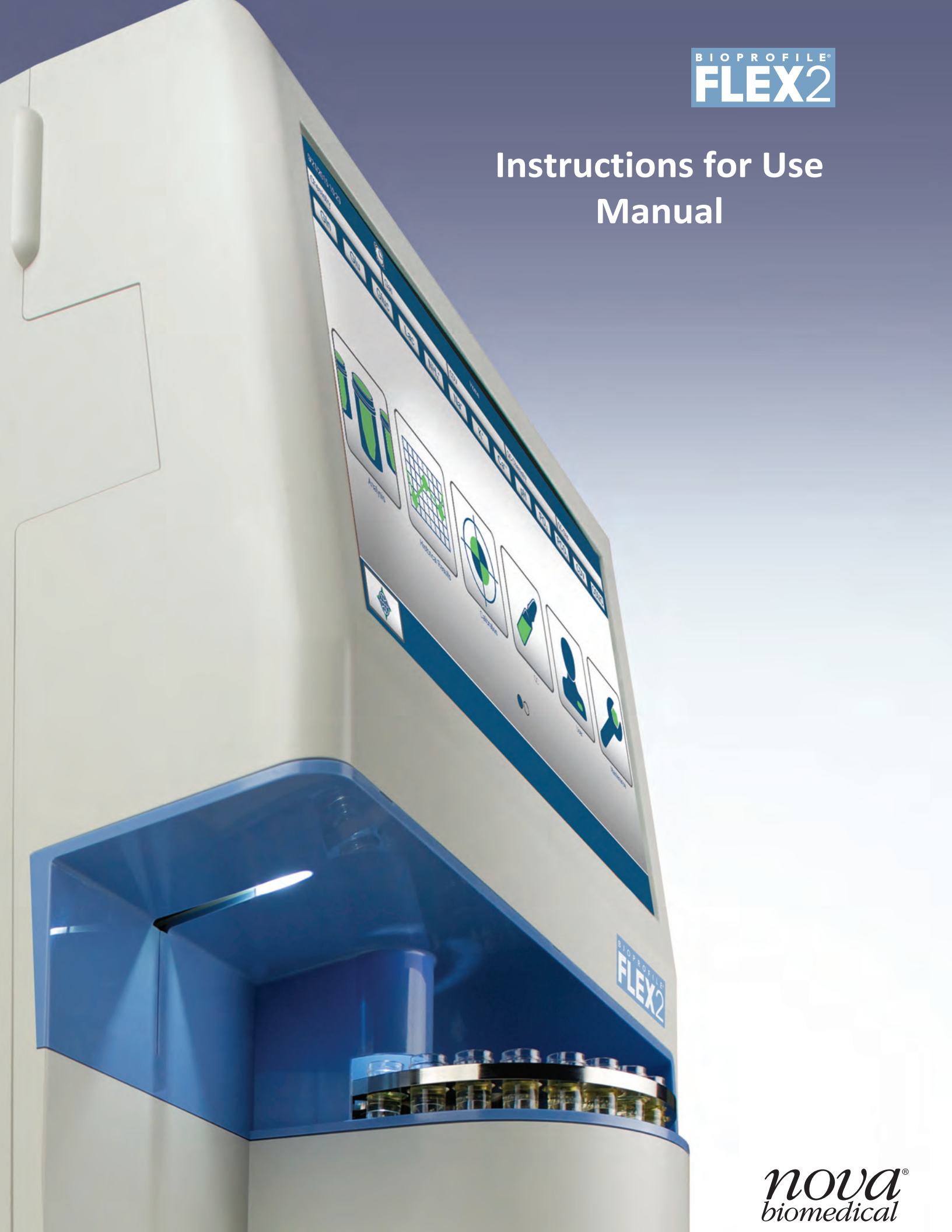
BIOPROFILE® FLEX2

Instructions for Use Manual



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BioProfile® FLEX2
Quick Reference Guide

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Perform a Sample Analysis

The BioProfile FLEX2 analyzer offers three default methods of sampling:

Manual Sampling

Load-and-GO

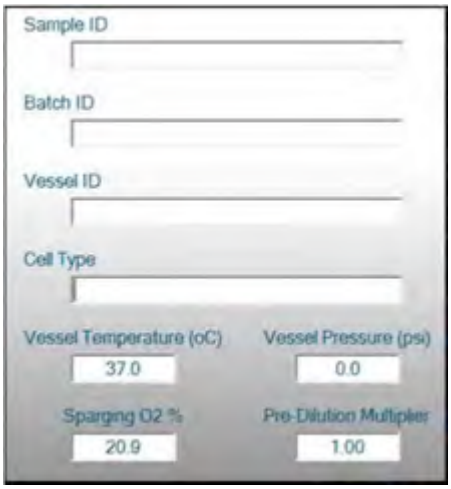
96-Well Microtiter Plate

Run a Manual Sample

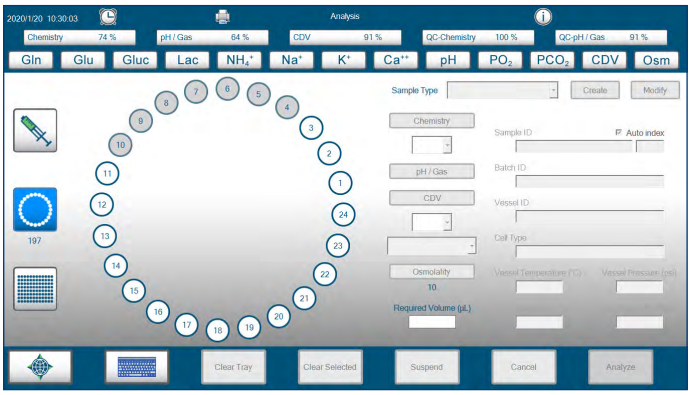
1. Select **Analysis** from the Left Home screen.
2. Select **Manual Analysis**.
3. Select a pre-configured Sample Type from the dropdown menu or use the Default Sample Type.
4. Select or deselect the desired modules by tapping the module buttons. A selected module will turn BLUE.
5. Configure the Chemistry Module dilution ratio by using the dropdown under **Chemistry**.
6. Configure the Cell Density Module dilution ratio and Cell Inspection Type by using the dropdown menus under **CDV**.

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

7. Enter sample information into the open fields.
8. Vessel Temperature, Vessel Pressure, Sparging O_2%, and Pre-Dilution Multiplier can be edited by selecting the appropriate field.
9. Press **Analyze** and wait for the probe to appear.
10. Present the sample to the probe and press **Aspirate**.



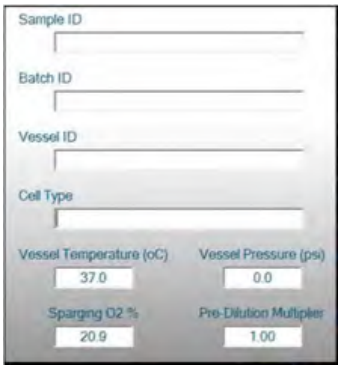
Run a Load-and-Go Carousel Tray Sample



1. Select **Analysis** on the Left Home screen.
2. Select **Load-and-Go Analysis**.
3. Select the cup location by tapping on the corresponding cup number on the screen.
4. Select a pre-configured Sample Type from the dropdown menu or use the Default Sample Type.

NOTE: *Only Sample Types with a 1:2 or 1:6 CDV dilution ratio can be used for Load-and-Go and 96-well plate sample analysis.*

5. Select or deselect the desired modules by tapping the module buttons. A selected module will turn BLUE.
6. Configure the Cell Density Module Dilution Ratio and Inspection Type by using the dropdown menus under **CDV**.

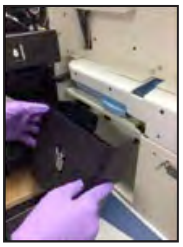


7. Enter sample information into the open fields.
8. Vessel Temperature, Vessel Pressure, Sparging O_2%, and Pre-Dilution Multiplier can be edited by selecting the appropriate field.
9. Pipet 400 µL into a sample cup and position it in the carousel.

NOTE: *Use the BioProfile FLEX2 Sample Cups (PN 58275) for Load-and-Go sampling. (Each cup should be filled to the fill line or pipette 400µL for best results.)*

10. Press **Analyze** to start analysis.

Empty the Waste Container



After each Load-and-Go carousel analysis, the used sample cup is deposited into the waste container located behind the main analyzer door. The waste container can hold up to 200 used cups and must be emptied once full.

1. Pull the tab on the left side of the analyzer to open the door.
2. Remove and empty the waste container located on the inside of the analyzer door beneath the Load-and-Go carousel.
3. Reinsert the waste container into the door and answer yes to the prompt asking "Did you empty the waste container?" to reset the cup counter.

Change a MicroSensor Card™

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

The Smart Maintenance feature will automatically detect the new MicroSensor Card and initiate the hydration sequence and the time to completion will be displayed in the top-right corner of the status bar. Upon completion of the hydration all respective module parameters should be calibrated and ready for use.

Warning: ***Users should monitor the system periodically during the hydration sequence to ensure the sequence completes successfully. A chemistry reagent and Calibrator Cartridge must be installed for either sensor card hydration to initiate.***

Change a pH/Gas Calibrator Cartridge

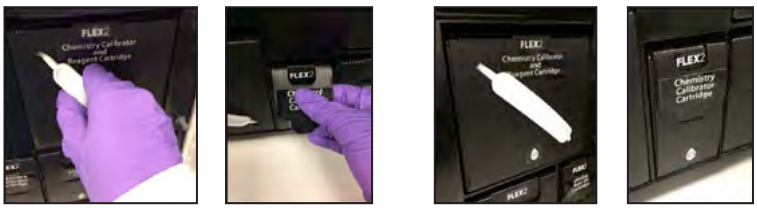
1. Pull the tab on the left side of the main analyzer door to open the door.
2. Remove the existing cartridge by pulling on the white handle on the front of the pack.
3. Replace the pH/Gas Calibrator Cartridge by positioning the new pack into the pack chamber and pushing it until the front of the pack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

The Smart Maintenance feature will automatically detect the new Calibrator Cartridge and will prime and calibrate the module. As this proceeds, the Countdown Timer icon will appear in the top right corner of the User Interface.

Change a Chemistry Calibrator Cartridge and Reagent Cartridge

The Chemistry module uses 2 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.

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



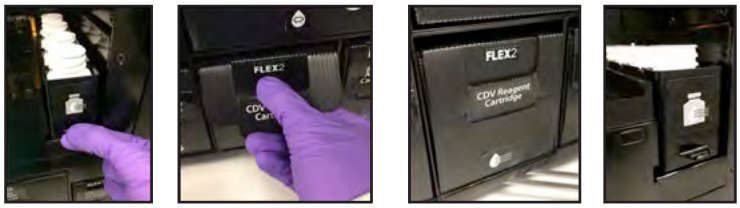
The Smart Maintenance feature will automatically detect the new Cartridge and will prime and calibrate the module. As this proceeds, the Countdown Timer icon will appear in the top right corner of the User Interface.

Change a CDV Bottle Pack and Reagent Cartridge

The CDV Module uses 2 cartridges: the Bottle Pack (small pack) and Reagent Cartridge (large pack).

These packs must be changed together. Remove bottle caps prior to installation.

1. Pull the tab on the left side of the main analyzer door to open the door.
2. Remove the existing Reagent Cartridge and Bottle Pack.
3. Replace the Reagent Cartridge and Bottle Pack by positioning each pack into the appropriate pack chamber and pushing it until the pack is flush with the analyzer chassis.
4. Close the analyzer door.



NOTE: *The Smart Maintenance feature will automatically detect and install the new cartridges, and run an Adjust Intensity sequence. As this proceeds, the Time to Completion icon will appear in the top right corner of the User Interface.*

Change Osmometer Tubes and Wiper Ring (Osm20)

NOTE: *The Osm20 requires a new wiper ring and clean, unused tubes in position 1-10 of the carousel tray in order to run a calibration of the Osmometer module.*

To change the Osmo tubes and wiper ring, select Osm in the Status Bar to open the Osmometer Module window.

1. Select **Change Wiper and Tubes** in the Osmometer Module window.
2. When the tray has moved to the home position (Position 1 at 12 O'clock), remove the tray by loosening the set screw at the center counterclockwise and gently lifting upwards until free.
3. Remove the dust cover and discard the used tubes and wiper ring, then install new tubes and a new wiper ring on the tray. Reinstall the Dust Cover and Osmometer Tray and press **Continue**. The Osmometer will align the tray and count the new tubes.

Change Osmometer Tubes (Osm48)

NOTE: *The Osm48 requires 6 clean tubes and a wash cup in order to initiate a module calibration.*

To change the tubes for the Osm48, select Osm in the Status Bar to open the Osmometer Module window.

1. Select **Change Tubes** on the Osmometer Module window. This will initiate the Change Tubes sequence and home the Osmometer Tray so it can be removed.
2. Gently remove the Osmometer Dust Cover.
3. Turn the set screw located in the center of the Osmometer Tray, counterclockwise and gently lift the screw and slide the tray straight out until free..
4. Slide the tray away from the Osmometer and lift up to completely remove it.
5. Discard the old tubes.
6. Install 49 new tubes into the slots.
7. Install the Osmometer Tray back into the Osmometer by lifting the set screw and sliding the tray forward until it will go no further. Tighten the set screw.
8. Install the Osmometer Dust Cover and ensure the magnet engages to hold it in place.
9. Select **Continue** in the Command Bar. The sequence will align the Osmometer Tray and count the newly installed tubes.

BioProfile® FLEX2 Instructions for Use Manual

Ordering Information

The *BioProfile® FLEX2 Instructions for Use Manual* can be ordered from Nova Biomedical Order Services. Write or call:

Nova Biomedical
200 Prospect Street
Waltham, MA 02454 U.S.A.

Telephone: 1-800-822-0911
FAX: 1-800-316-1178 (in the U.S.A.) or
+1-781-891-9718 (outside the U.S.A.)
Website: www.novabiomedical.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 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.

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Additional training can be found here:
http://www.brainshark.com/novabio/flex2

Table of Contents

1 INTRODUCTION

This manual provides all necessary instructions for the routine operation and upkeep of the BioProfile FLEX2 Analyzer. 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 Cartridges, pump tubing, etc) with care. Gloves and personal protective clothing are recommended.***

This section introduces the BioProfile FLEX2 Analyzer 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 Chemistry Analyzer.

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 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 Reagent Cartridges 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 analyzer. 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 analyzer complies with Part 15 of the FCC Rules: Operation is subject to the following conditions:

1. The BioProfile FLEX2 may not cause harmful interference.
2. The BioProfile FLEX2 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 should be operated indoors. Keep the working area around the system free of dirt & debris, corrosive fumes, vibration, and excessive temperature changes.

Caution: *The analyzer 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 near or on the same bench top may impact sample results.*

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

Electrical Requirements

- Operating Voltage Range: 90 – 264 VAC
- Operating Frequency: 47 – 63 Hz
- Power Consumption:
  - Without Osmometer Option: 480 Watts
  - With Osmometer Option: 590 Watts
- Fuses (2): SB 8A or T8A/250V

Ambient Operating Temperature

- 15°C to 30°C (59°F - 86°F)

Operate at Humidity

- 20 – 85% without condensation

Measurement	Without Osmometer	With Osmometer
Height	23.5 in (59.69 cm)	23.5 in (59.69 cm)
Width	16.75 in (42.55 cm)	24.75 in (62.86 cm)
Depth	25.0 in (63.50 cm)	25.0 in (63.50 cm)
Weight*	less than 125 lb (56.7 kg)	less than 145 lb (65.8 kg)

*With reagents installed

Lifting the Analyzer

1. Two people are needed to lift the analyzer.

Caution: *Never use the analyzer door(s) (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 the 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.

Note: *The analyzer should always be re-calibrated after it has been lifted or moved. This is especially important for systems that include the CDV module. 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 is intended for the quantitative determination of **pH, pO_2, pCO_2,** glutamine (**Gln**), glutamate (**Glu**), glucose (**Gluc**), lactate (**Lac**), ammonium (**NH_4^+**), sodium (**Na^+**), potassium (**K^+**), and calcium (**Ca^{++}**). With the installation of add-on modules, the BioProfile FLEX2 has the ability to measure Total Cell Density (**TCD**), Viable Cell Density (**VCD**), Cell Viability (**%**), Live Cell Diameter, and Osmolality (**Osm**).

By incorporating the Vessel Temperature, Vessel Pressure, and Sparging O_2 entered by the operator, the BioProfile FLEX2 offers 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

Modular System Design

Like the first-generation BioProfile FLEX system, the BioProfile FLEX2 analyzer was designed under modular construction methodology. This means that the desired analytical modules can be included at the time of initial purchase/installation or that the additional modules can be added as upgrades to the system at a later date. The BioProfile FLEX2 Analyzer is comprised of the following modules and test parameters:

- **Chemistry Module (a Dilute Module)**
  - Glutamine (Gln)
  - Glutamate (Glu)
  - Glucose (Gluc)
  - Lactate (Lac)
  - Ammonium (NH_4^+)
  - Sodium (Na^+)
  - Potassium (K^+)
  - Calcium (Ca^{++})
- **pH/Gas Module (a Non-Dilute Module)**
  - pH
  - pO_2
  - pCO_2
- **Cell Density & Viability Module (Optional)**
  - Total Cell Density (TCD)
  - Viable Cell Density (VCD)
  - Cell Viability
  - Live Cell Diameter
- **Osmometer Module (Optional)**
  - Osmolality by Freezing-Point Depression

1.6 The Sample

The sample materials appropriate for testing on the BioProfile FLEX2 analyzer are cell culture samples and media.

