIONS ICON

Destinations  is located at the Bottom left-hand side of the User Interface Command Bar.

Destinations is always visible in the Command Bar as an operator navigates throughout the various menus of the Command Interface.

Selecting **Destinations** displays a subset of the other available User Interface screens. Selecting the desired screen (*Analysis Screen, Historical Results Screen, etc.*) will bring the operator directly to that screen.



2.2.5 ANALYSIS MENUS

The **Analysis** Menu  is located within the Left Home Screen.

Selecting **Analysis** opens the sample Analysis screen. By Default, selecting **Analysis** opens up the **Manual Sample** analysis screen. From this screen, an operator can program and analyze a manual sample analysis from a syringe, cup or sample tube.

-  Manual Sampling
-  Sample Cup
-  Micro Centrifuge Tube Sampling
-  Microtiter Tray Sampling



2.19 Manual Sample Analysis Screen

The operator can also choose to sample from a Sample Cup Tray, Micro Centrifuge Tube Tray or Microtiter Tray by selecting the desired method on the left of the analysis screen. A green dot will be displayed beneath the Sample Cup or Micro Centrifuge Tube tray icon to indicate which tray is currently installed on the analyzer.

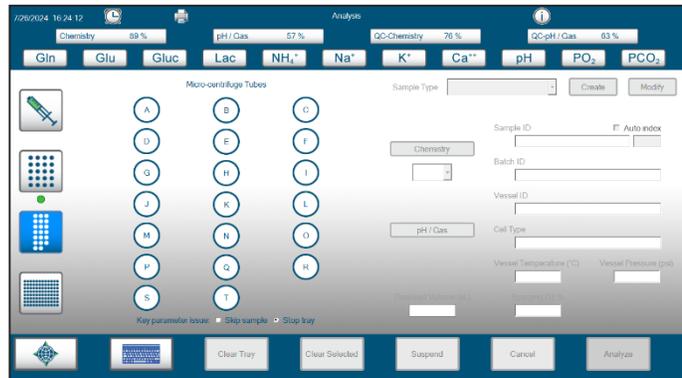
NOTE: For Sample Cup and Micro Centrifuge Tube trays, no samples can be configured until the respective tray is installed.

From within this screen, the operator can program **Sample Cup** tray sampling using the Sample Cup tray.



2.20 Sample Cup Analysis Screen

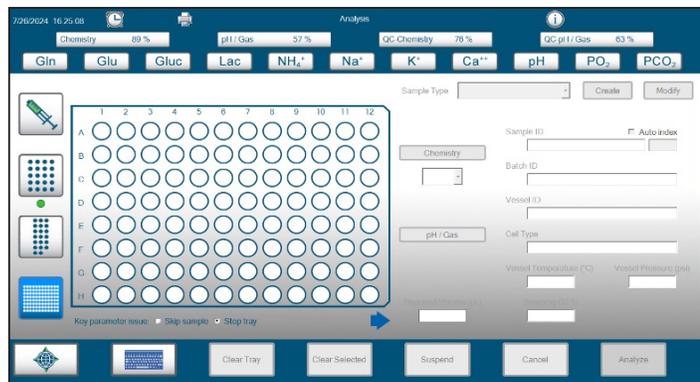
If an operator selects the **Micro Centrifuge Tube** tray icon, the Micro Centrifuge Tube tray analysis screen is displayed. From within this screen, the operator can program Micro Centrifuge Tube tray sampling using the Micro Centrifuge Tube tray.



2.21 Micro Centrifuge Tube Sample Analysis Screen

If the operator selects the **Microtiter Tray** sampling icon, the Microtiter Tray sample analysis screen is displayed.

From within this screen, the operator can program Microtiter Plate sampling using a 96-well Microtiter sample plate. By selecting a specific location on the plate, the operator can schedule all applicable tests.



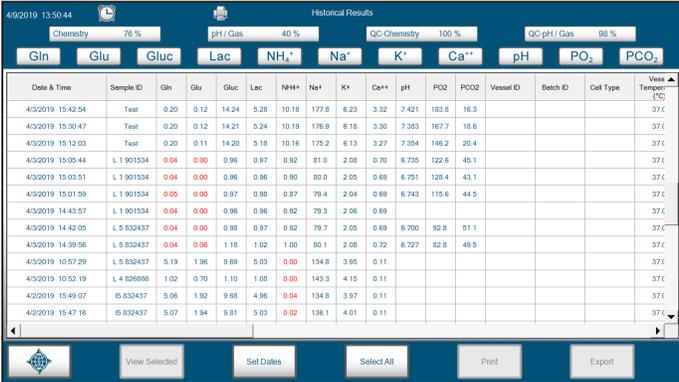
2.22 Microtiter Tray Sample Analysis Screen

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

2.2.6 HISTORICAL RESULTS MENU

The **Historical Results Menu** is located within the Left Home Screen.

Selecting **Historical Results** opens the historical results recall screen. By default, the historical results from the last 7 days are displayed. The operator can select an individual sample result to view or they can view the historical results from a range of selected dates.



The screenshot shows the 'Historical Results' interface. At the top, there are tabs for 'Chemistry 78%', 'pH / Gas 40%', 'QC-Chemistry 100%', and 'QC pH / Gas 88%'. Below these are buttons for 'Gln', 'Glu', 'Gluc', 'Lac', 'NH4+', 'Na+', 'K+', 'Ca++', 'pH', 'PO2', and 'PCO2'. The main area is a table with the following columns: Date & Time, Sample ID, Gln, Glu, Gluc, Lac, NH4+, Na+, K+, Ca++, pH, PO2, PCO2, Vessel ID, Batch ID, Cell Type, and Vessel Temp (°C). The table contains 18 rows of data, with some values highlighted in red (e.g., 0.04, 0.00, 0.06, 0.00, 0.04, 0.00, 0.04, 0.00, 0.04, 0.00, 0.04, 0.00, 0.04, 0.00, 0.04, 0.00, 0.04, 0.00). At the bottom, there are buttons for 'View Selected', 'Set Dates', 'Select All', 'Print', and 'Export'.

2.23 Historical Results Menu

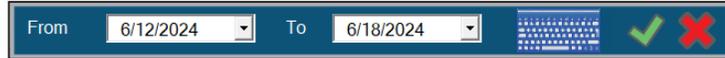
The historical results and sample data are stored permanently in the BioProfile FLEX2 Basic A, B, C database. Original (raw) sample result data cannot be altered, changed, or deleted from within the User Interface.

The following information is provided in the Historical Results screen:

- Sample Analysis Date & Time
- Sample ID
- Chemistry Module Parameter Data: Gln, Glu, Gluc, Lac, NH₄⁺, Na⁺, K⁺, Ca⁺⁺
- pH/Gas Module Parameter Data: pH, PCO₂, PO₂
- Valid Images
- Vessel ID
- Batch ID
- Cell Type
- Vessel Temperature (Default: 37°C)
- Vessel Pressure (Default: 0.0 psi)
- Sparging O₂% (Default: 20.9)
- Chemistry Module Dilution Ratio (Default: 1:1)
- Calculated pH at Corrected Temperature
- Calculated PCO₂ at Corrected Temperature (mmHg)
- Calculated PO₂ at Corrected Temperature (mmHg)
- Calculated O₂ Saturation (%)
- Calculated CO₂ Saturation (%)
- Calculated HCO₃⁻ Concentration (mmol/L)
- Chemistry Analysis Flow Time
- pH/Gas Analysis Flow Time
- Sample Tray Location
- Sample Time In Tray
- Original Sample Analysis Time
- Sample Type
- Operator

From within the Historical Results screen an operator can export sample result data to the internal Bridge Computer. An operator can also create, print and export **.pdf** reports for selected sample results.

To view historical data that is not visible in the Historical Results Screen, an operator can select **Set Dates** in the Command Bar, opening the Set Dates menu.



2.24 Set Dates Menu

June 2024						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	1	2	3	4	5	6

Today: 6/18/2024

2.25 Date Selection Calendar

With the Set Dates menu open, the operator can select the Dropdown for the From or To boxes to open the calendar selection screens.

Within the calendar screens the operator can select the time period for which they wish to view the data.

Once the From and To dates are selected, the check mark next to the dropdown boxes will turn green. Selecting the check mark will populate the historical results for the time period selected by the operator. Selecting the red X will close the window overlay.

Sorting Data and Viewing Individual Results

NOTE: *The BioProfile FLEX2 Basic A, B, C Analyzers are not supplied with a printer. Printable .pdf reports can be created by selecting **Print** on any applicable screen. These reports can be printed, exported to a USB drive or exported to the shared folder on the Bridge Computer.*

The Historical Results will be listed in table format with rows and columns. The raw data within the Historical Results screen cannot be altered or changed. An operator can sort the data by Date & Time or by Sample ID by selecting the header boxes of the Date & Time or Sample ID columns. An operator can select a single row of sample data or multiple rows of data by touching the screen and dragging up or down over the rows of data that they wish to select. The data can then be exported or printed by selecting **Export** or **Print** in the Command Bar. To unselect data, the operator can select **Unselect All** in the Command Bar.

NOTE: *The keyboard/mouse assembly can also be used to select data. Select a row of results, then hold down the Shift key and use the arrow up or down keys or drag the mouse to select additional rows of data.*

To view the data for an individual sample result in full-screen format, the operator can select an individual row of data. Selecting a row of sample data will highlight the row in blue. Once the row is highlighted, the operator can double tap the selected row or they can select **View Selected** in the Command Bar to open the individual sample result data in full-screen format.

When an individual sample result is opened, the sample data will be populated into a table containing all modules run during the analysis including the calculated sample results reported. The Sample ID, Date & Time, and Operator ID will also be provided at the top of the results screen. From this screen,

Parameter	Value	Units	Lower Limit	Upper Limit	Status
pH	7.421	-	5.000	8.000	-
PO2	183.8	mmHg	3.0	500.0	-
PO2 @ Temp	16.3	mmHg	3.0	300.0	-
O2 Saturation	100.0	%	0.05	12.00	-
CO2 Saturation	2.3	%	0.05	30.00	-
HCO3	10.7	mmol/L	0.05	12.00	-
Lac	5.28	g/L	0.05	12.00	-
NH4+	10.18	mmol/L	0.20	25.00	-
Na+	177.8	mmol/L	40.0	300.0	-
K+	6.23	mmol/L	1.00	100.00	-
Ca++	3.32	mmol/L	0.10	10.00	-

2.26 Historical Results Menu Sorted

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

an operator can also print the individual sample result data by selecting **Print** in the Command Bar. This also provides the option to export a PDF copy of the selected result to the Shared Folder on the Bridge Computer, or to a USB drive inserted into the back of the analyzer. Selecting **Historical Results** returns the operator to the Historical Results screen. Selecting the green upside-down triangle next to the Sample ID box will open up the sample information and configuration menu for the sample selected.

From within the sample information and configuration window, an operator can input or change the following:

- Sample ID
- Batch ID
- Vessel ID
- Cell Type
- Vessel Temperature
- Vessel Pressure
- Sparging O₂%

When a sample result is edited or reanalyzed, a new sample entry is generated in the Historical Results with a new date, timestamp, and new information/data. The original sample result is retained as-is. The edited/reanalyzed sample is traceable to the original sample in both the Historical Results and the Audit Log.

2.27 Sample Information and Configuration Window

2.2.7 CALIBRATION MENU

The **Calibration Menu**  is located on the Left Home Screen. Selecting **Calibration Menu** will initiate a simultaneous calibration of the pH/Gas and Chemistry modules.

NOTE: *The pH/Gas & Chemistry modules will calibrate automatically on a set schedule. Additionally, the pH/Gas & Chemistry modules will calibrate automatically whenever applicable maintenance is performed, e.g., whenever the reagent cartridges or MicroSensor Cards are installed.*

2.2.8 QC MENU

QC is found in the Left Home Screen. By selecting **QC**, the End User can view onboard QC data for the Chemistry, pH/Gas and Osmometer modules. If Auto QC cartridges are installed, QC can also be run from within this menu.

NOTE: *Only on board QC is stored here. QC that has been run manually is stored in Historical Results.*

Scheduling for onboard QC is configured under **Settings** (Right Home Screen), then under Scheduling. The onboard QC must be enabled before onboard QC analysis can be performed. More details about onboard QC are discussed in Section 3.4.

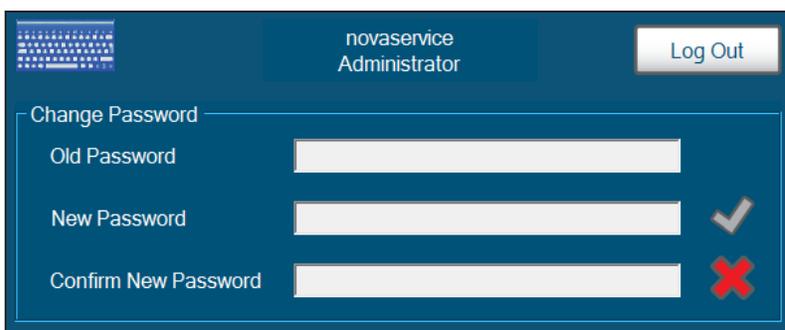
2.2.9 USER MENU

The **User Menu**  is located within the Left Home Screen.

Select **User** to display the User Menu.

The User Menu displays the User ID of the operator currently logged in to the system as well as the privilege level assigned

to that operator (Basic, Intermediate, Advanced, or Administrator). From this screen, the operator can log out of the system by selecting **Log Out**. The operator can also change their password. To change a password, the operator must enter their current password in the space provided. Next, they must enter a new password in the space provided; passwords must be a minimum of 8 alpha-numeric characters and must contain at least one capital letter, one lower case letter, and one number. The operator must then re-enter the new password in the Confirm New Password section. Once these steps are complete, the operator can apply the changes by selecting the green check mark to the right of the screen or they can cancel and close the menu by selecting the red **X**.



2.28 User Menu

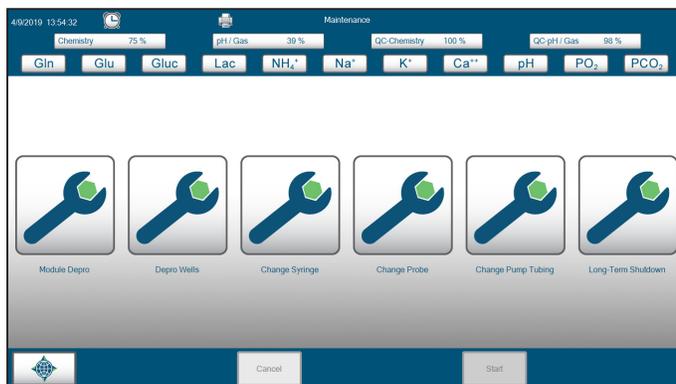
2.2.10 MAINTENANCE MENU

The **Maintenance Menu**  is located within the Left Home Screen.

Selecting **Maintenance** displays the system maintenance menu.

From within the **Maintenance Menu**, an operator with the appropriate privilege level can perform the following maintenance procedures:

- Module Depro
- Depro Wells
- Change Syringe
- Change Probe
- Change Pump Tubing
- Long-Term Shutdown



2.29 Maintenance Menu

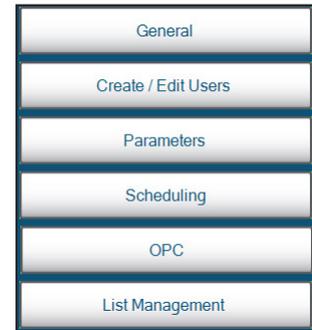
NOTE: See Chapter 4 for additional information on performing these maintenance steps.

2.2.11 SETTINGS MENU

The **Settings Menu**  is located within the Right Home Screen. Selecting **Settings** displays the system settings sub-menu.

The System Settings sub-menu provides the following functions:

General: An operator with the appropriate privilege level can program the Analyzer ID, Location, Language, Date Format, and Time Format. From this menu, the operator can also enable or disable Auto Logoff, Sample Results Auto Export, and Onboard QC.



2.30 System Settings Sub-Menu

Create/Edit Users: An operator with Administrator privileges can create and edit system user accounts and passwords.

Parameters: An operator with appropriate privileges can configure the units of measure for the various test parameters or turn on or off test suppression.

Scheduling: An operator with appropriate privileges can configure the schedule of automated maintenance routines such as onboard QC, Chemistry/pH/Gas Calibration Time and Depro Wells.

OPC: An operator with the appropriate privilege level can activate a temporary OPC license or install a permanent license.

List Management: An operator with appropriate privileges can edit the Sample ID, Vessel ID, Batch ID, Cell Type, and Initial Sample ID Indexing routine for saved samples lists.

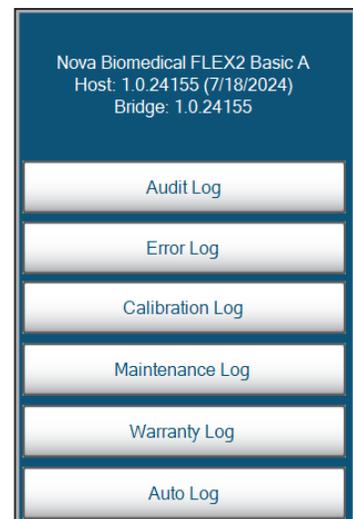
NOTE: See Section 3.4 for additional information on configuring the system settings.

2.2.12 LOGS MENU

The **Logs Menu**  is located within the Right Home Screen. Selecting **Logs** displays the system logs sub-menu.

The system logs sub-menu provides 6 buttons that allow the operator to view or export the **Audit Log**, **Error Log**, **Calibration Log**, **Maintenance Log**, **Warranty Log** and the **Diagnostic Logs**. The system logs sub-menu also provides the version of FLEX2 Basic A, B, C software that is currently installed on the analyzer.

NOTE: See Sections 3.7–3.10 for additional instructions on viewing, exporting, and printing the information captured by the various system logs.



2.31 System Logs Sub-Menu

2.2.13 DATABASE MENU

The **Database Menu**  (Right Home Screen) allows an operator with appropriate privileges and security credentials to backup or restore the system database.

NOTE: For more information see Section 3.12

2.2.14 SERVICE MENU

Selecting **Service**  (Right Home Screen) allows operators with an administrator privilege level access to additional service options for performing maintenance or for troubleshooting issues. Selecting **Service** will display the two sub-menu options shown: **Customer Service** and **Nova Service**.



2.32 Service Menu Options

2.2.14.1 CUSTOMER SERVICE

The Customer Service menu allows operators to access additional service options that do not require a password but do require an administrator privilege level.

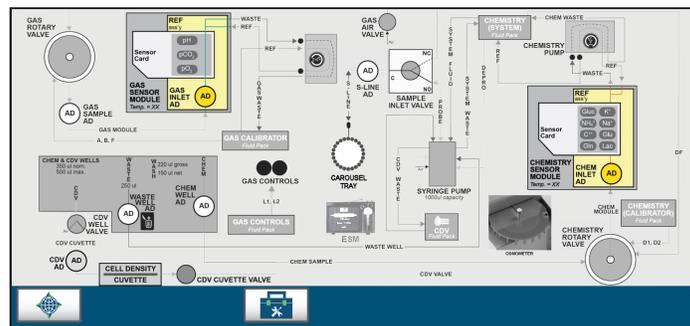


2.33 Customer Service Sub-Menu

Flowpath Service

Flowpath Service visualizes the flowpath within each module of the FLEX2 Basic A, B, C, displays sensor information, and provides manual control over all pumps and valves along the flow path.

NOTE: See Section 4.4.5 for additional instructions on how to utilize Flowpath Service.



2.34 Flowpath Service

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

RFID Test

RFID Test is used to confirm if the RFID card within each consumable pack and MicroSensor Card are communicating properly with your FLEX2 Basic A, B, C. This test is done by completing a series of write transactions from each RFID.

NOTE: See Section 4.4.1 for additional instructions on how to perform a RFID Test.

Duration (minutes)		30				
Device	Write Transactions	Read Failure %	Write Failure %	Query Failure %	Checksum Error %	Pass
Chemistry Pack	20	0.00	0.00	0.00	0.00	True
QC-Chemistry Pack	19	0.00	0.00	0.00	0.00	True
Chemistry Sensor Card	14	0.00	0.00	0.00	0.00	True
pH / Gas Pack	20	0.00	0.00	0.00	0.00	True
QC-pH / Gas Pack	20	0.00	0.00	0.00	0.00	True
pH / Gas Sensor Card	14	0.00	0.00	0.00	0.00	True

2.35 RFID Test

Resource Issues

The Resource Issues button will search your FLEX2 Basic A, B, C for all potentially installed modules and potential issues that may impact the operation of the device. This option should only be used when under the guidance of Nova Technical Support Personnel.

Door_Module	NotConnected
	NotInstalled
Osmo_Module	NotConnected
	NotInstalled
CDV_Module	NotInstalled
ESM_Module	NotConnected
	NotInstalled
NOsmo_Module	NotConnected
Autosampler_Module	NotInstalled

2.36 Resource Issues

Auto Log

The Auto Log option will provide a detailed list of logs from your FLEX2 Basic A, B, C device that Nova Technical Support can use to analyze and investigate if necessary. This option should only be used when under the guidance of Nova Technical Support Personnel.

NOTE: To troubleshoot errors on your FLEX2 Basic A, B, C, please see Section 3.7 Error Log Notation for more information.

PSoCs

The PSoCs test pings the programmable system on a chip, the PSoC board, for each module within the FLEX2 Basic A, B, C. Successful communication between the Host computer and the PSoCs indicates that the FLEX2 Basic A, B, C is properly communicating to each module within the system.

PSoC	Status	Version
Chemistry	Connected	1.026
ChemistryPump	Connected	0.206
Distribution	Connected	1.033
Door		
pH / Gas	Connected	1.026
GasPump	Connected	0.206
Probe	Connected	00.022
User	Connected	0.023

2.37 PSoC Menu

2.2.14.2 NOVA SERVICE

The Nova Service menu has additional options available for servicing your FLEX2 Basic A, B, C analyzer. The Nova Service menu can only be accessed by or under the guidance of Nova Technical Support Personnel and requires a daily coded Support password to access.

2.2.15 STANDBY MENU

Selecting **Standby**  (Right Home Screen) places the analyzer in & out of standby mode. When in standby mode, the system will still continue to idle a small volume of reagent through the pH/Gas & Chemistry modules as long as the required reagent cartridges are installed and have remaining fluid. However, a system in standby mode will not run auto-calibrations or any automated maintenance functions.

Coming Soon – Function not available at this Time.

2.2.16 SHUT DOWN

Selecting **Shut Down**  (Right Home Screen) will shut down the BioProfile FLEX2 Basic A, B, C analyzer.

When **Shut Down** is selected, the system will first display a prompt verifying that the End User wishes to shut the system down. After pressing **Yes**, wait for the screen to turn black. Then flip the switch at the back of the analyzer.

CAUTION: *Failure to shut down the BioProfile FLEX2 Basic A, B, C using the Shut Down icons from within the User Interface may cause system damage. DO NOT shut down the analyzer by flipping the switch on the back of the analyzer. Once the analyzer has been shut down using the Shut Down buttons from within the User Interface, the switch on the back of the analyzer can be moved to the OFF position.*

2.3 SYSTEM CALIBRATION

2.3.1 AUTOMATIC MODULE CALIBRATION

BioProfile FLEX2 Basic A, B, C analyzers automatically perform a 2-point calibration of the pH/ Gas & Chemistry Modules shortly after being powered on and regularly thereafter to maintain optimal MicroSensor Card performance. [A 1-point calibration of the pH/Gas and/or Chemistry module is performed during each sample analysis to ensure sensor performance is nominal between each 2-point calibration.] If a calibration error occurs, the error will be displayed in the error log. If any parameter fails to calibrate during a calibration sequence, the respective **parameter status** icon will be displayed with a **RED** background, indicating that the parameter is not available for sampling.

2.3.2 SMART MAINTENANCE FUNCTIONALITY

BioProfile FLEX2 Basic A, B, C analyzers have **Smart Maintenance** capability. The pH/Gas & Chemistry MicroSensor Cards and each of the reagent cartridges required by the systems are labeled with their own Radio Frequency Identification (**RFID**) tags. BioProfile FLEX2 Basic A, B, C analyzers recognize when a MicroSensor Card or reagent cartridge is installed or replaced and automatically perform the necessary maintenance (*priming, hydration, and calibration*) required to make each module ready for sampling.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

2.3.3 pH/GAS MODULE CALIBRATION

When required, the pH/Gas module can be manually calibrated from various locations within the User Interface. If an operator wishes to only calibrate the pH/Gas module independently of the Chemistry Module, they can select any of **pH/Gas Module** buttons in the Status Bar.

From within the pH/Gas Module Status Screen, selecting **Calibrate** will initiate a calibration of the pH/Gas Module only. The calibration will begin once selected and the countdown timer will appear in the Status Bar.



2.38 pH/Gas Buttons in the Status Bar

Calibration Status					Gas Cartridge	
Parameter	Status	Slope	Lower Limit	Upper Limit	Lot Number	Expiration Date
pH	C	10.39	8.50	12.00	24031021	8/4/2024
PO2	C	7.84	1.50	25.00		7/10/2024
PCO2	C	12.25	6.50	15.00		250

Gas Sensor Card	
Lot Number	24151055
Expiration Date	7/31/2024
Install Date	7/10/2024
Samples Remaining	395
Hydrated	True

Flow Times (sec)			
	Flow Time	Lower Limit	Upper Limit
Calibration	3.038	2.000	5.000
Analysis		3.000	5.000

Well Status	
Well	Status
Waste	Clear

2.39 pH/Gas Module Status Screen

NOTE: If Calibrate or Prime are not available from within the pH/Gas Module Status screen, this may mean that the pH/Gas Calibrator Cartridge and/or the pH/Gas MicroSensor Card is empty, invalid, or expired.

2.3.4 CHEMISTRY MODULE CALIBRATION

When required, the Chemistry module can be manually calibrated from various locations within the User Interface. If an operator wishes to only calibrate the Chemistry module independently of the pH/Gas Module, they can select any of the **Chemistry Module** buttons in the Status Bar.

Selecting any one of these buttons will display the Chemistry Module status screen.

From within the Chemistry Module Status Screen, selecting **Calibrate** will initiate a calibration of the Chemistry Module only. The calibration will begin as soon as the button is selected and the countdown timer will appear in the Status Bar.



2.40 Chemistry Module Buttons in the Status Bar

Calibration Status					Chemistry Cartridge	
Parameter	Status	Slope	Lower Limit	Upper Limit	Lot Number	Expiration Date
Gln	C	36.56	5.00	100.00	24171033	8/7/2024
Glu	C	63.81	5.00	100.00		7/24/2024
Gluc	C	72.44	5.00	150.00		250
Lac	C	56.44	5.00	100.00		
NH4+	C	11.44	8.50	12.50		
Na+	C	10.23	8.50	12.50		
K+	C	10.77	8.50	12.50		
Ca++	C	10.66	8.50	12.50		

Chemistry Sensor Card	
Lot Number	24172006
Expiration Date	8/7/2024
Install Date	7/24/2024
Samples Remaining	545
Hydrated	True

Flow Times (sec)			
	Flow Time	Lower Limit	Upper Limit
Calibration	1.796	1.000	3.000
Analysis		4.000	11.000

Well Status	
Well	Status
Chemistry	Clear
Waste	Clear

Primed	True
Connected	True

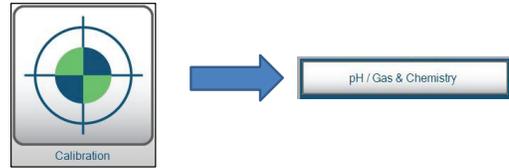
DePro Fluid Remaining	94%
-----------------------	-----

2.41 Chemistry Module Status Screen

NOTE: If the Calibrate, Clear Wells, or Prime buttons are not available from within the Chemistry Module Status screen, this may mean that the Chemistry Calibrator Cartridge & Reagent Cartridge and/or the Chemistry MicroSensor Card is empty, invalid, or expired.

2.3.5 pH/GAS & CHEMISTRY COMBINED

When required, the pH/Gas & Chemistry modules can be manually calibrated at the same time. To calibrate the pH/Gas & Chemistry modules, an Operator can select **Calibration** from the Left Home Screen, followed by **pH/ Gas & Chemistry**.



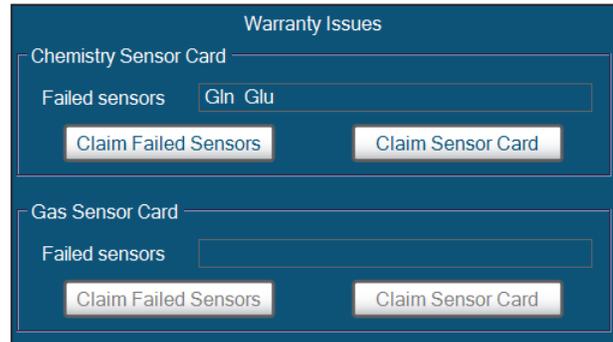
2.42 Calibration Button to the pH/Gas & Chemistry Button

Selecting **pH/Gas & Chemistry** will initiate a calibration of both the pH/Gas & Chemistry Modules simultaneously. The calibration will begin as soon as the button is selected and the countdown timer will appear in the Status Bar.

2.3.6 WARRANTY SUPPORT

If any MicroSensor Card parameters fail to calibrate 3 consecutive times, the option to claim warranty credit toward a new card is made available and a yellow icon will appear in the Status Bar.

When the icon is clicked, an overlay will appear that displays the parameter(s) eligible for a warranty claim. The user is given the option to Claim Failed Sensors or Claim Sensor Card for the affected module.



2.43 Warranty Overlay

It is important to note that dependent parameters will also be claimed in a warranty event when applicable. For example, if pH prompts a warranty, pCO₂ will also be included because it is dependent on pH.

To decide whether to claim the entire sensor card or only the applicable parameter(s), consider the importance of the parameter(s).

- If the parameter(s) are non-critical to the current analysis, select Claim Failed Sensors. This will only disable the affected parameter(s) prompting the warranty. They will appear with a red "W" in the module overlay. All unclaimed parameters will remain available for normal analysis.
- If the parameter(s) are critical to the current analysis, select Claim Sensor Card. This will disable all parameters on the card. All parameters on the card will appear red in the Status Bar and will have a red "W" in the module overlay.

When **Claimed Failed Sensors** is selected, a 16-digit Warranty code will be generated for the failed parameters. These can be redeemed for credit towards a future sensor card and will be recorded in the Warranty Log.

When **Claim Sensor Card** is selected, two 16-digit Warranty codes will be generated; one for the failed parameter(s), and one for the remaining parameter(s).

Calibration Status				
Parameter	Status	Slope	Lower Limit	Upper Limit
Gln	W	19.10	5.00	100.00
Glu	W	0.69	5.00	100.00
Gluc	C	67.48	5.00	150.00
Lac	C	25.76	5.00	100.00
NH4+	C	11.41	8.50	12.50
Na+	C	10.15	8.50	12.50
K+	C	10.77	8.50	12.50
Ca++	C	10.72	8.50	12.50

2.44 Warranty Claimed Fail

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

Each code must be submitted to receive all available credit generated during a warranty claim. To redeem the credit, submit the codes to Nova Technical Support or an authorized distributor. The amount of credit is determined either by when the warranty claim occurred in the card's use life or the samples remaining (whichever is less), along with the claim option selected.

Warranty Codes and their associated credit are kept in a database linked to the Nova customer number.

3 OPERATION

This section describes how to operate the analyzer. The BioProfile FLEX2 Basic A, B, C components consist of the following items:

1. Keyboard and Mouse Assembly
2. Analytical Unit

3.1 KEYBOARD, MOUSE, AND SCANNER (OPTIONAL)

The keyboard and mouse are an alternative to the touchscreen for analyzer control, as well as the primary means for text entry. The keyboard is used to login to the analyzer and to edit sample and system information where required.

Optionally, the BioProfile FLEX2 Basic A, B, C can interface with a Wireless Barcode Scanner. If your system was not purchased with the Barcode Scanner included, it can be purchased as an upgrade (PN 59942). Pricing includes all necessary hardware and the cost of installation.

The wireless scanner enables any 2D barcode to be scanned into the sample ID text fields of the FLEX2 Basic A, B, C User Interface. The wireless scanner must be installed by a Nova-qualified Field Support Specialist.



3.1 Wireless Barcode Scanner

3.2 ANALYTICAL UNIT

3.2.1 pH/GAS MODULE

3.2.1.1 pH/GAS CALIBRATOR CARTRIDGE

- The single cartridge pack contains all of the fluids necessary to calibrate all parameters in the pH/Gas Module (pH, PO_2 , PCO_2).
- The cartridge contains a waste pouch that collects all of the pH/Gas Module waste fluids.
- The cartridge contains Reference Solution (KCl).
- The RFID tag stores cartridge information and communicates cartridge status to the analyzer.
- The cartridge can be disassembled for reagent disposal.
- The cartridge is available in 3 sizes (High Sample Volume, Medium Sample Volume, or Low Sample Volume), designed to fit the End User's needs.



3.2 pH/Gas Calibrator Cartridge

NOTE:

Chemical and biohazardous waste disposal laws vary from state-to-state and country-to-country. Nova Biomedical does not make any recommendations for reagent waste disposal. It is the responsibility of the End User to follow all rules and regulations based on their laboratory's Standard Operating Procedures (SOPs). SDS sheets for all applicable Nova Biomedical products are available upon request.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

3.2.1.2 pH/GAS MICROSENSOR CARD

The micro sensors housed within the MicroSensor Cards are the core of the BioProfile FLEX2 Basic A, B, C system. The pH/Gas MicroSensor Card includes the following test parameters and methodology:

Parameter	Methodology
pH	Ion-selective MicroSensor
PO ₂	Amperometric MicroSensor
PCO ₂	Ion-selective MicroSensor



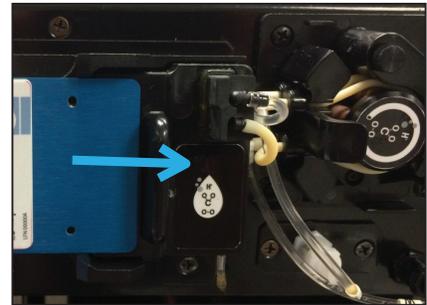
- The MicroSensor Card requires very low volume to minimize sample size.
- The RFID tag stores card information and communicates card status to the analyzer.
- The pH/Gas MicroSensor Card is available in 2 different configurations (High Volume or Low Volume) to meet the End User's needs.

3.3 pH/Gas MicroSensor Card

3.2.1.3 pH/GAS REFERENCE SENSOR

The pH/Gas Reference Sensor is mounted on the pH/Gas Sensor Module. It is continuously supplied with Reference Solution (KCl) from the pH/Gas Calibrator Cartridge.

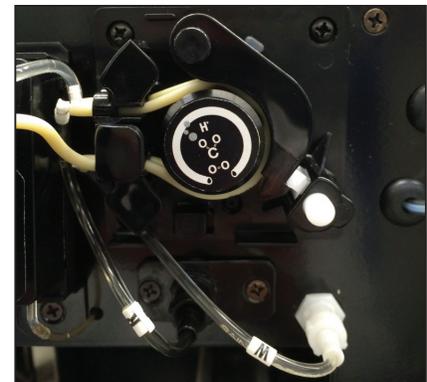
NOTE: *pH, PO₂, and PCO₂ require Reference Solution (KCl) for calibration and sample analysis.*



3.4 pH/Gas Reference Sensor

3.2.1.4 pH/GAS PUMP TUBING HARNESS

The pH/Gas Pump Tubing Harness is installed on the peristaltic pump assembly of the pH/Gas Module. The pump tubing moves the calibration standards, Reference Solution, and sample through the pH/Gas MicroSensor Card and then transports these solutions to the waste pouch of the pH/Gas Calibrator Cartridge.



3.5 pH/Gas Pump and Pump Tubing Harness

3.2.2 CHEMISTRY MODULE

3.2.2.1 CHEMISTRY CALIBRATOR AND REAGENT CARTRIDGES

- The dual cartridge contains all of the fluids necessary to calibrate all parameters in the Chemistry Module (Gln, Glu, Gluc, Lac, NH_4^+ , Na^+ , K^+ , Ca^{++}).
- The reagent cartridge contains a waste pouch that collects all of the Chemistry Module waste fluids and some of the CDV Module waste fluids if the CDV is installed.
- The reagent cartridge contains Reference Solution (KCl).
- The RFID tag stores cartridge information and communicates cartridge status to the analyzer.
- The cartridge can be disassembled for reagent disposal.
- The cartridge is available in 3 sizes (High, Medium, or Low Sample Volume), designed to fit the End User's needs.



3.6 Chemistry Calibrator & Reagent Cartridge

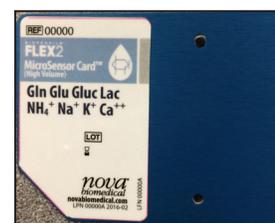
NOTE: *The chemistry calibrator and reagent cartridge are required for pH/Gas analysis. If the chemistry cartridge is expired, empty or not installed, the pH/gas module will be unavailable for analysis.*

NOTE: *Chemical and biohazardous waste disposal laws vary from state-to-state and country-to-country. Nova Biomedical does not make any recommendations for reagent waste disposal. It is the responsibility of the End User to follow all rules and regulations based on their laboratory's Standard Operating Procedures (SOPs). SDS sheets for all applicable Nova Biomedical products are available upon request.*

3.2.2.2 CHEMISTRY MICROSENSOR CARD

The micro sensors housed within the MicroSensor Cards are the core of the BioProfile FLEX2 Basic A, B, C system. The Chemistry MicroSensor Card includes the following test parameters and methodology:

Parameter	Methodology
Glutamine (Gln)	Amperometric MicroSensor
Glutamate (Glu)	Amperometric MicroSensor
Glucose (Gluc)	Amperometric MicroSensor
Lactate (Lac)	Amperometric MicroSensor
Ammonium (NH_4^+)	Ion-selective MicroSensor
Sodium (Na^+)	Ion-selective MicroSensor
Potassium (K^+)	Ion-selective MicroSensor
Ionized Calcium (Ca^{++})	Ion-selective MicroSensor



3.7 Chemistry MicroSensor Card

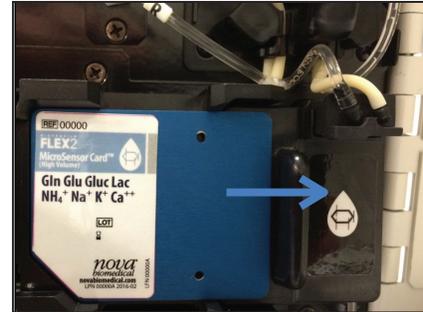
- The MicroSensor Card requires very low volume to minimize sample size.
- The RFID tag stores card information and communicates card status to the analyzer.
- The Chemistry MicroSensor Card is available in 2 different configurations (High Volume or Low Volume) to meet the End User's needs.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

3.2.2.3 CHEMISTRY REFERENCE SENSOR

The Chemistry Reference Sensor is mounted on the Chemistry Sensor Module. It is continuously supplied with Reference Solution (KCl) from the Chemistry Reagent Cartridge.

NOTE: *Gln, Glu, Gluc, Lac, NH₄⁺, Na⁺, K⁺, and Ca⁺⁺ require Reference Solution (KCl) for calibration and sample analysis.*



3.8 Chemistry Reference Sensor

3.2.2.4 CHEMISTRY PUMP TUBING HARNESS

The Chemistry Pump Tubing Harness is installed on the peristaltic pump assembly of the Chemistry Module. The pump tubing moves the calibration standards, Reference Solution, and sample through the Chemistry MicroSensor Card and then transports these solutions to the waste pouch of the Chemistry Reagent Cartridge.

3.3 ONBOARD QUALITY CONTROL

By selecting **QC** (Left Home Screen), the End User can view onboard QC lot numbers and previous results.

Using the BioProfile FLEX2 Basic A, B, C system's onboard quality control (QC) can save the End User time and QC can be scheduled to run automatically. The on-board pH/Gas QC septa are located on the left side of user domain, with the Chemistry QC refrigerator to the rear. Due to the stability of glutamine in the solution, the Chemistry QC is refrigerated onboard but must be stored frozen (-20°C) and then thawed prior to its installation. Before any onboard QC can be scheduled or run, it must be enabled in the Settings menu.



3.9 Chemistry Pump and Pump Tubing Harness

To enable the onboard QC:

1. Select **Settings** (Right Home Screen)
2. From the sub-menu, select **General**.
3. In the left hand column, select the check box next to Enable Onboard QC, then press **Save**.

In the Status Bar, 2 buttons will appear: **QC-Chemistry** and **QC-pH/Gas**. Once selected, an overlay appears containing the date of QC cartridge installation, percent remaining, expiration date, lot number and the number of samples remaining per cartridge. The overlay for pH/Gas QC has a **Prime** button to prime the lines from the cartridge to the septa.

NOTE: *No Prime button is available for the Chemistry QC as there are no lines or tubing to be primed.*

Chemistry QC Cartridge	
Lot Number	24142055
Expiration Date	8/2/2024
Install Date	7/19/2024
Samples Remaining	46

Gas QC Cartridge	
Lot Number	24129047
Expiration Date	8/14/2024
Install Date	7/10/2024
Samples Remaining	93
Primed	True
Prime	

3.10 Overlays for Onboard QC

Due to the pH/Gas and Chemistry modules requiring different QC solutions, a separate reagent cartridge is required for each. Each cartridge contains a high and low QC solution for the respective module and can operate independently of each other.

To install the onboard Chemistry Auto QC Cartridge:

1. Remove the Chemistry QC cartridge from the freezer and packaging and allow to thaw for at least 30 minutes at room temperature. Mix the cartridge thoroughly by inversion.

CAUTION: Failure to allow the Chemistry QC Cartridge to thaw completely to a liquid state may result in sample probe or analyzer damage.



3.11 Chemistry Auto QC Cartridge with round RFID

2. Open the analyzer door. The Chemistry QC ports are behind the pH/Gas QC septa on the left. Gently insert the cartridge into the ports, with the circular RFID tag towards the rear. Press down until the cartridge is seated in the refrigeration unit.
3. Close the analyzer door. The Smart Maintenance feature will read the RFID.



3.12 Chemistry Auto QC Cartridge

To install the onboard pH/Gas Auto QC Cartridge:

1. Remove the pH/Gas QC cartridge from the packaging. Included in the cartridge are two rubber septa. These must be changed with each new pH/Gas QC cartridge.

CAUTION: Failure to install a new pH/Gas QC septa with each new cartridge may result in onboard QC sampling errors.

pH/Gas QC Cartridge Front



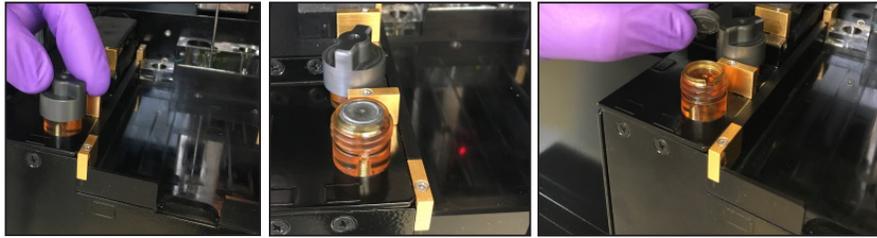
pH/Gas QC Cartridge Rear



3.13 pH/Gas Auto QC Cartridge

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

- Unscrew the tops of the pH/Gas QC septa ports. Remove and replace the black rubber septa, then tighten the caps until finger tight.



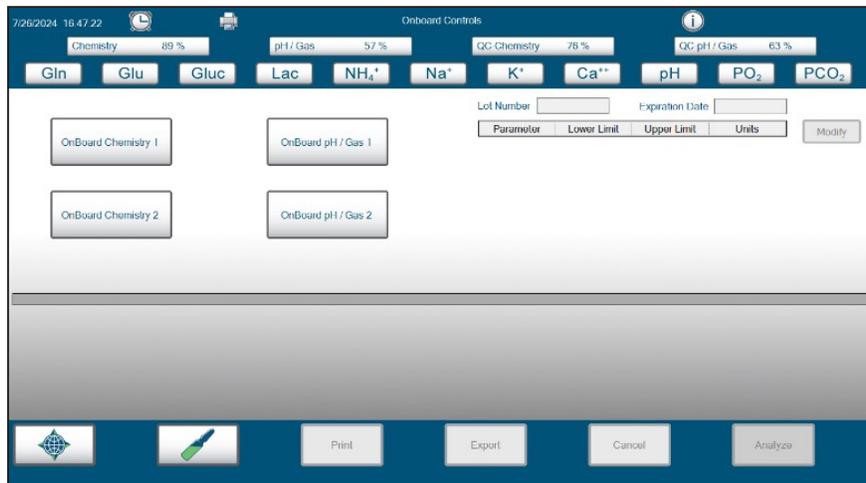
3.14 Changing Rubber Septa for pH/Gas Auto QC

- Invert the cartridge a few times. Then insert the cartridge into the port, and ensure the needle fitments pierce the rubber fitments at the back of the cartridge. The cartridge should be flush with the chassis.
- Close the analyzer door. The Smart Maintenance feature will read the RFID and prime the cartridge as needed.



3.15 pH/Gas Auto QC Cartridge Flush with Chassis

After selecting **QC** (Left Home Screen), the user can select either the lower or upper level of QC for the pH/Gas modules or Chemistry.



3.16 QC Menu

By selecting any of the 4 buttons, all recent QC data for the selected level will be displayed.

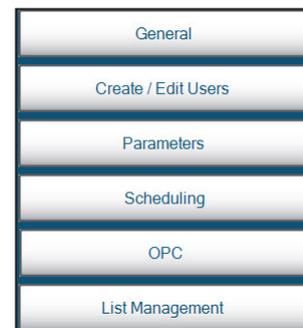
By default the on-board QC results for the past week will be displayed. To view a larger range of results, configure the desired date range using the Set Dates button.



3.17 QC Menu - Selected Level Data

The table to the upper right will automatically populate the lower and upper limits for the level of QC.

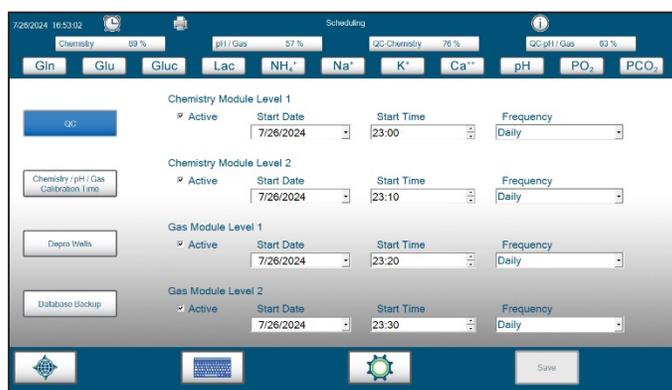
Modify at the upper right corner of the screen allows for the QC limits of each parameter to be changed from default range of ± 2 SD. If a new cartridge of the same lot is installed, the modified ranges will remain programmed.



3.18 Settings Sub-Menu

To set an automated schedule for QC analysis to run:

1. In the Settings submenu, select **Scheduling**.
2. Select QC from the scheduling options. Four scheduling options will appear, one for each level of Onboard QC.
3. Check the box next to Active to program a level of Onboard QC's Start Date, Start Time, and Frequency.
4. When completed, select **Save** from the command bar to save the changes to the schedule.



3.19 Scheduling Menu

Onboard QC can be turned off by deactivating it through **Settings** (Right Home Screen). It can be deactivated through the Scheduling menu under QC, or through the General Settings menu by unchecking the **Enable Onboard QC** box.

3.3.1 QC LOCKOUT FEATURE

QC Lockout is an optional function that can be configured when onboard QC is enabled and operational. It does not apply to external ampouled control solutions.

When the QC Lockout feature is enabled and any level of onboard QC reports an **Out of Range** error for the analysis, the parameter in question is **locked out** and the **Status** for it will turn red. If a parameter is locked out due to an out of range QC result, no sample results will be reported for that parameter during normal sampling.

A locked out parameter will remain as such until subsequent QC testing produces results that are within range for all applicable levels of QCs that failed. The QC Lockout function assists operators by ensuring that sample results are accurate.

Calibration Status				
Parameter	Status	Slope	Lower Limit	Upper Limit
Gln	C	32.33	5.00	100.00
Glu	C	48.72	5.00	100.00
Gluc	C	107.51	5.00	150.00
Lac	C	50.73	5.00	100.00
NH4+	C	11.35	8.50	12.50
Na+	QC [L1,L2]	10.40	8.50	12.50
K+	C	10.83	8.50	12.50
Ca++	C	10.80	8.50	12.50

3.20 Enable QC Lockout Checkbox

QC Lockout can be enabled by a user with the appropriate privilege level from the General Settings screen under **Settings** in the right home screen. To enable QC Lockout, simply press the **Enable QC Lockout** checkbox in the General Settings menu. After checking the box, **Save** must be selected to save the configuration. To disable QC Lockout, simply uncheck the box and press **Save**.

When a parameter has failed to fall within the QC range and has been locked out, its button in the Status bar will turn red. The Calibration Status overlay will indicate **QC** in red text. Additionally, no sample result will be reported during regular sample analyses for the locked out parameter. Instead, the Sample Results screen will show the parameter in red text and a status of QC, indicating it is locked out. Printed reports of the sample analysis will show no results for a locked out parameter and will also have an alert message of **QC** in the printout. If QC Lockout is NOT enabled, a parameter will continue to report sample results even if the last onboard QC analysis was not in range.

FLEX2 Basic A, B, C operators should note the following when using the QC Lockout feature:

- QC Lockout will impact parameter dependencies. For example...
 - If Glutamine is calibrated and available but Glutamate is locked out, no Glutamine result will be reported and a "dependency" error will be indicated the Sample Results screen and Error Log.
 - If Ammonium is calibrated and available but either Sodium and/or Potassium are locked out, no Ammonium result will be reported.
- A locked out parameter will retain its locked out status even if the analyzer is power cycled.
- QC Lockout always applies to the last onboard QC analysis performed, even if QC Lockout was not enabled at the time.
- If QC Lockout is enabled and a scheduled QC is missed for any reason, all applicable parameters will be locked out. For example, if a scheduled onboard QC analysis of any level is unable to run due to a reagent cartridge becoming invalid, expired or empty.

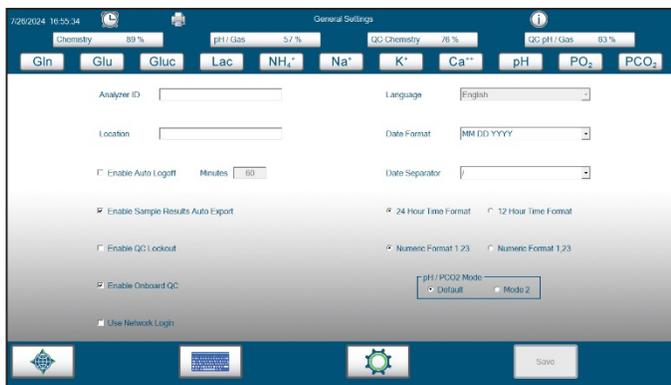
3.4 ANALYZER SETTINGS

This section provides instructions on configuring the various analyzer settings of the BioProfile FLEX2 Basic A, B, C systems. An operator with appropriate privileges can access each of the configuration menus detailed in this section by selecting **Settings** from the Right Home Screen, followed by the appropriate sub-menu.

When an operator opens any of the 6 submenu screens from within the Settings Menu, **Settings** is visible in the Command Bar. Selecting **Settings** will display each of the 6 sub-menu buttons so that the operator can navigate throughout the various Settings menus without having to return the Home Screen.

3.4.1 GENERAL SETTINGS

To access the General settings menu, select **Settings**, followed by **General**. This displays the General Settings Screen.

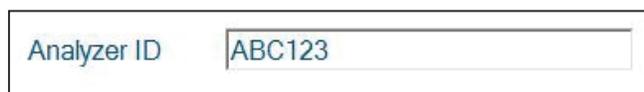


3.21 General Settings Menu

3.4.1.1 ANALYZER ID

In some cases it may be necessary to set an Analyzer ID for the BioProfile FLEX2 Basic A, B, C system. This is typically required when configuring the FLEX2 Basic A, B, C analyzer to communicate with a laboratory network. To setup an Analyzer ID, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. In the Analyzer ID entry box, enter the analyzer ID. The analyzer ID can include up to 30 alpha-numeric and special characters (!@#\$\$%^&*).
3. Once the analyzer ID is entered, select **Save** in the Command Bar to save the analyzer ID.



3.22 Analyzer ID

NOTE: Analyzer ID will appear in the file name of printed reports or exported data.

3.4.1.2 ANALYZER LOCATION

In some cases it may be necessary to input an analyzer Location for the BioProfile FLEX2 Basic A, B, C system. To setup an analyzer Location, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. In the Location entry box, enter the analyzer location. The analyzer location can include up to 30 alpha-numeric and special characters (!@#\$\$%^&*).
3. Once the analyzer location is entered, select **Save** in the Command Bar to save the analyzer location.

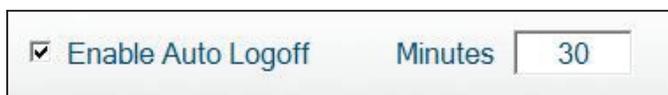


3.23 Analyzer Location

3.4.1.3 ENABLE/DISABLE AUTO LOGOFF

For security reasons, the system can be programmed to automatically logout of the currently logged-in User Account if the system is not used for a specified length of time. To enable the Auto Logoff function, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. Select the empty box next to the words Enable Auto Logoff. This will place a checkmark in the box and will also open the Minutes entry box.



3.24 Enable/Disable Logoff

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

3. Input the desired length of time (in minutes) in the Minutes box. This will be the specified amount of time that a User Account would need to remain inactive before the system automatically logs out.
4. Select **Save** in the Command Bar to save the Auto Logoff configuration.
5. To disable the Auto Logoff function, select the box next to the words Enable Auto Logoff to remove the checkmark, followed by **Save**.

3.4.1.4 ENABLE/DISABLE SAMPLE RESULTS AUTO EXPORT



3.25 Ethernet Port for Network Cable from LAN

The BioProfile FLEX2 Basic A, B, C Analyzer offers simple Local Area Network (LAN) connectivity for data and system report management. For security reasons, there is no direct access to the main FLEX2 Basic A, B, C operating system or database. However, the systems do include an internal Bridge Computer that can be connected to a LAN. Residing on the Bridge Computer is a Shared network folder to which all sample results data can be manually or automatically exported. Additionally, all FLEX2 Basic A, B, C system Error Log, Audit Log, Calibration Log, Warranty Log and Diagnostic Log files can also be manually exported to the shared network folder.

NOTE: Accessing the sample results and log data exported to the Bridge Computer requires the connection of a separate USB drive or Ethernet cable to the ports available on the back of the BioProfile FLEX2 Basic A, B, C. The End User is responsible for supplying any external USB drive or Ethernet cable

All sample result and log files exported from the FLEX2 Basic A, B, C analyzer will be in **.csv** format and each file name will include the Analyzer ID for the system. A unique analyzer ID can be set by operators with an intermediate privilege level or higher.

To set up an analyzer ID:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings screen.
2. Input the desired analyzer ID in the box provided then select **Save** in the Command bar.

To enable the automatic exportation of sample results to the Bridge Computer, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. Check the box next to the words Enable Sample Results Auto Export.
3. Select **Save** in the Command Bar to save the Sample Results Auto Export configuration.
4. To disable the Auto Export function, select the box next to the words Enable Sample Results Auto Export to remove the checkmark, followed by **Save**.



3.26 Enable Sample Results Auto Export

When the Enable Sample Results Auto Export function is enabled, every sample result produced on the BioProfile FLEX2 Basic A, B, C will be automatically exported to the shared folder on the Bridge Computer. The results will be stored to a **.csv** file containing all results for the respective month. At the start of each month a new **.csv** file will be created and appended with each new sample result.

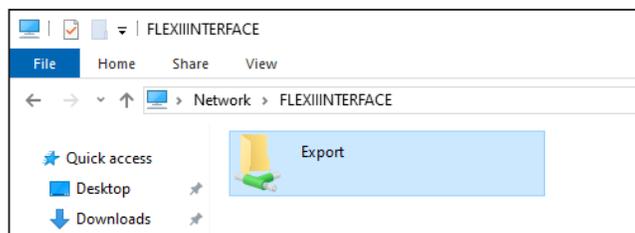
To access the FLEX2 Basic A, B, C data exported to the Shared Folder from a network:

1. Connect a network cable from the LAN to the Ethernet port located on the back of the FLEX2 Basic A, B, C.
2. From any computer connected to the LAN, navigate to the Network connections and locate the **FLEXIIINTERFACE** connection.



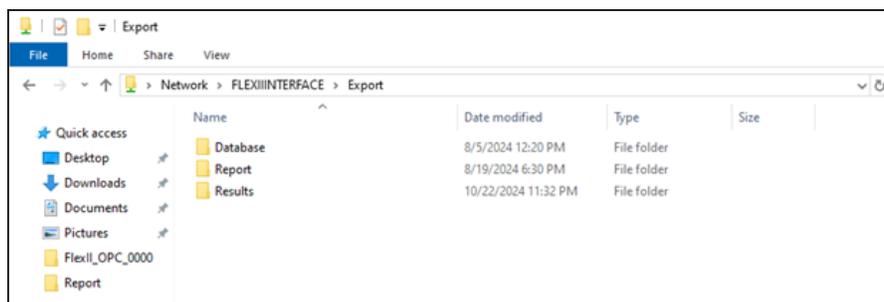
3.27 Interface Connection Icon

3. Select the **FLEXIIINTERFACE** network connection, and then select the **Export** folder as shown.



3.28 Network Export Folder

4. The **Export** folder can contain a **Logs** folder, **Results** folder or **Database** folder depending on the type of data that has been exported. All exported diagnostic logs will appear in the **Logs** folder. All manually or automatically exported sample results will appear in the **Results** folder. All database backup files will appear in the **Database** folder. All exported .pdf reports will appear in the Reports folder. All exported Audit Log, Error Log, Warranty Log and Calibration Log files will appear directly in the **Export** folder.



3.29 Expanded Export Folder

5. The exported sample results and log files can be opened in any spreadsheet program (like Microsoft™ Excel).

To share the FLEX2 Basic A, B, C Export Folder on the Bridge:

1. Click the **Printer** icon at the top of the FLEX2 User Interface touchscreen.
2. Open the **File Explorer**.
3. Navigate to the following file location: **C:\Export**.
4. Right click the folder and select **Share with**.
5. Select **Specific people** from the dropdown menu.
6. Select **Share with Everyone**.
7. Click **Add**.
8. Click **Share** to share the Export Folder.

When the Export Folder has been successfully shared, it will appear in the **FLEXIIInterface** folder. This is where you will be able to access exported results, logs, or database backup files.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

3.4.1.5 EXPORTED DATA DIRECTLY TO USB THROUGH BRIDGE COMPUTER

If a USB Thumb Drive is connected to one of the available ports on the back of the analyzer, FLEX2 Basic A, B, C data can be exported directly to the USB drive through the Bridge Computer. When an operator selects data to export and a USB drive is connected, they will have the option to export directly to that drive location. Data will be exported using the following file pathways and naming conventions respectively:

(Assume drive E:)

E:\NovaBiomedical\Export\Results\SampleResultsANALYZERIDYYYY-MM-DD_HHMMSS.csv

E:\NovaBiomedical\Export\Results\ChemistryLevel#QcResultsANALYZERIDYYYY-MM-DD_HHMMSS.csv

E:\NovaBiomedical\Export\Results\GasLevel#QcResultsANALYZERIDYYYY-MM-DD_HHMMSS.csv

3.4.1.6 ENABLE/DISABLE ONSCREEN KEYBOARD

The BioProfile FLEX2 Basic A, B, C Analyzers are supplied with a Logitech™ wireless external keyboard and mouse assembly for entering system and sample information where required.



3.30 External Keyboard and Mouse Assembly

The Onscreen Keyboard function can be opened from within various menu screens and overlays on the FLEX2 Basic A, B, C.

NOTE: To utilize the onscreen keyboard function it must first be enabled from the **Settings > General** screen.

To open the onscreen keyboard, press the **Keyboard** button.



3.31 Onscreen Keyboard

The onscreen keyboard will remain open on the User Interface until closed. To close the onscreen keyboard, simply press the red **X** to the right of the keyboard.

3.4.1.7 DATE FORMAT CONFIGURATION

The BioProfile FLEX2 Basic A, B, C has 3 different Date Format options:

- MM DD YYYY
- DD MM YYYY
- YYYY MM DD

To configure the Date Format, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. In the Date Format dropdown box, select the desired Date Format for the User Interface and for sample results reporting.
3. Select **Save** in the Command Bar to save the configured Date Format.



3.32 Date Format

3.4.1.8 DATE SEPARATOR CONFIGURATION

The BioProfile FLEX2 Basic A, B, C Analyzers have three different Date Separator options: (/), (-), and (.).

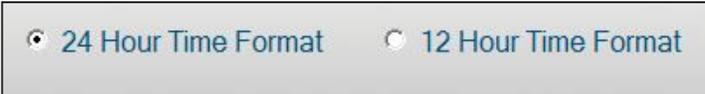
To configure the Date Separator, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. In the Date Separator dropdown box, select the desired Date Separator for the User Interface and for sample results reporting.  *3.33 Date Separator*
3. Select **Save** in the Command Bar to save the configured Date Separator.

3.4.1.9 HOUR TIME CONFIGURATION

The BioProfile FLEX2 Basic A, B, C can be configured for 24 Hour Time Format or 12 Hour Time Format.

To configure the Hour Time Format, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. Select 24 Hour or 12 Hour to configure the desired format.  *3.34 Date Format 24 or 12 Hour*
3. Select **Save** in the Command Bar to save the configured Hour Time Format.

Select **Save** in the Command Bar to save the configured Hour Time Format.

3.4.1.10 NUMERIC FORMAT CONFIGURATION

The BioProfile FLEX2 Basic A, B, C Analyzers have two different Numeric Format options for sample results reporting:

To configure the Numeric Format, perform the following steps:

1. From the Right Home Screen select **Settings**, then select **General** to open the General Settings Screen.
2. Select Numeric Format 1.23 or Numeric Format 1,23 to configure the desired format.  *3.35 Numeric Format*
3. Select **Save** in the Command Bar to save the configured Numeric Format.

3.4.1.11 ENABLE ONBOARD QC

By selecting Enable Onboard QC, the analyzer can perform automated QC analysis using the onboard QC for both the Chemistry and pH/Gas modules. If Enable Onboard QC is not selected, no QC buttons will appear at the Status bar, and no QC can be scheduled to run. Onboard QC is discussed further in Section 3.3.

3.4.1.12 USE NETWORK LOGIN

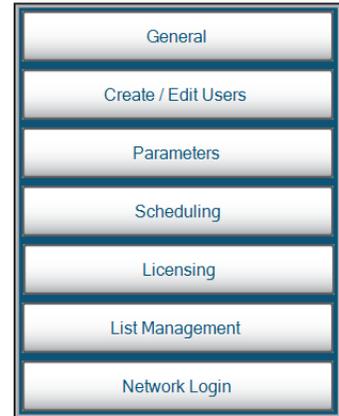
The FLEX2 Basic A, B, C Bridge Computer, when connected to a company domain, is able to utilize Active Directory. This is accomplished through the User Interface using the Use Network Login setting as enabling this feature allows for users to be assigned to a group policy replicating FLEX2 Basic A, B, C privilege levels. When selecting this setting, the Settings menu will change to include the Network Login option.



3.36 Use Network Login

3.4.2 CREATE/EDIT USERS

The BioProfile FLEX2 Basic A, B, C Analyzer allows an operator with Administrator privileges the ability to create and edit User Accounts for other system operators. Each User Account must have a unique User Name and Password.



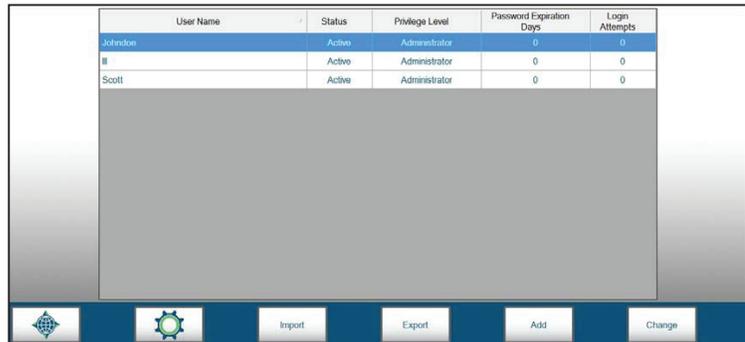
3.37 Network Login in Settings Menu

Once a User Account is created, it can be activated or deactivated but it can never be deleted or removed from the system database. User Accounts are assigned a specific privilege level (Basic, Intermediate, Advanced, or Administrator) based on the desired level of system access. A system administrator can set a password expiration date for individual User Accounts and can also set a limit to the number of failed log-in attempts for each user.

NOTE: *At the time of BioProfile FLEX2 Basic A, B, C installation, the Nova Service Representative performing the installation will create the initial Administrator account for the system. It is important that the User Name and Password for this administrator account is recorded by the system administrator for future reference.*

3.4.2.1 CREATING A USER ACCOUNT

1. Select **Settings** from the Right Home Screen, then select **Create/Edit Users** to open the Edit Users screen. The Edit Users screen displays all of the system User Accounts that have been previously created, their status, privilege level, their password expiration date, and the number of failed login attempts allowed for the account.
2. Select **Add** in the Command Bar to open the Add User Account window.
3. Enter a User Name in the box provided. User Names must be 3-25 alpha-numeric characters and are not case-sensitive. User names can include dashes (-) and underscores (_) but no spaces or special characters (!, @, #, \$, %, ^, &, * <).



User Name	Status	Privilege Level	Password Expiration Days	Login Attempts
Johndoe	Active	Administrator	0	0
Bill	Active	Administrator	0	0
Scott	Active	Administrator	0	0

3.38 Edit Users Screen



User Name:

Password:

Status:

Privilege Level:

Password Expiration Days:

Login Attempts:

3.39 Add User Account Window

- Enter a Password for the User Account. Passwords must be 8-25 alpha-numeric 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 of the previous section has been met.*

The screenshot shows a form with two input fields: 'User Name' and 'Password'. The 'User Name' field contains the text 'Ba' and has a yellow warning triangle icon to its right. The 'Password' field is empty.

3.40 Alert Icon Next to Inadequate User Name

- 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.
- Select the Privilege Level for the User Account (Basic, Intermediate, Advanced, or Administrator).

The screenshot shows the form with 'BasicUser' in the 'User Name' field and a masked password. The 'Status' dropdown menu is open, showing options: 'Inactive', 'Active', and 'Inactive' (highlighted). The 'Privilege Level' dropdown menu is also open, showing options: 'Basic' (highlighted), 'Intermediate', 'Advanced', and 'Administrator'. There are green checkmarks next to the 'Expiration Days' and 'Login Attempts' fields.