This section covers sample requirements and analytical ranges for the BioProfile FLEX2.

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 the sample is analyzed 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 Modules and Analytical Ranges

Chemistry Module

Parameter	Units	Linear Range Low End	Linear Range High End	User Selected Dilution Ratio
Gln	mmol/L	0.10 0.20 0.40	6.00 12.00 24.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Glu	mmol/L	0.10 0.20 0.40	6.00 12.00 24.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Gluc	g/L	0.10 0.20 0.40	15.00 30.00 60.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Lac	g/L	0.10 0.20 0.40	6.00 12.00 24.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
NH_4+	mmol/L	0.20 0.40 0.80	25.00 50.00 100.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Na^+	mmol/L	40.0 80.0 160.0	300.0 600.0 1200.0	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
K^+	mmol/L	1.00 2.00 4.00	100.00 200.00 400.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Ca^{++}	mmol/L	0.10 0.20 0.40	10.00 20.00 40.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4

Linear Range depends on selected dilution ratio.

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

Cell Density Module

Parameter	Units	Linear Range Low End	Linear Range High End
Total and Viable Cell Density 1:1 Dilution	1 x 10^5 Cells/mL 1 x 10^6 Cells/mL	1.00 0.10	350.00 35.00
Total and Viable Cell Density 1:2 Dilution	1 x 10^5 Cells/mL 1 x 10^6 Cells/mL	2.00 0.20	800.00 80.00
Total and Viable Cell Density 1:6 Dilution	1 x 10^5 Cells/mL 1 x 10^6 Cells/mL	6.00 0.60	1600.00 160.00
Live Cell Diameter	microns	4	70

Osmometer Module

Parameter	Units	Linear Range Low End	Linear Range High End
Osm20	mOsm/kg H_2O	0	1500
Osm48	mOsm/kg H_2O	0	2000

Note: *For the Osm20, the FLEX2 User Interface indicates an analytical range for the Osmometer up to 2000 mOsm/kg. This is the upper analytical limit (Osm20) specified by Advanced Instruments. The Osmometer can read samples higher than 1500 mOsm/kg, but the FLEX2 software only supports calibration to 1500 mOsm/kg.*

1.6.3 Alternate Units of Measure

The BioProfile FLEX2 supports the following alternate, user-selectable units of measure:

Unit	pO_2	pCO_2	Gln	Glu	Gluc	Lac	NH_4+
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.

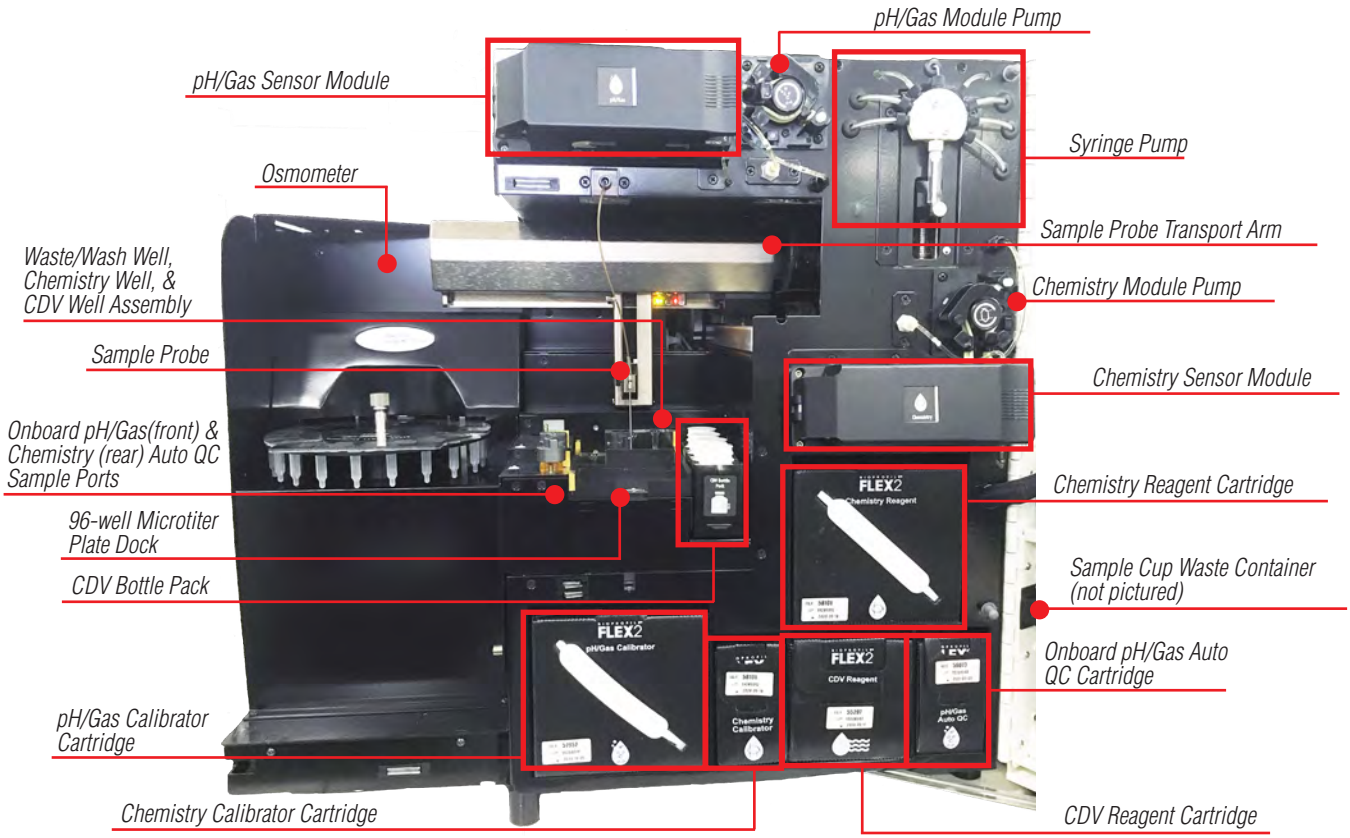
- Mannose (10 g/L) has been shown to increase Glucose concentration by approximately 0.20 g/L.
- Acetaminophen (10 mg/dL) has been shown to increase the Glucose concentration by approximately 15 mg/dL.

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.*

Warning: ***When sampling microcarrier cultures, it is critical to select a filtration method that will effectively remove the microcarrier beads from the sample prior to analysis to prevent analyzer damage. For more information, contact BioProfile Applications at BPApplications@novabio.com.***

2 GETTING STARTED

2.1 FLEX2 Analyzer Exterior



2.2 FLEX2 Analyzer Interior

2.1 Startup Procedure

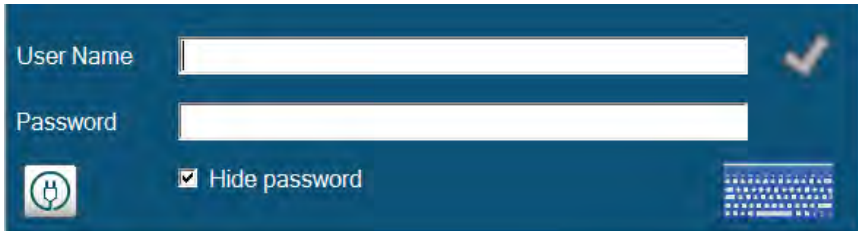
The BioProfile FLEX2 analyzer is powered on using the switch on the rear of the system. When the system is powered on, it will automatically load the required operating sequences and launch the Graphical User Interface (**GUI**) on the touchscreen display. The door will lock and the Load-and-Go sample carousel will rotate to initialize. After startup has completed successfully the analyzer will initiate calibration for the pH/gas and chemistry modules, Adjust Intensity for the CDV module, and complete Osmometer initialization as long as the necessary consumables are present.

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 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.*

2.2 Operational Overview

2.2.1 System Log-In

When the BioProfile FLEX2 analyzer is powered on, the operator is presented with the log-in window:



2.3 *User Name & Password Log-in Window*

At the time of installation, use the default administrator account (**Username:** Flex2admin **Password:** Password1) to log into the system. When logging into the Flex2admin user account for the first time, a prompt will require the password to be changed.

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 alphanumeric characters and is not case sensitive. User names can include dashes (-) and underscores (_) but no spaces or special characters (!,@,#,$,%,^,&,*,/,<). Passwords must be a minimum of 8 and a maximum of 25 alphanumeric characters and must contain at least one capital letter, one lower case letter and one number. Usernames and passwords can include dashes (-) and underscores (_) but no spaces or special characters (!,@,#,$,%,^,&,*,/,<).

Once the User Name and Password character requirements are met, the check mark to the right of the User Name box will turn green. The operator can press **Enter** on the keyboard or select 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.

Swipe Left

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

2.4 *Left Home screen*

Swiping 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.

Swiping to the right on the User Interface will display the Left Home screen again.

Swipe Right

2.5 *Right Home screen*

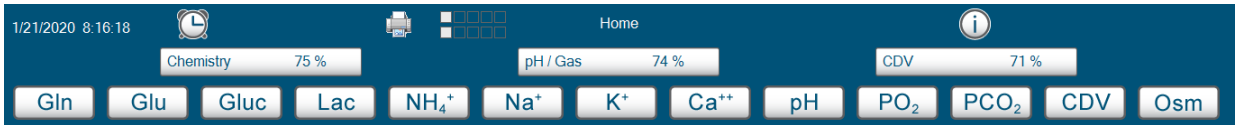
An operator can also switch between the Left and Right Home screens by selecting the left or right dot, respectively, at the bottom of the screen.

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:



2.7 *Status Bar*

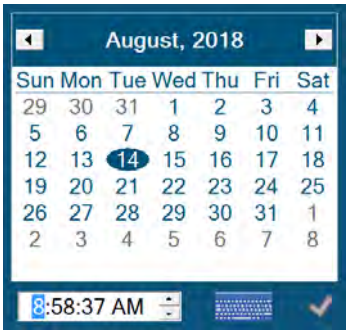
- Date & Time
- Current Screen in Display
- Next Scheduled Event Icon
- Module Status & Remaining Reagent Volume
- Parameter Status Icons
- Door Open Icon
- Analysis and Sequence Countdown Timer (when running)
- Alert Icon (if any)
- Warranty Alert Icon (if any)
- Print Icon
- Information Button
- On-line Autosampler Status Icon (if applicable)

Date & Time

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

2.8 *Date/Time*

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. (See Figures 2.8 and 2.9)



2.9 *Date/Time Change Window*

Note: *Any changes to the date/time settings will propagate to the Bridge Computer and are recorded in the Audit Log.*

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.

Select the Next Scheduled Event icon to 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.

2.10 *Next Scheduled Event Window*

Door Open Icon

Whenever the main analyzer or osmometer 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.

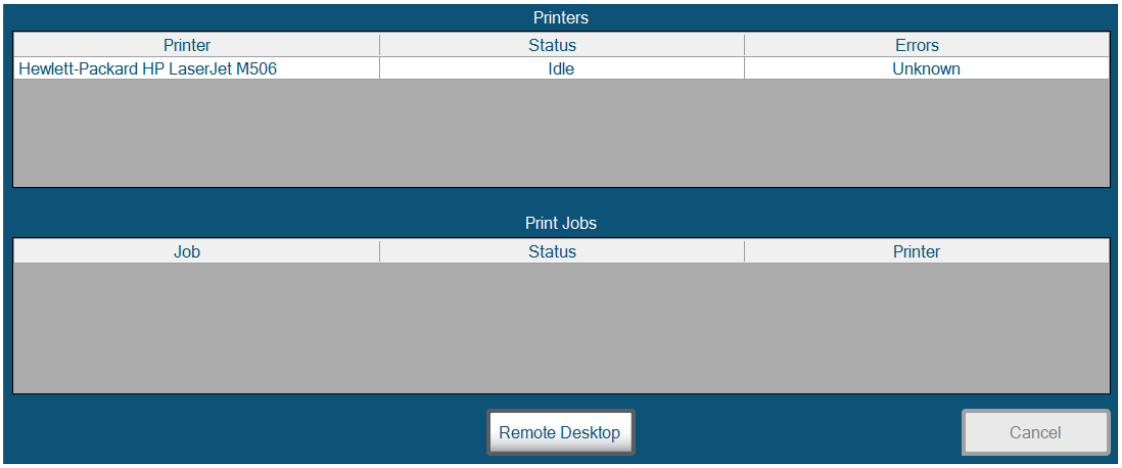
Warranty Alert Icon

If a Parameter fails to calibrate 3 consecutive times, the **Warranty Alert** icon will appear in the Status Bar and the option to claim warranty credit toward a new MicroSensor card is made available. Information about consumable warranties is found in **Section 3.3.6**.

Print Icon

The **Print** icon is always available in the Status Bar as the user navigates to various screens. Select the icon to show a list of local and/or network printers available on the Bridge PC and their print queue. The Printers window is also where administrator users can access Remote Desktop and remotely log into the Bridge computer.

NOTE: *The BioProfile FLEX2 Analyzer is not supplied with a printer. The Print icon in the Status Bar is used only to view printer and print job status. Printable .pdf reports can be created by selecting the Print button in the Command Bar on any applicable screen. These reports can be printed, exported to a USB drive or exported to the Shared Folder on the Bridge Computer.*



2.11 *Print Icon Window*

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, press the print icon and select **Remote Desktop** to login 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.*

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.

On-line Autosampler Icon

The **On-line Autosampler** icon will only be visible in the Status Bar if the analyzer is interfaced with the BioProfile FLEX2 OLS. Selecting the On-line Autosampler Icon allows operators with appropriate privilege levels to control the BioProfile FLEX2 OLS system. For information regarding the FLEX2 OLS, please refer to the BioProfile FLEX2 OLS Instructions For Use Manual.

Alert Icon

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

Select the Alert icon to open up a dialog box providing text information for the error or alert.

2.12 *Alert Icon Text Information*

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

Information Button

The Information Button is always visible in the Status Bar as users navigate the various screens. Press the Information Button then Video Help 

to display the BioProfile FLEX2 video training modules. The training video window will remain present on the screen when navigating the User Interface until the window is closed. An operator has the option to view a wide selection of training videos that cover all major aspects of analyzer operation and maintenance.

2.13 *Information Button Window*

Countdown Timer

The **Countdown Timer** appears in the upper right-hand corner of the Status Bar whenever a sequence is running.

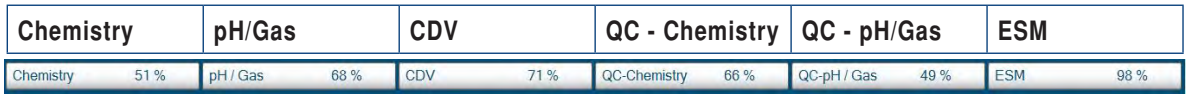
The estimated remaining time of the sequence is also shown to the right of the timer icon.

When the Countdown Timer is present, the operator can select it to view what sequence is currently running.

2.14 *Current Sequence Running Window*

Module Status & Remaining Reagent Volume Icons

The middle of the Status Bar displays icons for each of the installed modules that indicate 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 are as follows:



2.15 *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 color (yellow text) alerting the operator that the Reagent Cartridge will need to be replaced soon.

NOTE: *The remaining volume percentage will display <10% until the cartridge is empty.*

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 Cartridgeaging.

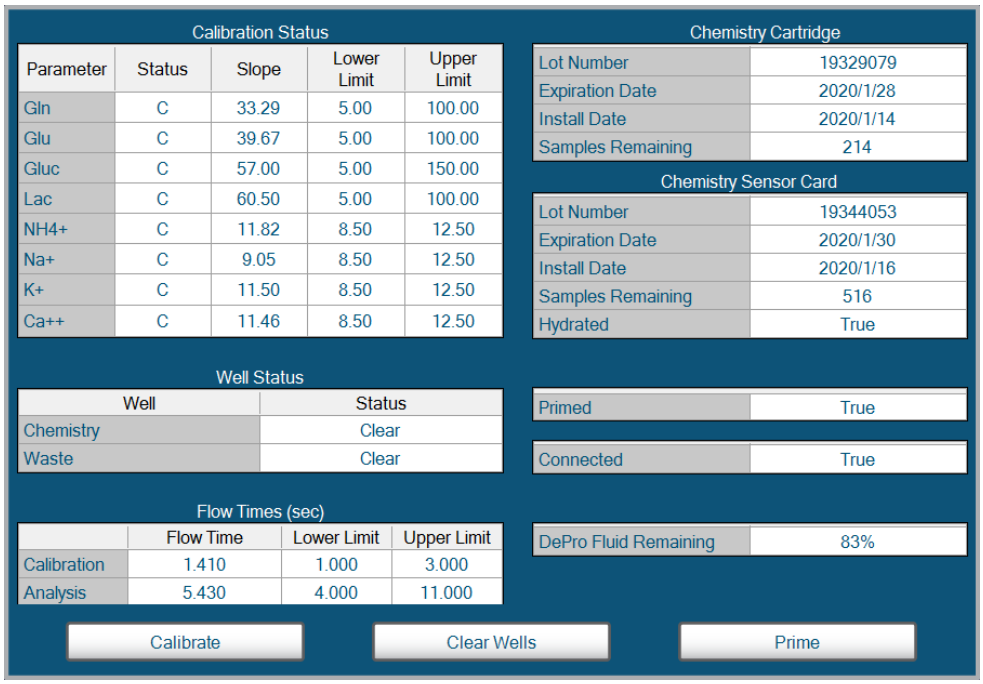
NOTE: *Once the Reagent Cartridge is within 1 day (24 hours) of expiring, the status icon text will change color (yellow text) alerting the operator that the Reagent Cartridge will need to be replaced soon.*

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 respective module.