3.41 User Account Status

- 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 zero, the password will have no expiration for this User Account.

- 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 zero, the User Account will have no limit to the number of failed login attempts.

The screenshot shows the form with 'BasicUser' in the 'User Name' field and a masked password. The 'Status' dropdown menu is set to 'Active'. The 'Privilege Level' dropdown menu is open, showing options: 'Basic' (highlighted), 'Basic', 'Intermediate', 'Advanced', and 'Administrator'. There are green checkmarks next to the 'Expiration Days' and 'Login Attempts' fields.

3.42 Privilege Level Selection

- When all of the 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.

NOTE: *User Accounts are permanently stored in the system database. They can be made active or inactive but can never be deleted.*

3.4.2.2 CHANGING A USER ACCOUNT

User Accounts can only be edited or changed by an operator with Administrator privileges; to edit or change a User Account:

- Select **Settings** (Right Home Screen), then select **Create/Edit Users** to open the Edit Users screen. The Edit Users screen will list all of the saved User Accounts.
- Open the individual User Account by double tapping on the User Name of the account or by selecting the User name and then pressing **Change** in the Command Bar. This will open the User Account Settings window for the selected User Account.
- Make all necessary edits or changes to the User Account information, then select the green checkmark to save the changes.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

3.4.2.3 IMPORTING & EXPORTING USER ACCOUNTS

The BioProfile FLEX2 Basic A, B, C system allows an individual User Account or a group of User Accounts to be imported from or exported to the Bridge Computer system. This feature is beneficial when a laboratory has multiple operators and their User Account credentials need to be programmed for multiple BioProfile FLEX2 Basic A, B, C analyzers. An operator with Administrator privileges can perform an import or an export of User Accounts from the Bridge Computer. To Export/Import User Accounts:

1. Insert a USB thumb drive into any open port on the back of the FLEX2 Basic A, B, C analyzer.
2. Select **Settings** (Right Home Screen), then select **Create/Edit Users** to open the Edit Users screen. The Edit Users screen will list all of the saved User Accounts.
3. Select the User Accounts that you wish to export, then select **Export** in the Command Bar.
4. Select the drive location that you wish to export the User Accounts to.
5. Once the User Accounts have been saved to the USB drive, install the USB drive on another BioProfile FLEX2 Basic A, B, C system.

NOTE: *Ensure the users .csv file is in the root directory of the drive.*

6. Select **Settings** (Right Home Screen), then select **Create/Edit Users** to open the Edit Users screen. The Edit Users screen will list all of the saved User Accounts.
7. Select **Import** from the Command Bar, then select the drive you wish to import the User Accounts from.

3.4.2.4 USER ACCOUNT PRIVILEGE LEVELS

This section details the available User Account privilege levels for the BioProfile FLEX2 Basic A, B, C Analyzer and the specific functions that can be performed by each level.

Menu	Privilege	Basic	Intermediate	Advanced	Admin
Analysis Menu	Run Manual sample analysis	✓	✓	✓	✓
	Cancel Manual sample analysis	✓	✓	✓	✓
	Run 96-well plate sample analysis	✓	✓	✓	✓
	Cancel 96-well plate sample analysis	✓	✓	✓	✓
	Run Sample Cup Tray analysis	✓	✓	✓	✓
	Cancel Sample Cup Tray analysis	✓	✓	✓	✓
	Run Micro Centrifuge Tube Tray analysis	✓	✓	✓	✓
	Cancel Micro Centrifuge Tube Tray analysis	✓	✓	✓	✓
	View Sample information	✓	✓	✓	✓
	Enter Sample ID	✗	✓	✓	✓
	Enter Batch ID	✗	✓	✓	✓
	Enter Vessel ID	✗	✓	✓	✓
	Create New Sample Type	✗	✓	✓	✓
	Modify Sample Type Settings	✗	✓	✓	✓
	Select or Change the Sample Type	✗	✓	✓	✓
	Change the Vessel Temperature (Defaulted to 37.0°C)	✗	✓	✓	✓
	Change the Vessel Pressure (Defaulted to 0.0 PSI)	✗	✓	✓	✓
	Change the Sparging O2% (Defaulted to 20.9%)	✗	✓	✓	✓
	Select/Deselect the pH/Gas Module	✗	✓	✓	✓
	Select/Deselect the Chemistry Module	✗	✓	✓	✓
	Change Chemistry dilution ratio	✗	✓	✓	✓

Menu	Privilege	Basic	Intermediate	Advanced	Admin
Historical Results Menu	View, Export, and Print Historical Results	✓	✓	✓	✓
Calibration Menu	Run pH/Gas & Chemistry Calibration	✓	✓	✓	✓
QC Menu	Run on-board QCs	✓	✓	✓	✓
	Export/Print QC results	✓	✓	✓	✓
	Modify on-board QC range limits	✗	✓	✓	✓
User Menu	Change Password	✓	✓	✓	✓
	Log out of current user	✓	✓	✓	✓
Maintenance Menu	Run Module Depro	✓	✓	✓	✓
	Run Depro Wells	✓	✓	✓	✓
	Change Syringe	✓	✓	✓	✓
	Change Probe	✓	✓	✓	✓
	Change Pump Tubing	✓	✓	✓	✓
	Long-Term Shutdown	✓	✓	✓	✓
General Settings	Modify General Settings	✗	✓	✓	✓
	Create/Edit Users	✗	✗	✗	✓
	Modify Parameters	✗	✗	✓	✓
	Modify Scheduling (Automatic Maintenance)	✗	✓	✓	✓
	Modify OPC	✗	✗	✗	✓
	Modify List Management	✗	✓	✓	✓
	Change analyzer date and time	✗	✗	✗	✓
Logs Menu	View Audit Logs	✓	✓	✓	✓
	Export Audit Logs	✓	✓	✓	✓
	View Error Logs	✓	✓	✓	✓
	Export Error Logs	✓	✓	✓	✓
	View Calibration Logs	✓	✓	✓	✓
	Export Calibration Logs	✓	✓	✓	✓
	View Maintenance Logs	✓	✓	✓	✓
	Export Maintenance Logs	✓	✓	✓	✓
	View Warranty Logs	✓	✓	✓	✓
	Print Warranty Logs	✓	✓	✓	✓
	Export Warranty Logs	✓	✓	✓	✓
	Export Diagnostic Logs	✓	✓	✓	✓
	Database Menu	Backup	✗	✗	✗
Restore		✗	✗	✗	✓
Archive		✗	✗	✗	✓
Shutdown Menu Button	Shutdown Analyzer	✗	✓	✓	✓
Chemistry Module Overlay	Run Chemistry Calibration	✓	✓	✓	✓
	Run Clear Wells	✓	✓	✓	✓
	Run Prime	✗	✓	✓	✓
pH/Gas Module Overlay	Run pH/Gas Calibration	✓	✓	✓	✓
	Run Prime	✓	✓	✓	✓

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

Menu	Privilege	Basic	Intermediate	Advanced	Admin
Warranty Issues Overlay	Claim Failed Sensors	✗	✓	✓	✓
	Claim Failed Sensor Card	✗	✓	✓	✓
Printer Overlay	Access Printer Overlay	✓	✓	✓	✓
	Access Remote Desktop	✗	✗	✗	✓
	Time/date Overlay	✗	✗	✗	✓

3.4.3 PARAMETERS SETTINGS

An operator with appropriate privileges can configure the units of measure for each parameter or suppress parameters when desired.

3.4.3.1 CONFIGURING UNITS OF MEASURE

The FLEX2 Basic A, B, C analyzer uses the following units of measure for each test parameter:

Directly Measured Parameters:

Parameter	Units (default units in bold)
Glutamine (Gln)	mmol/L or g/L
Glutamate (Glu)	mmol/L or g/L
Glucose (Gluc)	g/L or mmol/L
Lactate (Lac)	g/L or mmol/L
Ammonium (NH ₄ ⁺)	mmol/L or g/L
Sodium (Na ⁺)	mmol/L
Potassium (K ⁺)	mmol/L
Ionized Calcium (Ca ⁺⁺)	mmol/L
pH	N/A
PCO ₂	mmHg or kPa
PO ₂	mmHg or kPa

Calculated Parameters:

Parameter	Units (default units in bold)
pH @ Temp	N/A
PO ₂ @ Temp	mmHg or kPa
PCO ₂ @ Temp	mmHg or kPa
O ₂ Saturation	%
CO ₂ Saturation	%
Bicarbonate (HCO ₃ ⁻)	mmol/L

To configure the units of measure for each test parameter:

1. Select **Settings** from the Right Home Screen, then select **Parameters** to open the Parameters Settings screen.
2. In the Units column, choose the desired units of measure for each parameter from the dropdown lists.
3. Once all units of measure have been configured, select **Save** in the Command Bar to save the changes.

Parameter	Units	Suppressed
Gln	mmol / L	False
Glu	mmol / L	False
Gluc	g / L	False
Lac	g / L	False
NH4+	mmol / L	False
Na+	mmol / L	False
K+	mmol / L	False
Ca++	mmol / L	False
pH	-	False
PCO2	mmHg	False
PO2	mmHg	False

3.43 Parameter Settings

3.4.3.2 TEST SUPPRESSION

An operator with appropriate privileges can suppress test parameters if they have no interest in measuring or monitoring them. When a test parameter is suppressed, no data will be reported for that parameter, no errors will be reported for that parameter, and the User Interface will show no status for the parameter.

To configure test suppression:

1. Select **Settings** (Right Home Screen), then select **Parameters** to open the Parameters Settings screen.
2. In the Suppressed column, choose the desired status for each parameter from the dropdown lists. A parameter with a True status will be suppressed while a parameter with a False status will not be suppressed.
3. Select **Save** in the Command Bar to save any changes to parameter status.

Parameter	Units	Suppressed
Gln	mmol / L	False
Glu	mmol / L	False
Gluc	g / L	False
Lac	g / L	False
NH4+	mmol / L	False
Na+	mmol / L	False
K+	mmol / L	False
Ca++	mmol / L	False
pH	-	False
PCO2	mmHg	False
PO2	mmHg	False

3.44 Parameter Settings

NOTE: When suppressing parameters, be aware of parameter dependencies. When a parameter is suppressed, no data will be saved for any sample results obtained while that parameter was suppressed.

- PCO₂ is dependent on pH
- Glutamine (Gln) is dependent on Glutamate (Glu)
- Ammonium (NH₄⁺) is dependent on Sodium (Na⁺) and Potassium (K⁺)

3.4.4 SCHEDULING AUTOMATIC QC & MAINTENANCE

An operator with appropriate privileges can configure the scheduling of onboard QC and automatic maintenance. To configure the scheduling of onboard QC or automatic maintenance, select the Settings menu from the Right Home Screen, then select **Scheduling** to open the Scheduling Menu.

The Scheduling Menu displays a sub-menu with 4 scheduling options:

- Quality Control (QC)
- Chemistry/pH/Gas Calibration Time
- Depro Wells
- Database Backup

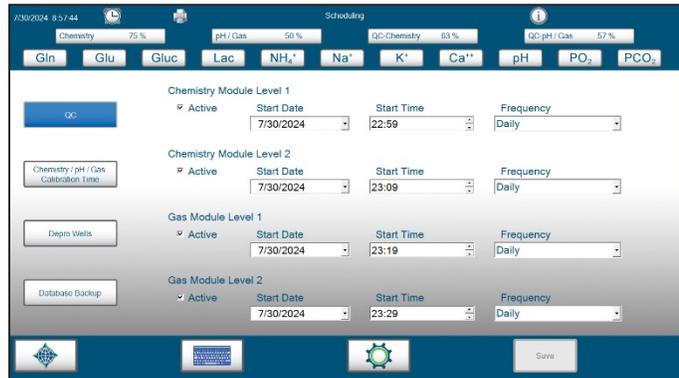


3.45 Scheduling Menu

3.4.4.1 ONBOARD QC SCHEDULING

Selecting **QC** displays the Onboard Quality Control (**QC**) scheduling menu. From within this menu, an operator can set the date, time and frequency that onboard automatic QC will be tested.

NOTE: *Onboard QC must be enabled through the Settings menu before any onboard QC can be scheduled.*



3.46 QC Scheduling Menu

To schedule onboard QC to run:

1. Select the Active checkbox to activate the onboard QC scheduling function for each level of QC.
2. Select a start date for the QC, then a time and the frequency for onboard QC to be run.

NOTE: *The start date and start time must be set for a time in the future in order to save.*

3. Press **Save** in the Command Bar to save the changes.

The scheduled QC can be viewed by selecting the **Clock** in the Status Bar, or via the Scheduling menu.

3.4.4.2 CHEMISTRY/GAS CALIBRATION TIME SCHEDULING

Selecting the Chemistry/pH/Gas Calibration Time button displays the calibration scheduling menu for the Chemistry and pH/Gas modules. From within this menu, an operator can set the time at which automatic calibrations of these modules will occur. To schedule the time of calibration:

1. Select the Time at which the automatic calibrations will begin in the Time box.
2. Select **Save** in the Command Bar to save the Chemistry/pH/Gas Calibration Time configuration.



3.47 Chemistry/Gas Calibration Scheduling Options

3.4.4.3 DEPRO WELLS SCHEDULING

Selecting **Depro Wells** displays the configuration menu for setting the automatic onboard Depro of the Waste Well. By default, Depro Wells will be scheduled to happen daily.

To change the schedule for automatic Depro cycles:

1. Select a Start Date for the Depro Wells function.
2. Select a Start Time for the Depro Wells function.
3. Select a Frequency (Daily, Weekly, Bi-Monthly, Monthly) for the Depro Wells function.

NOTE: *The start date and start time must be set for a time in the future in order to save.*

4. Select **Save** in the Command Bar to save the Depro Wells scheduling configuration.

NOTE: *A daily Depro of the Waste Well and CDV Well is recommended. Depro requirements will vary based on system usage. When the Depro Wells function is running, the system is made unavailable for sampling for about 5 minutes. If possible, configure this function to occur during times of the day when the BioProfile FLEX2 Basic A, B, C analyzer will not be used.*

3.4.4.4 DATABASE BACKUP SCHEDULING

An operator with appropriate privileges has the ability to enable a regularly scheduled Database Backup sequence.

To schedule a regular automatic Database Backup sequence:

1. Select the Active box to place a checkmark in it. This will activate the Database backup scheduling function.
2. Select a Start Date.
3. Select a Start Time.
4. Select a Frequency (Daily, Weekly, Bi-Monthly, Monthly) for the Database Backup sequence.

NOTE: *The start date and start time must be set for a time in the future in order to save.*

5. Select **Save** in the Command Bar to save the Database Backup schedule.

It is important to consider the following factors when choosing a time to schedule database backup:

- Only the most recent successful backup is stored in the Bridge directory. Each time a backup is initiated the entire database will be backed up and any previous backups in the Bridge C:\Export\Database directory will be overwritten.
- Backup files are compressed and encrypted.
- During a Backup, the system scheduler is made busy and no other tasks will execute, ensuring the database remains unchanged during the backup.
- Depending on the size of the database, the system may be unavailable for an extended period of time. Nova Biomedical recommends scheduling Database Backup to occur when the system will not be used.

NOTE: *For more information see Section 3.12 Database.*

3.4.5 OPC

The OPC Server used with the FLEX2 Basic A, B, C Analyzers is designed and managed directly by Nova Biomedical. It was developed to network the FLEX2 Basic A, B, C Analyzers to third party laboratory interface management systems (**LIMs**) and process controllers.

For information on how to purchase an OPC server and license for an existing FLEX2 Basic A, B, C analyzer, contact your regional Nova Biomedical Account Manager or authorized distributor. For information on setting up your OPC Server and licensing, please refer to the OPC Manual (**PN 60644**) or contact Nova Biomedical Technical Support.

3.4.6 ACTIVE DIRECTORY

The FLEX2 Basic A, B, C Bridge Computer, when connected to a company domain, now offers the ability to utilize Active Directory on the user interface. This new functionality will enable the utilization of domain credentials when logging in to the graphical user interface. Active Directory empowers system administrators or IT personnel with centralized control over the management of permissions and access to all FLEX2 Basic A, B, C instruments within the network. All users will be assigned to a group policy replicating the Privilege Levels described in Section 3.4.2.4.

To enable this feature, a local user with an administrator privilege level may enable the “Use Network Login” radio button on the General Settings screen. This setting is explained in further detail in Section 3.4.1.12.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

The FLEX2 Basic A, B, C default authorization groups are listed below in decreasing order of privilege level:

- NovaBio_FLEX2_Admin
- NovaBio_FLEX2_Advanced
- NovaBio_FLEX2_Intermediate
- NovaBio_FLEX2_Basic

3.4.7 SAMPLE INFORMATION LIST MANAGEMENT

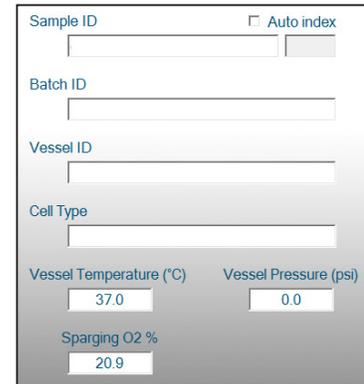
When an operator configures a sample analysis, they have the option to program a variety of information for the sample including:

- Sample ID
- Batch ID
- Vessel ID
- Cell Type

Each time new information is entered into any of these sample information input boxes, the BioProfile FLEX2 Basic A, B, C saves and keeps a running list of each identifier for future use. Whenever a new sample is configured, the sample information boxes automatically populate with the information entered for the previous sample and the sample is indexed accordingly. If the operator begins typing a new identifier in any of these boxes, dropdown lists will appear with selections based on the first characters entered in each box and sample identifiers that have been previously used.

An operator with appropriate privileges can manage these sample information lists from within the Settings menu. The List Management Settings menu allows an operator to delete saved sample list entries and configure the Sample ID auto-indexing format.

To manage sample lists, select **Settings** (Right Home Screen), then select **List Management** to display the List Management Settings menu.

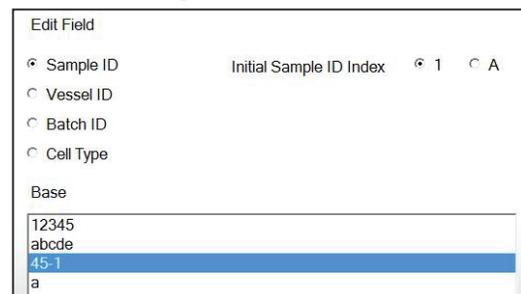


3.48 Sample Information

3.4.7.1 DELETING SAMPLE LIST ENTRIES

To delete a sample information list entry so that it no longer appears in a sample analysis entry field:

1. Under the Edit Field section, select the desired identifier list.
2. Select the circle next to the desired field to open the saved list for the identifier in the Base section. All of the previously used and saved identifiers will populate.
3. Select on the desired identifier in the Base list to highlight it in blue.
4. Once the identifier is highlighted, select **Delete** in the Command Bar to remove it from the list.
5. Select **Save** in the Command Bar to save all changes to the sample list settings.



3.49 Sample Identifier Selected

3.4.7.2 SAMPLE ID AUTO-INDEXING CONFIGURATION

To configure the format of the Sample ID Auto-Indexing, select the desired Initial Sample ID Index (1 or A). Then select **Save** to save the Auto-Index configuration.

3.5 RUNNING AN ANALYSIS

The BioProfile FLEX2 Basic A, B, C offers four default methods of sampling: Manual sampling, Sample Cup tray, Micro Centrifuge Tube tray, and 96-Well Microtiter Plate sampling. A green dot will be displayed beneath the Sample Cup or Micro Centrifuge Tube tray, indicating which tray is currently installed on the system. If neither the Sample Cup or Micro Centrifuge Tube trays are installed, then the 96-well Microtiter Plate will be available for sample configuration.

Each method of sampling can be initiated through the Analysis screen. It is important to note that the order of sample execution will not necessarily proceed in the order in which each sampling method is scheduled. Manual sampling is given the highest priority, followed by tray and 96-well Microtiter plate samples depending on which is installed. If a tray or 96-well Microtiter plate is set up to run, the plate analysis can be suspended and placed on hold to schedule and execute manual samples. Each level of sampling can resume when the sample mode with the higher priority has completed.

To configure and run sample(s), select **Analysis** from the Left Home Screen or from **Destinations**.

Selecting **Manual Analysis**  displays the Manual Sample Analysis screen.

From the Manual Sample Analysis screen, the operator can configure the sample and begin the analysis.

Selecting the **Sample Cup Tray** , **Micro Centrifuge Tube Tray** , or **96-Well Microtiter Plate**  displays the respective tray analysis screen.



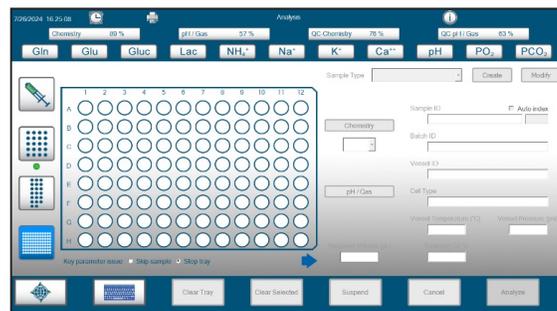
3.50 Manual Sample Analysis Menu



3.51 Sample Cup Tray Analysis Menu



3.52 Micro Centrifuge Tube Tray Analysis Menu



3.53 96-Well Microtiter Plate Analysis Menu

To configure any tray analysis, an operator must select one or more of the available well locations on the installed tray.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

From within the respective tray sample analysis screen, an operator can configure one or all available tray positions for sample analysis. When a well location is selected, the location will change color. Each position can be configured to run any combination of test modules or a pre-configured sample type. A position must be configured to run at least one module. If a location is selected but no test modules have been configured, the background will appear yellow alerting the operator that at least one test module must be configured before that position can be run. When at least one test module is selected, the location will turn light blue. If the operator selects **Analyze** or selects another location, the previous position turns dark blue. Sampling will begin at well A1 and will follow the order A1, A2, A3,...H12.

Clear Tray will clear all location configurations. To clear an individual location, select the desired position, then press **Clear Selected**.

Nova Biomedical recommends that all tray and plate analysis samples have a minimum of 400 μ L pipetted in each tray location for optimal performance.

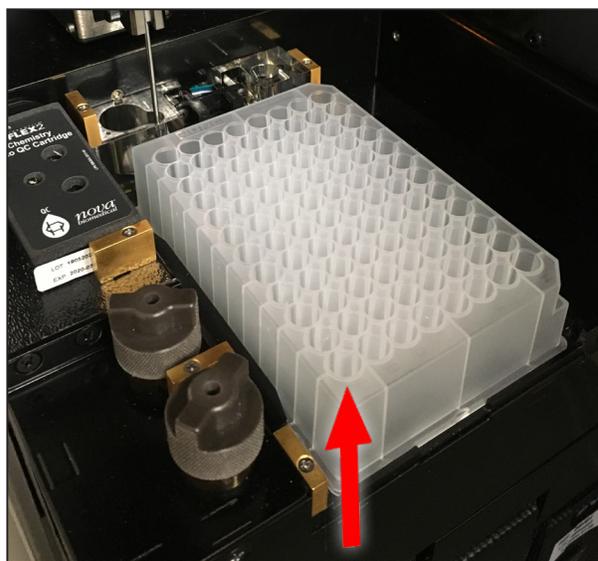
Nova Biomedical recommends the following criteria with respect to 96-well plate type:

Type:	WebSeal 96-well Non-coated Plastic Microplates
Source:	ThermoFisher Scientific™ (or similar supplier)
Catalog No.:	60180-P103 or 60180-P133
Height Total:	31.6 mm (Deep well plates)
Material:	Polypropylene
Volume Total:	1,300 μ L
Profile:	U-Shape, 8 mm Diameter
Fill Volume:	400 μ L (nominal pipette tolerance)

NOTE: Failure to supply a minimum volume of 400 μ L per well may result in **No Sample** errors.

For ease of configuration, the tray sample is pictured horizontally on the User Interface with position A1 in the upper left corner of the screen. However the actual orientation of the plate when loaded into the analyzer should be with the A1 position to the front left of the fluid deck.

When a 96-well plate is running, an operator can suspend the tray analysis to configure and run additional samples or Manual Sample analyses. Manual sampling takes priority over tray sampling. When a tray analysis is suspended, a warning will appear in the Status Bar, advising the operator of its suspension. When the manual sample analysis is completed, the system will continue running the lower priority analysis mode.



3.54 96-Well Plate

To suspend and configure additional plate samples, start by pressing **Suspend** in the Command Bar. This will cause a red **Tray Suspended** notice to appear in the Status Bar. Configure additional samples, then press **Resume** in the Command Bar to continue sampling from the plate.

NOTE: *A 96-well plate analysis may take several hours to complete, depending on the number of wells and modules configured to run. End Users should take care to evaluate the effects of time on sample results and the maximum number of wells to run at one time when sampling from 96-well plates.*

3.5.1 SELECT SAMPLE TYPE

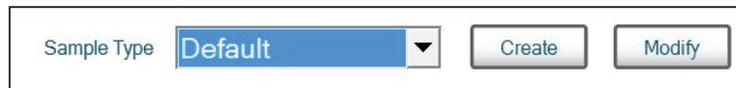
Create/Modify Sample Types

For easier sample configuration, the BioProfile FLEX2 Basic A, B, C allows the operator to create, modify, and select pre-configured Sample Types when running an analysis. A Sample Type can be stored indefinitely on the system for continued use. The FLEX2 Basic A, B, C comes pre-configured with the following Sample Types:

- Default
 - All modules selected
 - 1:1 Chemistry dilution ratio
- QC Level 1-5
 - Operator configured to match Nova QC Product Insert Sheets

To create a Sample Type:

1. From within any of the Sample Analysis screens, select Create next to the Sample Type Window. This will open the Create New Sample Type Window.



3.55 Create Button

2. In the entry box next to Sample Type, type the name of the new Sample Type.
3. On left side of the menu, configure the modules for the Sample Type. Selected modules will turn blue.
4. If the Chemistry module is selected for this Sample Type, configure the desired dilution ratio from the dropdown.
5. To configure correlation factors for each individual parameter for the inspection type, set the Offset Multiplier and Offset Intercept to the desired values.
6. To configure a specified analytical range for each parameter, set the Lower Limit and Upper Limit to the desired values.

Parameter	Offset Multiplier	Offset Intercept	Lower Limit	Upper Limit	Units	Key
pH	1.0000	0.000	5.000	8.000	-	False
PO2	1.00	0.0	3.0	500.0	mmHg	False
PCO2	1.00	0.0	3.0	300.0	mmHg	False
Gln	1.00	0.00	0.05	12.00	mmol / L	False
Glu	1.00	0.00	0.05	12.00	mmol / L	False
Gluc	1.00	0.00	0.05	30.00	g / L	False
Lac	1.00	0.00	0.05	12.00	g / L	False
NH4+	1.00	0.00	0.20	25.00	mmol / L	False
Na+	1.00	0.0	40.0	300.0	mmol / L	False
K+	1.00	0.00	1.00	100.00	mmol / L	False
Ca++	1.00	0.00	0.10	10.00	mmol / L	False

3.56 Create New Sample Type

NOTE: *The analytical range configured for a Sample Type is independent of the analytical range of the system. End users should reference how the analytical range of the chemistry parameters differ depending on chemistry dilution ratio selected.*

7. Save the Sample Type by selecting the green checkmark at the bottom right or select the red X to cancel the setup.

Key Parameters

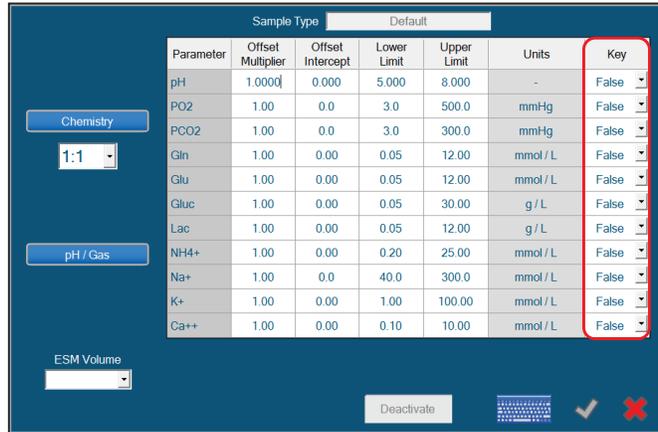
Key Parameters provide a means to suppress analysis of samples when specific **key** parameters are not available for any reason. An operator has the option of identifying which parameters are **key** when creating or modifying a Sample Type. The Key Parameters function only applies to samples supplied to the FLEX2 Basic A, B, C or when running a tray sample. The Key Parameters function does not apply to the manual sampling modes.

To configure Key Parameters from the Sample Type overlay, select **True** from the drop down in the column labeled **Key** then press the green checkmark to save the Sample Type.

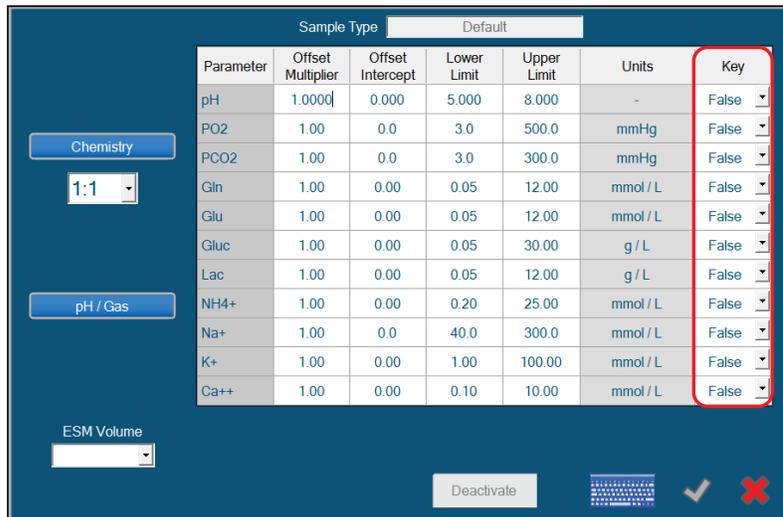
If running a tray sample with a Sample Type that has Key Parameters configured, the Key Parameters must be available for the sample to be analyzed. If a key parameter is unavailable for any reason (QC Lockout included) the FLEX2 Basic A, B, C will not run the sample. This feature prevents the loss of sample material when there may be limited volume (*such as 96-well plate sampling*).

In addition, if a key parameter is unavailable for a certain Sample Type, that Sample Type will appear red in the Sample Type dropdown menu. Nova Biomedical does not recommend setting up key parameters for any of the QC sample types pre-configured into the system.

When configuring a tray using a Sample Type that utilizes Key Parameters, the operator has the option of programming the tray analysis to skip a sample well if a Key Parameter is not available or have the system stop the entire tray from running any further. These options appear as buttons at the bottom of the of the tray map screen. One of the options must be selected for the analysis.



3.57 Sample Type Overlay – Key Parameter Column



3.58 Key Parameters Configuration



3.59 Buttons at Bottom of Well Map

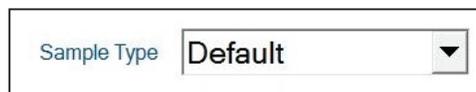
To modify or to deactivate a pre-configured Sample Type:

1. From within the Sample Analysis screens, select the desired Sample Type from the dropdown window, then select Modify to open the Modify Sample Type Window.
2. Modify the Sample Type to the desired configuration or select **Deactivate**, then save the modifications by selecting the green checkmark at the bottom right or cancel the modification by selecting the red **X**.

NOTE: *A deactivated Sample Type cannot be re-activated and no Sample Types can have the same name.*

3.5.2 SELECT PARAMETER PANEL

When a sample is configured, at least one test module must be available and configured for the sample in order for the analysis to be run.



A screenshot of a software interface showing a dropdown menu labeled 'Sample Type' with 'Default' selected. The dropdown arrow is visible on the right side of the box.

3.60 Sample Type Dropdown

To configure the test parameter panels, you can select a pre-configured Sample Type from the Sample Type dropdown.

Or, you can select the desired test parameters from the available buttons. Selected modules will turn blue. If the Chemistry module is selected, you can select the desired dilution ratio (1:1, 1:2 or 1:4).

NOTE: *Only FLEX2 Basic A Analyzers have the option for multiple dilution ratios. FLEX2 Basic B and C Analyzers only have the option for a 1:1 dilution ratio.*

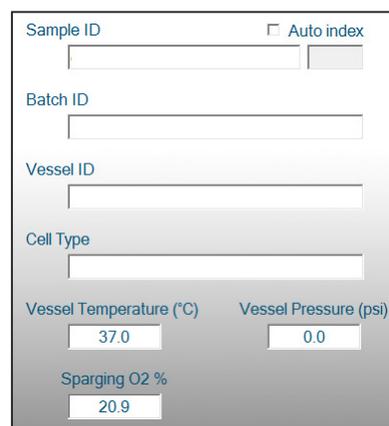
As modules are added to the test panel, the required sample volume is displayed in the box below the parameter panels.

3.5.3 ENTER SAMPLE INFORMATION

When a sample is configured, the operator can enter a **Sample ID**, **Batch ID**, **Vessel ID** and **Cell Type**. Every entry made for these sample information items is stored by the system as a list. When the operator begins typing in each entry box, previously used characters will be recognized by the system and dropdowns will appear with suggested entries for each item.

The operator also has the option to configure the Vessel Temperature (**°C**), Vessel Pressure (**psi**), and Sparging O₂%.

When samples are tested on the BioProfile FLEX2 Basic A, B, C, the raw data is always determined with the default Vessel Temperature of 37 °C, Vessel Pressure of 0.0 psi, and Sparging O₂% of 20.9. Changing these values will have no impact on the raw sample data, however changes to these values will impact the calculated results reported by the system.



A screenshot of the 'Sample Information Configuration' window. It contains several input fields: 'Sample ID' with an 'Auto index' checkbox, 'Batch ID', 'Vessel ID', and 'Cell Type'. Below these are three numerical input fields: 'Vessel Temperature (°C)' set to 37.0, 'Vessel Pressure (psi)' set to 0.0, and 'Sparging O2 %' set to 20.9.

3.61 Sample Information Configuration

Calculated Values

Changing these values depends on the state of the reactor. For example, the Sparging O₂% value should be changed to the composition of the oxygen sprarge inside the reactor. If ambient air is sparged, this value can remain at 20.9%, reflecting ambient air's O₂ composition. A change to this value will change the O₂ Saturation values in the Calculate Parameters field.

Vessel Temperature is defaulted as 37 °C. If the reactor is operating at any other temperature, it is important to change this value on the analyzer. Although the sample will be preheated to 37 °C by the analyzer, the value at the selected temperature will be calculated. A change to the vessel temperature field will change all 6 calculated values.

Vessel Pressure should also be changed to reflect the pressure maintained inside the reactor. Adjusting this will change the O₂ and CO₂ saturation values.

The sample information for Sample ID, Batch ID, Vessel ID, Cell Type, Vessel Temp, Vessel Pressure and Sparging O₂% have *sticky* properties. This means that the information from the previously configured sample will remain in the entry fields for the next configured sample.

3.5.4 MODULE CONFIGURATION & ANALYSIS

Once a sample has been fully configured with the following information,

- Sample Type
- Parameter Panels
- Dilution Ratios
- Sample ID, Batch ID, Vessel ID, Cell Type
- Vessel Temperature, Pressure, Sparging O₂%

select  to begin the sample analysis.

WARNING: *If running a manual sample, the manual sampling position will light up indicating where the sample probe will appear. To avoid bodily injury and analyzer damage, wait for the sample probe to appear and come to a complete stop before presenting the sample to the probe. DO NOT hold the sample under the manual sampling position prior to the probe stopping.*

For tray sampling, selecting **Analyze** will begin the analysis.

For Manual sampling, **Analyze** text will change to **Aspirate** and the sample probe will appear. Present the sample to the probe, then select **Aspirate**. Ensure that the sample probe does not make contact with the syringe plunger or the bottom of the sample tube or cup. While the analyzer draws the sample, ensure that the tip of the probe remains below the fluid line of the sample to avoid short-sampling. Do not remove the sample until the probe retracts.

NOTE: *If the pH/Gas module is selected for any tray analysis, the system will produce results for PO₂ and PCO₂ as well as the associated calculated results. The samples are exposed to room air and exposure to the atmosphere will cause varying degrees of PO₂ equilibration. End Users must use discretion when considering the accuracy of gas values generated from samples run on any tray. For optimal PO₂ and PCO₂ results, Manual sampling from a syringe or sealed tube/cup is recommended.*

3.6 AUDIT LOG NOTATION

The Audit Log serves as an electronic trail of the changes and/or updates made to the setup of the BioProfile FLEX2 Basic A, B, C Analyzer. The Audit Log documents the date/time, user, and action performed. A list of all the actions recorded in the Audit Log is provided in this section. To view the Audit Log, select **Logs** (Right Home Screen), then select **Audit Log**. An operator cannot delete or modify the Audit Log. Notations in the Audit Log can be sorted by **Date and Time**, **User**, or **Action** if the header for each column is selected.

3.62 Audit Log

The following is a list of actions that are stored in the Audit Log if performed by a BioProfile FLEX2 Basic A, B, C Operator:

When Exporting the Audit Log:

- A copy of the selected portion of the Audit Log will be exported to the FLEX2 Basic A, B, C internal Bridge Computer or a USB drive.
- The exported Audit Log can be viewed in any spreadsheet program.

Action	Output
Change to Parameter Configuration Units	Changed {parameter_name} Units from {old_value} to {new_value}
Change to Parameter Configuration Suppression	Parameter {parameter} {suppressed_or_unsuppressed}
Change to Barometer Calibration	Changed Barometer from {old_value} to {new_value}
Change to Sample Type Settings	Changed {sample_type_name} {parameter_name} {field_name} from {old_value} {units} to {new_value} {units}
Deactivation of User Account	User {user_name} deactivated for exceeding maximum number of login attempts
Login to the system	User {user_name} logged in
Logout from the system	User {user_name} logged out
Execute Analysis Run	Executed Sample Analysis Sample ID {sample_ID} Sample Time {sample_time} Sample Type {sample_type} Batch ID {batch_ID} Vessel ID {vessel_ID} Cell Type {cell_type}
Analysis Canceled	Canceled Sample Analysis Sample ID {sample_ID} Reason: {reason}
Analysis Results Edited	Changed Sample Time {sample_time} {field_name} from {old_value} to {new_value}
Analysis Results Image ReAnalysis	Re-Analyzed Sample Time {sample_time} Sample Time {sample_time} Changed {field_name} from {old_value} to {new_value}
Updated Host Software	Updated Host Software from {old_version} to {new_version}
Updated Analyzer Software	Updated Analyzer Software from {old_version} to {new_version}

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

Action	Output
Execute File Backup	Database Backup
Change to Analyzer Information	Changed Analyzer Information {field_name} from {old_value} to {new_value}
Change to QC Configuration Parameter Lower Limit	Changed Lower QC Limit for {parameter_name} in Lot {lot_number} {module} Level {level} from {old_value} {units} to {new_value} {units}
Change to QC Configuration Parameter Upper Limit	Changed Upper QC Limit for {parameter_name} in Lot {lot_number} {module} Level {level} from {old_value} {units} to {new_value} {units}
Execute QC Analysis Run	Executed QC Analysis for Lot {lot_number} Level {level} Sample Time {sample_time}
QC Analysis Canceled	Canceled QC Analysis for Lot {lot_number} Level {level} Reason: {reason}
File Archive	Archive database up to date {least_current_date}
Flowpath Service Start	Flow Path Service Start
Flowpath Service Finish	Flow Path Service Finish
Execute Database Restore	Database Restore completed
Execute Database Backup	Database Backup completed
Execute Database Archive	Archived Database up to {date} completed
Change to General Settings	Changed {field_name} from {old_value} to {new_value}
Change to Use Network Time	Changed Use Network Time from {old_value} to {new_value}
Execute Import Users	Import Users
Execute Export Users	Export Users
Added New User	Added New User {new_username} with Privilege Level {privilege_level}
Changed User Password	Changed User {username} Password
Changed User Status	Changed User {username} Status from {old_value} to {new_value}
Changed User Privilege	Changed User {username} Privilege Level from {old_value} to {new_value}
Changed User Password Duration	Changed User {username} Password Expiration Days from {old_value} to {new_value}
Changed User Login Attempts	Changed User {username} Login Attempts from {old_value} to {new_value}
Change Password	User {username} changed password
Enter Service Screen	User {username} entered service screen
Exit Service Screen	User {username} exited service screen
Execute System Shutdown	System Shut Down
Execute Calibrate Chemistry	Calibrate Chemistry
Execute Calibrate Gas	Calibrate pH/Gas
Activated Temporary OPC License	Activated Temporary OPC License
OPC License Requested	OPC License Requested
Installed OPC License	Installed OPC License

Action	Output
Create a new Sample Type	Created Sample Type {sample_type_name}
Deactivate a Sample Type	Deactivated Sample Type {sample_type_name}
Change to Sample Type Settings - Chemistry Dilution Ratio	Changed Chemistry Dilution Ratio for Sample Type {sample_type_name} from {old_value} to {new_value}
Change to Sample Type Settings - Included/Excluded Module	{included_excluded} Module {module} for Sample Type {sample_type_name}
Viewed Historical Result	Viewed Historical Result for Sample Time {sample_time}
Exported Historical Result	Exported Historical Result
Printed Historical Result	Printed Historical Result
Exported Historical QC Result	Exported Historical QC Result
Printed Historical QC Result	Printed Historical QC Result
Execute Calibrate Gas & Chemistry	Calibrate pH/Gas and Chemistry
Execute File Restore	Database Restore
Change to Manual Analysis Settings	Changed Manual Sample Analysis Settings {field_name} from {old_value} to {new_value}
Manual Analysis Settings Changed - Sample ID Index	Changed Manual Sample Analysis Settings Sample ID Index from {old_value} to {new_value}
Manual Analysis Settings Changed - Included/Excluded Module	Changed Manual Sample Analysis Settings {included_excluded} Module {module}
Manual Analysis Settings Changed - Chemistry Dilution Ratio	Changed Manual Sample Analysis Settings Chemistry Dilution Ratio from {old_value} to {new_value}
Activate Scheduled Event	{event_type} Scheduling Active
Deactivate Scheduled Event	{event_type} Scheduling Inactive
Change to Scheduled Event	Changed {event_type} Scheduling {field_name} from {old_value} to {new_value}
Tray Analysis Settings Changed	Changed {tray_type} Tray Settings {field_name} from {old_value} to {new_value} for Cup {cup_id}
Tray Analysis Settings Changed - Sample ID Index	Changed {tray_type} Tray Settings Sample ID Index from {old_value} to {new_value} for Cup {cup_id}
Tray Analysis Settings Changed - Sample Type	Changed {tray_type} Tray Settings Sample Type from {old_sample_type} to {new_sample_type} for Cup {cup_id}
Tray Analysis Settings Changed - Select Cup	Selected {tray_type} Tray Cup {cup_id} with Sample Type {sample_type}
Tray Analysis Settings Changed - Unselect Cup	Unselected {tray_type} Tray Cup {cup_id}
Tray Analysis Settings Changed - Clear Tray	Cleared all {tray_type} Tray Cups
Change to Scheduled Calibration Event	Changed Chemistry/pH/Gas Calibration Time Scheduling Schedule Time from {old_value} to {new_value}
Changed Date	Changed Date from {old_value} to {new_value}
Changed Time	Changed Time from {old_value} to {new_value}
Changed Key Parameter Issue Option	Changed Microtiter Tray Settings Key Parameter Issue Option from {old_value} to {new_value}

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

Action	Output
Deleted List Management Entry	Deleted List Management {field_type} Entry {entry_value}
Tray Suspended	Tray Suspended
Tray Resumed	Tray Resumed
Microtiter Tray Key Parameters Skipped Or Stopped	Microtiter Tray {skipped_or_stopped_at} Cup {cup_id} Due to Key Parameters Error in Sample Type {sample_type}
Selected 24 Hours Time Format	Selected 24 Hours Time Format
Selected 12 Hours Time Format	Selected 12 Hours Time Format
Selected US Numeric Format	Selected US Numeric Format
Selected Euro Numeric Format	Selected European Numeric Format
Changed Sample ID Index	Changed Initial Sample ID index from {old_value} to {new_value}
Time Change from the Bridge Computer	Network time changed from {old_time} to {new_time}
Time Zone Change	Time Zone Changed from UTC {old_time} to UTC {new_time}

3.7 ERROR LOG NOTATION

The Error Log serves as an electronic trail of the errors generated and reported by the BioProfile FLEX2 Basic A, B, C Analyzer. The Error Log documents the date/time and a description of each error reported. To view the Error Log, select **Logs** (Right Home Screen), then select **Error Log**. An operator cannot delete or modify the Error Log. Notations in the Error Log can be sorted by Date & Time or Description if the header for each column is selected.

When viewing the Error Log, the operator must select a date range of errors to view using **Set Dates** in the Command Bar.

When Exporting the Error Log:

- A copy of the selected portion of the Error Log will be exported to the FLEX2 Basic A, B, C internal Bridge Computer or USB drive.
- The exported Error Log can be viewed in any spreadsheet program.

3.8 CALIBRATION LOG

The Calibration Log serves as an electronic trail of all manually initiated and automatic Gas & Chemistry module calibrations performed by the BioProfile FLEX2 Basic A, B, C Analyzer. The Calibration Log documents the following information for each applicable calibration:

- Date & Time
- Chemistry & pH/Gas Flow Time
- Chemistry Temp
- Chemistry & pH/Gas Parameter Status
- Chemistry & pH/Gas Parameter Slope
- Chemistry Parameter Baseline mV (where applicable)
- Chemistry & pH/Gas Parameter Calibration Standard mV

Date & Time	Chemistry Flow Time	Chemistry Temp	Gln Status	Gln Slope	Gln Baseline (mV)	Gln Cal D1 (mV)
4/9/2019 13:59:56	-	-	-	-	-	-
4/9/2019 13:59:55	1.715	37.0	C	26.54	7.95	94.21
4/9/2019 13:52:29	-	-	-	-	-	-
4/9/2019 13:52:29	1.702	37.1	C	26.54	8.95	95.55
4/9/2019 13:38:42	-	-	-	-	-	-
4/9/2019 13:38:38	1.681	36.9	C	26.26	96.30	116.76
4/9/2019 12:00:00	-	-	-	-	-	-
4/9/2019 12:00:00	1.734	36.9	C	25.66	5.40	89.31
4/9/2019 10:07:54	1.745	37.2	C	25.31	1.71	88.22
4/9/2019 10:00:00	-	-	-	-	-	-
4/9/2019 10:00:00	1.741	37.1	C	29.93	2.12	121.45
4/9/2019 8:00:00	-	-	-	-	-	-
4/9/2019 8:00:00	1.707	37.1	C	30.05	2.30	121.81
4/9/2019 8:00:00	-	-	-	-	-	-

3.63 Calibration Log

- Barometric Pressure
- pH/Gas Calibration Standard Concentration
- Chemistry and pH/Gas Reagent Cartridge and MicroSensor Card lot number

To view the Calibration Log, select **Logs** (Right Home Screen), then select **Calibration Log**. An operator cannot delete or modify the Calibration Log. Notations in the Calibration Log can be sorted by Date & Time or Description if the header for each column is selected. An operator can use **Select All** to select all rows of information for export.

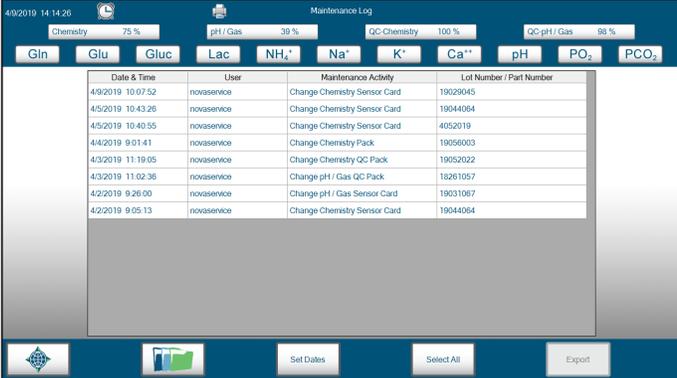
When viewing the Calibration Log, the operator must select a date range of calibrations to view using **Set Dates** in the Command Bar.

When Exporting the Calibration Log:

- A copy of the selected portion of the Calibration Log will be exported to the FLEX2 Basic A, B, C internal Bridge Computer or USB drive.
- The exported Calibration Log can be viewed in any spreadsheet program.

3.9 MAINTENANCE LOG

The Maintenance Log provides an auditable report for all the maintenance actions performed on the analyzer (*i.e. replacing MicroSensor cards, reagent cartridges, performing onboard maintenance actions*). An operator can sort and filter the Maintenance Log by using **Set Dates** in the command bar. The Maintenance Log also captures the date and time of the action, the user who performed the action, a description of the action and the applicable lot number or part number of the item replaced.



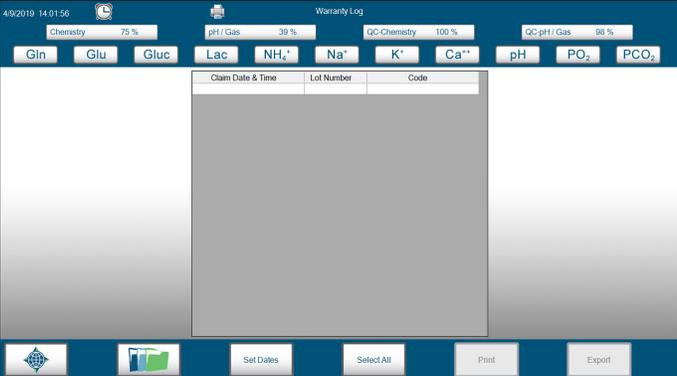
Date & Time	User	Maintenance Activity	Lot Number / Part Number
4/9/2019 10:07:52	novoservice	Change Chemistry Sensor Card	19029045
4/5/2019 10:43:26	novoservice	Change Chemistry Sensor Card	19044064
4/5/2019 10:40:55	novoservice	Change Chemistry Sensor Card	4052019
4/4/2019 9:01:41	novoservice	Change Chemistry Pack	19056003
4/3/2019 11:19:05	novoservice	Change Chemistry QC Pack	19052022
4/3/2019 11:02:36	novoservice	Change pH / Gas QC Pack	18261057
4/2/2019 9:26:00	novoservice	Change pH / Gas Sensor Card	19031067
4/2/2019 9:05:13	novoservice	Change Chemistry Sensor Card	19044064

3.64 Maintenance Log

The Maintenance Log can be exported to a USB drive or to the Shared Folder on the Bridge Computer, accessible via network connection.

3.10 WARRANTY LOG

The Warranty Log displays the list of warranty codes that have been claimed through the Warranty Support Icon. For more detail regarding Warranty support, see Section 2.3.5

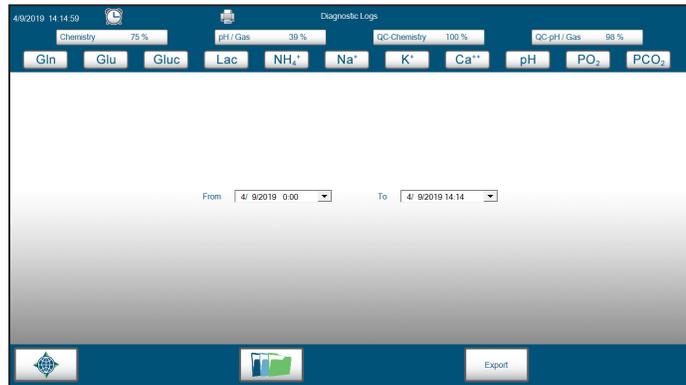


Claim Date & Time	Lot Number	Code

3.65 Warranty Log

3.11 DIAGNOSTIC LOGS

The Diagnostic Logs screen provides a way for Nova service engineers and operators with the appropriate privilege level to export system diagnostic files. These files can then be sent to Nova Biomedical for review in the event of a system malfunction. The Diagnostic Log files are not visible on the User Interface.



3.66 Diagnostic Logs

To export the Diagnostic Logs, select **Logs** (Right Home Screen), then select **Diagnostic Logs**. This will open the Diagnostic Logs Screen.

Select the date and time range for which you would like the diagnostic logs for and select the green checkmark.

NOTE: *Diagnostic Log files include a significant amount of data and are large files. Exporting these files can take several minutes for the export to complete. It is recommended that these files only be exported for the time in which you wish to investigate. Log files are only retained by the software for 2 weeks.*

Insert a USB drive into an available port on the back of the FLEX2 Basic A, B, C analyzer and select **Export**.

3.12 DATABASE

Database is available in the Right Home Screen. After selecting, the End User has the option to either Backup or Restore the FLEX2 Basic A, B, C database. When using the Database function, the database is backed up to and restored from the Bridge Computer.

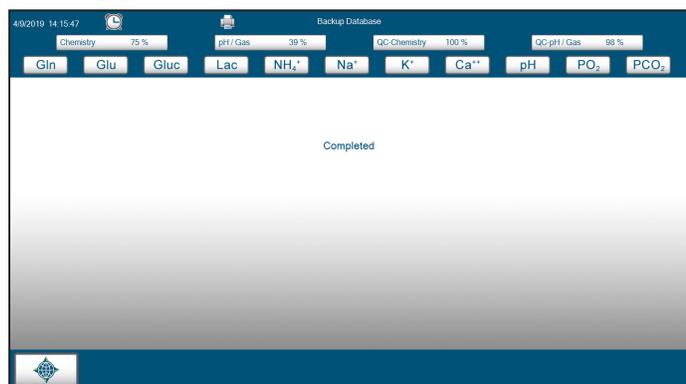
NOTE: *Archive Database is not yet available.*

3.12.1 BACKING UP THE DATABASE

Selecting the Backup function from the dropdown will open the Backup Database screen and begin the backup database process. The database will be backed up to the C:\Export\Database directory of the FLEX2 Basic A, B, C Bridge Computer.

During a backup, several images are displayed on the screen:

1. Initializing
2. Creating Backup file
3. Completed



3.67 Backup Database

On the Bridge Computer the folder will now contain a sub directory for this backup. The sub directory contains a **DatabaseBackup.dbb** file and a **Persist.dbb** file.

3.12.2 RESTORING THE DATABASE

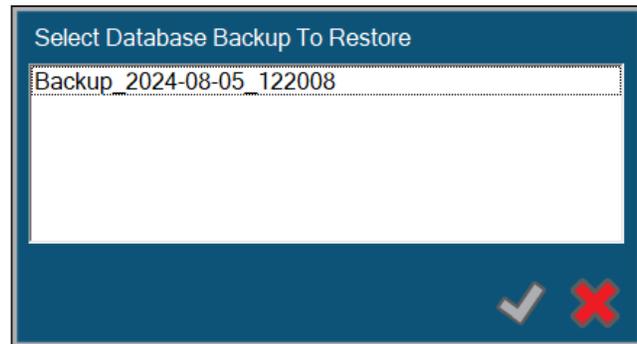
Selecting the Restore function from the dropdown will open the **Select Database Backup to Restore** window

If no database has been previously backed up, the screen will say **No Database Backup Found**.

To restore the database from a previously backed up copy, select the backup file with the desired date and time stamp, then select the green checkmark to begin the restoration process.

Upon selecting the green checkmark, the window closes and the restore process begins. The screen displays **Copying Backup**. A succession of messages are then shown on the screen:

1. Copying Backup
2. Copying database
3. Completed
4. Restarting



3.68 Copying Backup Screen

The analyzer will fully restart.

It is important to note the following with the Database functions:

- Only the most recent successful backup is stored in the Bridge directory.
- Backup files are compressed and encrypted.
- During a Backup/Restore, the system scheduler is made busy and no other tasks will execute, ensuring the database remains unchanged during the backup.
- The backup file (**.dbb**) must reside in the same location on the shared folder as the original backup in order to execute a restore.

4 MAINTENANCE

The following sections provide detailed information and directions to operate and maintain the BioProfile FLEX2 Basic A, B, C analyzer. From the Left Home Screen, press Maintenance.

WARNING: *Cell culture samples are potential sources of infectious agents. Handle all sample and flow path components with care. Gloves and protective clothing are recommended.*

It is important to perform routine maintenance as scheduled.

NOTE: *All maintenance functions are performed from within the Maintenance menu. These menus are accessed by clicking on **Maintenance** on the Left Home Screen.*

4.1 SYSTEM MAINTENANCE SCREEN

When **Maintenance** (Left Home Screen) is selected, a sub menu appears. This sub menu includes:

- Module DePro
- DePro Wells
- Change Syringe
- Change Probe
- Change Pump Tubing
- Long-Term Shutdown



4.1 Maintenance Screen

4.1.1 MODULE DEPRO

The Module DePro function allows an operator with appropriate privileges to perform a DePro of the pH/Gas & Chemistry modules.

NOTE: *In order to perform a Module DePro, the operator must first install the pH/Gas DePro Card (PN 58645) and Chemistry DePro Card (PN 58644) into the pH/Gas & Chemistry modules and have valid reagent cartridges installed for the respective modules.*

To perform a Module DePro:

1. Remove the pH/Gas & Chemistry module MicroSensor cards from their sensor module.
2. Install the respective DePro cards into the pH/Gas & Chemistry sensor module card holders.
3. Select **Maintenance** from the Left Home Screen to display the Maintenance menu.
4. Select **Module DePro**.
5. Select **Start** in the Command Bar to begin the module DePro.
6. When the DePro sequence is complete, re-install the pH/Gas and Chemistry MicroSensor Cards.

NOTE: *Nova Biomedical recommends that the Module DePro be run monthly to maintain optimal analyzer performance.*

4.1.2 DePro Wells

The DePro Wells function allows an operator with appropriate privileges to DePro the Waste Well. The DePro Wells function will soak the well with DePro solution for 5 minutes.

NOTE: *This function does NOT DePro the Chemistry well.*

To perform a DePro Wells sequence:

1. Select **Maintenance** from the Left Home Screen to display the Maintenance menu.
2. Select **DePro Wells**.
3. Select **Start** in the Command Bar to begin the DePro Wells sequence

4.1.3 CHANGE SYRINGE

The Change Syringe function allows an operator with appropriate privileges to replace the syringe and barrel of the syringe pump assembly.

To change the syringe:

1. Select **Maintenance** from the Left Home Screen to display the Maintenance menu.
2. Select **Change Syringe**.
3. Select **Start** in the Command Bar.
4. Enter the Lot/Part Number of the new Syringe into the text box and select the green check mark to begin the Change Syringe sequence. The analyzer will remove any remaining fluid from the syringe and will position it all the way to the bottom of its axis.
5. Loosen the silver set screw attaching the bottom of the plunger to the syringe pump.
6. Unscrew the top threaded section of the glass barrel from the syringe pump valve and remove the syringe assembly.



4.2 Syringe Pump Assembly



4.3 Syringe Barrel & Plunger Removal

7. Install the new syringe and barrel, by reversing steps 5 and 6, making sure to secure the threaded connections.
8. When the new syringe is installed, select the **Continue** button to prime the syringe pump.

4.1.4 CHANGE PROBE

The Change Probe function allows an operator with appropriate privileges to change the sample probe and S-line tubing.

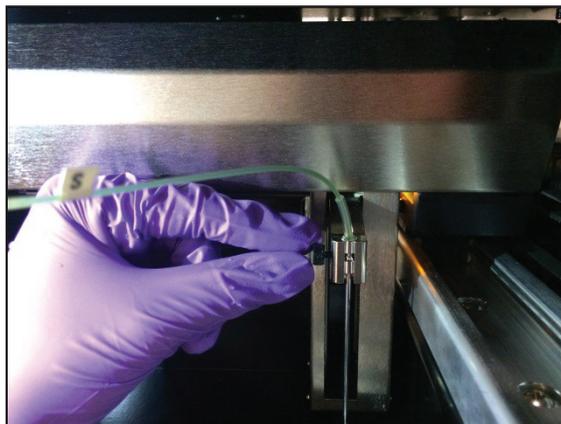
NOTE: *Before attempting to change the probe, make sure all of the gold touch-points inside the FLEX2 Basic A, B, C cabinet are clean and free of debris. Thoroughly cleaning the touch-points with alcohol and a swab is recommended.*

To change the Sample Probe:

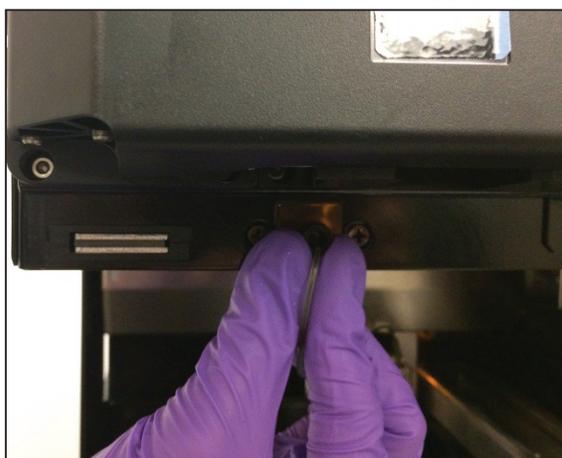
1. Select **Maintenance** from the Left Home Screen to display the Maintenance menu.
2. Select **Change Probe**.
3. Select **Start** in the Command Bar to begin the Change Probe sequence. The analyzer will move the Sample Probe to its Home position. When **Start** changes to **Continue**, it is safe to remove the Sample Probe and S-Line.

CAUTION: *Do not attempt to remove the probe until it is in its Home position.*

4. Remove the Sample Probe by loosening the set screw that holds it into the Z-axis of the probe transport arm.
5. Remove the S-line tubing by unscrewing the threaded fitting from the sample line port on the analyzer chassis.
6. Install the new sample probe and S-line tubing. Thread the new sample line tubing into the sample line port. Place the sample probe into the Z-axis of the transport arm, making sure it is fully seated. Tighten the probe set screw to make sure that it cannot fall out of place. Ensure all connections are tightly secured.
7. Close the analyzer door and press **Continue**. The probe will teach itself all required positions using the probe alignment targets inside the analyzer.



4.4 Probe Set Screw



4.5 Sample Line Port

4.1.5 CHANGE PUMP TUBING

The Change Pump Tubing function allows an operator with appropriate privileges to change the pH/Gas or Chemistry module pump tubing assemblies.

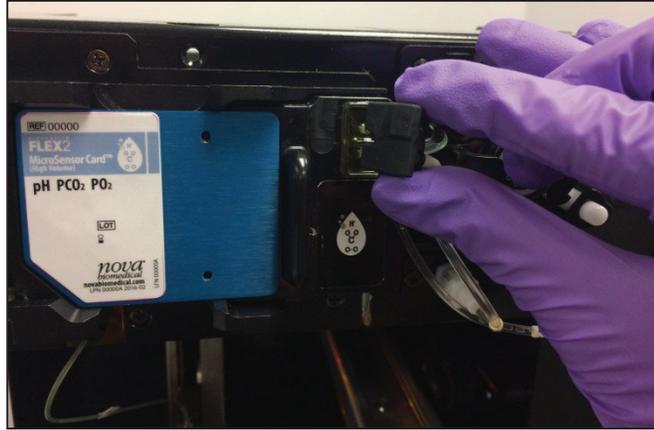
NOTE: *Nova Biomedical recommends that the pump tubing typically be changed every 6 months. This frequency may vary depending on analyzer usage.*

To change the Pump Tubing:

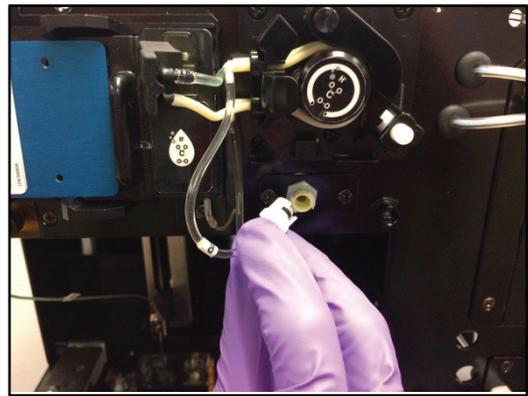
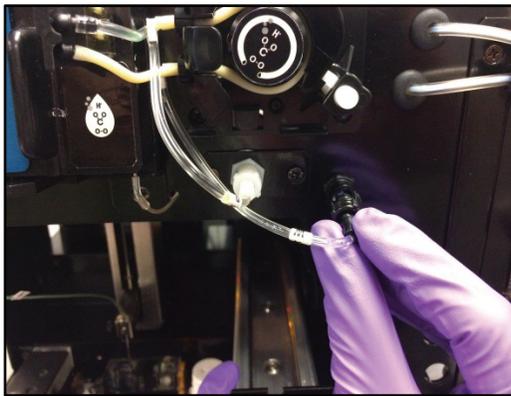
1. Select **Maintenance** (Left Home Screen) to display the Maintenance menu.
2. Select **Change Pump Tubing**.
3. Select **Start** in the Command Bar.
4. Enter the Lot/Part Number of the new Pump Tubing into the text box and select the green check mark to begin the Change Pump Tubing sequence. The analyzer will purge the fluid from the pH/Gas and Chemistry Module flow paths. When **Start** changes to **Continue**, it is safe to remove the Pump Tubing Assembly.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

5. Disconnect the black Waste tubing fitting from the port on the chassis by turning the twist-lock connector 1/8-turn counter clockwise.
6. Disconnect the white Reference tubing fitting from the port on the chassis by turning the twist-lock connector 1/8-turn counter clockwise.

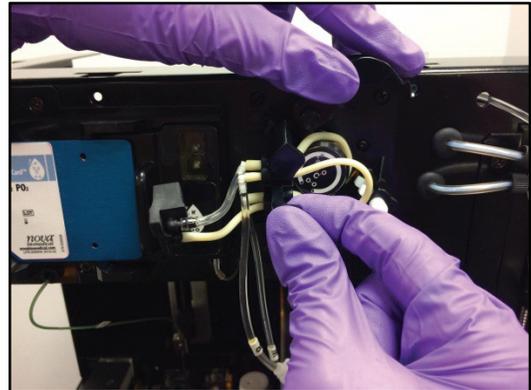
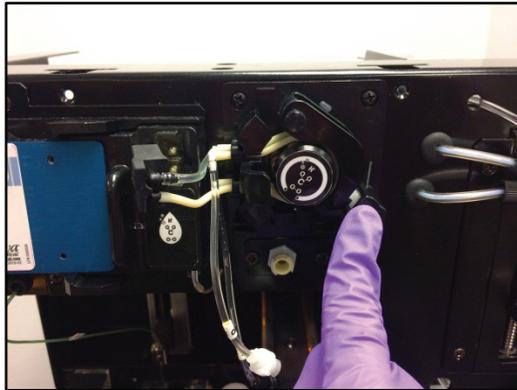


4.6 Disconnect Pump Tubing Manifold



4.7 Waste Tubing Fitting (Left) and Reference Tubing Fitting (Right)

7. Push the white button on the pump tubing retaining clip to release the tension on the tubing harness and remove the tubing harness assembly by sliding it forward off of the peristaltic pump.