Chemistry Module

Select any **Chemistry Module** parameter or Reagent Cartridge indicator to display the Chemistry Module Status window.



2.16 *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.

Chemistry Sensor Card

Provides all of the information for the currently installed Chemistry Module Sensor 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**).

Flow Times (sec)

Provides the flow times in seconds for the Chemistry Module calibration and the last Chemistry Module analysis. The flow time lower and upper limits are also displayed.

Depro Fluid Remaining

Displays the estimated percent of Depro cleaning solution remaining in the chemistry cartridge. When this percentage reaches zero, Depro and Depro Wells sequences will no longer execute, but the pack will not be marked as empty as long as there are samples remaining in the chemistry cartridge.

Well Status

Shows the current status (**Blocked** or **Clear**) of the Waste Well and Chemistry Well. These wells must be clear in order for the module to be available for sampling. If the well status indicates that the Waste Well and/or Chemistry Well is blocked, additional troubleshooting is required.

Chemistry Cartridge

Provides all of the information for the currently installed Chemistry module Reagent Cartridges including the Lot Number, Expiration Date, Installation Date of the cartridges, and the number of sample tests remaining.

Connected Status

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**.

Primed Status

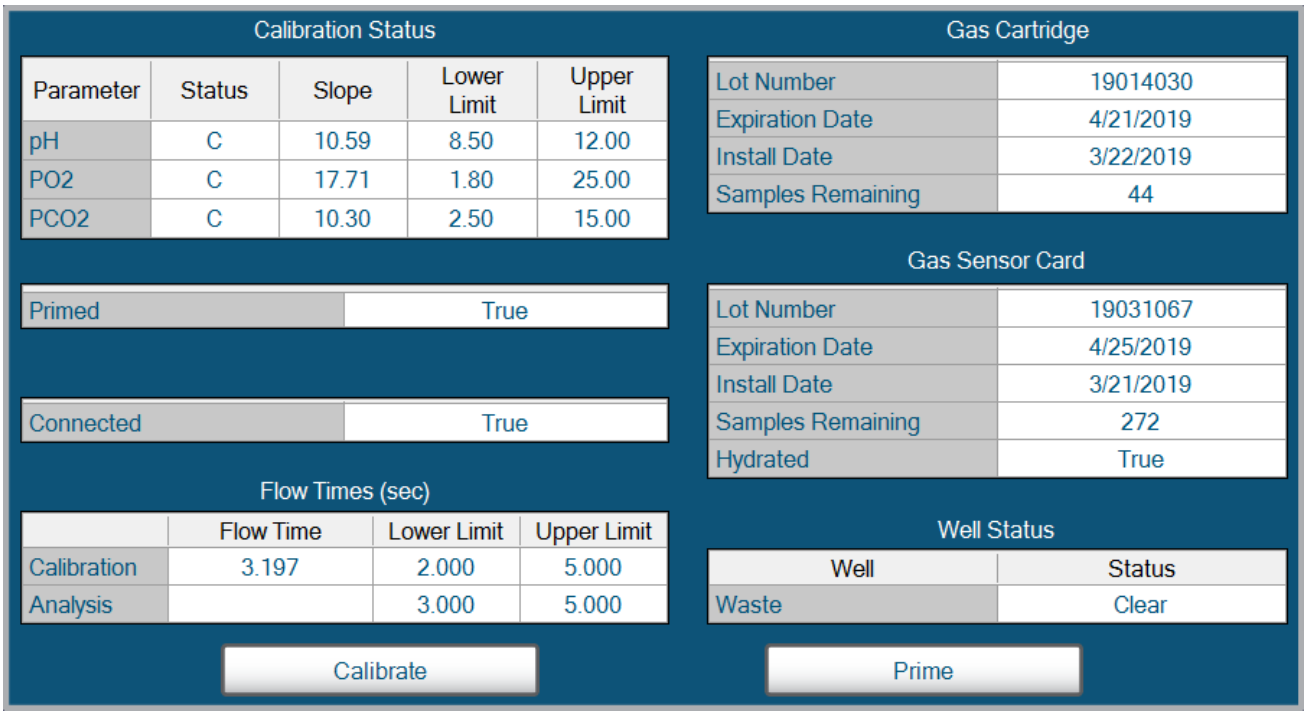
Indicates if the module is primed with the required reagent. The module must be primed to be available for sampling. If the module is primed, the prime status will read **True**. If the module is not primed, the status will read **False**.

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

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

pH/Gas Module

Select any **pH/Gas Module** parameter or Reagent Cartridge indicator to display the pH/Gas Module Status Window.



2.17 *pH/Gas Module Status Window*

Parameter 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.

Connected Status

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**.

Flow Times (sec)

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.

Primed Status

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**.

Well Status

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.

pH/Gas Cartridge

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

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**).

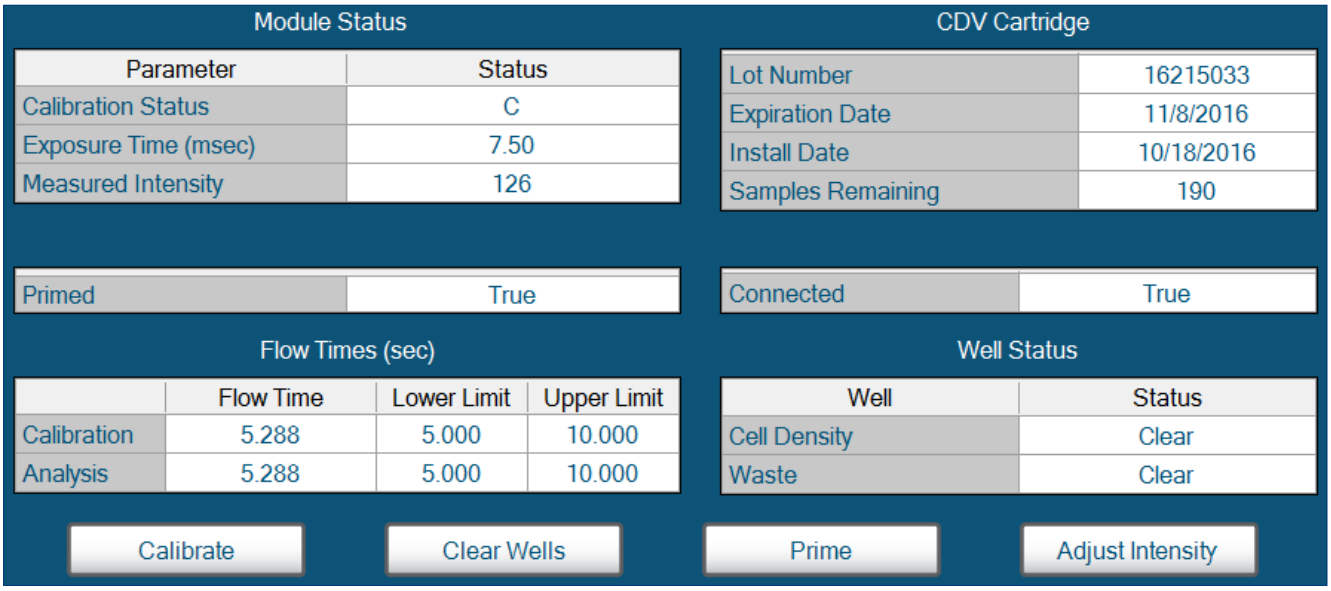
From within the pH/Gas Module Status window, an operator with the applicable privileges can:

Calibrate — Calibrate the pH/Gas Module

Prime — Prime the pH/Gas module

CDV Module

Select the **CDV Module** parameter or Reagent Cartridge indicator to display the CDV Module Status Window.



2.18 *CDV Module Status Window*

Calibration Status

Shows the calibration status (**C** = Calibrated, **UC** = Uncalibrated) of the CDV Module. This section also provides the Exposure Time (msec) of the CDV imaging camera, and the measured background intensity for the most recent CDV Module calibration.

Connected Status

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**.

Flow Times (sec)

Provides the flow times in seconds for the CDV Module calibration and the last CDV Module analysis. The flow time lower and upper limits are also displayed.

Primed Status

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**.

Well Status

Shows the current status (**Blocked** or **Clear**) of the Waste Well and CDV Well. These wells must be clear in order for the module to be available for sampling. If the well status indicates that the Waste Well and/or CDV Well is blocked, additional troubleshooting is required.

CDV Cartridge

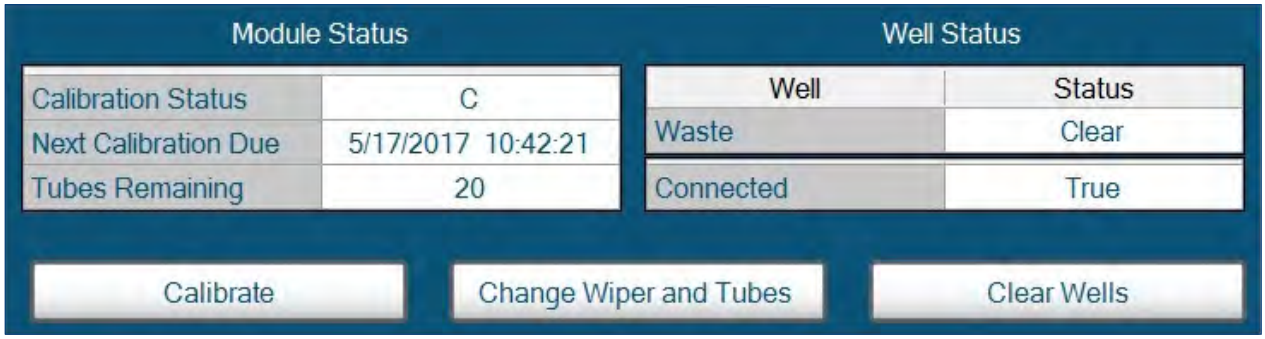
Provides all of the information for the currently installed CDV module Reagent Cartridges including the Lot Number, Expiration Date, the Installation date of the cartridges, and the number of samples remaining.

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

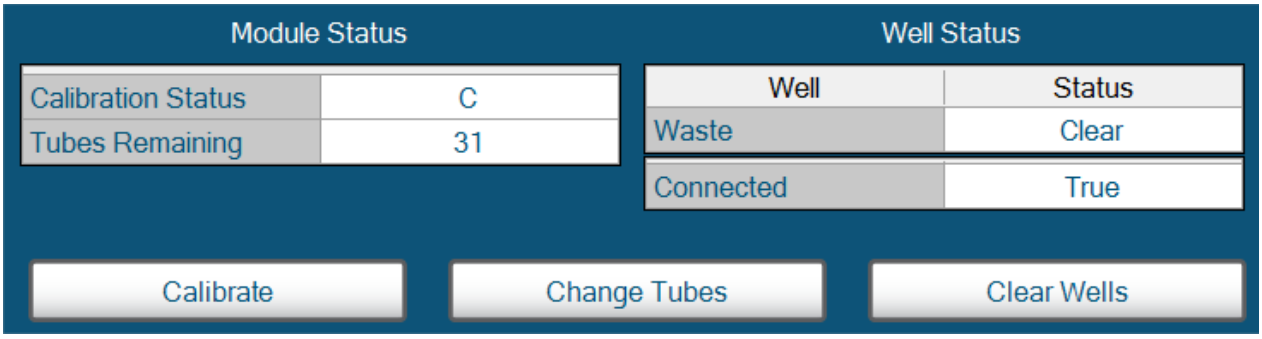
Calibrate	Calibrate the CDV Module
Clear Wells	Run a Clear Wells sequence
Prime	Prime the CDV Module
Adjust Intensity	Run an Adjust Intensity sequence

Osmo Module

Select the **Osmo Module** parameter indicator to display the Osmometer Module Status Window.



2.19 *Osm20 Module Status Window*



2.20 *Osm48 Module Status Window*

Module Status

Shows the calibration status (**C** = Calibrated, **UC** = Uncalibrated or **QC**= QC Locked Out) of the Osmometer Module. This section also provides the date and time for when the next Osmometer calibration will be due (Osm20 only) and the number of tubes remaining on the Osmometer carousel tray.

Well Status

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.

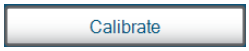
Connected Status

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**.

Next Calibration Due (Osm20 Only):

The date and time when the Osm20 module will require calibration is displayed.

From the Osmometer Module status window, an operator with the appropriate privileges can also:



Perform an Osmometer calibration.

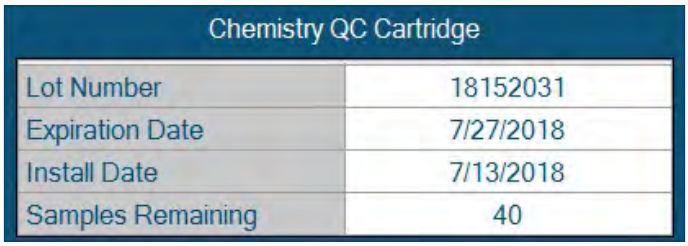
Osm48 Change Tubes

Osm20 Change Tubes and Wiper

Perform a Clear Wells sequence.

Chemistry QC

Select the **Chemistry QC** Reagent Cartridge indicator from the Status Bar to open the Chemistry QC Cartridge Status Window.



2.21 Chemistry QC Cartridge Status Window

Expiration Date:

The date the QC cartridge expires. This is the post-install expiration. The shelf life expiration can be found on the cartridge or on the cartridge packaging.

Lot Number:

The lot number of the onboard Chemistry QC cartridge.

Samples Remaining:

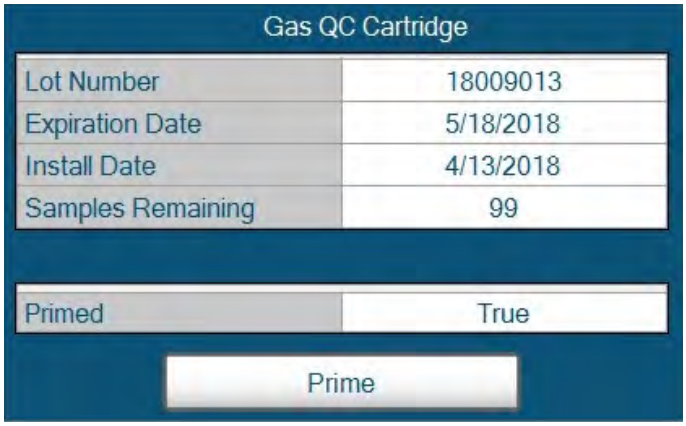
The number of samples remaining based on the amount of Chemistry QC remaining in the installed cartridge.

Install Date:

The date the QC cartridge was installed on the analyzer.

pH/Gas QC

Select the **pH/Gas QC** Reagent Cartridge indicator in the Status Bar to display the pH/Gas QC Cartridge Status Window.



2.22 pH/Gas QC Cartridge Status Window

Primed Status:

The pH/Gas QC cartridge must remain primed for sampling. If the cartridge is primed the primed status will read **True**. If the cartridge is not primed the primed status will read **False**.

Expiration Date:

The date the QC cartridge expires. This is the post-install expiration. The shelf life expiration can be found on the cartridge or on the cartridge packaging.

Lot Number:

The lot number of the onboard pH/Gas QC cartridge.

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 QC cartridge was installed on the analyzer.

From within the pH/Gas QC Cartridge window, an operator with applicable privileges can:

Prime — Prime the pH/Gas QC cartridge.

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 as shown here.

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

A parameter may be in alert for the following reasons:

- For the pH/Gas, Chemistry and CDV Modules, the parameter icons will turn yellow when the Reagent Cartridge or MicroSensor card has ≤10% samples or volume remaining, or is within 24 hours of expiring. When applicable, the Reagent Cartridge status text will also change to yellow within these criteria.
- For the Osmometer module, the Osm parameter icon will turn yellow within 3 days of the osmometer calibration expiring (Osm20 only). Fewer than 3 unused osmometer tubes remaining will also trigger the icon warning.
- 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 specific action(s) required to resolve the alert.

When a parameter is not ready and is unavailable for sampling, the parameter icon will have a red background as 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 0 samples remaining, is not hydrated, 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.
- In the case of the Osmometer, the Osmo status icon will turn red when there are no longer any available tubes remaining on the Osmo tray for sampling.
- The warranty has been claimed for the parameter or MicroSensor card.

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

2.2.4 Destinations Icon

The **Destinations** icon is located at the bottom left-hand corner of the User Interface. It is always visible in the Command Bar as an operator navigates throughout the various menus of the User Interface.

When selected, a subset of the other available User Interface screens is displayed. To navigate, select the desired screen:

- Home screen
- Historical Results Screen
- CDV Images Screen (if applicable)
- Individual Sample Result Screen (if applicable)
- Analysis Screen

2.23 *Destinations Icon Selected*

2.2.5 Analysis Menus

Select **Analysis** (Left Home screen) to open the Analysis screen. From this screen an operator can program and execute Manual, Load-and-Go, and 96-Well Plate sample analysis.

2.24 *Manual Sample Analysis Screen*

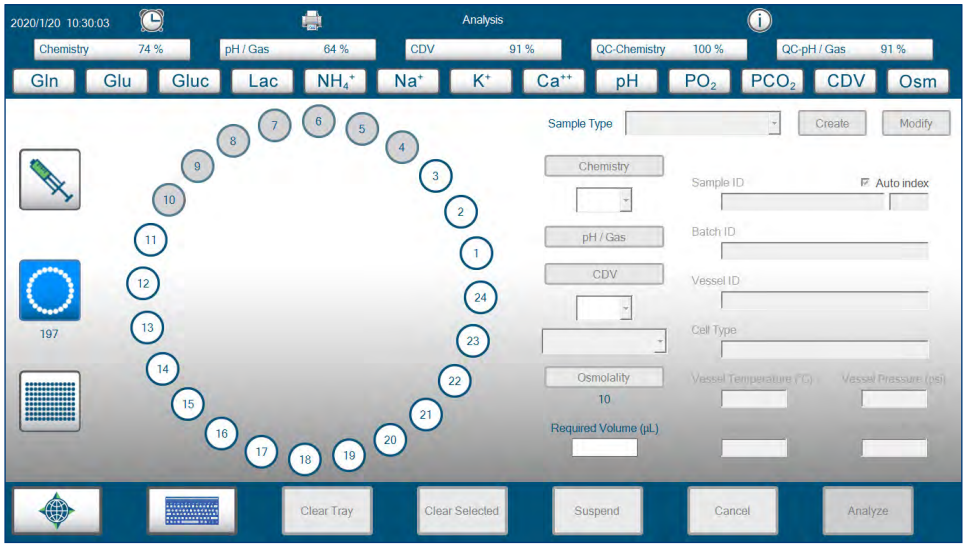
The operator can choose between the 3 main sampling options by selecting the desired sampling icon to the left of the screen.

 Manual Sampling Icon

 Load-and-Go Sampling Icon

 Microtiter Tray Sampling Icon

If an operator selects **Load-and-Go Sampling**, the Load-and-Go sample analysis screen is displayed.



2.25 *Load-and-Go Sample Analysis Screen*

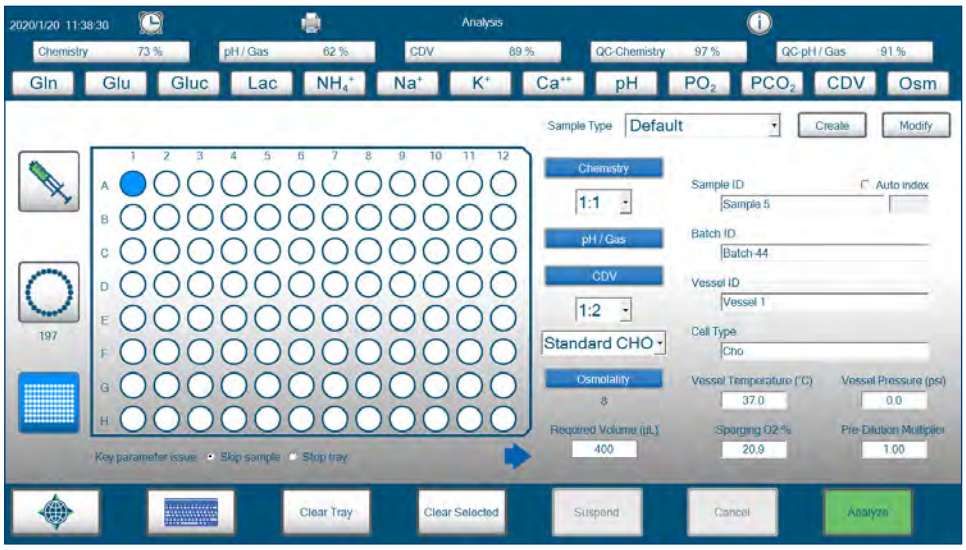
From this screen, the operator can program Load-and-Go sampling using the 24-position continuous loading carousel.

The number below the **Load-and-Go** icon indicates the number of samples that can be run before the Load-and-Go waste container will need to be emptied. The waste container can hold up to 200 used sample cups. When the number of samples remaining reaches 20, the text for the number of samples that can be run will change to yellow as an alert. When the number of remaining samples reaches 0, the text changes to red and the waste container must be emptied.

If the waste container is not present, an X will appear under the **Load-and-Go** icon.

NOTE: *Load-and-Go samples cannot be analyzed until the waste container is returned to its position.*

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



2.26 *Microtiter Plate Sample Analysis Screen*

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 configure all applicable tests.

NOTE: *For analyzer configurations that include the optional ESM module or FLEX2 On-line Autosampler, 96-well plate analysis will not be available due to the 96-well plate sampling area being occupied by the ESM or Autosampler sampling septum.*

2.2.6 Historical Results Menu

Select **Historical Results** (Left Home screen) to open 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 historical results and sample data are stored permanently in the BioProfile FLEX2 database. Original (raw) sample result data cannot be altered, changed, or deleted.

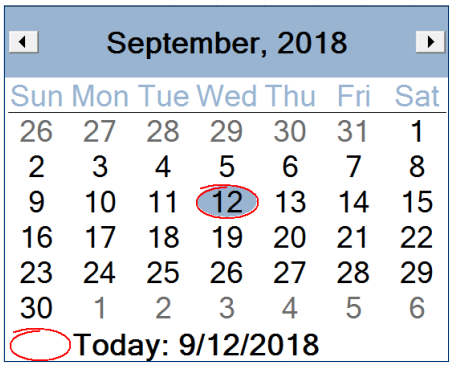
To view historical data that is not visible in the Historical Results Screen, an operator can select **Set Dates** in the Command Bar. Select **Set Dates** to open the Set Dates menu.

2.27 Set Dates Menu

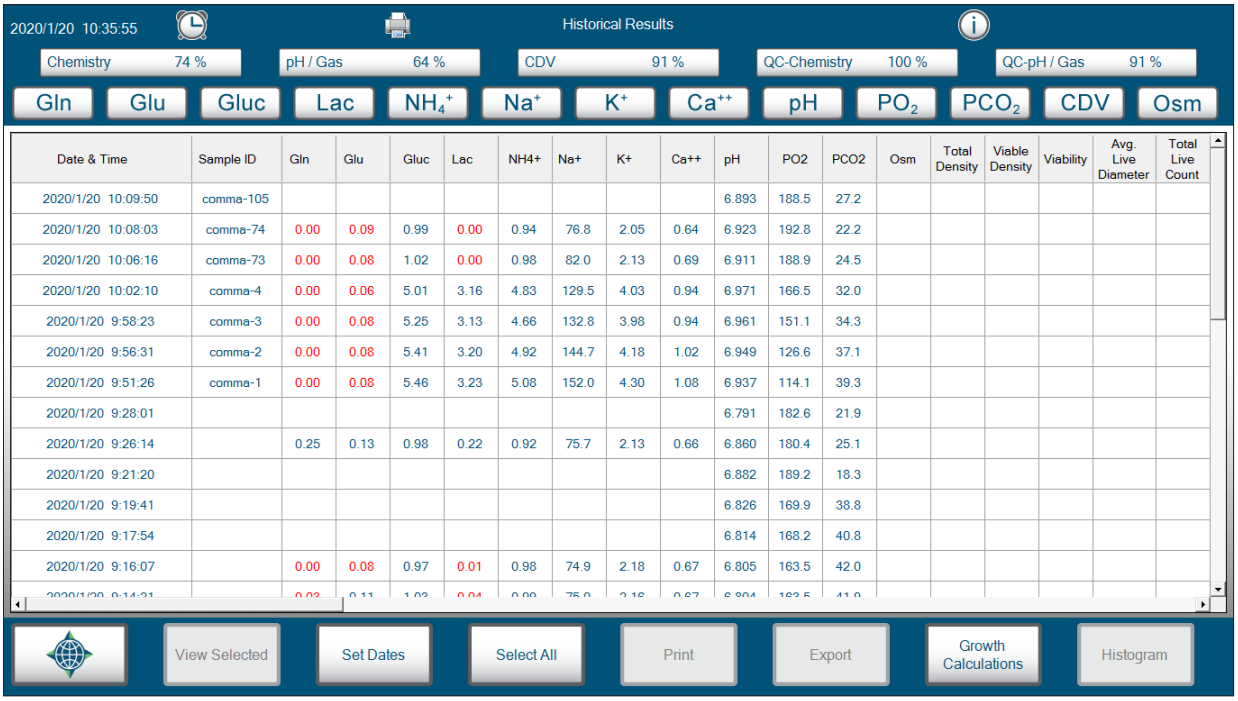
With the Set Dates menu open, the operator can select the dropdown for the From or To boxes to open the calendar selection screens.

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. Select the check mark to populate the historical results for the time period selected by the operator. Select the red X to close the window.



2.28 Date Selection Calendar



Date & Time	Sample ID	Gln	Glu	Gluc	Lac	NH4+	Na+	K+	Ca++	pH	PO2	PCO2	Osm	Total Density	Viable Density	Viability	Avg. Live Diameter	Total Live Count
2020/1/20 10:09:50	comma-105									6.893	188.5	27.2						
2020/1/20 10:08:03	comma-74	0.00	0.09	0.99	0.00	0.94	76.8	2.05	0.64	6.923	192.8	22.2						
2020/1/20 10:06:16	comma-73	0.00	0.08	1.02	0.00	0.98	82.0	2.13	0.69	6.911	188.9	24.5						
2020/1/20 10:02:10	comma-4	0.00	0.06	5.01	3.16	4.83	129.5	4.03	0.94	6.971	166.5	32.0						
2020/1/20 9:58:23	comma-3	0.00	0.08	5.25	3.13	4.66	132.8	3.98	0.94	6.961	151.1	34.3						
2020/1/20 9:56:31	comma-2	0.00	0.08	5.41	3.20	4.92	144.7	4.18	1.02	6.949	126.6	37.1						
2020/1/20 9:51:26	comma-1	0.00	0.08	5.46	3.23	5.08	152.0	4.30	1.08	6.937	114.1	39.3						
2020/1/20 9:28:01										6.791	182.6	21.9						
2020/1/20 9:26:14		0.25	0.13	0.98	0.22	0.92	75.7	2.13	0.66	6.860	180.4	25.1						
2020/1/20 9:21:20										6.882	189.2	18.3						
2020/1/20 9:19:41										6.826	169.9	38.8						
2020/1/20 9:17:54										6.814	168.2	40.8						
2020/1/20 9:16:07		0.00	0.08	0.97	0.01	0.98	74.9	2.18	0.67	6.805	163.5	42.0						

2.29 Historical Results Recall Screen

The following information is provided in the Historical Results screen:

- **Cell Density Module Data:**
  - Total Cell Density (**TCD**)
  - Viable Cell Density (**VCD**)
  - Cell Viability (**%**)
  - Average Live Cell Diameter (**µm**)
  - Live Cell Standard Deviation (**µm**)
  - Total Live Cell Count
  - Total Cell Count
- **pH/Gas Module Parameter Data:**
  - pH
  - pO_2
  - pCO_2
- **Chemistry Module Parameter Data:**
  - Gln
  - Glu
  - Gluc
  - Lac
  - NH_4^+
  - Na^+
  - K^+
  - Ca^{++}
- **Calculated Values:**
  - pH at Corrected Temperature
  - pO_2 at Corrected Temperature (**mmHg**)
  - pCO_2 at Corrected Temperature (**mmHg**)
  - O_2 Saturation (**%**)
  - CO_2 Saturation (**%**)
  - HCO^-_3 Concentration (**mmol/L**)
- **Osmometer Module Data:**
  - Osmolality (**Osm**)
- Sample ID
- Sample Type
- Sample Analysis Date & Time
- Original Sample Analysis Time
- Sample Tray Location
- Sample Time In Tray
- Vessel ID
- Vessel Temperature (**Default: 37°C**)
- Vessel Pressure (**Default: 0.0 psi**)
- Cell Type
- Cell Density Dilution Ratio
- Cell Density Analysis Flow Time
- Cell Inspection Type used for analysis
- Chemistry Module Dilution Ratio
- Chemistry Analysis Flow Time
- Operator
- Batch ID
- RSM (For autosampler only)
- pH/Gas Analysis Flow Time
- Valid Images
- Sparging O_2% **(Default: 20.9)**
- Pre-Dilution Multiplier applied to CDV results

NOTE: *The Sample Tray Location field will have details regarding how the sample was acquired by the analyzer. An integer will be displayed if the sample was acquired via the carousel. An alphanumeric value (A1, A2, A3...) will be displayed if the sample was acquired via a 96-well plate. This field will appear blank if the sample was acquired via the manual syringe.*

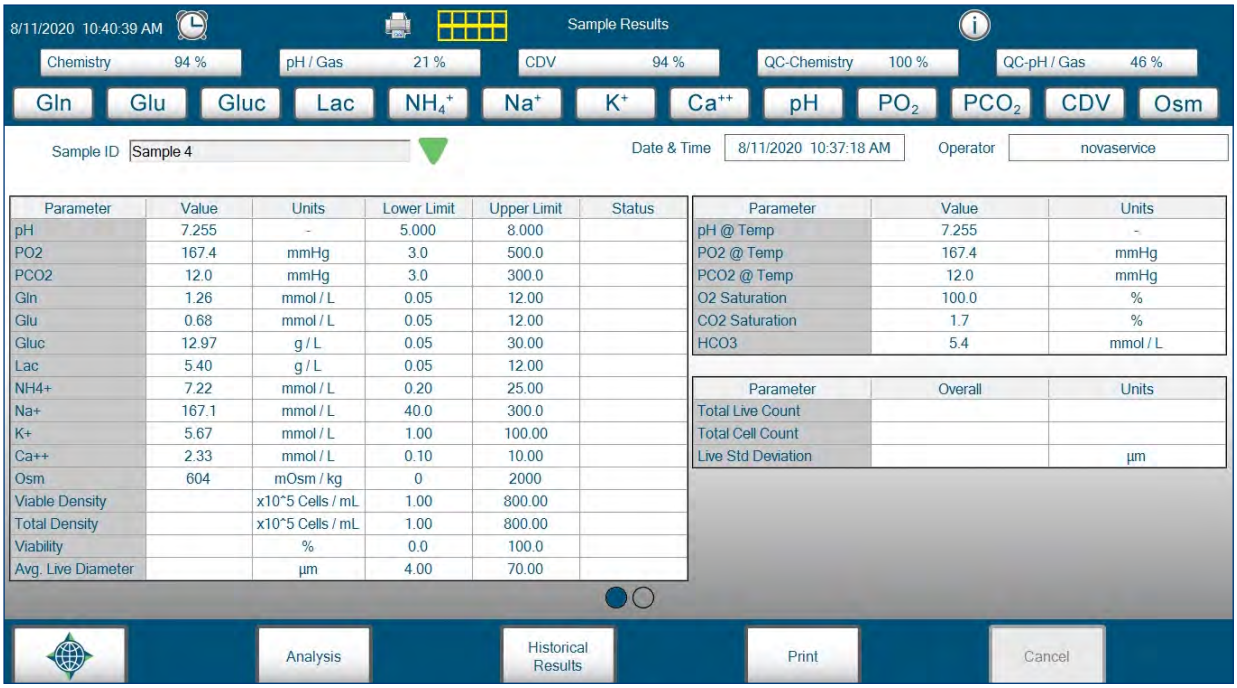
From within the Historical Results screen an operator can export sample result data to the internal Bridge Computer. An operator can also create, print and export **.pdf** reports for selected sample results.

Sorting Data and Viewing Individual Results

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 row 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 press **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 to highlight the row in blue. Once the row is highlighted, the operator can double tap the selected row or press **View Selected** in the Command Bar to open the individual sample result data in full-screen format as seen in Figure 2.30.



Parameter	Value	Units	Lower Limit	Upper Limit	Status
pH	7.255	-	5.000	8.000	
PO2	167.4	mmHg	3.0	500.0	
PCO2	12.0	mmHg	3.0	300.0	
Gln	1.26	mmol / L	0.05	12.00	
Glu	0.68	mmol / L	0.05	12.00	
Gluc	12.97	g / L	0.05	30.00	
Lac	5.40	g / L	0.05	12.00	
NH4+	7.22	mmol / L	0.20	25.00	
Na+	167.1	mmol / L	40.0	300.0	
K+	5.67	mmol / L	1.00	100.00	
Ca++	2.33	mmol / L	0.10	10.00	
Osm	604	mOsm / kg	0	2000	
Viable Density		x10^5 Cells / mL	1.00	800.00	
Total Density		x10^5 Cells / mL	1.00	800.00	
Viability		%	0.0	100.0	
Avg. Live Diameter		µm	4.00	70.00	

Parameter	Value	Units
pH @ Temp	7.255	-
PO2 @ Temp	167.4	mmHg
PCO2 @ Temp	12.0	mmHg
O2 Saturation	100.0	%
CO2 Saturation	1.7	%
HCO3	5.4	mmol / L

Parameter	Overall	Units
Total Live Count		
Total Cell Count		
Live Std Deviation		µm

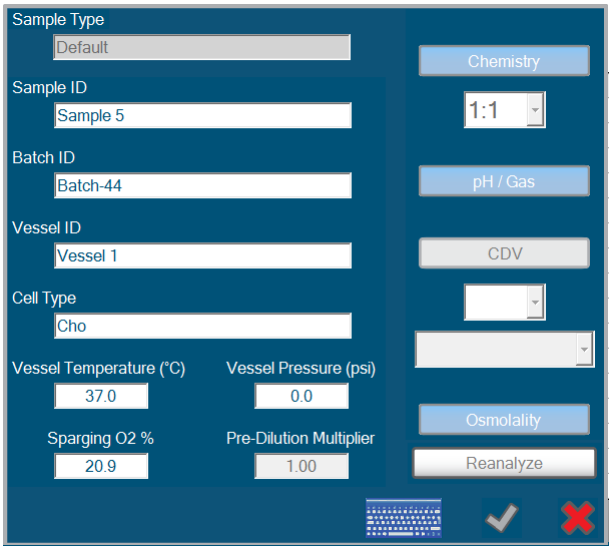
2.30 *Sample Result Screen*

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

Select the green upside-down triangle next to the Sample ID on the Sample Results screen box to open the sample information and configuration menu for the sample being viewed.