4.8 Harness Release Button (Left) and Remove Harness (right)

8. Install the new pump tubing harness by stretching the pump tubing around the peristaltic pump rollers. Make sure that the two pieces of pump tubing are not touching each other when they are stretched around the rollers.
9. Clamp down the pump tubing retaining clip. Reconnect the Waste and Reference line fittings and the tubing manifold to the Reference Sensor.
10. Close the analyzer door and press **Continue**. The analyzer will prime the pH/Gas and Chemistry modules.

NOTE: The images shown here depict replacement of the pH/Gas Module pump tubing harness. Use the same directions for replacing the Chemistry Module pump tubing harness.

4.1.6 LONG-TERM SHUTDOWN

The Long-Term Shutdown function is an important Maintenance menu item that an operator should be familiar with performing. If the BioProfile FLEX2 Basic A, B, C will be powered off for a period of time greater than 72 hours, the system MUST be purged of all residual fluid in the internal tubing or flowpaths. Failure to purge the system for long periods of shutdown will result in reagent crystallization and internal tubing blockages, which may require service.

WARNING: *Leaving the analyzer in a powered-down state or without installed valid fluid cartridges for more than 3 days may result in damage. Any shutdown period lasting longer than 3 days should be preceded by purging the flowpath in accordance with this procedure.*

Purging the system requires the use of the following:

- PN 58355 Flush Fixture 6 Port (x2)
- PN 57530 Flush Fixture 2 Port
- 2–3 Beakers with at least 250 mL of DI H₂O
- 2–3 Empty Beakers (capable of holding 250 mL of water waste)

To perform a Long-Term Shutdown and Flowpath Purge:

1. Remove all reagent cartridges and packs from the BioProfile FLEX2 Basic A, B, C system; all sensor cards, reference sensors, and pump tubing must remain installed.
2. Install the two 6 port Flush Fixtures into the Chemistry and pH/Gas reagent pack bays. Make sure that the needle fitments at the rear of each fixture engage with the needle shrouds at the rear of the pack bays.
3. Install the 2 port Flush Fixture into the Chemistry Calibrator Cartridge pack bay. Make sure the needle fitments at the rear of the fixture engage with the needle shrouds at the rear of the pack bay.
4. Locate the length of tubing labeled W (Waste) on each fixture and place the end of each waste tubing into an empty waste collection beaker.
5. Gather all of the remaining lengths of tubing on each fixture and place them into a beaker containing at least 250 mL of DI H₂O. Make sure the ends of each piece of tubing are submerged.
6. Select the Long-Term Shutdown button and then select Start to begin the Flowpath Purge sequence.
7. The analyzer will drain all residual reagent from its internal tubing and will flush each flowpath with the DI water for several minutes.
8. When the sequence is complete, remove each piece of flush fixture tubing from the DI water beaker; leave the W tubing in the waste collection beaker.
9. Select **Start** again to purge the residual DI water from the internal flowpaths and flush each with air.
10. When the 2nd sequence is complete, remove the flush fixtures and power down the analyzer by using one of the Shutdown buttons.

NOTE: *The sample probe will flush water into the onboard pH/gas QC sample lines. This will cause a small amount of water to build up in the pH/gas QC bay and should be cleaned at the end of the long term shutdown procedure.*

4.2 pH/Gas MODULE

4.2.1 INSTALLING pH/GAS CALIBRATOR CARTRIDGE

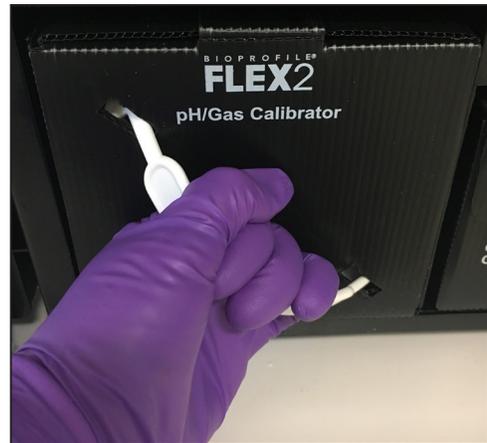
The BioProfile FLEX2 Basic A, B, C Analyzer reagent cartridges are equipped with smart installation technology. Once a new reagent cartridge is installed in the analyzer and the door is closed, the unit will automatically prime and install the cartridge. If the user presses **Module** (e.g. pH/Gas 98%), the Calibration Status, Well Status, Flow Time, Sensor Card, and Pack Information will all be displayed in the pH/Gas module overlay. For all reagent cartridges, clicking **Module** will display the lot number, expiration date, installation date of the cartridge, and the number of sample tests remaining for the cartridge.



4.9 pH/Gas Calibrator Cartridge

To install a new pH/Gas Calibrator Cartridge

1. Open the BioProfile FLEX2 Basic A, B, C front panel door.
2. Remove the old pH/Gas Calibrator Cartridge by pulling on the handle.
3. Remove the new pH/Gas Calibrator Cartridge from its shipping packaging and gently invert back and forth a few times.
4. Gently slide the new pH/Gas Calibrator Cartridge into the pH/Gas pack bay. You should feel some resistance as the needle fitments at the back of the pack engage with the needle shrouds at the rear of the pack bay. Continue pushing until the face of the pack is flush with the face of the analyzer chassis.
5. Close the analyzer door. The system will automatically recognize the new reagent cartridge and will prime and calibrate the pH/Gas module.



4.10 Remove Old Cartridge

WARNING: *Needle fitments inside the pack bay are sharp. To avoid injury, never stick your hands inside the pack bay.*

4.2.2 INSTALLING pH/GAS SENSOR CARD

The pH/Gas MicroSensor Card comes equipped with all sensors for pH and gas measurements.

To install a new Sensor Card:

1. Open the BioProfile FLEX2 Basic A, B, C front panel door.
2. Open the pH/Gas Module Holder door, located in the top left of the analyzer chamber.



4.11 Open Sensor Module Door and Remove Old and Install New Sensor Card

3. Remove the used or expired Sensor Card, and replace with a new Sensor Card. Be careful to handle the Sensor Card by its edges; avoiding touching the components on the back of the card, as debris and oil can decrease the use life of the sensor card.
4. Close the Sensor Module Door and then close the analyzer door. The system will automatically recognize the new sensor card and will prime, hydrate, and calibrate the pH/Gas Module.

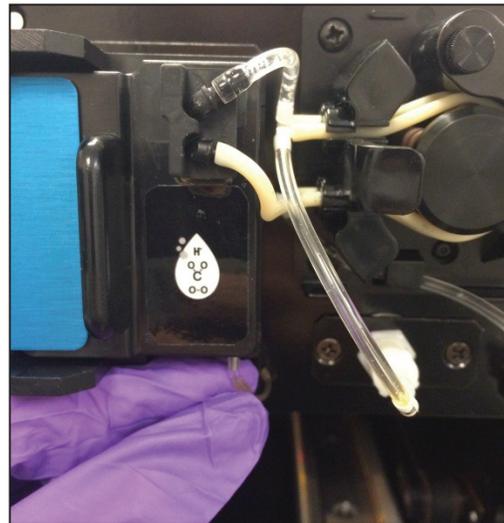
NOTE: When a new MicroSensor Card is installed, the system will automatically hydrate the new card. This process takes about 90–120 minutes to complete.

4.2.3 INSTALLING THE pH/GAS REFERENCE SENSOR

The pH/Gas Reference Sensor provides the reference voltage required by the pH/Gas Module. This assembly is part of the pH/Gas module and is connected to the pH/Gas MicroSensor Card and Pump Tubing Harness when installed. Nova Biomedical recommends replacement of the Reference Sensor every 12 months.

To install a new pH/Gas Reference Sensor:

1. Open the BioProfile FLEX2 Basic A, B, C front panel door.
2. Open the pH/Gas Sensor Module door, located at the top left of the analyzer chamber
3. Disconnect the pH/Gas sample line tubing from the bottom of the Reference Sensor.



4.12 Disconnect Sample Line Tubing

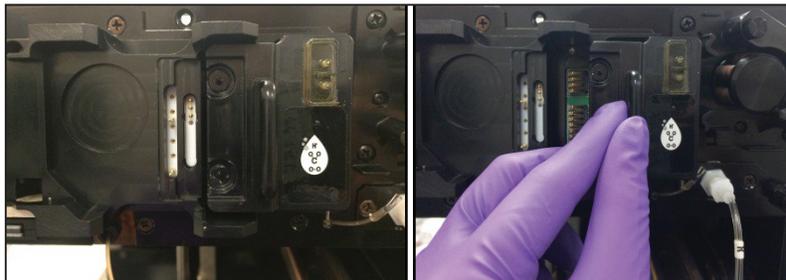
BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

4. Disconnect the pH/Gas Pump Tubing Manifold from the Reference Sensor.



4.13 Disconnect Tubing Manifold

5. Remove the pH/Gas MicroSensor Card and then remove the pH/Gas Reference Sensor by gripping the tab and sliding to the right.



4.14 Remove Sensor Card & Reference Sensor

6. Remove the new reference sensor from its packaging and install it into the pH/Gas Sensor Module by reversing step 5.
7. Re-install the pH/Gas MicroSensor Card.
8. Reconnect the pH/Gas Pump Tubing Manifold.
9. Reconnect the pH/Gas sample line tubing.
10. Close the sensor module door then close the analyzer door.
11. Prime and calibrate the pH/Gas Module.

4.3 CHEMISTRY MODULE

4.3.1 INSTALLING CHEMISTRY CALIBRATOR CARTRIDGE

The BioProfile FLEX2 Basic A, B, C Analyzer reagent cartridges are equipped with smart installation technology. The Chemistry Module reagent cartridge includes 2 separate cartridges that must be replaced together. The pack consists of a larger Reagent Cartridge, and a smaller Calibrator Cartridge.



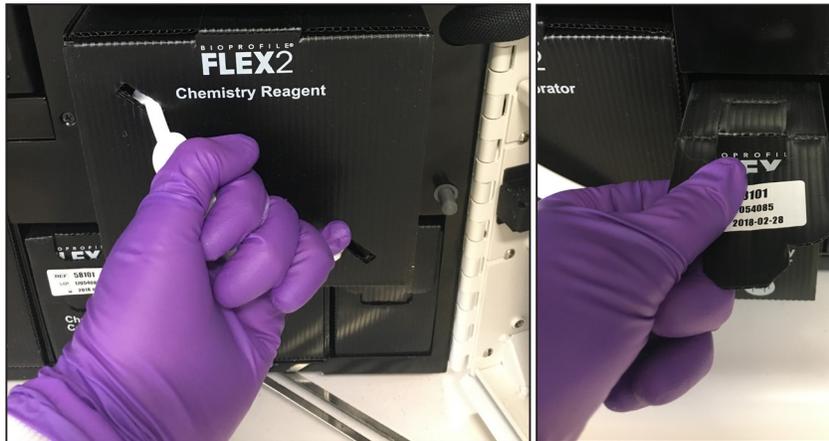
4.15 Chemistry Reagent and Calibrator Cartridges

The smaller Calibrator Cartridge must be activated prior to installation on the FLEX2 Basic A, B, C analyzer. This can be done by removing the clips that separate the lyophilized glutamine cups from the rest of the solution. Once the clips have been removed, gently push the cups into the fluid by manipulating them through the bag and vigorously shake the pack back and forth for two minutes to dissolve the glutamine powder.

Similarly to the pH/Gas Calibrator Cartridge, once a new reagent cartridge is installed in the analyzer and the door is closed, the unit will automatically prime and install the cartridge. If the user presses **Module** (e.g., *Chemistry 98%*), the Calibration Status, Well Status, Flow Time, Sensor Card, and Pack Information will all be displayed in the Chemistry Module overlay. For all reagent packs, clicking **Module** will indicate the lot number, expiration date, and installation date of the pack.

To install new Chemistry Calibrator & Reagent Cartridges:

1. Open the FLEX2 Basic A, B, C front panel door.
2. Remove the old Chemistry Cartridges by pulling on the handle on the larger pack and the pull tab on the smaller pack.

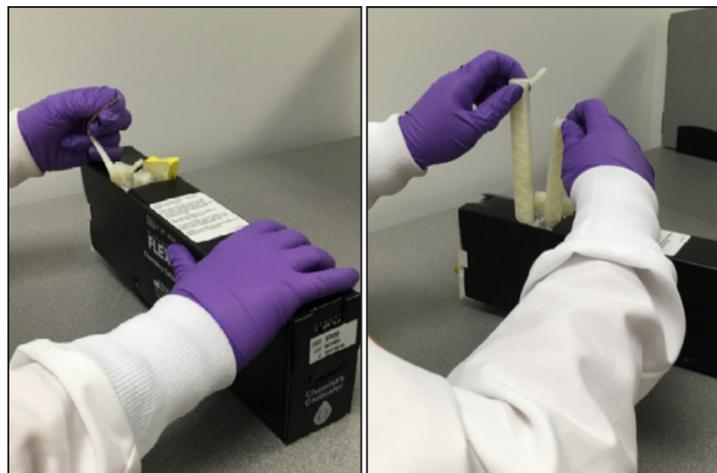


4.16 Remove Old Cartridges

3. Remove the new Chemistry Calibrator and Reagent Cartridges from their shipping packaging and gently invert the larger pack back and forth a few times.

4. Locate and remove the reagent pouch clips inside the smaller pack. Remove the yellow tape. Lift the tabs, then twist the clips sideways to slide out.

5. Squeeze each pouch and locate the glutamine cups inside the portion near the needle fitments. Slide the cups through the crease in each pouch and into the reagent. Take care not to puncture or damage the pouches.



4.17 Remove Tape/Lift Tabs

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

- Vigorously shake the cartridge back and forth for 2 minutes to completely dissolve the glutamine powder in the reagent. Ensure that no creases remain in the pouches and liquid moves freely during shaking.

NOTE: *Failure to completely dissolve the lyophilized glutamine in the reagent may lead to calibration and/or Quality Control testing failures.*

- Gently slide the new Chemistry Calibrator and Reagent Cartridges into their pack bays. You should feel some resistance as the needle fitments at the back of each pack engage with the needle shrouds at the rear of the pack bay. Continue pushing until the face of each pack is flush with the face of the analyzer chassis.
- Close the analyzer door. The system will automatically recognize the new reagent cartridges and will prime and calibrate the Chemistry module.



4.18 Chemistry Calibrator (left) and Chemistry Reagent (right) Cartridges in Pack Bay

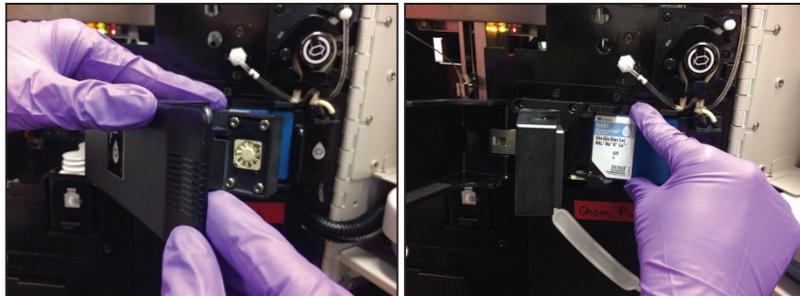
WARNING: *Needle fitments inside the pack bay are sharp. To avoid injury, never stick your hands inside the pack bay.*

4.3.2 INSTALLING CHEMISTRY MICROSENSOR CARD

The Chemistry MicroSensor Card comes equipped with the sensors for all nutrient, metabolite, and electrolyte measurements.

To install a new MicroSensor Card:

- Open the BioProfile FLEX2 Basic A, B, C front panel door.
- Open the Chemistry Sensor Module door, located at the middle right of the analyzer chamber
- Remove the used or expired Sensor Card, and replace with a new Sensor Card. Be careful to handle the Sensor Card by its edges; avoiding touching the components on the back of the card, as debris and oil can decrease the use life of the sensor card.
- Close the Sensor Module Door and then close the analyzer door. The system will automatically recognize the new Sensor Card and will prime, hydrate, and calibrate the Chemistry Module.



4.19 Open Sensor Module Door (left)/Remove Old/Install New MicroSensor Card (right)

NOTE: *When a new MicroSensor Card is installed, the system will automatically hydrate a new card and attempt to pass QC. This process takes about 90–120 minutes to complete.*

4.3.3 INSTALLING THE CHEMISTRY REFERENCE SENSOR

The Chemistry Reference Sensor provides the reference voltage required by the Chemistry Module. This assembly is part of the Chemistry module and is connected to the Chemistry MicroSensor Card and Pump Tubing Harness when installed. Nova Biomedical recommends replacement of the Reference Sensor every 12 months.

To install a new Chemistry Reference Sensor:

1. Open the BioProfile FLEX2 Basic A, B, C front panel door.
2. Open the Chemistry Sensor Module door, located at middle right of the analyzer chamber.
3. Disconnect the Chemistry Sample Line tubing from the bottom of the Reference Sensor.
4. Disconnect the Chemistry Pump Tubing Manifold from the Reference Sensor.

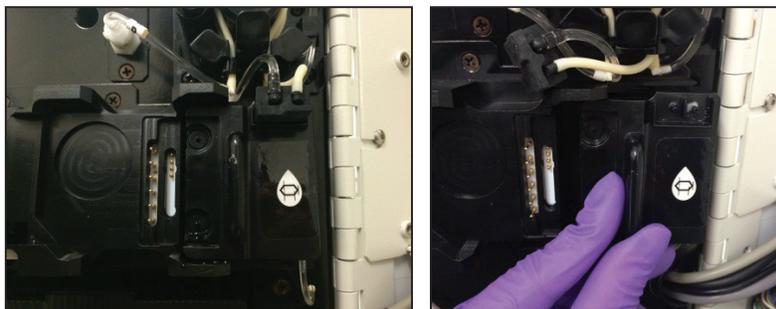


4.20 Disconnect Sample Line Tubing



4.21 Disconnect Tubing Manifold

5. Remove the Chemistry MicroSensor Card and then remove the Chemistry Reference Sensor by gripping the tab and sliding to the right.



4.22 Remove MicroSensor Card & Reference Sensor

6. Remove the new reference sensor from its packaging and install it into the Chemistry Sensor Module by reversing Step 5.
7. Re-install the Chemistry MicroSensor Card.
8. Reconnect the Chemistry Pump Tubing Manifold.
9. Reconnect the Chemistry Sample Line tubing.
10. Close the Sensor Module Door then close the analyzer door.
11. Prime and calibrate the Chemistry Module.

4.4 SERVICE MENU

The Service Menu allows Administrators additional access to service options that can be used to perform maintenance or to troubleshoot issues on their FLEX2 Basic A, B, C analyzer. Selecting **Service**  (Right Home Screen) will display the two sub-menu options described below, **Nova Service** and **Customer Service**.

The **Nova Service** menu is used by Nova Trained Service and Applications personnel during onsite visits or by an Administrator under the guidance of trained Nova Technical Support personnel. Access to the Nova Service Menu requires a date-coded password provided by Technical Support personnel.

The **Customer Service** menu allows Administrators access to additional service options that do not require a password for servicing their FLEX2 Basic A, B, C. Administrators will have access to the Flowpath Service, the RFID Test, a Resource Issues section, an Auto Log, and the PSoCs Test.



4.23 Customer Service Menu

4.4.1 RFID TEST

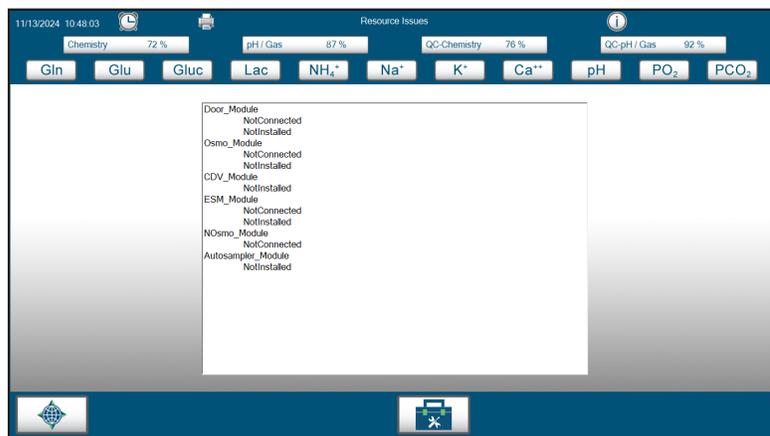
The RFID Test is used to confirm that the RFID within each consumable pack and MicroSensor Card is communicating properly with your FLEX2 Basic A, B, C. This test will display the amount of write transactions completed, Read Failure %, Write Failure %, Query Failure %, Checksum Error %, and a True or False value to show if the RFID is communicating properly.

To Run the RFID Test:

1. Select the Service button, then select the Customer Service menu.
2. Select RFID Test.
3. Select Start.
4. Let the test run and review the results. For initial readings of pack performance, click Cancel after 5 minutes.
5. The results will be presented. The right-hand column, Pass, indicates whether the RFID successfully communicated to the FLEX2 Basic A, B, C. True indicates proper communication; False indicates a failure in communication.
6. Contact Technical Support for any communication failure from the RFID Test.

4.4.2 RESOURCE ISSUES

The Resource Issues button will search your FLEX2 Basic A, B, C for all potentially installed modules and potential issues that may impact the operation of the analyzer. This option should be used with the guidance of Nova Technical Support Personnel.



4.24 Resource Issues

4.4.3 AUTO LOG

The Auto Log option will provide a detailed list of logs from your FLEX2 Basic A, B, C device that Nova Technical Support can use to analyze and investigate, if necessary. This option should only be used when under the guidance of Nova Technical Support Personnel.

NOTE: To troubleshoot errors on your FLEX2 Basic A, B, C device, see Section 5.

4.4.4 PSoCs TEST

The PSoCs Test pings the programmable system on a chip, the PSoC board, for each module within the FLEX2 Basic A, B, C. The test results will display the status of the PSoC communication link and version number. Successful communication between the Host Computer and PSoCs board indicates that the FLEX2 Basic A, B, C is properly communicating to each module within the system. If you notice an empty Status column, it may indicate that the module is not installed on your analyzer. If you notice an empty or disconnected Status column for an installed module, contact Technical Support for further assistance.



4.25 PSoCs Test

4.5 CLEANING FLEX2 BASIC A, B, C SURFACES

Nova understands that cleaning and disinfection of the laboratories where BioProfile analyzers are installed is an essential industry requirement. Cleaning of walls, floors, ceilings, and lab benches in the proximity of the analyzers could introduce short-term and long-term problems with analyzer electronics. This can especially occur when chemicals labeled as corrosive to metals are aerosolized.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

Cleaning chemicals and solutions not listed in the IFU should never be sprayed directly onto or into any BioProfile system or accessory device. Extreme caution should be used when using these chemicals within the lab as well. The instrument should be removed from the laboratory prior to disinfection if chemical cleaners are to be used. Nova is not responsible for damage incurred to the analyzers caused by chemical attack of certain disinfectants and cleaners.

Nova Biomedical Corporation recommends using 70% Reagent Alcohol (V/V) or Isopropyl Alcohol (IPA) for cleaning the various analyzer surfaces or components when required. Use a lint-free cloth or Kimwipe® lightly dampened with the cleaning reagent to wipe down analyzer surfaces. Never spray or pour reagent directly onto or into the analyzer. Once wiped down, all residual fluid should be dried with a lint-free cloth or Kimwipe.

CAUTION: *Vapor from other cleaning reagents used within the lab may be corrosive to the BioProfile FLEX2 analyzer and could result in system damage. Use caution and protect the analyzer, as needed, when using reagents that produce toxic vapors.*

4.5.1 FLOWPATH SERVICE

Users with Administrative privileges have access to Flowpath Service from within the Customer Service menu. Flowpath Service allows operators to troubleshoot flow errors in a timely manner that would otherwise require an onsite corrective maintenance visit. When you first enter Flowpath Service, you will see an overview of all flowpaths within the FLEX2 Basic A, B, C.

WARNING: *The instrument door may be opened freely while in Flowpath Service. Caution should be taken to help prevent injury from moving parts in the instrument.*

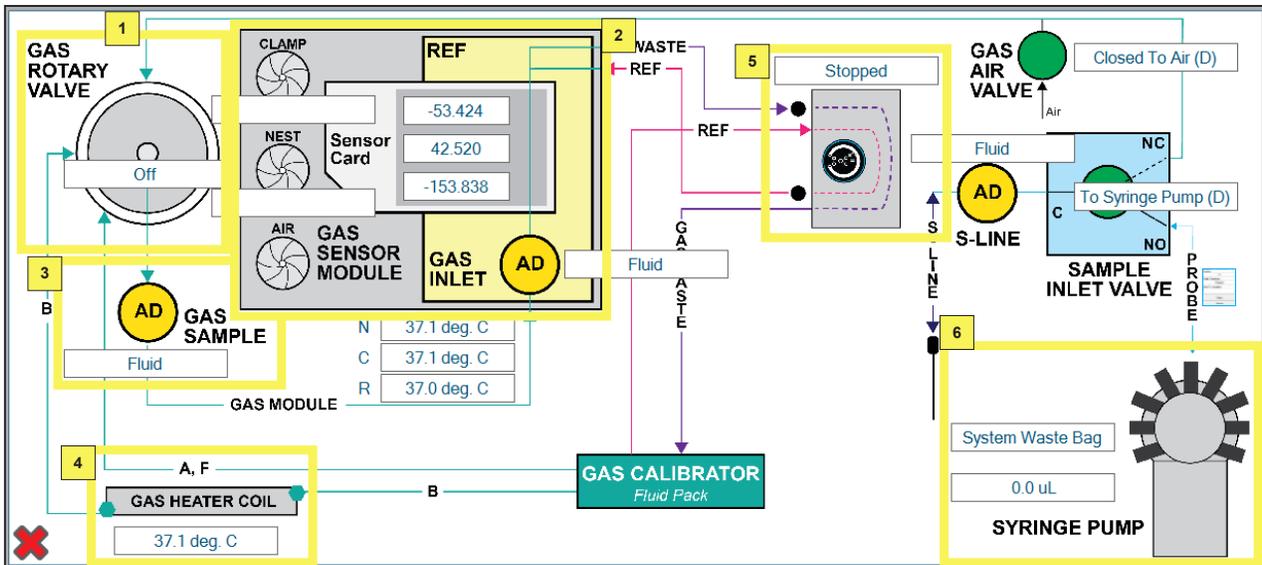
On this page, there are black and white as well as some colored images. All colored images, when selected, will open a sub-menu of Flowpath Services that shows additional module information and allows operators to control a portion of the FLEX2 Basic A, B, C flowpath. The following options can be selected on the Flowpath Service screen:

1. **Gas Sensor Module**
2. **Chemistry Sensor Module**

4.5.1.1 GAS SENSOR MODULE

The Gas Sensor Module, when selected, will open a sub-window with an overview of the Gas Sensor Module flowpath. On this page, you will see the following information:

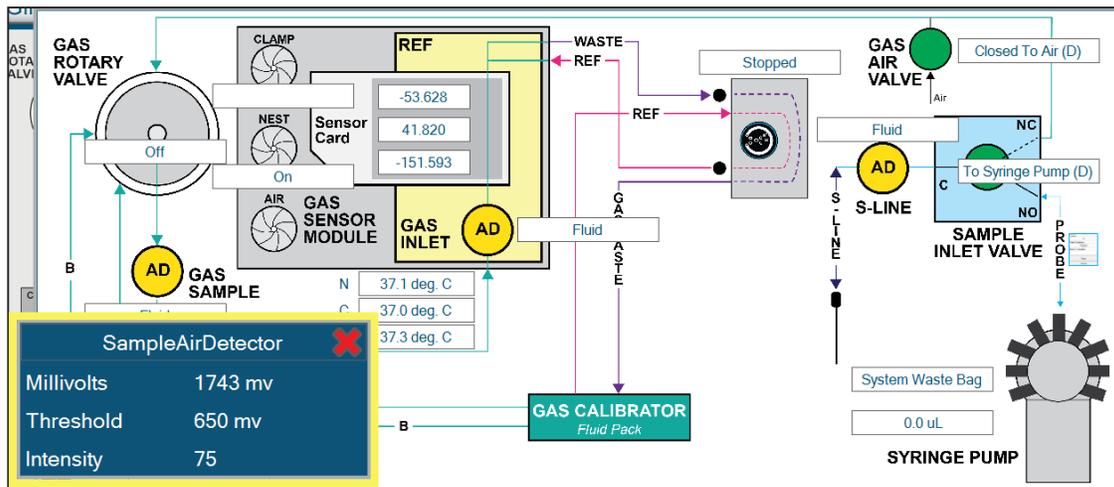
1. **Gas Rotary Valve** displays the rotary valve status and allows for device control.
2. **Gas Module Sensor** displays information from the Gas Module and allows operators to control the Gas Module Sensor.
3. **Gas Module Air Detector:** The air detectors display (air/fluid) based on the current sensor signal strength. Selecting the reading brings up the sensor label.
4. **Gas Module Heater Temperature** displays the current temperature of the Gas Module Heater.
5. **Pump Status** displays the status of the peristaltic pump and allows for device control.
6. **Syringe Pump** displays the current valve position and aspirated volume. This also allows for control over the Syringe Pump which is important when troubleshooting.



4.26 Gas Module Control Window

Gas Sample Air Detector

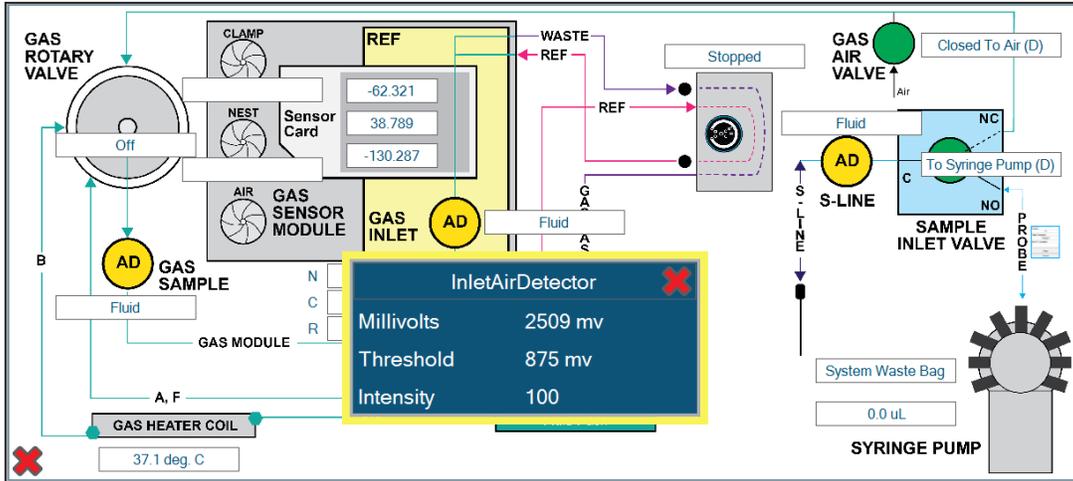
This air detector is in the common line tube of the Gas Rotary Valve. Select the information box below the air detector to see the associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value are all displayed.



4.27 Gas Sample Air Detector Information

Gas Inlet Air Detector

The Gas Inlet Air Detector is in the Reference Sensor. Select the information box to the right of the air detector to see the associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value are all displayed.



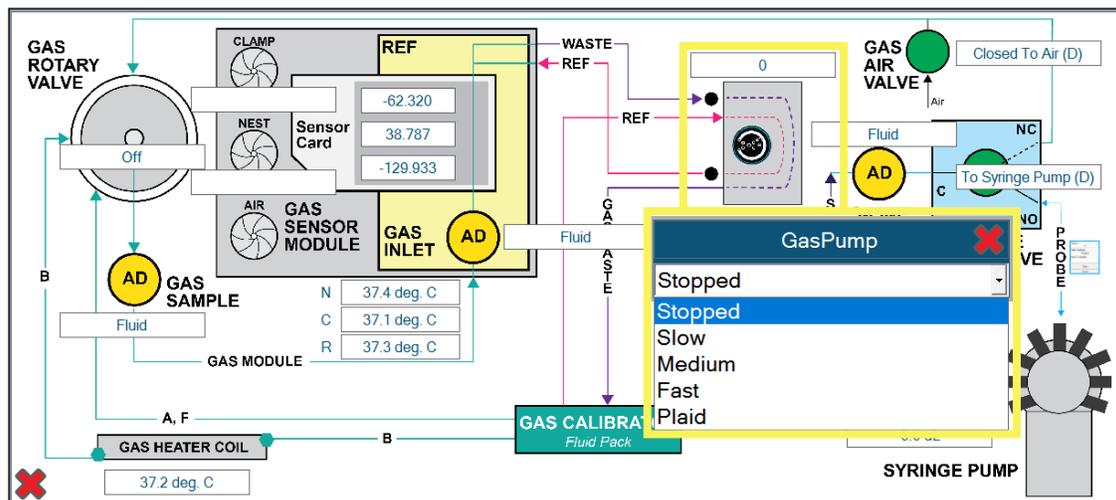
4.28 Gas Inlet Air Detector Information

Gas Module Peristaltic Pump Control

To control the Gas Module Peristaltic Pump:

1. Select the information box above the Gas Pump symbol to bring up the action item list as shown in the picture below.
2. Select the pump speed from the drop-down menu to draw fluid from the Gas Calibrator Cartridge.