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

- Sample ID
- Batch ID
- Vessel ID
- Cell Type
- Vessel Temperature
- Vessel Pressure
- Sparging O_2%
- Pre-Dilution Multiplier
- Cell Inspection Type (if applicable)



2.31 *Sample Information/Configuration Window*

Reanalyzing Sample Results

When a sample result is edited or reanalyzed, a new sample entry is generated in the Historical Results with a new date and timestamp and new information and/or data depending on the sample information changes that were made. The new sample result maintains the original sample record's date and timestamp in the Sample Time column for traceability. Any edits made will also be captured in the Audit Log.

If CDV results were reported for the sample within the last 30 days, an operator can reanalyze the CDV sample images by selecting a different Cell Inspection Type in the sample information and configuration window. To make these changes take effect, the operator must select **Reanalyze** in the lower right-hand corner of the window. To cancel any changes or to close the sample information window, the operator can select the red X in the bottom right-hand corner.

Viewing Cell Density/Cell Viability Images

If a sample was analyzed using the CDV module, an operator can view the captured CDV images from within the individual sample result screen. With a sample result open in full-screen format, swiping to the left on the touch screen or tapping the right dot at the bottom of the screen will display all of the sample images captured (1 – 50) in small-tile format.

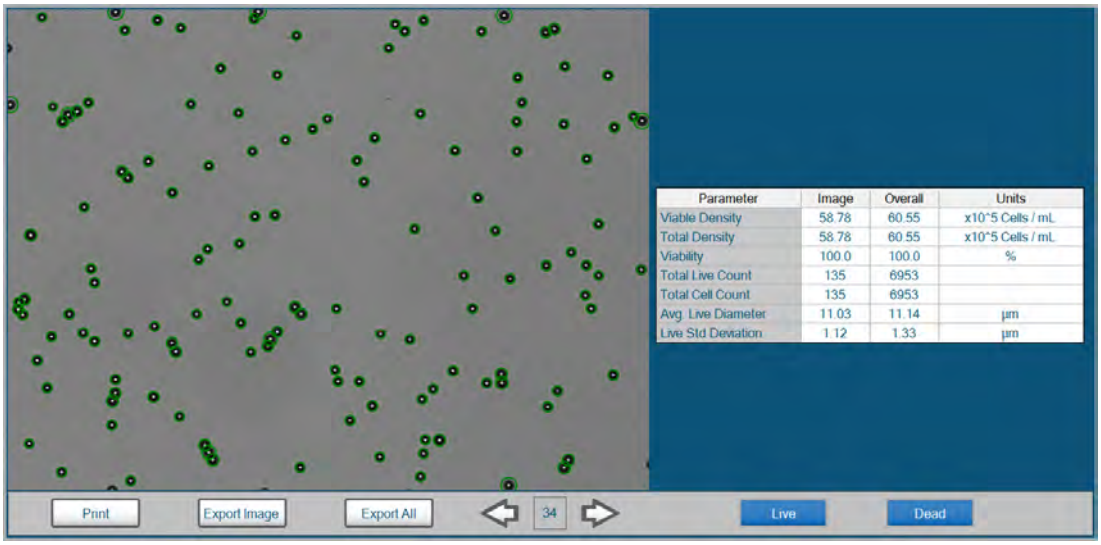
2.32 *CDV Images Screen*

All of the CDV images populated may not fit in the field of view. A slide bar at the bottom of the image tiles allows the operator to slide left and right to see all of the images populated. Select **Live** or **Dead** below the image tiles to turn on the Live and Dead cell indicators:

- Live cells will be marked with GREEN (o) circles.
- Dead cells will be marked with a RED X.
- Clumps of dead cells will be indicated with ORANGE numbers; the number provided indicates the number of dead cells counted in the clump.

Selecting any image tile will display an expanded view of that image along with the CDV data for the individual image and the sample as a whole.

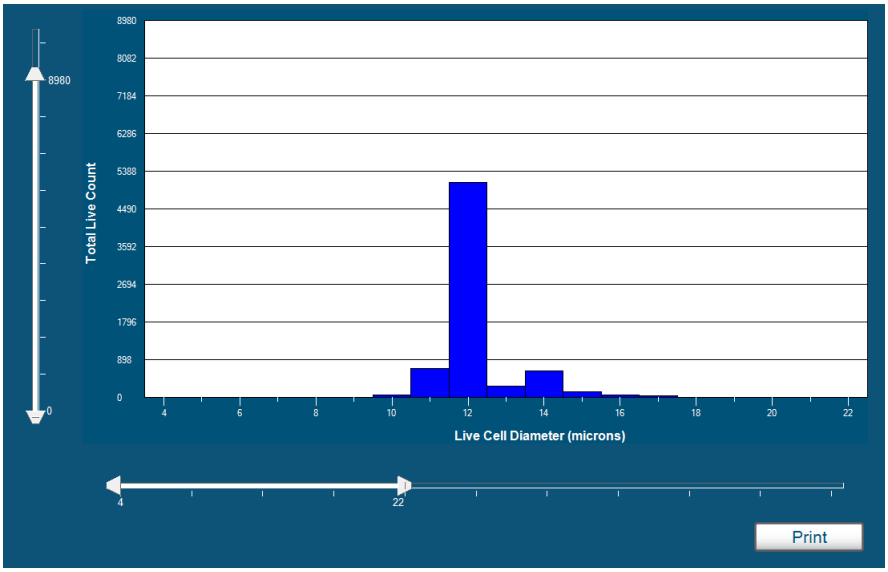
Select **Live** and **Dead** in the Command bar to turn on the Live and Dead cell indicators for the image frames. Select the **right** and **left** arrows at the center of the Command bar to scroll through each of the reported image frames. The image can be printed by selecting **Print**. An operator can export the individual image or export all images by selecting **Export Image** or **Export All**.



2.33 *Expanded CDV Image View*

By selecting **Histogram**, a histogram of the Live Cell Diameter for the selected sample is created. The 2 graph axes can be adjusted by clicking and dragging the arrow to the desired range. Histogram data can only be viewed for a single result at a time.

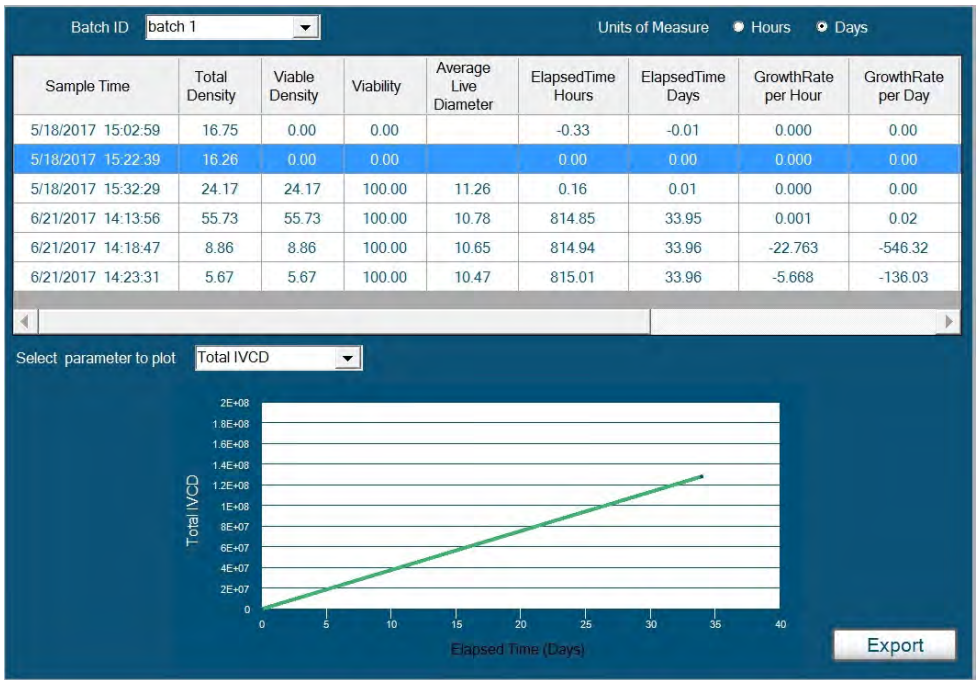
To print the histogram, the User can select **Print** in the bottom right corner.



2.34 *CDV Sample Histogram*

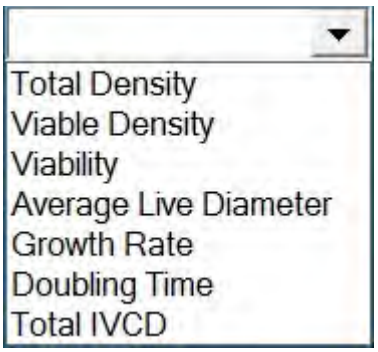
In addition to the Histogram, the BioProfile FLEX2 can also display growth calculations for a range of samples configured with the same Batch ID. By highlighting a sample from the Historical Results screen, the **Growth Calculations** button becomes available for selection.

Select **Growth Calculations** to show the growth calculations window. The end user may filter by Batch ID using the dropdown menu in the upper left corner of the window.



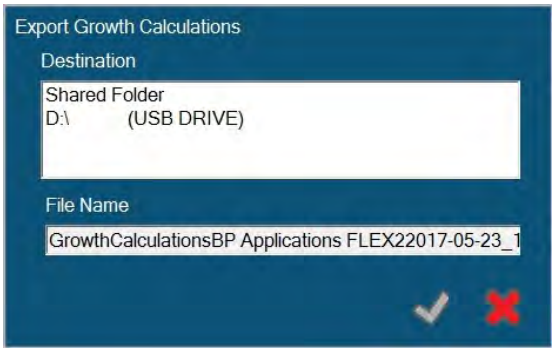
2.35 *Growth Calculation Window*

Selecting the parameter of interest from the lower dropdown menu will change the dependent variable plotted on the growth calculation graph.



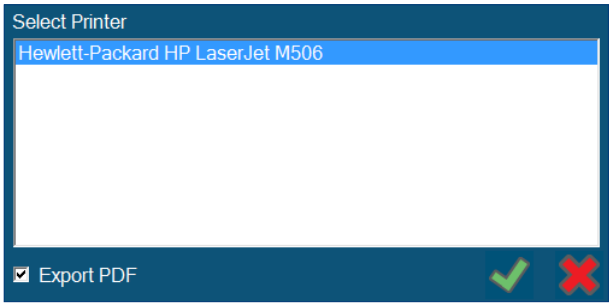
2.36 *Growth Calculation Plot Selection*

Growth Calculations can be exported by highlighting the sample entries of interest and selecting **Export** (bottom right corner). This will export a .csv file with the sample results and growth calculation parameters to the Bridge Computer Shared Folder or a USB drive.



2.37 *Export Growth Calculations Window*

Exporting and Printing Historical Results



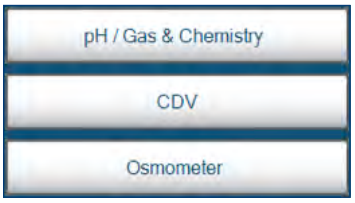
2.38 Printer Selection and Export Location Windows

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

To print, begin by selecting **Print** in the Command Bar of the Sample Result screen, Historical Results Screen, or QC Results screen. A window will appear showing a list of printers available on the Bridge PC. Select the desired printer, then the green check mark to send a job to the printer. Similarly, if the **Export PDF** box is selected within the **Select Printer** window, an additional window will appear with a list of export destinations after selecting the green check mark. If both a printer and the Export PDF box are selected, both actions will occur.

2.2.7 CALIBRATION MENU

Select **Calibration** (Left Home screen) to display the calibration options for each available module.



2.39 Module Calibration Menu

Select **pH/Gas & Chemistry** to initiate calibration of the pH/Gas & Chemistry modules simultaneously.

NOTE: *The pH/Gas & Chemistry modules will calibrate automatically every 2 hours. Additionally, the pH/Gas & Chemistry modules will calibrate automatically whenever certain maintenance is performed, e.g., whenever the Reagent Cartridges or MicroSensor Cards are installed.*

Selecting **CDV** will initiate the Cell Density module calibration.

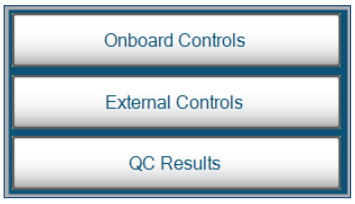
NOTE: *Calibration of the Cell Density module requires the use of the external ampuled Cell Density Module Calibration Solution (PN 43034). See **Section 3.3.7** for instructions on calibrating the Cell Density Module.*

Selecting **Osmometer** will initiate the Osmometer module calibration.

NOTE: *Calibration of the Osm20 or Osm48 requires the use of the external ampuled calibration standards. See **Section 3.3.8** for instructions on calibrating the Osmometer Module.*

2.2.8 QC MENU

Select **QC** (Left Home screen) to view QC sample results or execute onboard and external QC analysis.

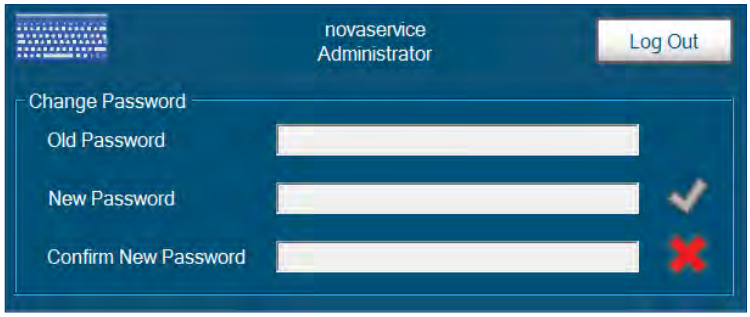


2.40 QC Menu

NOTE: *More details about QC are discussed in **Section 3.4**.*

2.2.9 USER MENU

Select **User** (Left Home screen) to display the User Menu.



2.41 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

1. The operator must enter their **Old Password** in the space provided.
2. Next, they must enter a **New Password** in the space provided.

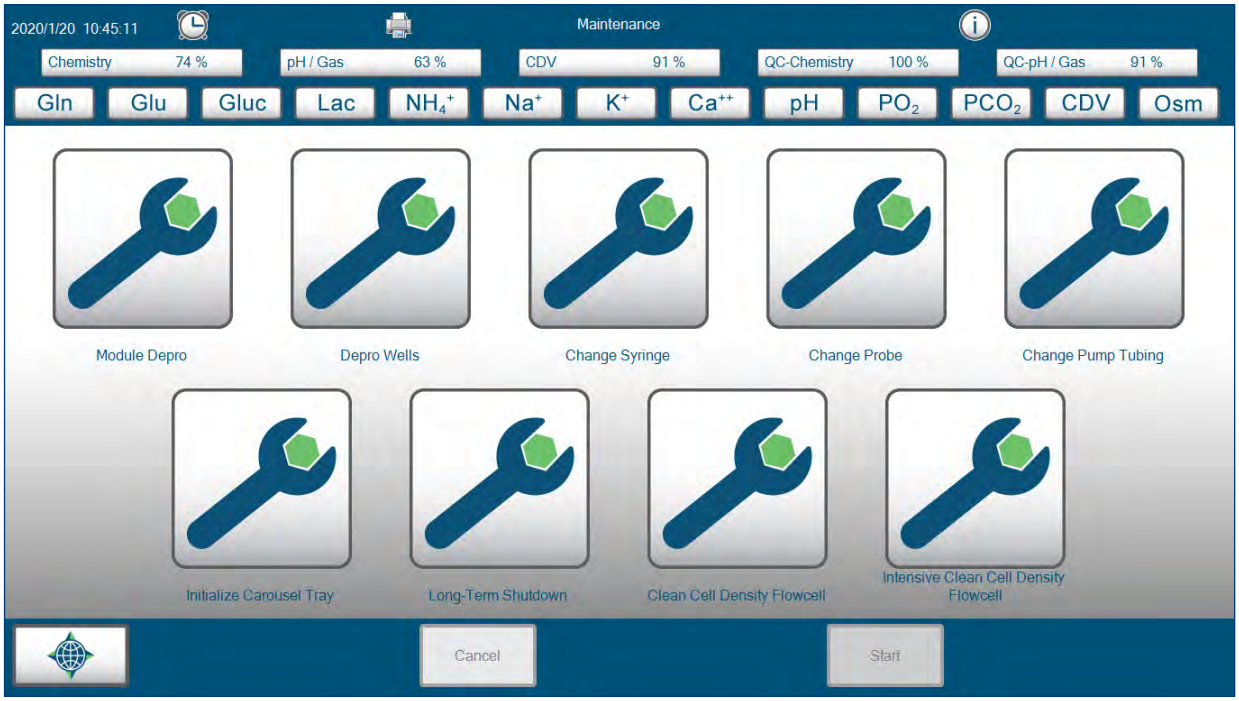
Note: *Passwords must be a minimum of 8 alphanumeric characters and must contain at least one capital letter, one lower case letter, and one number. Refer to **Section 2.2.1** for password requirements.*

3. 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.

2.2.10 Maintenance Menu

Select **Maintenance** (Left Home screen) to display the Maintenance screen.



2.42 *Maintenance Screen*

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
- Initialize Carousel Tray
- Long-Term Shutdown
- Clean Cell Density Flowcell
- Intensive Clean Cell Density Flowcell

Note: *See **Section 4** for additional information on performing these maintenance steps.*

If you have an ESM or OLS system added to your FLEX2 device configuration, you will have an additional option displayed at the bottom of the Maintenance Menu. This option will bring you to a sub-menu in which you will have additional options to perform maintenance on the ESM or OLS system respectively.

2.43 *Maintenance Menu for FLEX2 + ESM*

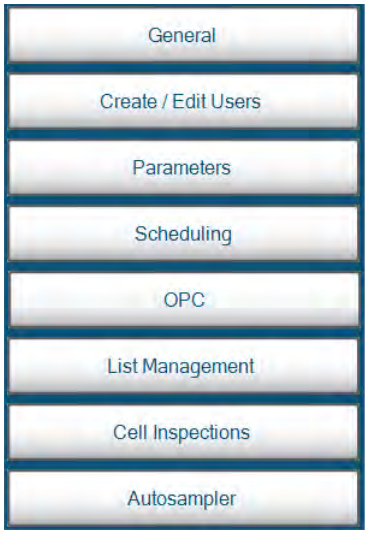
2.44 *Maintenance Menu for FLEX2 + OLS*

NOTE: *For additional information on the ESM or Autosampler Maintenance sub-menus, please see the ESM Instructions for Use Manual (PN: 59698) or the On-Line AutoSampler Instructions for Use Manual (PN: 63623).*

2.2.11 SETTINGS MENU

Select **Settings** (Right Home screen) to display the system settings sub-menu.

The System Settings sub-menu provides the following functions.



2.45 *System Settings Sub- Menu*

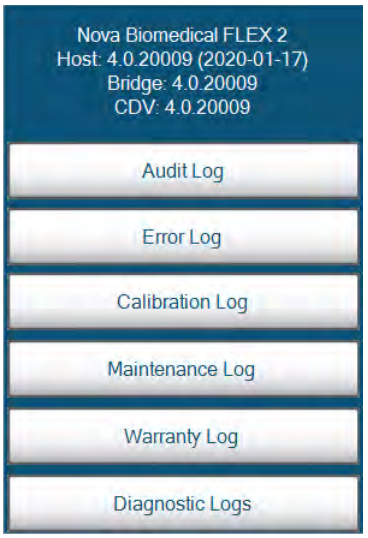
- **General:** An operator with the appropriate privilege level can program the Analyzer ID, Location, Language, Date Format, Date Separator, Number Format and Time Format. From this menu, the operator can also enable or disable Auto Logoff, Sample Results Auto Export, pH/pCO_2 Mode 2, Onboard QC and QC Lockout.
- **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 scheduling of various automated maintenance routines such as onboard QC, Chemistry/pH/Gas Calibration Time, Depro Wells, Cell Density maintenance and Database backup. Additionally, if your FLEX2 device has an ESM module, you will see an option to schedule ESM Depro.
- **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.
- **Cell Inspections:** An operator with appropriate privileges can create, configure, and edit Cell Inspection settings and parameters used for CDV module sampling.
- **Autosampler:** An operator with appropriate privileges can modify RSM configuration and sampling schedules.

NOTE: *See **Section 3.5** for additional information on configuring the system settings.*

2.2.12 LOGS MENU

Select **Logs** (Right Home screen) to display the system logs sub-menu.

The system logs sub-menu provides 6 buttons that allow the operator to view, export or print the **Audit Log**, **Error Log**, **Calibration Log**,



2.46 *System Logs Sub- Menu*

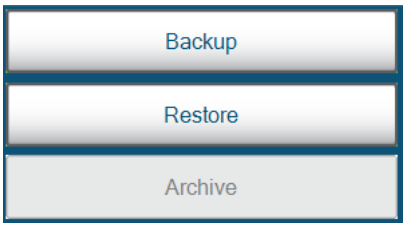
Maintenance Log, **Warranty Log** and the **Diagnostic Logs**. The system logs sub-menu also provides the Version of FLEX2 software that is currently installed on the analyzer.

Note: *See **Section 3.7** for additional instructions on viewing, exporting, and printing the information captured by the various system logs.*

2.2.13 Database Menu

Selecting **Database** (Right Home screen) allows an operator with appropriate privileges to backup or restore the system database.

Note: *For more information see **Section 3.8***



2.47 *Database Menu*

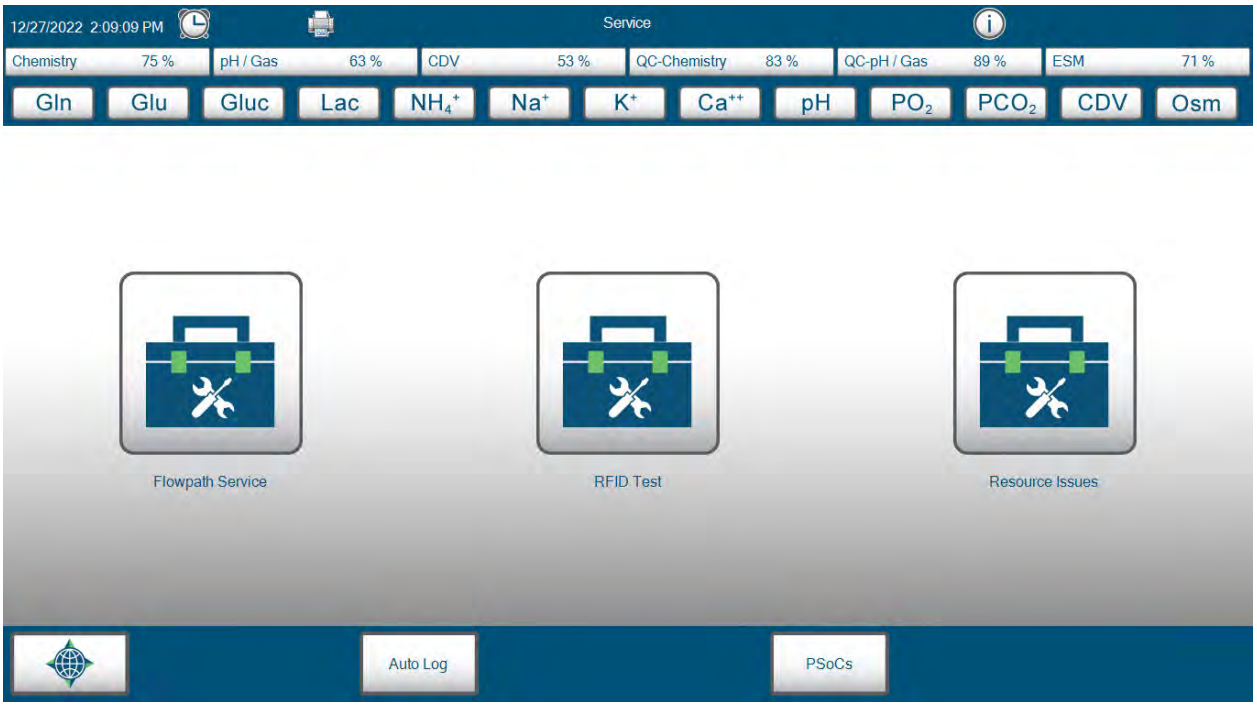
2.2.14 Service Menu

The Service menu (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.

2.48 *Service Sub-Menu*

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.

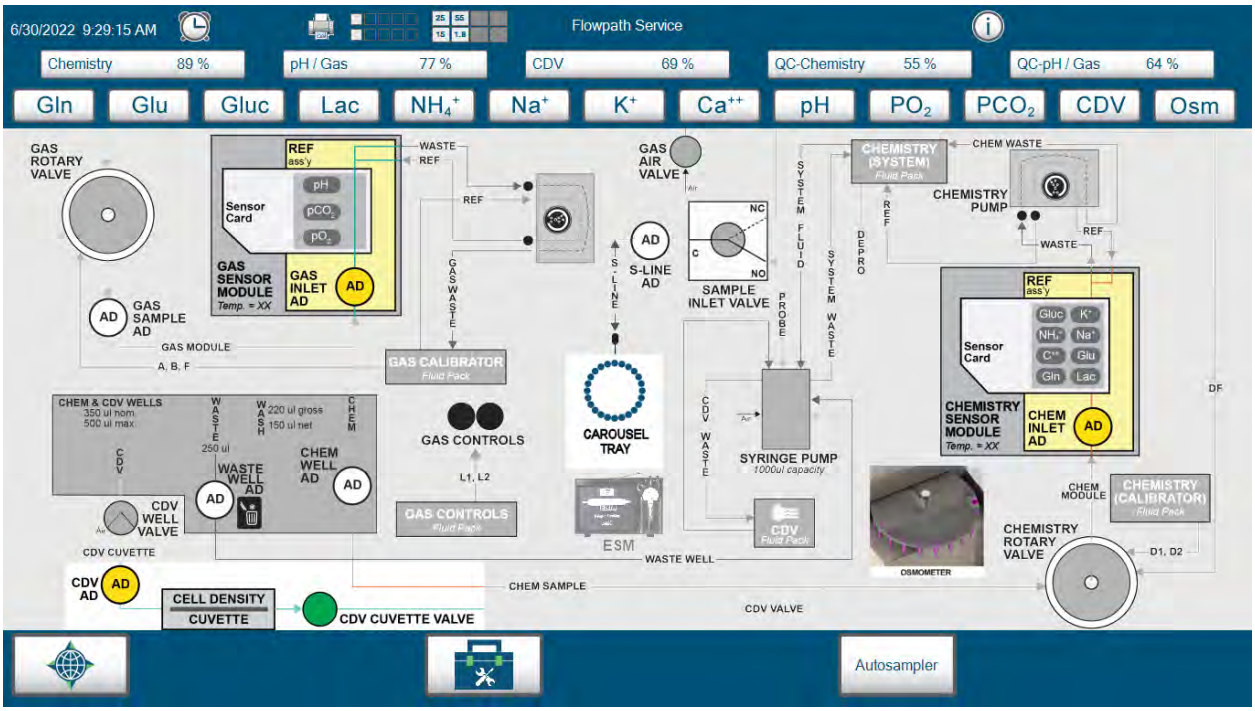


2.49 *Customer Service Sub-Menu*

Flowpath Service

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

NOTE: *See **Section 4.7** for additional instructions on how to utilize Flowpath Service.*

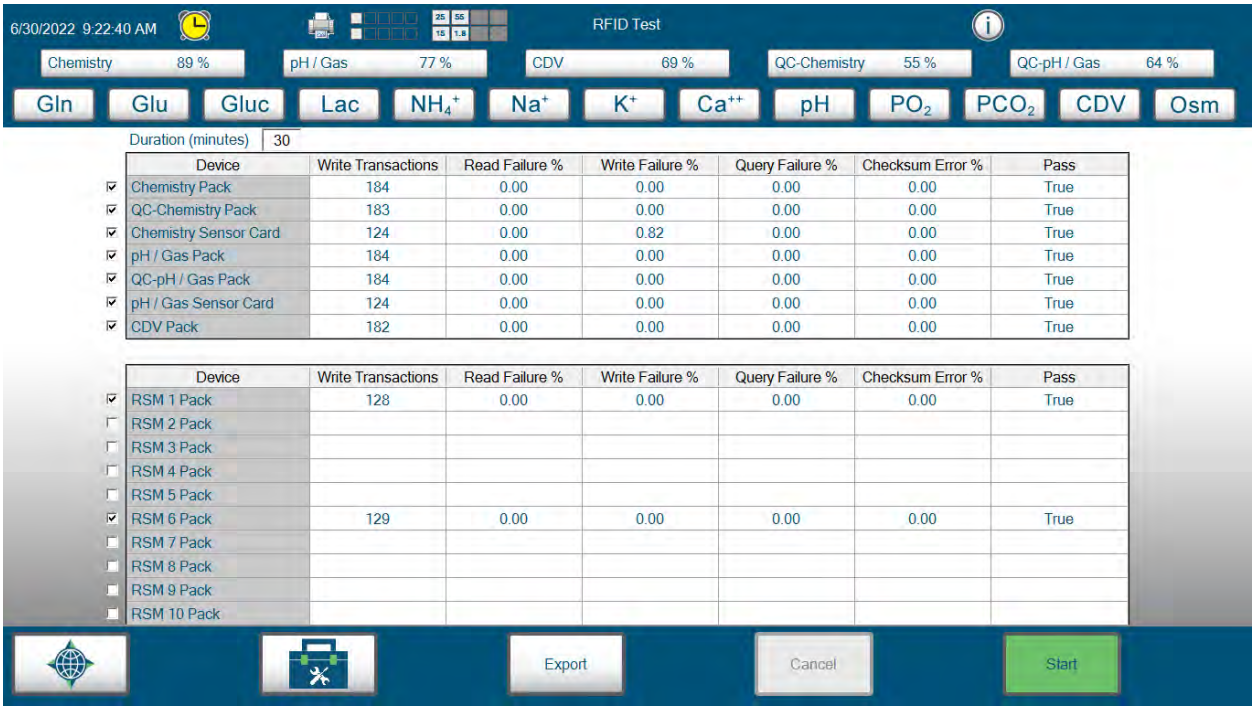


2.50 *Flowpath Service*

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. This test is done by completing a series of write transactions from each RFID.

NOTE: *See **Section 4.7** for additional instructions on how to perform a RFID Test.*



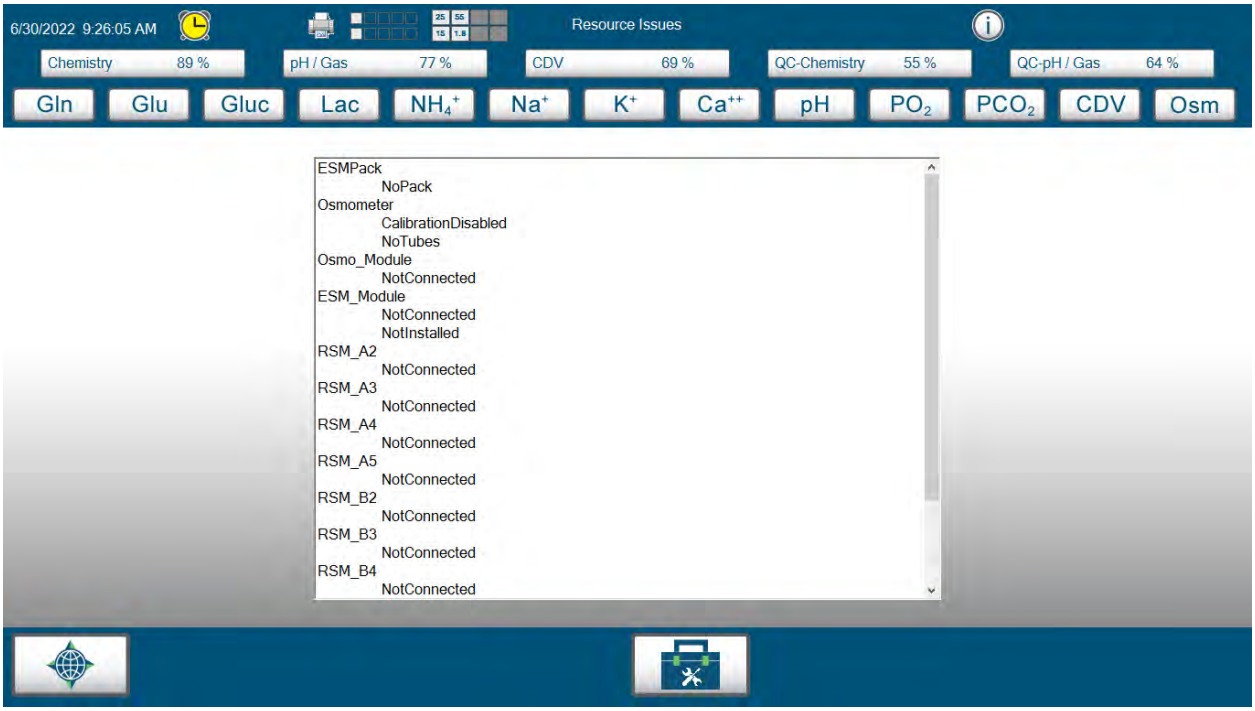
Device	Write Transactions	Read Failure %	Write Failure %	Query Failure %	Checksum Error %	Pass
Chemistry Pack	184	0.00	0.00	0.00	0.00	True
QC-Chemistry Pack	183	0.00	0.00	0.00	0.00	True
Chemistry Sensor Card	124	0.00	0.82	0.00	0.00	True
pH / Gas Pack	184	0.00	0.00	0.00	0.00	True
QC-pH / Gas Pack	184	0.00	0.00	0.00	0.00	True
pH / Gas Sensor Card	124	0.00	0.00	0.00	0.00	True
CDV Pack	182	0.00	0.00	0.00	0.00	True

Device	Write Transactions	Read Failure %	Write Failure %	Query Failure %	Checksum Error %	Pass
RSM 1 Pack	128	0.00	0.00	0.00	0.00	True
RSM 2 Pack						
RSM 3 Pack						
RSM 4 Pack						
RSM 5 Pack						
RSM 6 Pack	129	0.00	0.00	0.00	0.00	True
RSM 7 Pack						
RSM 8 Pack						
RSM 9 Pack						
RSM 10 Pack						

2.51 *RFID Test Results After Analysis*

Resource Issues

The Resource Issues button will search your FLEX2 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.