NOTE: *The Gas Rotary Valve determines what fluid gets drawn. You can observe the flow through the Gas Module tubing to help identify flow issues.*

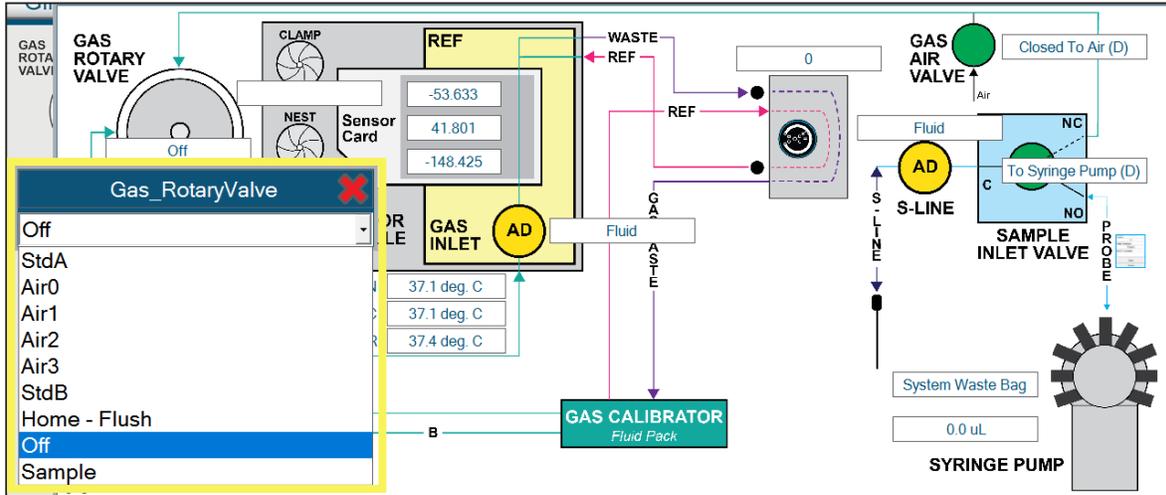


4.29 Gas Module Peristaltic Pump Control

Gas Module Rotary Valve Control

To control the Gas Module Rotary Valve:

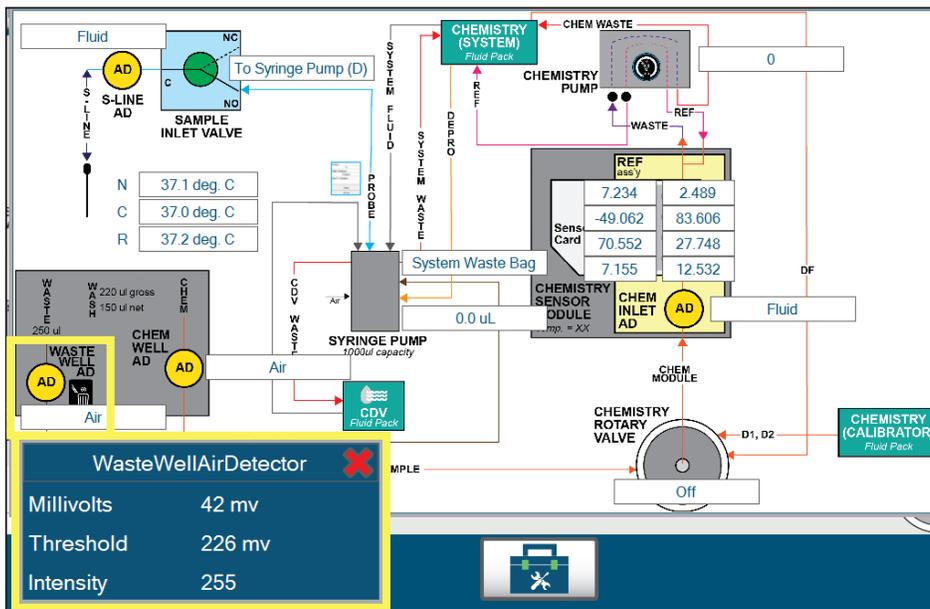
1. Select the information box on the Rotary Valve that displays the current position.
2. A drop-down menu will appear where you can change the position of the Gas Rotary Valve to control which fluid is being drawn. Observe the flow of fluid through the Gas Module Pump Tubing and listen for movement of the rotary valve to help troubleshoot flow issues.



4.30 Gas Module Pump Control

Waste Well Air Detector

The Waste Well Air Detector information can be accessed through either the Cell Density Viability Module or Chemistry Module Windows. Select the information box to the right of the air detector to view its associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value are all displayed.



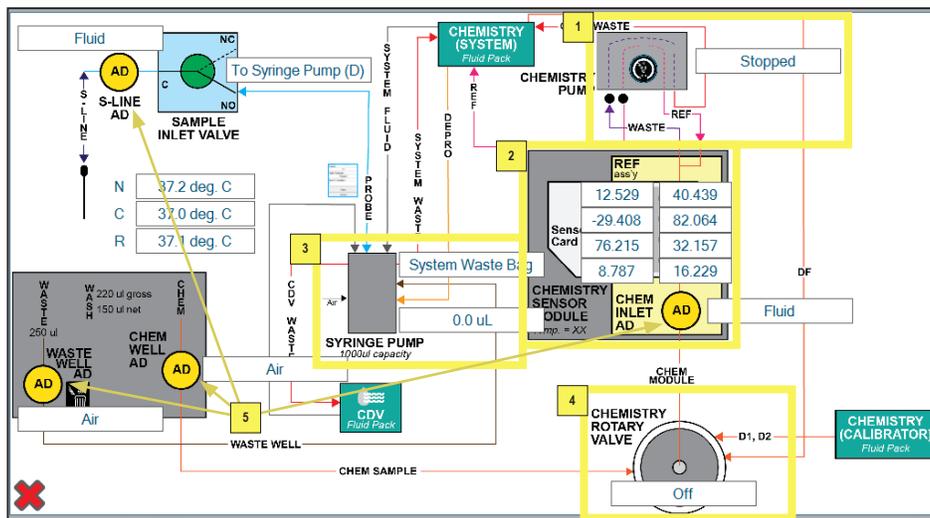
4.31 Waste Well Air Detector

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

4.5.1.2 CHEMISTRY SENSOR MODULE

The Chemistry Sensor Module, when clicked, will open a sub-window with an overview of the Chemistry Sensor Module flowpath. On this page, you will see the following information:

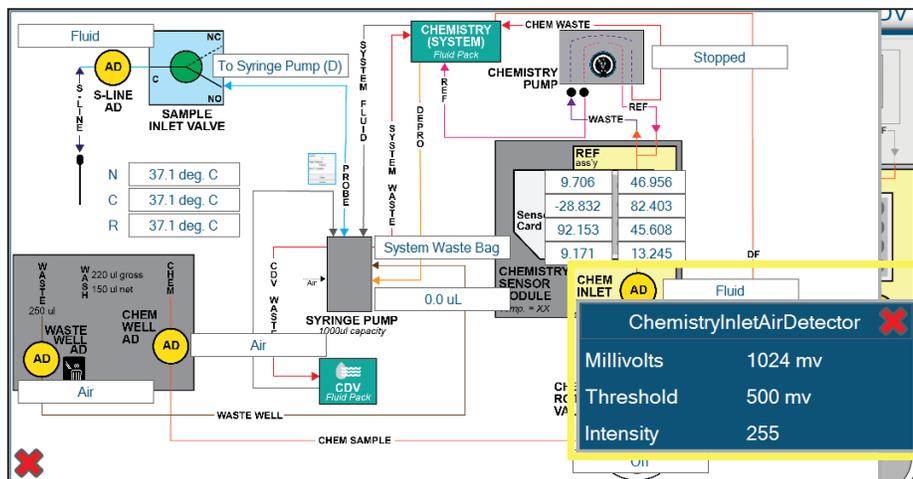
1. **Chemistry Peristaltic Pump** displays the status of the peristaltic pump and allows for device control.
2. **Chemistry Sensor Module** displays the current sensor signal strength. Selecting the reading brings up the sensor label.
3. **Syringe Pump** displays the current syringe pump position and aspirated volume. This also allows for control over the syringe pump, which is important for troubleshooting.
4. **Chemistry Rotary Valve** displays the rotary valve status and allows for device control.
5. **Air Detectors** display (air/fluid) based on the current sensor signal strength. Selecting the reading brings up the sensor label.



4.32 Chemistry Module Submenu Screen

Chemistry Inlet Air Detector

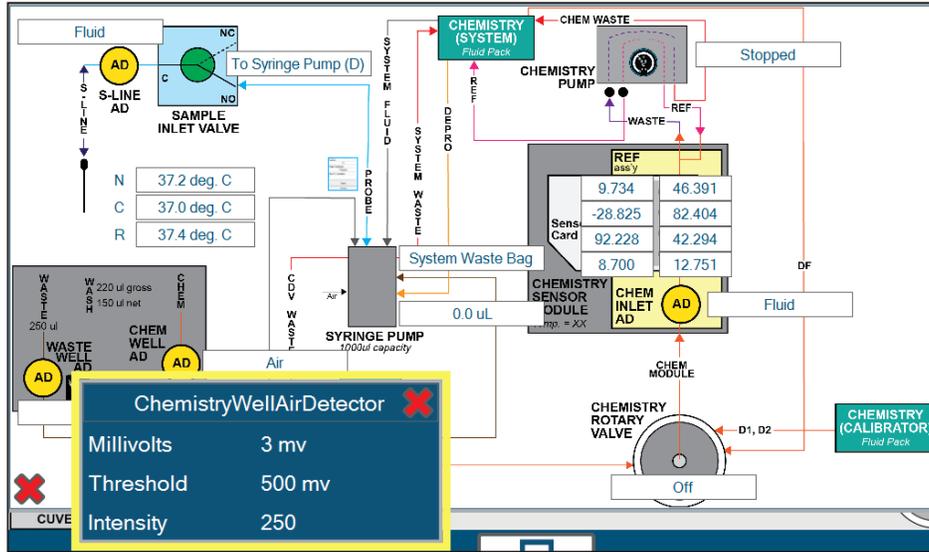
The Chemistry Inlet Air Detector is in the reference sensor. Select the information box to the right of the air detector to see the associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value are all displayed.



4.33 Chemistry Module Submenu Screen

Chemistry Well Air Detector

The Chemistry Well Air Detector is embedded in the User Domain well block. Select the information box to the right of the air detector to bring up its associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value (software defined) are all displayed.



4.34 Chemistry Well Air Detector

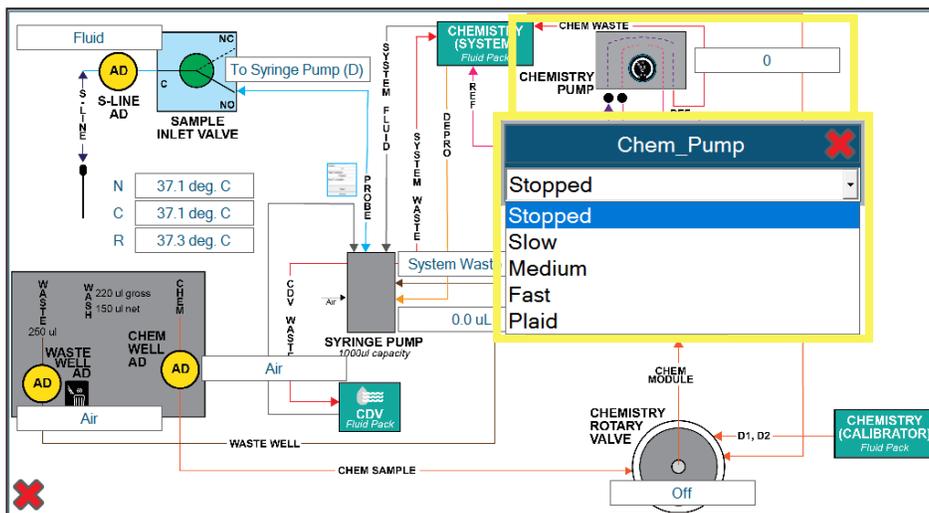


Chemistry Peristaltic Pump Control

To control the Chemistry Peristaltic Pump:

1. Select the information box to the right of the Chemistry Pump to bring up the action item list as shown in the example below.
2. Select the pump speed from the drop-down Bag menu to draw fluid from the Chemistry Calibrator and Reagent Cartridge.

NOTE: *The Chemistry Rotary Valve determines what fluid gets drawn. You can observe the flow through the Chemistry Module tubing to identify flow issues.*

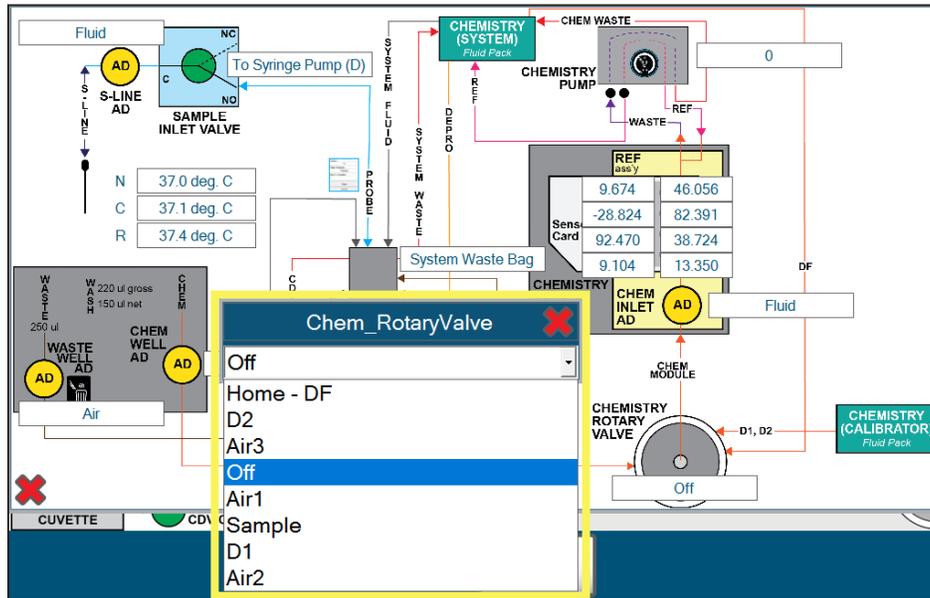


4.35 Chemistry Peristaltic Pump Control

Chemistry Module Rotary Valve Control

To control the Chemistry Module Rotary Valve:

1. Select the information box on the Rotary Valve that displays the Rotary Valve's current position.
2. In the drop-down menu that appears, you can change the position of the Chemistry Rotary Valve to control which fluid is being drawn. Observe the flow of fluid through the Chemistry Module pump tubing and listen for movement of the valve to help troubleshoot flow issues.



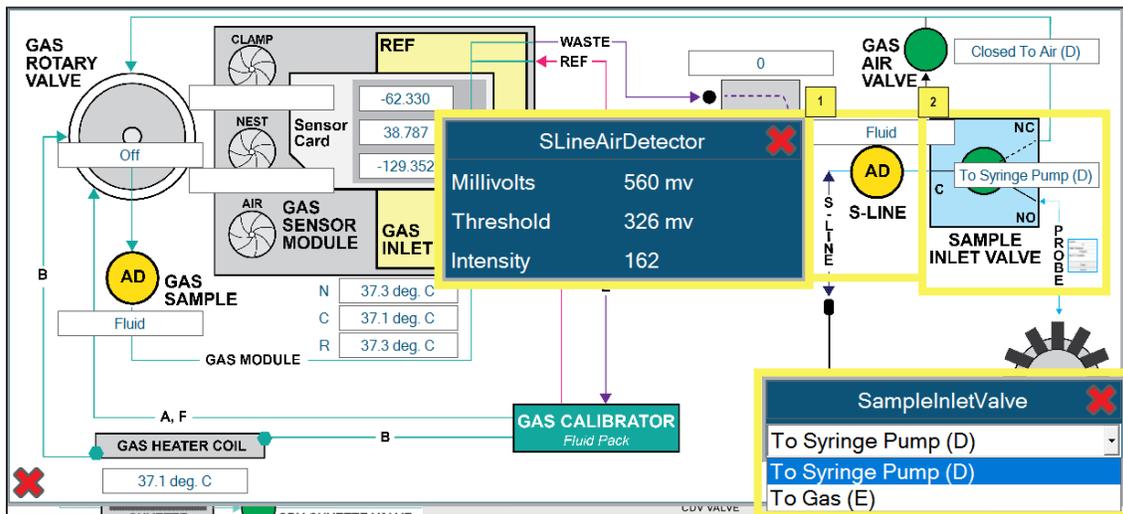
4.36 Chemistry Rotary Valve Control

4.5.1.3 ADDITIONAL FLOWPATH SERVICE CONTROLS

The Sample Inlet Manifold information and control options are available on all module windows, as are the System Probe and Syringe Pump control options.

The Sample Inlet Manifold contains the following information:

1. The **S-Line Air Detector** is in the Sample Inlet Manifold. Selecting the ADT information box brings up the information window.
2. The **Sample Inlet Valve** is in the Sample Inlet Manifold. Selecting the information box next to the Inlet Valve brings up the control window.



4.37 S-Line Air Detector and Sample Inlet Valve

Sample Inlet Valve Control

To control the Sample Inlet Valve:

1. Select the information box on the Sample Inlet Valve that displays the current position.
2. In the drop-down menu, you can change the position of the Sample Inlet Valve to control the fluid flow to the sample probe. Listen for movement of the valve or control the fluid flow through the sample probe to help troubleshoot flow issues.

Sample Inlet Air Detector

The Sample Inlet Air Detector is embedded in the Sample Inlet flowpath. Select the information box below the Air Detector to view its associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value (software defined) are all displayed.

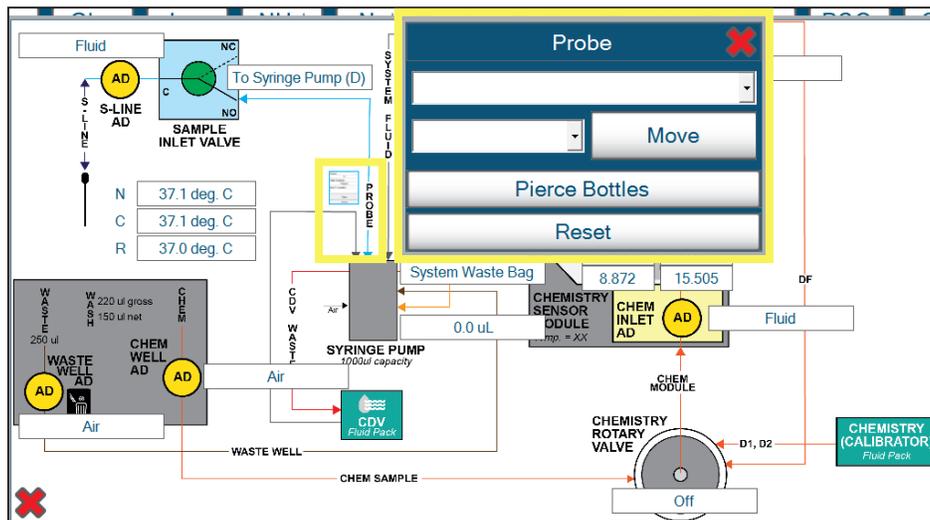
System Probe Control

The System Probe control menu is available on any module window by clicking the image next to the word PROBE. This option is located at a different position depending on the Module Window that is open. In the System Probe control menu, the System Probe can be moved to any preset position. It can then be lowered or raised to check its function.

To move the System Probe:

1. Open the System Probe control menu by clicking the image next to the word **PROBE**.
2. Select the probe position in the first drop-down menu.
3. Select the probe depth in the second drop-menu.
4. Select **Move**.

NOTE: Before lowering the Probe, ensure it is not above any obstructions.



4.38 System Probe Control Menu on the Chemistry Module Window

Syringe Pump

In Flowpath Service, the Syringe Pump can be controlled to help flush certain wells, confirm flow from certain reagents, or flush different flow paths. The following steps contain details on how to perform basic actions with the Syringe Pump to aspirate and dispense reagents from the different module windows.

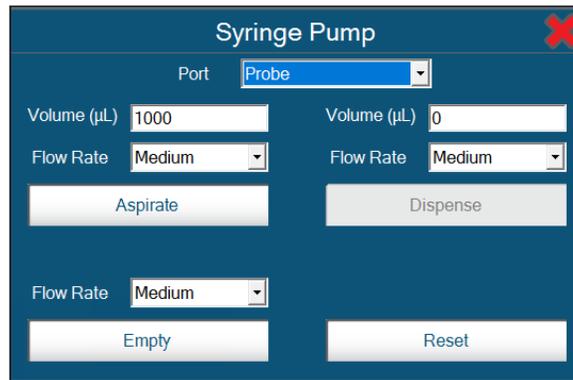
BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

To control the Syringe Pump:

1. Click **Service**.
2. Click **Customer Service**.

NOTE: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

3. Click **Flowpath Service**.
4. Click on either the **CDV Module**, the **Gas Sensor Module**, or the **Chemistry Sensor Module**.
5. Click the **Syringe Pump information box** from an applicable module overlay to open the Syringe Pump menu. This is the text box to the side of the Syringe Pump above the volume information box.



4.39 Syringe Pump Menu with Port Drop-down Menu

6. In the Port drop-down menu, select the path you would like to aspirate from (i.e., Depro).
7. Enter a volume on the left-hand side if different from the default 1000µL.
8. Click **Aspirate**.
9. In the Port drop-down menu, select the path you would like to dispense to (i.e., Waste Well).
10. Enter a volume on the left-hand side if different from the default 1000µL.
11. Click **Dispense**.

CAUTION: *To prevent contamination, do not accidentally aspirate from waste and dispense elsewhere in the flowpath.*

NOTE: *The volume of the Syringe Pump barrel is **1000µL**, therefore a maximum of **1000µL** can be aspirated/dispensed at a time.*

NOTE: *When dispensing into a well, it is important to bear in mind the well volume as not to overfill it:*

- **Waste Well Volume: 2500µL**
- **Chemistry Well Volume: 500µL**

5 TROUBLESHOOTING

This section describes the error solutions and explains the troubleshooting procedures for the BioProfile FLEX2 Basic A, B, C.

WARNING: *Cell culture samples are potential sources of infectious agents. Handle all sample and flow path components with care. Gloves and protective clothing are recommended.*

5.1 TROUBLESHOOTING PROCEDURES

The recommended troubleshooting procedures use the most logical and direct steps to resolve the error code. The solutions are setup in a block format that lists groups of steps to perform in order to restore 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. It is helpful to have printed or written down the error codes, flow times, and slope performance numbers.

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.

5.2 ERROR CODES

The following is a list with page references for the error solutions.

C	5-4	Chemistry Module Not Available ..5-6
Ca ⁺⁺ Analytical Range High	5-4	Chemistry Module Sensor Card
Ca ⁺⁺ Analytical Range Low	5-4	Expired Error.....5-7
Ca ⁺⁺ Drift	5-4	Chemistry Module Sensor Card
Ca ⁺⁺ Instability.....	5-4	Not Present Error.....5-7
Ca ⁺⁺ No Reading.....	5-4	Chemistry No Air.....5-7
Ca ⁺⁺ Not Calibrated.....	5-5	Chemistry No Fluid
Ca ⁺⁺ Overload	5-5	Chemistry Pack No Samples
Ca ⁺⁺ Slope	5-5	Remaining.....5-7
Chemistry Back Flow	5-5	Chemistry Reference Flow
Chemistry Card Not Hydrated.....	5-5	Chemistry Sensor Card
Chemistry Flow Fast.....	5-6	No Samples Remaining.....5-8
Chemistry Flow Slow	5-6	Chemistry Temperature Range
Chemistry Found Fluid When		Failure.....5-8
Expected Air.....	5-6	Chemistry Well Blocked.....5-8
Chemistry No Sample.....	5-6	Chemistry Well Flow Time
		5-8

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

D	5-8	K	5-15
Door Open Error	5-8	K+ Analytical Range High	5-15
G	5-9	K+ Analytical Range Low	5-16
Gas Found Fluid When Expected Air	5-9	K+ Drift	5-16
Gln Analytical Range High	5-9	K+ Instability	5-16
Gln Analytical Range Low	5-9	K+ No Reading	5-16
Gln Baseline	5-9	K+ Not Calibrated	5-16
Gln Dependency	5-9	K+ Overload	5-17
Gln Drift	5-10	K+ Slope	5-17
Gln Instability	5-10	L	5-17
Gln No Reading	5-10	Lac Analytical Range High	5-17
Gln Not Calibrated	5-10	Lac Analytical Range Low	5-17
Gln Overload	5-11	Lac Baseline	5-18
Gln Slope	5-11	Lac Drift	5-18
Glu Analytical Range High	5-11	Lac Instability	5-18
Glu Analytical Range Low	5-11	Lac No Reading	5-18
Glu Baseline	5-12	Lac Not Calibrated	5-18
Glu Drift	5-12	Lac Overload	5-19
Glu Instability	5-12	Lac Slope	5-19
Glu No Reading	5-12	N	5-19
Glu Not Calibrated	5-13	Na+ Analytical Range High	5-19
Glu Overload	5-13	Na+ Analytical Range Low	5-19
Glu Slope	5-13	Na+ Drift	5-20
Gluc Analytical Range High	5-13	Na+ Instability	5-20
Gluc Analytical Range Low	5-14	Na+ No Reading	5-20
Gluc Baseline	5-14	Na+ Not Calibrated	5-20
Gluc Drift	5-14	Na+ Overload	5-20
Gluc Instability	5-14	Na+ Slope	5-21
Gluc No Reading	5-14	NH4+ Analytical Range High	5-21
Gluc Not Calibrated	5-15	NH4+ Analytical Range Low	5-21
Gluc Overload	5-15	NH4+ Dependency	5-21
Gluc Slope	5-15	NH4+ Drift	5-21
H	5-15	NH4+ Instability	5-22
Hardware Error	5-15	NH4+ No Reading	5-22

NH ₄ ⁺ Not Calibrated.....	5-22	pH/Gas Sensor Card No Samples Remaining.....	5-30
NH ₄ ⁺ Overload	5-22	pH/Gas Temperature Range Failure.	5-30
NH ₄ ⁺ Slope.....	5-22	pH Analytical Range High.....	5-30
No Air	5-23	pH Analytical Range Low.....	5-30
No DFlush.....	5-23	pH Drift.....	5-30
No Fluid	5-23	pH Instability	5-31
No Flush	5-23	pH No Reading	5-31
No Sample Acquired.....	5-24	pH Not Calibrated	5-31
No Standard A.....	5-24	pH Overload.....	5-31
No Standard B	5-24	pH Slope	5-31
No Standard D1	5-25	PO ₂ Analytical Range High.....	5-32
No Standard D2.....	5-25	PO ₂ Analytical Range Low	5-32
P	5-26	PO ₂ Drift	5-32
PCO ₂ Analytical Range High	5-26	PO ₂ Instability.....	5-32
PCO ₂ Analytical Range Low	5-26	PO ₂ No Reading.....	5-33
PCO ₂ Dependency	5-26	PO ₂ Not Calibrated.....	5-33
PCO ₂ Drift.....	5-26	PO ₂ Overload	5-33
PCO ₂ Instability	5-27	PO ₂ Slope.....	5-33
PCO ₂ No Reading	5-27	R	5-33
PCO ₂ Not Calibrated	5-27	Refrigeration Module Temperature Out Of Range Error.....	5-33
PCO ₂ Overload.....	5-27	Refrigeration Module Thermistor Failure.....	5-34
PCO ₂ Slope	5-27	S	5-34
pH/Gas Back Flow	5-28	Software Error.....	5-34
pH/Gas Flow Fast.....	5-28	W	5-34
pH/Gas Flow Slow	5-28	Waste Well Blocked	5-34
pH/Gas Module Not Available....	5-28	Waste Well Flow Time	5-34
pH/Gas Module Sensor Card Expired Error.....	5-28		
pH/Gas Module Sensor Card Not Hydrated.....	5-28		
pH/Gas Module Sensor Card Not Present Error.....	5-29		
pH/Gas No Air.....	5-29		
pH/Gas No Fluid	5-29		
pH/Gas No Sample.....	5-29		
pH/Gas Pack No Samples Remaining.....	5-30		

C

Ca⁺⁺ Analytical Range High

During the last analysis, the measured result exceeded the upper limit of the Ca⁺⁺ sensor measurement range.

Recommended Solutions:

1. Repeat the analysis and be sure to select the appropriate dilution option.
2. Run the applicable QC level(s) and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Ca⁺⁺ Analytical Range Low

During the last analysis, the measured result exceeded the lower limit of the Ca⁺⁺ sensor measurement range.

Recommended Solutions:

1. Repeat the analysis and be sure to select the appropriate dilution option.
2. Run the applicable QC level(s) and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Ca⁺⁺ Drift

During the last analysis sequence, the 1-point calibration reading of the Ca⁺⁺ sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
4. Recalibrate the Chemistry module 3 times and verify that the Ca⁺⁺ slope is stable.
5. Install a new Chemistry MicroSensor Card.
6. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Contact Nova Biomedical Technical Support.

Ca⁺⁺ Instability

During the last calibration or analysis sequence, the Ca⁺⁺ sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Ca⁺⁺ No Reading

During the last analysis or calibration, a successful Ca⁺⁺ sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Ca⁺⁺ Not Calibrated

During the last analysis, the Ca⁺⁺ sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Ca⁺⁺ Overload

During the last calibration or analysis sequence, the Ca⁺⁺ sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Ca⁺⁺ Slope

The measured difference between the Ca⁺⁺ calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the Ca⁺⁺ slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

Chemistry Back Flow

During the last calibration or analysis, the Reference solution was detected by the air detector in the Chemistry Module.

Recommended Solutions:

1. Reseat the Chemistry Reference Sensor and prime the Chemistry module.
2. Replace the Chemistry Reference Sensor and prime the Chemistry module.
3. Contact Nova Biomedical Technical Support.

Chemistry Card Not Hydrated

After the Chemistry Card was installed, it did not properly hydrate. The Chemistry Card needs to hydrate before chemistry analysis can be completed.

Recommended Solutions:

1. Verify that the Chemistry Reagent Cartridge and the Chemistry Calibrator Cartridge are both seated properly to enable proper flow.
2. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
3. Check the Error Log to help identify the reason the MicroSensor Card is not hydrating. If an error related to reagent flow (e.g., No Standard D1) is identified, troubleshoot that error before continuing to the next step.

4. Perform a Module Depro sequence through the Maintenance menu.
5. Reseat the Chemistry Pump Tubing Harness.
6. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Reseat the Chemistry Reference Sensor. Prime and recalibrate the Chemistry module.
8. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
9. Contact Nova Biomedical Technical Support.

Chemistry Flow Fast

During the last analysis, calibration, or maintenance sequence, the chemistry flow time exceeded the specified limits. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
2. Contact Nova Biomedical Technical Support.

Chemistry Flow Slow

During the last analysis, calibration, or maintenance sequence, the chemistry flow time exceeded the specified limits. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
2. Contact Nova Biomedical Technical Support.

Chemistry Found Fluid When Expected Air

During the last analysis, calibration, or maintenance sequence, the chemistry air detector found fluid when air was expected. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
2. Contact Nova Biomedical Technical Support.

Chemistry No Sample

During the last analysis, the chemistry sample volume was not sufficient.

Recommended Solutions:

1. Repeat the analysis.
2. Verify the percent remaining in the Chemistry Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
3. Contact Nova Biomedical Technical Support.

Chemistry Module Not Available

During the last analysis, the Chemistry module was not available for analysis.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
2. Calibrate the Chemistry Module.
3. Contact Nova Biomedical Technical Support.

Chemistry Module Sensor Card Expired Error

The Chemistry Module Sensor Card has reached its expiration.

Recommended Solutions:

1. Replace the Chemistry Module Sensor Card.
2. Contact Nova Biomedical Technical Support.

Chemistry Module Sensor Card Not Present Error

The Chemistry Module Sensor Card is not being detected by the module.

Recommended Solutions:

1. Reseat the Chemistry Module Sensor Card.
2. Replace the Chemistry Module Sensor Card.
3. Contact Nova Biomedical Technical Support.

Chemistry No Air

During the last calibration or analysis sequence, the Chemistry module air detector failed to see air when expected. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Repeat the analysis or calibration.
2. Reseat the Chemistry Pump Tubing Harness.
3. Reseat the Chemistry Reference Electrode.
4. Contact Nova Biomedical Technical Support.

Chemistry No Fluid

During the last analysis, calibration, or maintenance sequence, the chemistry air detector did not detect fluid when expected.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
2. Prime the Chemistry module from the module status screen.
3. Contact Nova Biomedical Technical Support.

Chemistry Pack No Samples Remaining

The Chemistry Pack has reached its use life expiration.

Recommended Solutions:

1. Replace the Chemistry cartridge set.
2. Contact Nova Biomedical Technical Support.

Chemistry Reference Flow

During the last analysis, calibration, or maintenance sequence, the chemistry reference sensor did not detect the presence of Reference Solution.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridges. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge set.
2. Prime the Chemistry module from the status screen.
3. Replace the Chemistry module Pump Tubing.
4. Replace the Chemistry module Reference Sensor.
5. Contact Nova Biomedical Technical Support.

Chemistry Sensor Card No Samples Remaining

The Chemistry Sensor Card has reached its use life expiration.