2.52 *Resource Issue*

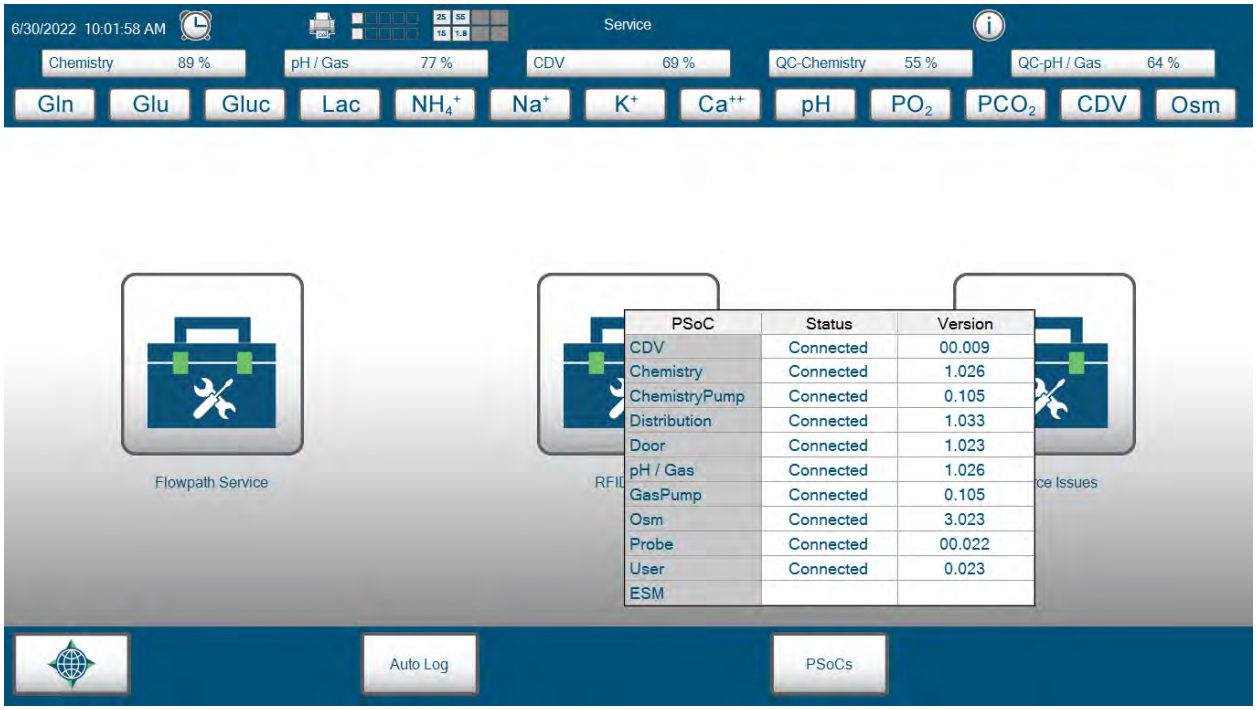
Auto Log

The Auto Log option will provide a detailed list of logs from your FLEX2 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 device, please see* ***Section 3.7.2 Error Log*** *for more information.*

PSoCs

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



2.53 *PSoCs Test*

2.2.14.2 NOVA SERVICE

The Nova Service menu has additional options available for servicing your FLEX2 device. 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

Select **Standby** (Right Home screen) to place 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.

Function not available at this time.

2.2.16 SHUT DOWN

Select **Shut Down** (Right Home screen) to power off the BioProfile FLEX2 Analyzer. When selected, the system will first display a prompt verifying that the operator 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 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 NETWORKING AND CONNECTIVITY

The FLEX2 analyzer contains two Single Board Computers (SBC's) commonly referred to as the "AU" and the "Bridge". The AU controls the FLEX2 Analytical Unit (AU) and the Bridge acts as a bridge between the AU and the outside world. Communications between the AU and Bridge computers are restricted to create a secure system and mitigate cyber security concerns.

2.3.1 Internal Computer Overview

Analytical Unit (AU)

The AU is responsible for the analyzer's primary functions; including sample analysis, mechanical control, data storage, and operation of the user interface (UI). The AU is restricted and should not be reconfigured in any way. Changes to the AU configuration may compromise the functionality of the system and void the warranty. For protection against cyber threats, there is no direct external access to the AU besides the wireless keyboard and touch screen display. Data may be exported to a sharable folder on the Bridge computer or to a USB drive. An OPC UA and DA Server may also be utilized to export data to an OPC Client.

Bridge Computer

The Bridge computer provides external access to data produced by the FLEX2 system and acts as a buffer between the outside world and the AU. Access to the Bridge desktop is unrestricted to allow integration with company networks and domains without jeopardizing functionality or security of the AU. Active directory is supported on the Bridge computer to allow access to the Bridge desktop from a corporate network. Active directory is not supported for log-in of the FLEX2 User Interface. All FLEX2 user accounts must be created from within the FLEX2 User Interface. For more information on how to create FLEX2 user accounts see **Section 3.5.2.1**.

Specifications:

- 128GB solid-state drive (SSD) or 512GB SSD
- 4GB memory
- Microsoft® Windows 10 Enterprise 2016 64-bit OS (Software Version 3.3 or newer)
- Microsoft® Windows 7 Embedded 64-bit OS (Software Version 3.2 or older)

User Access:

- USB 3.0 port (top)
- USB 2.0 port (bottom)
- HDMI port
- Ethernet port (configurable)

Accounts (default):

- Username: **FlexII**
- Password: **FlexII**

Bridge Hostname (default):

- FlexIIinterface

Customization of the Bridge Computer

Almost all aspects of the Bridge can be configured to meet domain policy and company asset requirements. This includes changing the computer name, adding user accounts, configuring a static IP, installing anti-virus software, installing printer drivers, and altering shared properties, etc. However, the following should not be disabled in any way:

Service Account

A local administrator account must remain accessible to Nova Field Service personnel for software updates and instrument repairs. The default local admin account is **FlexII.** If you choose to alter or create your own service account, please inform your local field service representative(s) accordingly.

Services

The following services must remain configured for Automatic startup:

- FlexII LaunchControlService – coordinates startup and shutdown of the analyzer, performs time synchronization and provides limited file transfer capability between Bridge and AU.
- FlexII AutomationService – required for customers interfacing with Nova approved devices.
- OPC Expert UA Server – Critical for use of OPC and allows access to OPC tags by UA connection.
- OPC FlexII Automation Server (on host LOCALHOST) – Allows access to OPC tags by DA connection.

TCP/IP Ports

The following ports must remain open to incoming connections:

- 9000 – FLEX2 Launch Control – required for orderly startup and shutdown of the analyzer.
- 9009 – FLEX2 File Transfer – required for installation of software updates, as well as data export and database backup functionality.
- 9010 – FLEX2 Installer - required to coordinate installation of software updates.
- 59888 – FLEX2 OPC – required for OPC functionality.

The following ports must remain open to outgoing connections:

- 9040 – FLEX2 Automation Gateway Port – required for communication between the AutomationService and the AU.
- 59888 – FLEX2 OPC – required for OPC functionality.

NOTE: *For software versions 3.6.19196 and older, the pre-configured Ethernet adapter with static IP 10.1.1.102 and subnet mask 255.255.255.0 should not be altered. This address is embedded into the system software for security reasons and will result in loss of Bridge/AU communication if changed. If your company network utilizes the same IP subnet, you will need to utilize routing tables to resolve IP conflicts.*

NOTE: *For software versions 4.0.20128 and newer, the pre-configured Ethernet adapter with static IP 223.255.255.2 and subnet mask 255.255.255.252 should not be altered. This address is embedded into the system software for security reasons and will result in loss of Bridge/AU communication if changed. If your company network utilizes the same IP subnet, you will need to utilize routing tables to resolve IP conflicts.*

WARNING: ***Nova cannot test all possibilities of domain restrictions or anti-virus providers to guarantee uninhibited Bridge computer functionality once changed or installed respectively.***

2.3.2 ACCESSING THE BRIDGE COMPUTER

If you wish to configure the FLEX2 Bridge computer to a domain or utilize the Shared Folder export capabilities, it will be necessary to access the Bridge desktop. There are two ways to access the Bridge:

1. Via External Monitor

To access the Bridge computer via the external HDMI port you will need an HDMI monitor (or equivalent adapter), a USB mouse, and a USB keyboard. If there are no available USB ports a USB hub can be utilized. Once the necessary components are acquired, follow the steps below:

1. Plug your monitor into the HDMI port on the back of the analyzer.

2. Power cycle the analyzer

   a. Select Shut Down from the FLEX2 UI and confirm you would like to power down the analyzer.

   b. Wait for screen to go blank.

c. Switch off the power on the back of analyzer.

d. Wait 30 seconds and switch the power on.

3. If prompted, Log into the default user account:

Username: **FlexII**

Password: **FlexII**

Note: *The monitor will display a desktop upon the reboot; this is the Bridge computer.*

2. Via Remote Connection from the User Interface (Software Version 3.3 or newer)

Only users with Administrator privilege level will have access to the Remote Desktop connection to the Bridge computer. To access the Bridge desktop, from the User Interface, follow the steps below:

1. Select the Print icon from the analyzer Status Bar.

2. Select Remote Desktop.

3. Log into the default Bridge Administrator account:

Username: **FlexII**

Password: **FlexII**

4. If prompted, accept the security certificate changes.

Note: *A remote connection window will be displayed over the FLEX2 UI and can be controlled using the supplied wireless keyboard.*

2.3.3 Exporting and Printing Data from the FLEX2

1. Export to a USB device

To export to a USB device, simply insert your device into an available USB port on the back of the analyzer. When presented with an option to Export on the UI, highlight your USB device from the list of export destinations and select the green check mark. Results will be exported to the selected destination as a comma separated value (.csv) file that can be opened using Microsoft Excel or other compatible programs.

2.54 *USB Port On Rear of FLEX2*

File locations and names for data exported to a USB drive (assume drive E:) are as follows:

Note: *If an Analyzer ID is configured in Settings it will appear in the file name of printed reports and exported data.*

Sample and QC Results - E:\NovaBiomedical\Export\Results

Export result(s) from the Historical Results screen:
SampleResultsYYYY-MM-DD_HHMMSS.csv

Export result(s) from the QC Results screen:
QcResultsYYYY-MM-DD_HHMMSS.csv

Export Growth Calculations:
GrowthCalculationsYYY-MM-DD_HHMMSS.csv

CDV Images - E:\NovaBiomedical\Export\Images

Individual enlarged sample image OR export all:
SampleID-Image#_YYYY-MM-DD_HHMMSS.JPEG

Printed Reports - E:\NovaBiomedical\Export\Reports

Print/export result from View Individual Result screen:
SampleResultsYYYY-MM-DD_HHMMSS.pdf

Print/export sample image(s) from View Individual Result screen:
CellDensityImageReportYYYY-MM-DD_HHMMSS.pdf

Print one or more results from Historical Results screen:
HistoricalSampleResultsYYYY-MM-DD_HHMMSS.pdf

Print/export sample histogram:
LiveCellHistogramReportYYYY-MM-DD_HHMMSS.pdf

Maintenance and Diagnostic Logs - E:\NovaBiomedical\Export\Logs

Maintenance Log: *MaintenanceLogYYYY-MM-DD_HHMMSS.csv*

All other exportable files will be sent to E:\NovaBiomedical\Export:

AuditableActionYYYY-MM-DD_HHMMSS.csv
CalibrationLogYYYY-MM-DD_HHMMSS.csv
WarrantyLogYYYY-MM-DD_HHMMSS.csv
ErrorsYYYY-MM-DD_HHMMSS.csv
Users.csv

2. Export to the Shared Folder

The FLEX2 Shared Folder is located on the Bridge computer in the location C:\Export. This file destination is hardcoded into the AU software and cannot be changed. When presented with an option to Export on the UI, highlight Shared Folder from the list of export destinations and select the green check mark. Results will be exported to the Bridge location C:\Export as a comma separated value (.csv) file that can be opened using Microsoft Excel or other compatible programs.

File locations and names for data exported to the Bridge computer Shared Folder are as follows:

NOTE: *If an Analyzer ID is configured in Settings it will appear in the file name of printed reports and exported data.*

Sample and QC Results - C:\Export\Results

Single result or group of results from Historical Results screen:
SampleResultsYYYY-MM-DD_HHMMSS.csv

Single Results or group of QC results from QC Results screen:
QcResultsYYYY-MM-DD_HHMMSS.csv

Export Growth Calculations:
GrowthCalculationsYYY-MM-DD_HHMMSS.csv

CDV Images - C:\Export\Images

Export Image(s):

SampleID-Image#_YYYY-MM-DD_HHMMSS.JPEG

Printed Reports - C:\Export\Reports

Print/export result from View Individual Result screen:
SampleResultsYYYY-MM-DD_HHMMSS.pdf

Print/export sample image(s) from View Individual Result screen:
CellDensityImageReportYYYY-MM-DD_HHMMSS.pdf

Print one or more results from Historical Results screen:
HistoricalSampleResultsYYYY-MM-DD_HHMMSS.pdf

Print/export Sample Histogram:
LiveCellHistogramReportYYYY-MM-DD_HHMMSS.pdf

Maintenance and Diagnostic Logs - C:\Export\Logs

Maintenance Log: *MaintenanceLogYYYY-MM-DD_HHMMSS.csv*

Database Backups - C:\Export\Database (For more information refer to **Section 3.8** Database)

All other exportable files will be sent to C:\Export:

AuditableActionYYYY-MM-DD_HHMMSS.csv
CalibrationLogYYYY-MM-DD_HHMMSS.csv
WarrantyLogYYYY-MM-DD_HHMMSS.csv
ErrorsYYYY-MM-DD_HHMMSS.csv
Users.csv

When Auto Export is enabled under the analyzer Settings > General screen, results are automatically exported to the Shared Folder at the end of each sample analysis. A monthly .csv file is created in the C:\Export\Results folder that is appended with each new sample result for the respective month. Separate monthly .csv files are generated for sample and QC results:

SampleResultsYYYY-Month.csv
QCResultsYYYY-Month.csv

3. Printing Data

In addition to creating an electronic PDF report, the FLEX2 enables direct printing of reports to local and network printers. Install printer drivers on the Bridge computer to make them available for selection when printing from the FLEX2 User Interface. A list of all available printers on the Bridge PC and their print queue is visible from the UI when the Printer icon is selected from the Status Bar.

4. Real-time Data via OPC Server (license sold separately)

The FLEX2 analyzer comes with a proprietary OPC server installed on the Bridge. Once licensed, the server allows a real-time stream of sample data and other analyzer information for easy integration into automation environments. If you would like more information about the FLEX2 OPC server please see the BioProfile FLEX2 OPC Manual (PN 60644).

2.3.4 NETWORKING AND SHARED FOLDER ACCESS

The BioProfile FLEX2 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 operating system or database. However, the system does 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 system Error Log, Audit Log, Calibration Log, Warranty Log and Diagnostic Log files can 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. The End User is responsible for supplying any external USB drive or Ethernet cable.*

All sample result and log files exported from the FLEX2 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. (See **Section 3.5.1**)

To access the FLEX2 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. (See Figure 2.55)

2.55 *Ethernet Port for Network Cable from LAN*

2. From any computer connected to the LAN, navigate to the Network connections and locate the **FLEXIIINTERFACE** connection.

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

2.56 *Network "Export" Folder*

4. The **Export** folder may contain a **Results, Report, Backup** and/or **Logs** folders depending on the data 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 exported PDF reports will appear in the Report folder. All exported Audit Log, Error Log, Warranty Log and Calibration Log files will appear directly in the **Export** folder. Only the most recent database backup will show in the Backup folder.

2.57 *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 Export Folder

FLEX2 version 4.2 software provides customer control of the Export Folder, which is one of the features added to enhance the analyzer's cybersecurity. The Export Folder will no longer be automatically shared.

FLEX2 analyzers upgraded from version 4.1 to version 4.2 may not be able to export the database until the Export Folder is shared within the Bridge Computer. If the database backup fails, a notification will appear on the user interface, "Database Backup Unsuccessful." This issue can be resolved by sharing the Export Folder on the Bridge.

To share the FLEX2 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. Locate the **FLEX2(C:) Export Folder** from the left-hand menu.
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.
9. 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.

3 OPERATION

This section describes how to operate the analyzer. The BioProfile FLEX2 components consist of the following items:

1. Keyboard and Mouse Assembly
2. Analytical Unit

3.1 KEYBOARD, MOUSE, AND SCANNER (OPTIONAL)

The BioProfile FLEX2 Analyzer is supplied with a Logitech™ wireless keyboard and mouse assembly that can be used as an alternative to the touchscreen keyboard for text entry and navigation.

3.1 External Keyboard and Mouse Assembly

As an optional accessory, the BioProfile FLEX2 can interface with the Wireless Barcode Scanner Kit, supplied and installed by Nova Biomedical. 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 User Interface.

NOTE: *The wireless scanner must be installed by a Nova-qualified Field Support Specialist.*

3.2 Wireless Barcode Scanner

3.1.1 ONSCREEN KEYBOARD

The Onscreen Keyboard function can be opened from within various menu screens and windows on the FLEX2.

Select the keyboard icon  , to open the onscreen keyboard.

3.3 Onscreen Keyboard

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

3.2 Analytical Unit

3.2.1 pH/Gas Module

3.2.1.1 pH/Gas Calibrator Cartridge

- The single cartridge 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.