Recommended Solutions:

1. Replace the Chemistry Sensor Card.
2. Contact Nova Biomedical Technical Support.

Chemistry Temperature Range Failure

The temperature reading on the Chemistry module exceeded specifications.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support

Chemistry Well Blocked

During the last analysis, the Chemistry Well became blocked. A well blockage will inhibit analysis of the respective module and will also disable the Depro Wells function.

Recommended Solutions:

1. Verify that all Reagent Cartridges are seated properly to enable well drainage to the waste bag.
2. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
3. Visually inspect the Chemistry Well. If there is fluid in the well, use a transfer pipette/flush tool to remove the residual fluid from the well.
4. On the Home page, run Clear Wells from the Chemistry Module Overlay screen to help clear the obstruction. Run this option multiple times to try to clear the obstruction.
5. If the well is still blocked, flush the Chemistry Well through Flowpath Services. For instructions on how to perform this step, see Section 5.3.4.
6. Contact Nova Biomedical Technical Support.

Chemistry Well Flow Time

During the last analysis, calibration, or maintenance sequence, the Chemistry Well flow time exceeded the specified limits.

Recommended Solutions:

1. Verify the percent remaining in the Chemistry Calibrator Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
2. Open the door of the analyzer and verify that the Chemistry Well is empty.
 - a. If the well is not empty, run the Clear Wells sequence from the Cell Density module status screen. Run this option multiple times to try and clear the obstruction.
 - b. If the well is empty, run a Prime from the Cell Density module status screen.
3. Run a Module Depro sequence from the Maintenance menu.
4. Contact Nova Biomedical Technical Support.

D

Door Open Error

The sequence was not able to be completed due to the sensor detecting that the door was open at an inappropriate time.

Recommended Solutions:

1. Open and close the analyzer door to ensure it is fully closed.
2. Contact Nova Biomedical Technical Support.

G

Gas Found Fluid When Expected Air

During the last analysis, calibration, or maintenance sequence, the gas air detector found fluid when air was expected. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
2. Contact Nova Biomedical Technical Support.

Gln Analytical Range High

During the last analysis, the measured result exceeded the high limit of the Gln sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis selecting a 1:2 dilution ratio.
2. Run Level 5 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Gln Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the Gln sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 4 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Gln Baseline

During the last calibration or analysis sequence, the baseline reading of the Gln sensor was greater than the allowable limits for the Gln calibration standards.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. If the error occurred during an analysis, repeat the analysis after the Chemistry module has been recalibrated.
3. Contact Nova Biomedical Technical Support.

Gln Dependency

During the last analysis or calibration, a successful Gln sensor reading could not be obtained. Without a successful Glu measurement, the Gln cannot be calculated. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and resolve the associated Glu status message.
2. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
3. If the Glu parameter remains uncalibrated, install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Gln Drift

During the last analysis sequence, the 1-point calibration reading of the Gln sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry & free of debris.
2. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the Gln slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

Gln Instability

During the last calibration or analysis sequence, the Gln sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Recalibrate the Chemistry module 3 times and verify that the Gln slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Contact Nova Biomedical Technical Support.

Gln No Reading

During the last analysis or calibration, a successful Gln sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Gln Not Calibrated

During the last analysis, the Gln sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Gln Overload

During the last calibration or analysis sequence, the Gln sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Gln Slope

The measured difference between the Gln calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
6. Recalibrate the Chemistry module 3 times and verify that the Gln slope is stable.
7. Install a new Chemistry MicroSensor Card.
8. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
9. Contact Nova Biomedical Technical Support.

Glu Analytical Range High

During the last analysis, the measured result exceeded the high limit of the Glu sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis selecting a 1:2 dilution ratio.
2. Run Level 5 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Glu Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the Glu sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 4 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Glu Baseline

During the last calibration or analysis sequence, the baseline reading of the Glu sensor was greater than the allowable limits for the Glu calibration standards.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. If the error occurred during an analysis, repeat the analysis after the Chemistry module has been recalibrated.
3. Contact Nova Biomedical Technical Support.

Glu Drift

During the last analysis sequence, the 1-point calibration reading of the Glu sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the Glu slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

Glu Instability

During the last calibration or analysis sequence, the Glu sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Recalibrate the Chemistry module 3 times and verify that the Glu slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Contact Nova Biomedical Technical Support.

Glu No Reading

During the last analysis or calibration, a successful Glu sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Glu Not Calibrated

During the last analysis, the Glu sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Glu Overload

During the last calibration or analysis sequence, the Glu sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Glu Slope

The measured difference between the Glu calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
6. Recalibrate the Chemistry module 3 times and verify that the Glu slope is stable.
7. Install a new Chemistry MicroSensor Card.
8. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
9. Contact Nova Biomedical Technical Support.

Gluc Analytical Range High

During the last analysis, the measured result exceeded the high limit of the Gluc sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis selecting a 1:2 dilution ratio.
2. Run Level 5 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Gluc Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the Gluc sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 4 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Gluc Baseline

During the last calibration or analysis sequence, the baseline reading of the Gluc sensor was greater than the allowable limits for the Gluc calibration standards.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. If the error occurred during an analysis, repeat the analysis after the Chemistry module has been recalibrated.
3. Contact Nova Biomedical Technical Support.

Gluc Drift

During the last analysis sequence, the 1-point calibration reading of the Gluc sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
4. Recalibrate the Chemistry module 3 times and verify that the Gluc slope is stable.
5. Install a new Chemistry MicroSensor Card.
6. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Contact Nova Biomedical Technical Support.

Gluc Instability

During the last calibration or analysis sequence, the Gluc sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Gluc No Reading

During the last analysis or calibration, a successful Gluc sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Gluc Not Calibrated

During the last analysis, the Gluc sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Gluc Overload

During the last calibration or analysis sequence, the Gluc sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Gluc Slope

The measured difference between the Gluc calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the Gluc slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

H

Hardware Error

Signifies an internal hardware error.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

K

K⁺ Analytical Range High

During the last analysis, the measured result exceeded the upper limit of the K⁺ sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 3 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

K⁺ Analytical Range Low

During the last analysis, the measured result exceeded the lower limit of the K⁺ sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 1 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

K⁺ Drift

During the last analysis sequence, the 1-point calibration reading of the K⁺ sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
4. Recalibrate the Chemistry module 3 times and verify that the K⁺ slope is stable.
5. Install a new Chemistry MicroSensor Card.
6. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Contact Nova Biomedical Technical Support.

K⁺ Instability

During the last calibration or analysis sequence, the K⁺ sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

K⁺ No Reading

5. During the last analysis or calibration, a successful K⁺ sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

K⁺ Not Calibrated

During the last analysis, the K⁺ sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

K⁺ Overload

During the last calibration or analysis sequence, the K⁺ sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

K⁺ Slope

The measured difference between the K⁺ calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the K⁺ slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

L

Lac Analytical Range High

During the last analysis, the measured result exceeded the high limit of the Lac sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis selecting a 1:2 dilution ratio.
2. Run Level 3 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Lac Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the Lac sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 1 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Lac Baseline

During the last calibration or analysis sequence, the baseline reading of the Lac sensor was greater than the allowable limits for the Lac calibration standards.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. If the error occurred during an analysis, repeat the analysis after the Chemistry module has been recalibrated.
3. Contact Nova Biomedical Technical Support.

Lac Drift

During the last analysis sequence, the 1-point calibration reading of the Lac sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
4. Recalibrate the Chemistry module 3 times and verify that the Lac slope is stable.
5. Install a new Chemistry MicroSensor Card.
6. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Contact Nova Biomedical Technical Support.

Lac Instability

During the last calibration or analysis sequence, the Lac sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Lac No Reading

During the last analysis or calibration, a successful Lac sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Lac Not Calibrated

During the last analysis, the Lac sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Lac Overload

During the last calibration or analysis sequence, the Lac sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Lac Slope

The measured difference between the Lac calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the Lac slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

N

Na⁺ Analytical Range High

During the last analysis, the measured result exceeded the upper limit of the Na⁺ sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 3 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Na⁺ Analytical Range Low

During the last analysis, the measured result exceeded the lower limit of the Na⁺ sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 1 control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

Na⁺ Drift

During the last analysis sequence, the 1-point calibration reading of the Na⁺ sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
4. Recalibrate the Chemistry module 3 times and verify that the Na⁺ slope is stable.
5. Install a new Chemistry MicroSensor Card.
6. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Contact Nova Biomedical Technical Support.

Na⁺ Instability

During the last calibration or analysis sequence, the Na⁺ sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Na⁺ No Reading

During the last analysis or calibration, a successful Na⁺ sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Na⁺ Not Calibrated

During the last analysis, the Na⁺ sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

Na⁺ Overload

During the last calibration or analysis sequence, the Na⁺ sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

Na⁺ Slope

The measured difference between the Na⁺ calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
5. Recalibrate the Chemistry module 3 times and verify that the Na⁺ slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

NH₄⁺ Analytical Range High

During the last analysis, the measured result exceeded the upper limit of the NH₄⁺ sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 3 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

NH₄⁺ Analytical Range Low

During the last analysis, the measured result exceeded the lower limit of the NH₄⁺ sensor's measurement range.

Recommended Solutions:

1. Repeat the analysis.
2. Run Level 1 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

NH₄⁺ Dependency

During the last analysis or calibration, a successful NH₄⁺ sensor reading could not be obtained. Without a successful Na⁺ and/or K⁺ measurement, the NH₄⁺ cannot be calculated. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and resolve the associated Na⁺ and K⁺ status message(s).
2. If the Na⁺ and K⁺ parameters remain uncalibrated, install a new Chemistry MicroSensor Card.
3. Contact Nova Biomedical Technical Support.

NH₄⁺ Drift

During the last analysis sequence, the 1-point calibration reading of the NH₄⁺ sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.

3. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
4. Recalibrate the Chemistry module 3 times and verify that the NH₄⁺ slope is stable.
5. Install a new Chemistry MicroSensor Card.
6. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Contact Nova Biomedical Technical Support.

NH₄⁺ Instability

During the last calibration or analysis sequence, the NH₄⁺ sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

NH₄⁺ No Reading

During the last analysis or calibration, a successful NH₄⁺ sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

NH₄⁺ Not Calibrated

During the last analysis, the NH₄⁺ sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

NH₄⁺ Overload

During the last calibration or analysis sequence, the NH₄⁺ sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new Chemistry MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

NH₄⁺ Slope

The measured difference between the NH₄⁺ calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the Chemistry module and recalibrate.
2. Ensure that the Chemistry MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.

5. Recalibrate the Chemistry module 3 times and verify that the NH₄⁺ slope is stable.
6. Install a new Chemistry MicroSensor Card.
7. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Contact Nova Biomedical Technical Support.

No Air

During the last sequence, air was not detected at the appropriate time.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

No DFlush

During the last sequence, no Standard DF was detected from the Chemistry Reagent Cartridge.

Recommended Solutions:

1. Verify that the Chemistry Reagent and Chemistry Calibrator Cartridges are seated properly to enable proper flow.
2. Check the integrity of the Chemistry Reagent and Chemistry Calibrator Cartridges, including all ports on the back of the cartridges.
3. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Reseat the Chemistry Pump Tubing Harness.
6. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
7. Reseat the Chemistry Reference Sensor. Prime and recalibrate the Chemistry module.
8. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
9. Flush the internal tubing to the Chemistry Reagent Cartridge. For instructions on how to perform this step, see Section 5.3.5.
10. Contact Nova Biomedical Technical Support.

No Fluid

During the last sequence, fluid was not detected at the appropriate time.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

No Flush

During the last sequence, no Flush Solution was detected from the pH/Gas Calibrator Cartridge.

Recommended Solutions:

1. Verify that the pH/Gas Calibrator Cartridge is seated properly. Reseat the pH/Gas Calibrator Cartridge and confirm fluid flow.
2. Check the integrity of the pH/Gas Calibrator Cartridge, including all ports on the back of the cartridge.
3. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Reseat the pH/Gas Pump Tubing Harness.
6. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.

7. Reseat the pH/Gas Reference Sensor and prime the pH/Gas module.
8. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
9. Flush the internal tubing to the pH/Gas Calibrator Cartridge. For instructions on how to perform this step, see Section 5.3.3.
10. Contact Nova Biomedical Technical Support.

No Sample Acquired

During the last analysis, no sample was acquired.

Recommended Solutions:

1. Repeat the analysis.
2. Analyze the QC material to confirm if the results are within range.
3. Flush the Sample Inlet Manifold and the S-Line Probe. See Section 5.3.2 for flushing steps.
4. Contact Nova Biomedical Technical Support.

No Standard A

During the last sequence, no Standard A was detected from the pH/Gas Calibrator Cartridge.

Recommended Solutions:

1. Verify that the pH/Gas Calibrator Cartridge is seated properly. Reseat the pH/Gas Calibrator Cartridge and confirm fluid flow.
2. Check the integrity of the pH/Gas Calibrator Cartridge, including all ports on the back of the cartridge.
3. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Reseat the pH/Gas Pump Tubing Harness.
6. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
7. Reseat the pH/Gas Reference Sensor and prime the pH/Gas module.
8. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
9. Flush the internal tubing to the pH/Gas Calibrator Cartridge. For instructions on how to perform this step, see Section 5.3.3.
10. Contact Nova Biomedical Technical Support.

No Standard B

During the last sequence, no Standard B was detected from the pH/Gas Calibrator Cartridge.

Recommended Solutions:

1. Verify that the pH/Gas Calibrator Cartridge is seated properly. Reseat the pH/Gas Calibrator Cartridge and confirm fluid flow.
2. Check the integrity of the pH/Gas Calibrator Cartridge, including all ports on the back of the cartridge.
3. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
4. Perform a Module Depro sequence through the Maintenance menu.
5. Reseat the pH/Gas Pump Tubing Harness.
6. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
7. Reseat the pH/Gas Reference Sensor and prime the pH/Gas module.
8. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.

9. Flush the internal tubing to the pH/Gas Calibrator Cartridge. For instructions on how to perform this step, see Section 5.3.3.
10. Contact Nova Biomedical Technical Support.

No Standard D1

During the last sequence, no Standard D1 was detected from the Chemistry Calibrator Cartridge.

Recommended Solutions:

1. Verify that the Chemistry Reagent and Chemistry Calibrator Cartridges are seated properly to enable proper flow.
2. Check the integrity of the Chemistry Reagent and Chemistry Calibrator Cartridges, including all ports on the back of the cartridges.
3. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
4. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
5. Perform a Module Depro sequence through the Maintenance menu.
6. Reseat the Chemistry Pump Tubing Harness.
7. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Reseat the Chemistry Reference Sensor. Prime and recalibrate the Chemistry module.
9. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
10. Flush the internal tubing to the Chemistry Reagent Cartridge. For instructions on how to perform this step, see Section 5.3.5.
11. Contact Nova Biomedical Technical Support.

No Standard D2

During the last sequence, no standard D2 was detected from the Chemistry Calibrator Cartridge.

Recommended Solutions:

1. Verify that the Chemistry Reagent and Chemistry Calibrator Cartridges are seated properly to enable proper flow.
2. Check the integrity of Chemistry Reagent and Chemistry Calibrator Cartridges, including all ports on the back of cartridges.
3. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
4. Confirm that the Chemistry Calibrator Cartridge is properly mixed for 2 minutes prior to installation. Remove, mix, and reinstall the Chemistry Calibrator Cartridge. After, prime and recalibrate the Chemistry module.
5. Perform a Module Depro sequence through the Maintenance menu.
6. Reseat the Chemistry Pump Tubing Harness.
7. Replace the Chemistry Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
8. Reseat the Chemistry Reference Sensor. Prime and recalibrate the Chemistry module.
9. Replace the Chemistry Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the Chemistry module.
10. Flush the internal tubing to the Chemistry Reagent Cartridge. For instructions on how to perform this step, please see Section 5.3.5.
11. Contact Nova Biomedical Technical Support.

P

PCO₂ Analytical Range High

During the last analysis, the measured result exceeded the high limit of the *PCO₂* sensor's measurement range.

Recommended Solutions:

1. Repeat the sample analysis.
2. Run Level 1 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

PCO₂ Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the *PCO₂* sensor's measurement range.

Recommended Solutions:

1. Repeat the sample analysis.
2. Run Level 3 QC control and verify that the result is within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

PCO₂ Dependency

During the calibration or analysis, a successful reading from the *PCO₂* sensor could not be obtained. Without a successful pH calibration or measurement, the *PCO₂* cannot be calculated. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the pH/Gas module and resolve the associated pH status message.
2. If the pH parameter remains uncalibrated, install a new pH/Gas MicroSensor Card.
3. Contact Nova Biomedical Technical Support.

PCO₂ Drift

During the last analysis sequence, the 1-point calibration reading of the *PCO₂* sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
4. Recalibrate the pH/Gas module 3 times and verify that the pCO₂ slope is stable.
5. Install a new pH/Gas MicroSensor Card.
6. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
7. Contact Nova Biomedical Technical Support.

PCO₂ Instability

During the last calibration or analysis sequence, the *PCO₂* sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new pH/Gas MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

PCO₂ No Reading

During the last analysis or calibration, a successful *pCO₂* sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the pH/Gas module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

PCO₂ Not Calibrated

During the last analysis, the *PCO₂* sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the pH/Gas module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

PCO₂ Overload

During the last calibration or analysis sequence, the *PCO₂* sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new pH/Gas MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

PCO₂ Slope

The measurement difference between the *PCO₂* calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
5. Recalibrate the pH/Gas module 3 times and verify that the PCO₂ slope is stable.
6. Install a new pH/Gas MicroSensor Card.
7. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
8. Contact Nova Biomedical Technical Support.

pH/Gas Back Flow

During the last calibration or analysis, the Reference Solution was detected by the air detector in the pH/Gas module.

Recommended Solutions:

1. Reseat the pH/Gas Reference Sensor and prime the pH/Gas module.
2. Replace the pH/Gas Reference Sensor and prime the pH/Gas module.
3. Contact Nova Biomedical Technical Support.

pH/Gas Flow Fast

During the last analysis, calibration, or maintenance sequence, the pH/Gas flow time exceeded the specified limits. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
2. Contact Nova Biomedical Technical Support.

pH/Gas Flow Slow

During the last analysis, calibration, or maintenance sequence, the pH/Gas flow time exceeded the specified limits. Please note, no action is required if this message occurs infrequently.

Recommended Solutions:

1. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
2. Contact Nova Biomedical Technical Support.

pH/Gas Module Not Available

During the last analysis, the pH/Gas module was not available for analysis.

Recommended Solutions:

1. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
2. Calibrate the pH/Gas module.
3. Contact Nova Biomedical Technical Support.

pH/Gas Module Sensor Card Expired Error

The pH/Gas Module Sensor Card has reached its expiration.

Recommended Solutions:

1. Replace the pH/Gas Module Sensor Card.
2. Contact Nova Biomedical Technical Support.

pH/Gas Module Sensor Card Not Hydrated

After the pH/Gas Card was installed, it did not properly hydrate. The pH/Gas Card needs to hydrate before pH/Gas analysis can be completed.

Recommended Solutions:

1. Verify that the pH/Gas Reagent Cartridge and the Chemistry Reagent Cartridge Set are seated properly.
2. Verify the percent remaining in the pH/Gas Reagent Cartridge. If there is less than 10% remaining or the cartridge is within 1 day of expiration, replace the cartridge.
3. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.

4. Check the Error Log to help identify the reason the MicroSensor Card is not hydrating. If an error related to reagent flow (e.g., No Standard A) is identified, troubleshoot that error before continuing to the next step.
5. Perform a Module Depro sequence through the Maintenance menu.
6. Reseat the pH/Gas Pump Tubing Harness.
7. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
8. Reseat the pH/Gas Reference Sensor and prime the pH/Gas module.
9. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
10. Flush the internal tubing to the pH/Gas Calibrator Cartridge. For instructions on how to perform this step, see Section 5.3.3.
11. Contact Nova Biomedical Technical Support.

pH/Gas Module Sensor Card Not Present Error

The pH/Gas Module Sensor Card is not being detected by the module.

Recommended Solutions:

1. Reseat the pH/Gas Module Sensor Card.
2. Replace the pH/Gas Module Sensor Card.
3. Contact Nova Biomedical Technical Support.

pH/Gas No Air

During the last calibration or analysis sequence, the pH/Gas module air detector failed to see air when expected. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Repeat the analysis or calibration.
2. Reseat the pH/Gas Pump Tubing Harness.
3. Reseat the pH/Gas Reference Electrode.
4. Contact Nova Biomedical Technical Support.

pH/Gas No Fluid

During the last analysis, calibration, or maintenance sequence, the pH/Gas air detector did not detect fluid when expected.

Recommended Solutions:

1. Verify the percent remaining in the pH/Gas Calibrator Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge.
2. Prime the pH/Gas module from the module status screen.
3. Contact Nova Biomedical Technical Support.

pH/Gas No Sample

During the last analysis sequence, the pH/Gas module air detector failed to see sample when expected. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Repeat the analysis.
2. Reseat the pH/Gas Pump Tubing Harness.
3. Reseat the pH/Gas Reference Electrode.

4. See error code "No Sample Acquired" for additional troubleshooting steps.
5. Call Nova Biomedical Technical Support.

pH/Gas Pack No Samples Remaining

The pH/Gas Cartridge has reached its use life expiration.

Recommended Solutions:

1. Replace the pH/Gas Cartridge.
2. Contact Nova Biomedical Technical Support.

pH/Gas Sensor Card No Samples Remaining

The pH/Gas Sensor Card has reached its use life expiration.

Recommended Solutions:

1. Replace the pH/Gas Sensor Card.
2. Contact Nova Biomedical Technical Support.

pH/Gas Temperature Range Failure

The temperature reading on the pH/Gas module exceeded specifications.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

pH Analytical Range High

During the last analysis, the measured result exceeded the high limit of the pH sensor's measurement range.

Recommended Solutions:

1. Repeat the sample analysis.
2. Run Level 3 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

pH Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the pH sensor's measurement range.

Recommended Solutions:

1. Repeat the sample analysis.
2. Run Level 1 QC control and verify that the result is within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

pH Drift

During the last analysis sequence, the 1-point calibration reading of the pH sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry & free of debris.
2. Perform a Module Depro through the Maintenance menu.
3. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
4. Recalibrate the pH/Gas module 3 times and verify that the pH slope is stable.

5. Install a new pH/Gas MicroSensor Card.
6. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
7. Contact Nova Biomedical Technical Support.

pH Instability

During the last calibration or analysis sequence, the pH sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new pH/Gas MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

pH No Reading

During the last analysis or calibration, a successful pH sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the pH/Gas module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

pH Not Calibrated

During the last analysis, the pH sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the pH/Gas module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

pH Overload

During the last calibration or analysis sequence, the pH sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new pH/Gas MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

pH Slope

During the last calibration sequence, the slope calculated is less than the lower slope limit or greater than the upper slope limit.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
5. Recalibrate the pH/Gas module 3 times and verify that the pH slope is stable.
6. Install a new pH/Gas MicroSensor Card.

7. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
8. Contact Nova Biomedical Technical Support.

PO₂ Analytical Range High

During the last analysis, the measured result exceeded the high limit of the PO₂ sensor's measurement range.

Recommended Solutions:

1. Repeat the sample analysis.
2. Run Level 3 QC control and verify that the results are within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

PO₂ Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the PO₂ sensor's measurement range.

Recommended Solutions:

1. Repeat the sample analysis.
2. Run Level 1 QC control and verify that the result is within range.
3. Verify the result on an alternate reference method.
4. Contact Nova Biomedical Technical Support.

PO₂ Drift

During the last analysis sequence, the 1-point calibration reading of the PO₂ sensor has changed significantly since the last successful 2-point calibration.

Recommended Solutions:

1. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
2. Perform a Module Depro sequence through the Maintenance menu.
3. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
4. Recalibrate the pH/Gas module 3 times and verify that the pO₂ slope is stable.
5. Install a new pH/Gas MicroSensor Card.
6. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
7. Contact Nova Biomedical Technical Support.

PO₂ Instability

During the last calibration or analysis sequence, the PO₂ sensor reading was unstable. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new pH/Gas MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

***PO*₂ No Reading**

During the last analysis or calibration, a successful *PO*₂ sensor reading could not be obtained. Please note, no action is required if the message occurs infrequently.

Recommended Solutions:

1. Recalibrate the pH/Gas module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

***PO*₂ Not Calibrated**

During the last analysis, the *PO*₂ sensor was not calibrated prior to sample acquisition.

Recommended Solutions:

1. Recalibrate the Chemistry module and repeat the sample analysis.
2. Contact Nova Biomedical Technical Support.

***PO*₂ Overload**

During the last calibration or analysis sequence, the *PO*₂ sensor reading was outside the software's limits.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Install a new pH/Gas MicroSensor Card.
4. Contact Nova Biomedical Technical Support.

***PO*₂ Slope**

The measurement difference between the *PO*₂ calibrators during the last 2-point calibration did not meet the minimum specifications for a properly performing sensor.

Recommended Solutions:

1. Prime the pH/Gas module and recalibrate.
2. Ensure that the pH/Gas MicroSensor Card chamber is clean, dry, & free of debris.
3. Perform a Module Depro sequence through the Maintenance menu.
4. Replace the pH/Gas Pump Tubing Harness per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
5. Recalibrate the pH/Gas module 3 times and verify that the pH slope is stable.
6. Install a new pH/Gas MicroSensor Card.
7. Replace the pH/Gas Reference Sensor per the recommended maintenance frequency. Prime and recalibrate the pH/Gas module.
8. Contact Nova Biomedical Technical Support.

R

Refrigeration Module Temperature Out Of Range Error

The temperature reading on the Refrigeration Module exceeded specifications.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support

Refrigeration Module Thermistor Failure

The thermistor on the Refrigeration module failed to meet specifications.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support

S

Software Error

Signifies an internal software error.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

W

Waste Well Blocked

During the last analysis, the Waste Well became blocked. A well blockage will inhibit analysis of the respective module and will also disable the Depro Wells function.

Recommended Solutions:

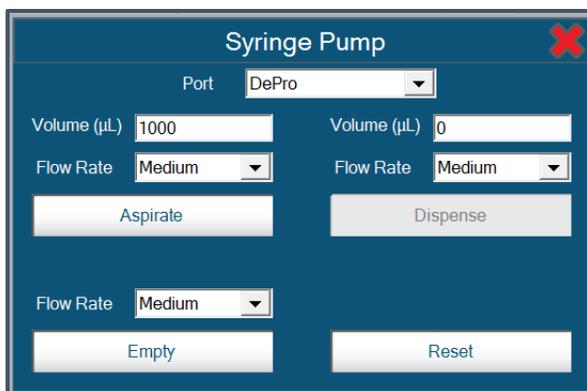
1. Verify that all Reagent Cartridges are seated properly to enable well drainage to the waste bag.
2. Verify that all Reagent Cartridges are valid and not expired.
3. Verify the percent remaining in the Chemistry Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
4. Visually inspect the Waste Well. If there is fluid, use a transfer pipette/flush tool to remove the residual fluid from the well.
5. On the Home page, run Clear Wells from the Cell Density or Chemistry module status screen to help clear the obstruction. Run this option multiple times to try and clear the obstruction.
6. If the well is still blocked, flush/deproteinize the Waste Well through Flowpath Services. For instructions on how to perform this step, see Section 5.3.1.
7. Contact Nova Biomedical Technical Support.

Waste Well Flow Time

During the last analysis, calibration, or maintenance sequence, the well flow time exceeded the specified limits.

Recommended Solutions:

1. Open the door of the analyzer and verify that the waste well is empty.
 - a. If the well is not empty, run the Clear Wells sequence from the Cell Density or Chemistry module status screen.
 - b. If the well is empty, run a Prime from the Cell Density or Chemistry module status screen.
2. Run a Depro Wells sequence in the Maintenance menu.
3. Contact Nova Biomedical Technical Support.



5.2 Syringe Pump Menu

6. Perform the following steps on the Syringe Pump menu:
 - a. Select **DePro** from the Port drop-down menu.
 - b. On the left-hand side, enter a volume of 1000µL into Syringe Pump.
 - c. Select **Aspirate**.
 - d. Select **Waste Well** from the Port drop-down menu.

NOTE: *Keep the Port drop-down menu set to Waste Well for steps 6e - 6i.*

- e. Select **Dispense** on the right-hand side to dispense 1000µL into the well.
 - f. Select **Aspirate**.
 - g. Select **Dispense**.
 - h. Repeat steps 6f - 6g multiple times for a deeper cleaning of the well.
 - i. Select **Aspirate** 1000µL.
 - j. Select **System Waste Bag** from the Port drop-down menu.
 - k. Select **Dispense** 1000µL.
7. Exit Flowpath Service and navigate back to the Home screen.
8. Select **Clear Wells** from the Cell Density or Chemistry module status screen.

NOTE: *If the Clear Wells option is not available after exiting Flowpath Service, wait 2-5 minutes for this option to become available.*

9. Select the **Maintenance** menu.
 10. Select **Depro Wells**.

5.3.2 No SAMPLE ACQUIRED ERROR

If presented with a No Sample Error, the Sample Inlet Manifold may need to be flushed manually and/or through Flowpath Service.

The following materials are necessary for flushing:

1. Kimwipes®
2. Blunt needle tip syringe
3. Deionized water

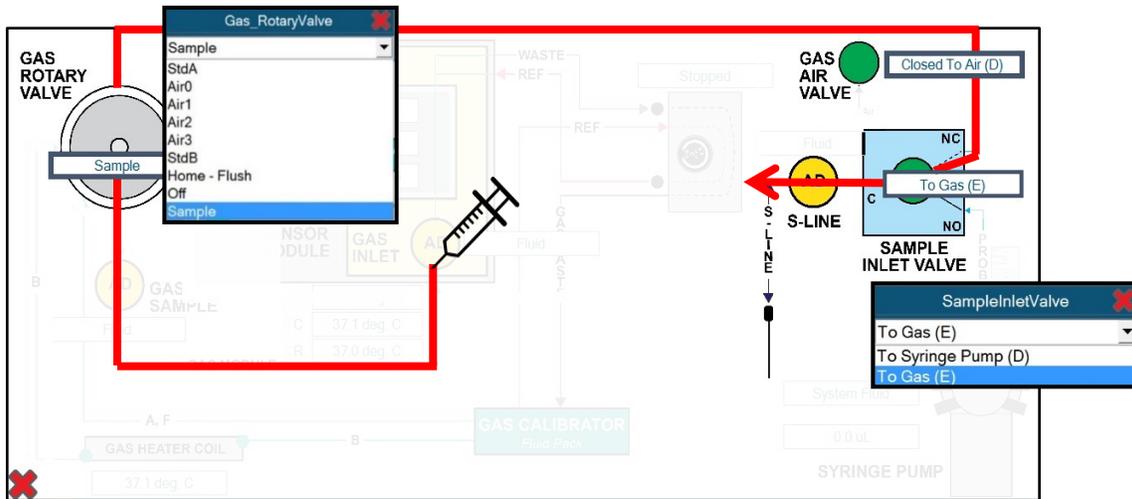
To flush the Sample Inlet Manifold through the Sample Inlet Valve:

1. Select **Service**.
2. Select **Customer Service**.

NOTE: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

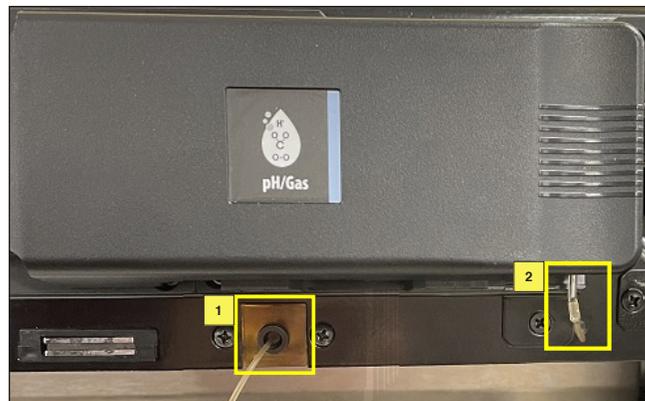
3. Select **Flowpath Service**.

- Select the Gas Sensor Module in Flowpath Service.



5.3 Sample Inlet Valve and Gas Rotary Valve Menus

- On the Sample Inlet Valve, select **To Gas (E)** (Figure 5.3).
- On the Gas Rotary Valve, select **Sample** (Figure 5.3).
- On the Gas Air Valve, select **Closed to Air (D)** (Figure 5.3).
- Open the door of the FLEX2 and unscrew the S-Line Tubing from the Sample Inlet Valve (Figure 5.4).
- Place a Kimwipe® at the Sample Inlet Manifold where the S-Line Tubing was unscrewed from.
- Disconnect the pH/Gas Sample Inlet Tubing from the bottom right-hand side of the pH/Gas Reference Sensor (Figure 5.4).



5.4 Unscrew the S-Line Tubing (1) and Disconnect the pH/Gas Sample Inlet Tubing (2)

- Fill a blunt needle tip flushing syringe with 5 mL of DI water.
- Connect the flushing syringe to the pH/Gas Sample Inlet Tubing (do not connect to the Reference Sensor).
- Flush the pH/Gas Sample Inlet Tubing and check for flow at the Sample Inlet Manifold.
- Repeat steps 11–13 to help clear any obstruction.
- Fill a blunt needle tip flushing syringe filled with 5mL of air.
- Connect the flushing syringe to the pH/Gas Sample Inlet Tubing (do not connect to the Reference Sensor).
- Flush the pH/Gas Sample Inlet Tubing with air.
- Reconnect the S-Line Tubing to the Sample Inlet Valve and repeat Steps 11-17 to flush the S-Line Probe Tubing.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

19. Disconnect the flushing syringe from the pH/Gas Sample Inlet Tubing and reconnect the pH/Gas Sample Inlet Tubing to the bottom right of the pH/Gas Reference Sensor.
20. Exit Flowpath Service and navigate back to the Home screen.
21. Select a pH/Gas Parameter on the Home screen.
22. Select **Prime** to prime the pH/Gas module.

NOTE: *If the Prime option is not available after exiting Flowpath Service, wait 2-5 minutes for this option to become available.*

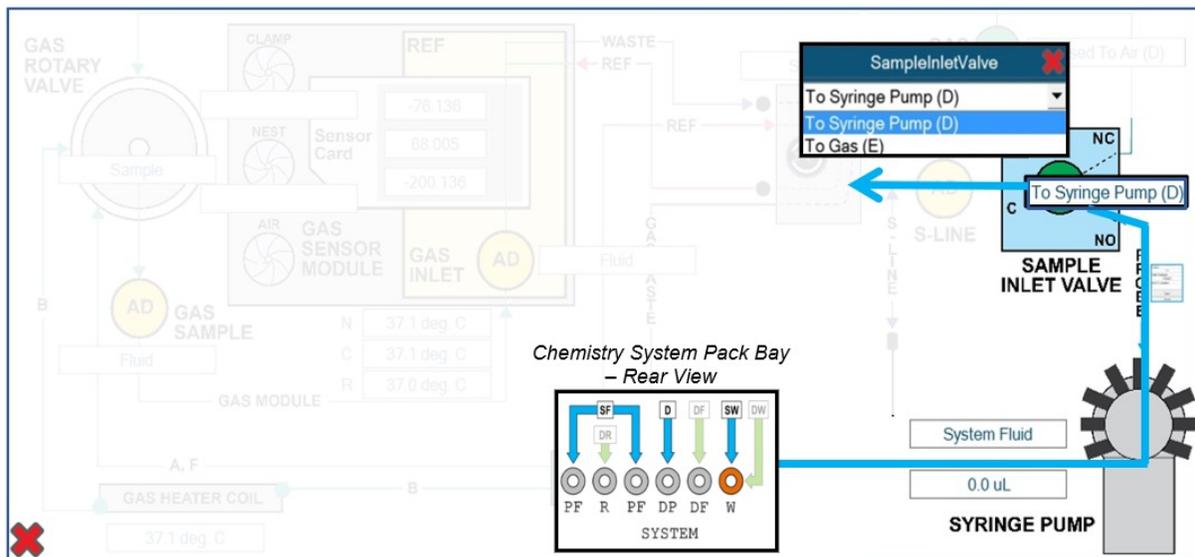
23. Run QC to confirm if the sample is properly acquired.

To flush the Sample Inlet Valve through the P-Line:

1. Select **Service**.
2. Select **Customer Service**.

NOTE: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Service for further assistance. You will need a daily coded password to continue.*

3. Select **Flowpath Service**.
4. Select the Gas Sensor module in Flowpath Service.



5.5 pH/Gas Module Flowpath

5. Open the door of the FLEX2 and unscrew the S-Line Tubing from the Sample Inlet Valve (Figure 5.4).
6. Place a Kimwipe® at the Sample Inlet Manifold where the S-Line Tubing was unscrewed from.
7. On screen, select the information box on the Sample Inlet Valve.
8. Select To Syringe Pump (D) on the Sample Inlet Valve drop-down menu (Figure 5.5).
9. Select the Syringe Pump information box to open the Syringe Pump menu (Figure 5.2). This is the text box to the side of the Syringe Pump above the volume information box.
10. Perform the following steps on the Syringe Pump menu:
 - a. Select **System Fluid** from the Port drop-down menu.
 - b. On the left-hand side, enter a volume of 1000µL into the Syringe Pump.
 - c. Select **Aspirate** on the left-hand side.
 - d. Select **Probe** from the Port drop-down menu.
 - e. Select **Dispense** on the right-hand side to dispense 1000µL into the Probe.
 - f. Look for fluid flow at the Sample Inlet Manifold.
 - g. Repeat steps 10a–10f and observe fluid flow.

11. Reconnect the S-Line to the Sample Inlet Valve and repeat step 10.
12. Run QC to confirm if the sample is properly acquired.

5.3.3 pH GAS NO STANDARD A, NO STANDARD B, OR NO FLUSH ERROR

After performing the steps in Section 5.2, if the error persists, the error could stem from a clogged internal tubing line. The steps below contain more information on how to flush this internal tubing from the Flowpath Service screen.

The following materials are necessary for flushing:

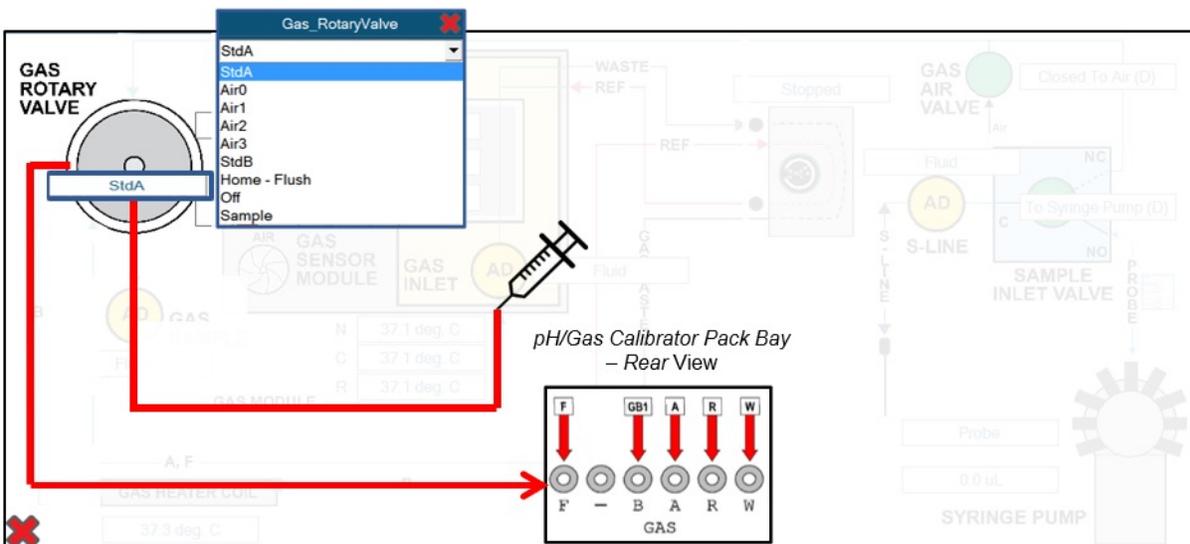
1. Kimwipes®
2. Blunt needle tip syringe
3. Deionized water

To flush internal pH/Gas Calibrator lines:

1. Select **Service** from the Home screen.
2. Select **Customer Service**.

NOTE: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

3. Select **Flowpath Service**.
4. Select the Gas Sensor module in Flowpath Service.



5.6 pH/Gas Module Flowpath

5. Open the door of the FLEX2 and remove the pH/Gas Calibrator Cartridge from the analyzer.
6. On the screen, select the pH/Gas Rotary Valve icon and set it to **StdA/StdB/Home-Flush** depending on the error (Figure 5.6).
7. Disconnect the Sample Inlet Tubing from the port on the bottom right of the Gas Reference Sensor (Figure 5.4).
8. Fill a blunt needle tip flushing syringe with 5mL of DI water and connect the flushing syringe to the pH/Gas Sample Inlet Tubing (do not connect the flushing syringe to the Reference Sensor).
9. Flush the pH/Gas Sample Inlet Tubing. Check for flow at needle shroud in the back of the pack bay.
10. Fill a blunt needle tip flushing syringe with 5mL of air and connect the flushing syringe to the pH/Gas Inlet Tubing (do not connect to the Reference Sensor). Flush the pH/Gas Sample Inlet Tubing with air.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

11. Disconnect the flushing syringe from the pH/Gas Sample Inlet Tubing and reconnect the pH/Gas Sample Inlet Tubing to the bottom of the pH/Gas Reference Sensor.
12. Clean up the fluid flushed into the pH/Gas pack bay. Re-install the pH/Gas Reagent Cartridge in the analyzer and close the door.
13. Exit Flowpath Service and navigate back to the Home screen.
14. Select a pH/Gas Parameter on the Home screen.
15. Select **Prime** to prime the pH/Gas module.

NOTE: *If the Prime option is not available after exiting Flowpath Service, wait 2-5 minutes for this option to become available.*

16. Select **Calibrate** on the pH/Gas module.

5.3.4 CHEMISTRY WELL BLOCKED

If the Chemistry Well appears as blocked from the Module Overlay screen, Chemistry analysis will not run until the blockage is cleared. If the Chemistry Well continues to appear as blocked after completing the steps in Section 5.2, the Chemistry Well and tubing will need to be manually flushed to try and clear the blockage.

The following materials are necessary for flushing the Chemistry module:

1. Transfer pipette/flushing tool
2. KimWipes®
3. Blunt needle tip syringe

NOTE: *When flushing with an external syringe, make sure to use a blunt needle tip as to not puncture the Sample Inlet Tubing.*

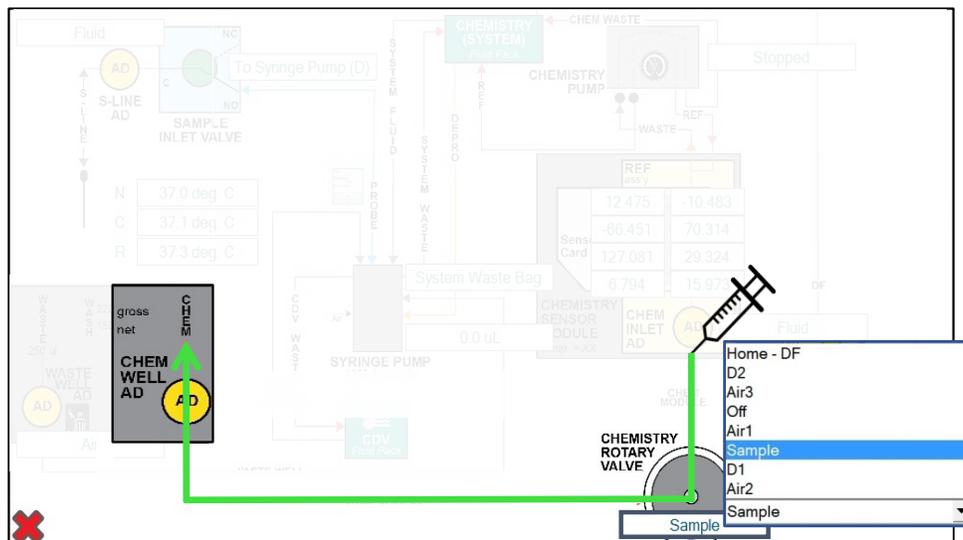
4. Deionized water or Depro solution

To flush the Chemistry Well:

1. Select **Service** from the Home screen.
2. Select **Customer Service**.

NOTE: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

3. Select **Flowpath Service**.
4. Select the Chemistry Sensor module in Flowpath Service.



5.7 Chemistry Module Flowpath Service

5. On the Chemistry Rotary Valve, select **Sample** (Figure 5.7).
6. Fill a blunt needle tip flushing syringe with 5mL of DI water or 5 mL of Depro.

NOTE: *Chemistry Well Volume: 500 μ L*

7. Disconnect the Sample Inlet Tubing from the port on the bottom right of the Chemistry Reference Sensor (Figure 5.8).



5.8 Chemistry Inlet Tubing

8. Connect the flushing syringe to the Chemistry Inlet Tubing on the bottom right of the Chemistry Reference Sensor. Do not connect the flushing syringe to the Reference Sensor.
9. Flush the Chemistry Sample Inlet Tubing and check for flow in the Chemistry Well. Do not overfill the well. Pipette out the fluid in the well.
10. Flush the Chemistry Sample Inlet Tubing again and check for flow in the Chemistry Well of the analyzer. Flush back and forth by aspirating and dispensing fluid in the attached syringe to help clear any obstructions.
11. Fill the blunt needle tip flushing syringe with 5mL of air.
12. Connect the flushing syringe to the Chemistry Inlet Tubing on the bottom right of the Chemistry Reference Sensor. Do not connect the flushing syringe to the Reference Sensor.
13. Flush the Chemistry Sample Line with 5mL of air.
14. Disconnect the flushing syringe and reconnect the Chemistry Inlet Tubing to the bottom right of the Chemistry Reference Sensor.
15. Exit Flowpath Service and navigate back to the Home screen.
16. Select a Chemistry Parameter on the Home screen.
17. Select **Clear Wells**.

NOTE: *If the Clear Wells option is not available after exiting Flowpath Service, please wait 2-5 minutes for this option to become available.*

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

5.3.5 CHEMISTRY NO STANDARD D1, NO STANDARD D2, AND NO DFLUSH ERROR

When presented with a Chemistry flow error, such as No Standard D1, No Standard D2, or No Standard DF, after completing the steps in Section 5.2, if the error continues, the error could stem from a clogged internal tubing line. The steps below contain more information on how to flush this internal tubing from the Flowpath Service screen.

The following materials are necessary for flushing:

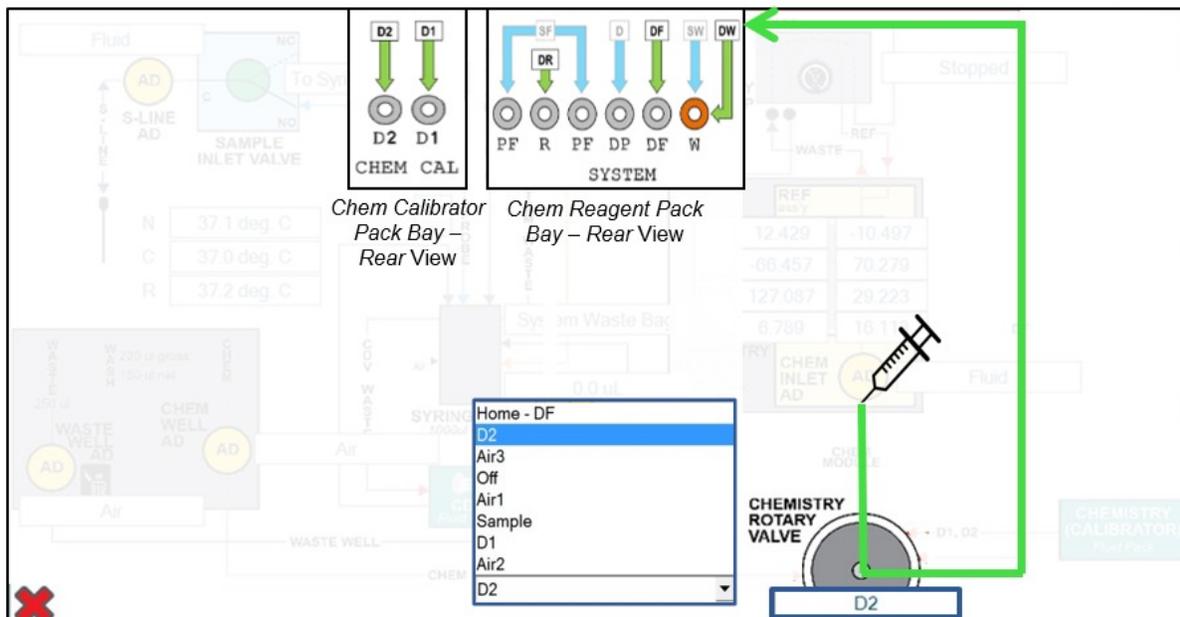
1. Kimwipes®
2. Blunt needle tip syringe
3. Deionized water

To flush Internal Chemistry Reagent Tubing:

4. Select **Service** from the Home screen.
5. Select **Customer Service**.

NOTE: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

6. Select **Flowpath Service**.
7. Select the Chemistry Sensor module in Flowpath Service.
8. Open the door of the FLEX2 and remove the Chemistry Calibrator Cartridge and the Chemistry Reagent Cartridge.
9. On the FLEX2 screen, set the Chemistry Rotary Valve to **D1**, **D2**, or **DF**, depending on the error.



5.9 Internal Chemistry Reagent Tubing Flowpath Service Menu

10. Disconnect the Sample Inlet Tubing from the port on the bottom right of the Chemistry Reference Sensor (Figure 5.8).
11. Connect the flushing syringe filled with 5mL of DI water to the Chemistry Inlet Tubing. Do not connect the flushing syringe to the Reference Sensor.
12. Flush the Chemistry Sample Inlet Tubing. Check for a steady flow from the needle shroud in the back of the pack bay.
13. Connect the flushing syringe filled with 5mL of air to the Chemistry Inlet Tubing. Do not connect the flushing syringe to the Reference Sensor. Flush the Chemistry tubing with air.

14. Disconnect the flushing syringe and reconnect the Chemistry Inlet Tubing to the bottom right of the Chemistry Reference Sensor.
15. Clean up the fluid flushed into the Chemistry pack bays.
16. Re-install the Chemistry Reagent Cartridge and Chemistry Calibrator Cartridge in the analyzer.
17. Exit Flowpath Service and navigate back to the Home screen.
18. Select a Chemistry Parameter on the Home screen.
19. Select **Prime** to prime the Chemistry module.

NOTE: *If the Prime option is not available after exiting Flowpath Service, wait 2-5 minutes for this option to become available.*

20. Select **Calibrate** on the Chemistry module.

A INSTRUMENT SPECIFICATIONS

This section includes instrument specifications for the Nova BioProfile FLEX2 Basic A, B, C.

A.1 INSTRUMENT SPECIFICATIONS

Measurement Range:

FLEX2 Basic A

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gln	mmol/L	0.10	6.00	Dil. Ratio = 1:1
		0.20	12.00	Dil. Ratio = 1:2
		0.40	24.00	Dil. Ratio = 1:4
Glu	mmol/L	0.10	6.00	Dil. Ratio = 1:1
		0.20	12.00	Dil. Ratio = 1:2
		0.40	24.00	Dil. Ratio = 1:4
Gluc	g/L	0.10	15.00	Dil. Ratio = 1:1
		0.20	30.00	Dil. Ratio = 1:2
		0.40	60.00	Dil. Ratio = 1:4
Lac	g/L	0.10	6.00	Dil. Ratio = 1:1
		0.20	12.00	Dil. Ratio = 1:2
		0.40	24.00	Dil. Ratio = 1:4
NH ₄ ⁺	mmol/L	0.20	25.00	Dil. Ratio = 1:1
		0.40	50.00	Dil. Ratio = 1:2
		0.80	100.00	Dil. Ratio = 1:4
Na ⁺	mmol/L	40.0	300.0	Dil. Ratio = 1:1
		80.0	600.0	Dil. Ratio = 1:2
		160.0	1200.0	Dil. Ratio = 1:4
K ⁺	mmol/L	1.00	100.00	Dil. Ratio = 1:1
		2.00	200.00	Dil. Ratio = 1:2
		4.00	400.00	Dil. Ratio = 1:4
Ca ⁺⁺	mmol/L	0.10	10.00	Dil. Ratio = 1:1
		0.20	20.00	Dil. Ratio = 1:2
		0.40	40.00	Dil. Ratio = 1:4

Range depends on selected dilution ratio.

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

FLEX2 Basic B

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gln	mmol/L	0.10	6.00	Dil. Ratio = 1:1
Glu	mmol/L	0.10	6.00	Dil. Ratio = 1:1
Gluc	g/L	0.10	15.00	Dil. Ratio = 1:1
Lac	g/L	0.10	6.00	Dil. Ratio = 1:1
NH ₄ ⁺	mmol/L	0.20	25.00	Dil. Ratio = 1:1
Na ⁺	mmol/L	40.0	300.0	Dil. Ratio = 1:1
K ⁺	mmol/L	1.00	100.00	Dil. Ratio = 1:1
Ca ⁺⁺	mmol/L	0.10	10.00	Dil. Ratio = 1:1

FLEX2 Basic C

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gluc	g/L	0.10	15.00	Dil. Ratio = 1:1
Lac	g/L	0.10	6.00	Dil. Ratio = 1:1
Na ⁺	mmol/L	40.0	300.0	Dil. Ratio = 1:1
K ⁺	mmol/L	1.00	100.00	Dil. Ratio = 1:1
Ca ⁺⁺	mmol/L	0.10	10.00	Dil. Ratio = 1:1

Analysis Rate:

Test Panel	Time
Manual	
Chemistry	110 seconds
Gas	110 seconds
Chem and Gas	110 seconds

Sample Volume:

Test Panel	Volume
Manual Chemistry	135 µL
Gas	265 µL
Chem and Gas	265 µL
96-well plate Any Combination	400 µL Minimum
Micro Centrifuge Tube Tray Any Combination	400uL Minimum
Sample Cup Tray Any Combination	400uL Minimum

Reagents: Multiple Calibrator and Reagent Cartridges Slope Limits:

Parameter	Slope
Glutamine	5 - 100
Glutamate	5 - 100
Glucose	5 - 150
Lactate	5 - 100

Parameter	Slope
Ammonium	8.5 - 12.5
Sodium	8.5 - 12
Potassium	8.5 - 12
Calcium	8.5 - 12
pH	8.5 - 12
PO2	6 - 25
PCO2	2.5 - 15

Analytical Specifications:

Parameter	Units	Within Run CV%	Within Run SD	Day-To-Day CV%	Day-To-Day SD
pH	-	-	0.007	-	0.018
PO2	mmHg	5.0	3.0	7.0	4.2
PCO2	mmHg	5.0	1.0	7.0	2.8
Gln	mmol/L	5.0	0.10	7.0	0.14
Glu	mmol/L	5.0	0.10	7.0	0.14
Gluc	g/L	5.0	0.03	7.0	0.07
Lac	g/L	5.0	0.03	7.0	0.07
NH4+	mmol/L	5.0	0.10	7.0	0.14
Na+	mmol/L	3.0	2.3	4.5	3.2
K+	mmol/L	4.0	0.15	5.6	0.21
Ca++	mmol/L	4.0	0.05	5.6	0.07

Electrical Compliance: Conforms to 73/23/EEC, Low Voltage Directive, 89/336/EEC, EMC Directive, EN61010-1-2001, EN61010-2-081:2002, Measurement, Control, and Laboratory Equipment

Electrical Requirements:

Operating Voltage Range	100–240	VAC
Operating Frequency	50–60	Hz

Power Consumption:

FLEX2 Basic A, B, C	480	Watts
Fuses (2)	SB 8A or T8A/250V	

Temperature Thermostatting: 37°C ± 0.1°C

Dimensions:

Height	23.5 in (59.69 cm)
Width	16.75 in (42.55 cm)
Depth	25.0 in (63.50 cm)

Weight: Less than 125lb (56.69kg) with installed reagent packs

Ambient Operating Temperature: 15°C to 30°C (59°F – 86°F)

Operate at Humidity: 20–85% without condensation

BIOPROFILE FLEX2 BASIC A, B, C INSTRUCTIONS FOR USE MANUAL

A.2 BIOPROFILE FLEX2 BASIC A, B, C SPARE PARTS & SUPPLIES LIST

Description	Part Number (PN)
Sensor Cartridges	
BioProfile FLEX2 pH/Gas MicroSensor™ Card LV	57510
BioProfile FLEX2 pH/Gas MicroSensor™ Card HV	57526
BioProfile FLEX2 Chemistry MicroSensor™ Card LV	57512
BioProfile FLEX2 Chemistry MicroSensor™ Card HV	57528
BioProfile FLEX2 Basic Chemistry MicroSensor™ Card LV (<i>C Model Only</i>)	66469
BioProfile FLEX2 Basic Chemistry MicroSensor™ Card HV (<i>C Model Only</i>)	66470
BioProfile FLEX2 pH/Gas Reference Sensor	57467
BioProfile FLEX2 Chemistry Reference Sensor	57466
Calibrator Cartridges	
BioProfile FLEX2 pH/Gas Calibrator Cartridges LV	57957
BioProfile FLEX2 pH/Gas Calibrator Cartridges MV	58102
BioProfile FLEX2 pH/Gas Calibrator Cartridges HV	54507
BioProfile FLEX2 Chemistry Calibrator and Reagent Cartridges LV	58003
BioProfile FLEX2 Chemistry Calibrator and Reagent Cartridges MV	58101
BioProfile FLEX2 Chemistry Calibrator and Reagent Cartridges HV	53937
BioProfile FLEX2 Basic Chemistry Calibrator and Reagent Cartridges LV (<i>C Model Only</i>)	66451
BioProfile FLEX2 Basic Chemistry Calibrator and Reagent Cartridges MV (<i>C Model Only</i>)	66467
BioProfile FLEX2 Basic Chemistry Calibrator and Reagent Cartridges HV (<i>C Model Only</i>)	66468
Internal QC	
BioProfile FLEX2 pH/Gas Auto QC Cartridge	56073
BioProfile FLEX2 Chemistry Auto QC Cartridge	57035
BioProfile FLEX2 Basic Chemistry Auto QC Cartridge (<i>C Model Only</i>)	66471
External QC	
BioProfile Control Level 1 (30ampules/box)	22600
BioProfile Control Level 2 (30ampules/box)	22601
BioProfile Control Level 3 (30ampules/box)	22602
BioProfile Control Level 4 (30ampules/box–Contains Gln,Glu,Gluc, Lac)	24617
BioProfile Control Level 5 (30ampules/box– Contains Gln,Glu,Gluc,Lac)	24619
Linearity Standard Low (30 ampules/box– Contains Gln,Glu,Gluc,Lac)	45278
Linearity Standard High (30ampules/box– Contains Gln,Glu,Gluc,Lac)	45279
Tubing	
BioProfile FLEX2 S-Line Probe Assembly	55288
BioProfile FLEX2 Chemistry Pump Tubing Harness	55281
BioProfile FLEX2 pH/Gas Pump Tubing Harness	55283
BioProfile FLEX/FLEX2 Syringe Replacement	42400

Accessories

BioProfile FLEX/FLEX2 Flush Fixture 6 Port..... 58355

BioProfile FLEX2 Flush Fixture 2 Port..... 57530

BioProfile FLEX2 Flowpath Troubleshooting Kit..... 66287

BioProfile FLEX2 Sample Cup Waste Container (2 pk) 58164

BioProfile FLEX2 Sample Cups (250/bag) 58275

BioProfile FLEX2 pH/Gas Module Deproteinization Card 58645

BioProfile FLEX2 Chemistry Module Deproteinization Card 58644

BioProfile FLEX2 Wireless Barcode Scanner (upgrade kit, includes install) 59942

Pre-Pierced Septum (for Gas QC) 3/pack 59228

BioProfile FLEX2 pH/Gas Shutdown Cartridge 60608

BioProfile FLEX2 Chemistry Module Shutdown Cartridge 60610

BioProfile FLEX2 pH/Gas Auto QC Shutdown Cartridge..... 60613

B THEORY

This section explains instrument theory of the BioProfile FLEX2 BasicA, B, C Analyzers.

B.1 pH/GAS AND CHEMISTRY SENSOR CALIBRATION

B.1.1 TWO-POINT CALIBRATION

The analyzer uses a 2-point calibration to set the electrode slope and verify electrode performance. The calibrator cartridges contain the standards that are used for this purpose. A calibration can be initiated manually by pressing CALIBRATE from the appropriate menu screen and will also occur automatically at regular intervals.

B.1.2 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. Electrode drift is the slow variation in electrode response over time. To monitor and minimize the effect of electrode drift on the analytical results, the analyzer uses a 1-point calibration during each sample analysis. A drift error will occur when the 1-point calibration is beyond the acceptable drift limits and the result will not be reported.

B.2 PRINCIPLE OF MEASUREMENT

Measuring Technology: Three Planar Sensors (pH, PCO_2 , PO_2) on the pH/Gas MicroSensor Card and Eight Planar Sensors (Na^+ , K^+ , NH_4^+ , iCa , Glucose, Lactate, Glutamine, and Glutamate) on the Chemistry MicroSensor Card.

B.2.1 SODIUM, POTASSIUM, IONIZED CALCIUM, AND AMMONIUM

These parameters are measured by the Ion-Selective Electrode (ISE), which selectively measures the activity of ionic species. When the ISE is in contact with a sample, a potential is developed. The potential is proportional to the logarithm of the ionic activity and is measured versus a reference electrode. The ionic activity is related to the concentration of the ion in the sample.

B.2.2 pH MEASUREMENT

pH is measured using a hydrogen ion selective membrane. One side of the membrane is in contact with a solution of constant pH. The other side is in contact with a solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions.

This change in potential is measured against a reference electrode of constant potential. The magnitude of the potential difference is a measure, therefore, of the pH of the unknown solution.

B.2.3 PARTIAL PRESSURE OF CARBON DIOXIDE (PCO_2)

The partial pressure (tension) of carbon dioxide in solution is defined as the partial pressure of carbon dioxide in the gas phase in equilibrium with the sample.

The PCO_2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a hydrogen ion selective membrane. CO_2 diffuses across the membrane into a thin layer of bicarbonate buffer in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure of the fluid in contact with the outer surface of the membrane. CO_2 in the solution becomes hydrated producing carbonic acid which results in a change in hydrogen ion activity. The pH of this internal solution varies with the PCO_2 . The measured potential is related to the logarithm of the PCO_2 of the sample after compensation of the measured potential of the pH sensor.

B.2.4 PARTIAL PRESSURE OF OXYGEN (PO_2)

The partial pressure (tension) of oxygen in solution is defined as the partial pressure of oxygen in the gas phase in equilibrium with the sample.

The PO_2 is measured amperometrically by the generation of a current at the sensor surface. As oxygen diffuses through a gas permeable membrane, the oxygen molecules are reduced at the cathode, consuming 4 electrons for every molecule of oxygen reduced. This flow of electrons is then measured by the sensor and is directly proportional to the partial pressure of oxygen.

B.2.5 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.

B.2.6 LACTATE

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

B.2.7 GLUTAMINE AND GLUTAMATE

Glutamine measurement is based on the level of glutamate produced during the enzymatic reaction between glutamine and water molecules in the presence of the glutaminase enzyme. The glutamate measurement is based on the level of H_2O_2 produced during the enzymatic reaction between glutamate and oxygen molecules in the presence of the glutamate oxidase enzyme. The current generated by the flow of electrons at the surface of the platinum sensor is proportional to the glutamate concentration of the sample.

B.3 CALCULATED VALUES

The analyzer has a microcomputer that uses the measured results to calculate other valuable parameters. This section outlines the equations used to calculate these values.

B.3.1 TEMPERATURE CORRECTION FOR MEASURED VALUES

The BioProfile FLEX2 Basic A, B, C Analyzer allows you to enter the sample temperature when this differs from 37 °C. The pH, PCO₂, and PO₂ sample values, at the sample's actual temperature, are then calculated as follows:

$$pH_{(corrected)} = pH + [- 0.0147 + 0.0065 (7.400 - pH)](T - 37) \quad \text{Equation 1}$$

$$PCO_{2(corrected)} = PCO_2 \times e^{(0.04375(T - 37))} \quad \text{Equation 2}$$

$$PO_{2(corrected)} = PO_2 \times 10^U \quad \text{Equation 3}$$

$$\text{where } U = \left(\left[\frac{(5.49 \times 10^{-11}) Y + 0.071}{(9.72 \times 10^{-9}) Y + 2.30} \right] \times (T - 37) \right) \text{ and } Y = e^{[3.88 \times \ln(PO_2)]}$$

B.3.2 CALCULATED PARAMETERS

O₂ Saturation %

$$O_2 \text{ Saturation \%} = \frac{PO_2 \text{ mmHg}}{(BP^* \text{ mmHg} - 47) \times 0.209} \times 100\% \quad \text{Equation 4}$$

NOTE: Equation 4 assumes analyzer defaults entered for sample analysis. If values other than defaults are entered, the following conditions apply:

- Equation uses temperature corrected PO₂ value
- BP* adds additional vessel pressure value entered to the barometric pressure reading taken at the time of sampling
- Value of 0.209 changes to the value entered for Sparging O₂%

CO₂ Saturation %

$$CO_2 \text{ Saturation \%} = \frac{PCO_2 \text{ mmHg}}{(BP^* \text{ mmHg} - 47)} \times 100\% \quad \text{Equation 5}$$

NOTE: Equation 5 assumes analyzer defaults entered for sample analysis. If values other than defaults are entered, the following conditions apply:

- Equation uses temperature corrected pCO₂ value
- BP* adds additional vessel pressure value entered to the barometric pressure reading taken at the time of sampling



Calculated Bicarbonate Concentration [HCO₃⁻]

Bicarbonate Concentration (mmol/L) is calculated using the Henderson-Hasselbalch equation:

$$\text{pH} = \text{pK} + \log \frac{[\text{HCO}_3^-]}{\alpha(\text{PCO}_2)} \quad \text{Equation 6}$$

where pH and PCO_2 are measured.

$$\text{pK} = 6.091$$

$\alpha = 0.0307$ = solubility coefficient of CO_2 in water at 37 °C

Rearranging Equation 6 gives:

$$\text{Log}_{10} [\text{HCO}_3^-] = \text{pH} + \log_{10} \text{PCO}_2 - 7.604 \quad \text{Equation 7}$$

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 warranted 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 pH/Gas and Chemistry MicroSensor Cards are warranted as stated on the insert, provided they are stored refrigerated and placed into service prior to the expiration date on the packaging. This warranty is invalid under the conditions specified after item 4.
2. The reference sensors are warranted for six (6) months from the date of installation provided they are stored at room temperature and placed into service prior to the use before date on the packaging. In the event that a sensor does not meet that use life, then Nova Biomedical will replace that sensor at no charge under this warranty. This warranty is invalid under the conditions specified after item 4.
3. 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.
4. 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.