3.4 *pH/Gas Calibrator Cartridge*

Note: *Chemical and biohazardous waste disposal laws vary between states and countries. 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.*

3.2.1.2 pH/Gas MicroSensor Card

The microsensors housed within the MicroSensor Cards are the core of the BioProfile FLEX2 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

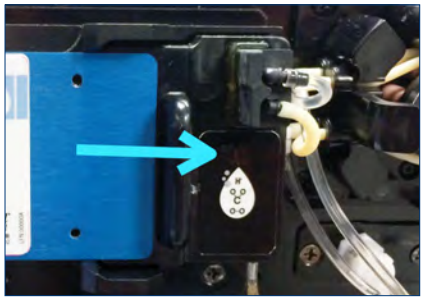
- The MicroSensor Card requires very low volume to minimize sample size.
- The RFID tag stores card information and communicates card status to the analyzer.
- The pH/Gas MicroSensor Card is available in 2 different configurations (High Volume or Low Volume) to meet the End User's needs.

3.5 *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 and is replaceable by the end user. It is continuously supplied with Reference Solution (KCl) from the pH/Gas Calibrator Cartridge.

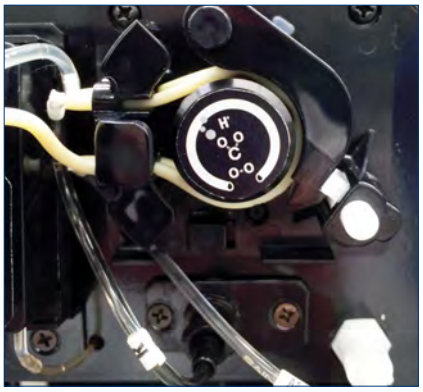
Note: *pH, pO_2, and pCO_2 require Reference Solution (KCl) for calibration and sample analysis.*



3.6 *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.



3.7 *pH/Gas Pump and Pump Tubing Harness*

3.2.2 Chemistry Module

3.2.2.1 Chemistry Calibrator and Reagent Cartridges

3.8 *Chemistry Calibrator & Reagent Cartridge*

- The dual cartridge set contains all the fluids necessary to calibrate all parameters in the Chemistry Module (Gln, Glu, Gluc, Lac, NH_4^+, Na^+, K^+, Ca^{++}).
- The Reagent Cartridge (larger) 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 on the Reagent Cartridge stores cartridge information and communicates cartridge status to the analyzer.
- The cartridge set can be disassembled for reagent disposal.
- The cartridge set is available in 3 sizes (High, Medium, or Low Sample Volume), designed to fit the End User's needs.

NOTE: *Chemical and biohazardous waste disposal laws vary between states and countries. 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 microsensors housed within the MicroSensor Cards are the core of the BioProfile FLEX2 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

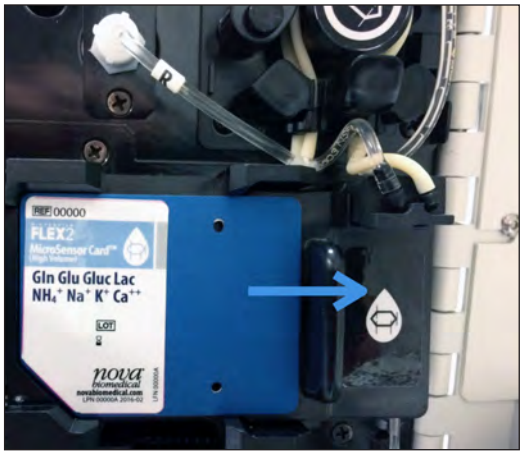
3.9 *Chemistry MicroSensor Card*

- 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.

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, NH_4^+, Na^+, K^+, and Ca^{++} require Reference Solution (KCl) for calibration and sample analysis.*



3.10 *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.

3.11 *Chemistry Pump and Pump Tubing Harness*

3.2.3 CELL DENSITY AND VIABILITY MODULE

3.2.3.1 CDV MODULE REAGENT CARTRIDGES

- The Reagent Cartridge set for the BioProfile FLEX2 CDV Module includes 2 separate cartridges (one PN):
  - 1 Bottle Pack
  - 1 Reagent Cartridge.

3.12 *CDV Module Reagent Cartridges*

The bottle pack contains the Trypan Blue dye required for the Trypan Blue exclusion assay and cleaning solution used to keep the CDV flow cell assembly clean and free of debris. The bottle pack also contains the Depro solution used to keep the CDV module flowpath clean of cell culture build up and debris. The Reagent Cartridge and bottle pack contain the System Fluid (diluent) necessary for priming and onboard dilutions. In addition, the Reagent Cartridge includes the waste pouch used to collect CDV module waste fluids.

- The RFID tag stores the Reagent Cartridge information and communicates cartridge status to the analyzer.
- The CDV Reagent Cartridges can be disassembled for reagent disposal.

CAUTION: *The white caps of the CDV bottle pack must be removed when the CDV Reagent Cartridges are installed. Failure to remove these caps will result in sample probe and system damage. The seals underneath the caps should not be removed.*

WARNING: ***The CDV bottle pack contains Trypan Blue dye. Trypan Blue is a known carcinogen. Take appropriate precautions when handling and disposing the CDV bottle pack; gloves and protective clothing are recommended. The waste pouch of the CDV and Chemistry Reagent Cartridge will contain waste Trypan Blue dye. The same precautions should be taken when handling and disposing these cartridges.***

3.3 System Calibration

3.3.1 Automatic Module Calibration

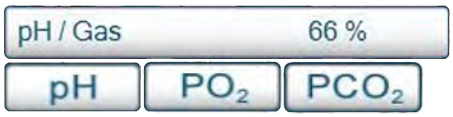
The BioProfile FLEX2 analyzer automatically performs a 2-point calibration of the pH/Gas & Chemistry Modules shortly after being powered on and every 2 hours thereafter to maintain optimal MicroSensor Card performance. A 1-point calibration of the pH/Gas and/or Chemistry module is performed during each 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, that parameter's status icon will be displayed with a RED background, indicating that the parameter is not available for sampling.

3.3.2 Smart Maintenance Functionality

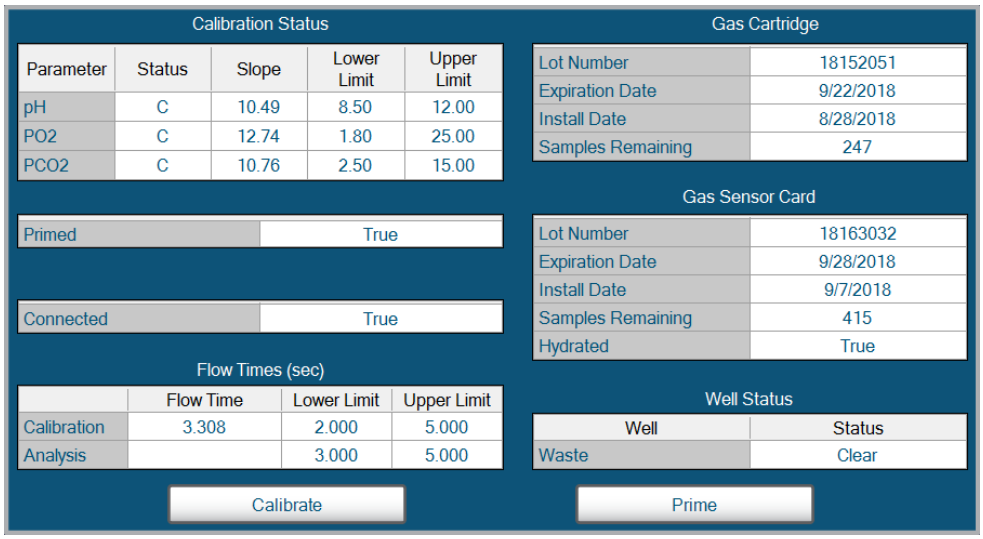
The BioProfile FLEX2 has **Smart Maintenance** capability. The pH/Gas & Chemistry MicroSensor Cards and each of the Reagent Cartridges required by the system are labeled with their own Radio Frequency Identification (RFID) tags. The BioProfile FLEX2 recognizes when a MicroSensor Card or Reagent Cartridge is installed or replaced and automatically performs the necessary maintenance (priming, hydration, and calibration) required to make each module ready for sampling.

3.3.3 pH/Gas Module Calibration

When required, the pH/Gas module can be manually calibrated from 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 the pH/Gas Module icons in the Status Bar to display the pH/Gas Module Status Window.



3.13 *pH/Gas Module Icons in the Status Bar*



3.14 *pH/Gas Module Status Window*

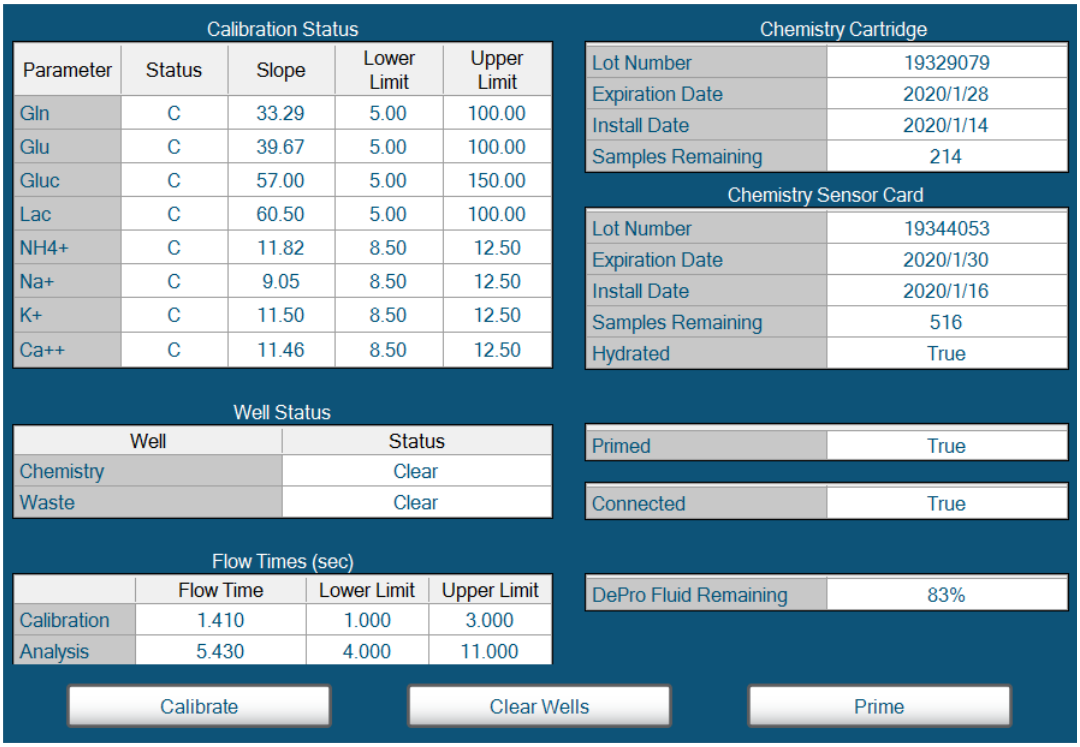
From within the pH/Gas Module Status Window, select **Calibrate** to initiate a calibration of the pH/Gas Module only. The calibration will begin as soon as the button is selected and the countdown timer will appear in the Status Bar.

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.*

3.3.4 CHEMISTRY MODULE CALIBRATION

When required, the Chemistry module can be manually calibrated from 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 icons in the Status Bar to display the Chemistry Module Status Window.

3.15 *Chemistry Module Icons in the Status Bar*



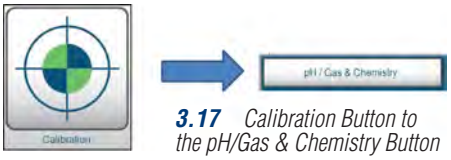
3.16 *Chemistry Module Status Window*

From within the Chemistry Module Status Window, select **Calibrate** to 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.

NOTE: *If **Calibrate**, **Clear Wells**, or **Prime** 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.*

3.3.5 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, select **Calibration** (Left Home screen), followed by **pH/Gas & Chemistry**.



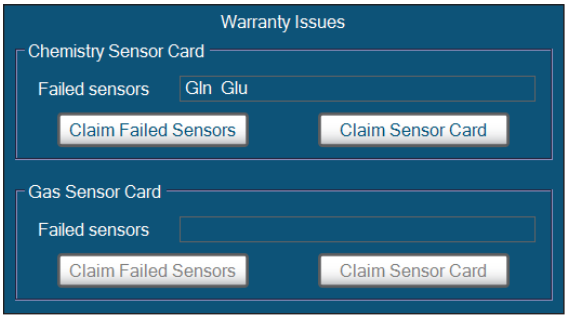
3.17 *Calibration Button to the pH/Gas & Chemistry Button*

The calibration will begin when the button is selected and the countdown timer will appear in the Status Bar.

3.3.6 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. A yellow icon will appear in the Status Bar.

When the icon is selected, a window 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.



3.18 *Warranty Window*

3.19 *Warranty Log Window*

Before making a warranty claim, it is important to take parameter dependencies (listed below) into consideration. Dependent parameters will also be claimed in a warranty event, when applicable:

- pCO2 is dependent on pH
- Glutamine (Gln) is dependent on Glutamate (Glu)
- Ammonium (NH_4^+) is dependent on Sodium (Na^+) and Potassium (K^+)

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

- 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 status window. All unclaimed parameters will remain available for 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 status window and a new card will need to be installed.

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

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

3.20 *Module Status Window, Warranty Claimed*

If **Claim Sensor Card** is selected, at least two 16-digit Warranty codes will be generated in the Warranty Log; one for each of the failed parameter(s), and one for the remaining parameter(s).

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.

NOTE: *You cannot claim a sensor or a sensor card under warranty while another card is hydrating.*

3.3.7 CELL DENSITY/VIABILITY (CDV) MODULE CALIBRATION

The Cell Density Module calibration is used to calibratethe focus and light intensity of the camera system. It is not used to check cell counting accuracy.

3.21 *Cell Density Calibrator Solution*

The calibration of the Cell Density Module is a manual calibration. It requires the use of Nova Cell Density Calibrator Solution (PN 43034). The Cell Density Calibrator Solution comes in a box of 30 sealed glass ampules. The solution is a suspension of polystyrene particles (beads). The Cell Density Calibrator Solution ampules must be vortexed at high speed for 10 seconds just prior to use to ensure homogeneous mixture of the polystyrene beads. Care should be taken not to form large bubbles inside of the ampule as the beads could get trapped in the bubbles.

CAUTION: *DO NOT run the Cell Density Calibration Solution or Quality Control Levels 8 & 9 (CDV controls) on the pH/Gas or Chemistry modules. Running the Cell Density Calibration Solution and/or QC Levels 8 & 9 through the pH/Gas or Chemistry modules may cause blockages in the flow path and will damage the MicroSensor Cards.*

During CDV calibration, the beads are pumped into the CDV module cuvette (flow cell) assembly. As the software establishes focal range, the bead images go in and out of focus. Optimal focus is established for each section of the Cell Density cuvette.

When required, the CDV module can be calibrated from within the User Interface. To calibrate the CDV module, the operator can select either of the CDV Module buttons in the Status Bar.

3.22 *CDV Module Buttons in the Status Bar*

Select one of these buttons to display the CDV Module status window.

Module Status

Parameter	Status
Calibration Status	C
Exposure Time (msec)	16.41
Measured Intensity	126
Primed	True

CDV Cartridge

Lot Number	19346065
Expiration Date	2020/2/04
Install Date	2020/1/14
Samples Remaining	200
Connected	True

Flow Times (sec)

	Flow Time	Lower Limit	Upper Limit
Calibration	5.297	5.000	10.000
Analysis		5.000	10.000

Well Status

Well	Status
Cell Density	Clear
Waste	Clear

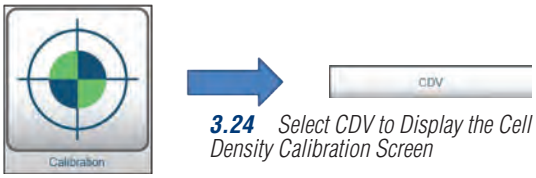
Calibrate | Clear Wells | Prime | Adjust Intensity

3.23 *CDV Module Status Window*

From the CDV Module Status Window, select **Calibrate** to display the Calibrator Aspiration Screen.

Note: *If the **Calibrate**, **Clear Wells**, **Prime**, or **Adjust Intensity** buttons are not available from within the CDV Module Status screen, this may mean that the CDV Calibrator Cartridge is empty, invalid, or expired.*

Alternatively, an operator can calibrate the CDV module by selecting **Calibration** (Left Home screen), followed by **CDV**.



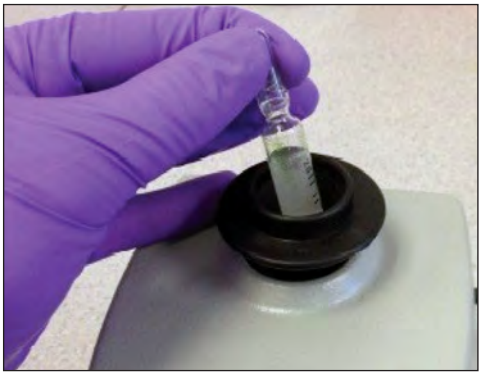
3.24 *Select CDV to Display the Cell Density Calibration Screen*

3.3.7.1 Performing A CDV Module Calibration

To perform a CDV module calibration:

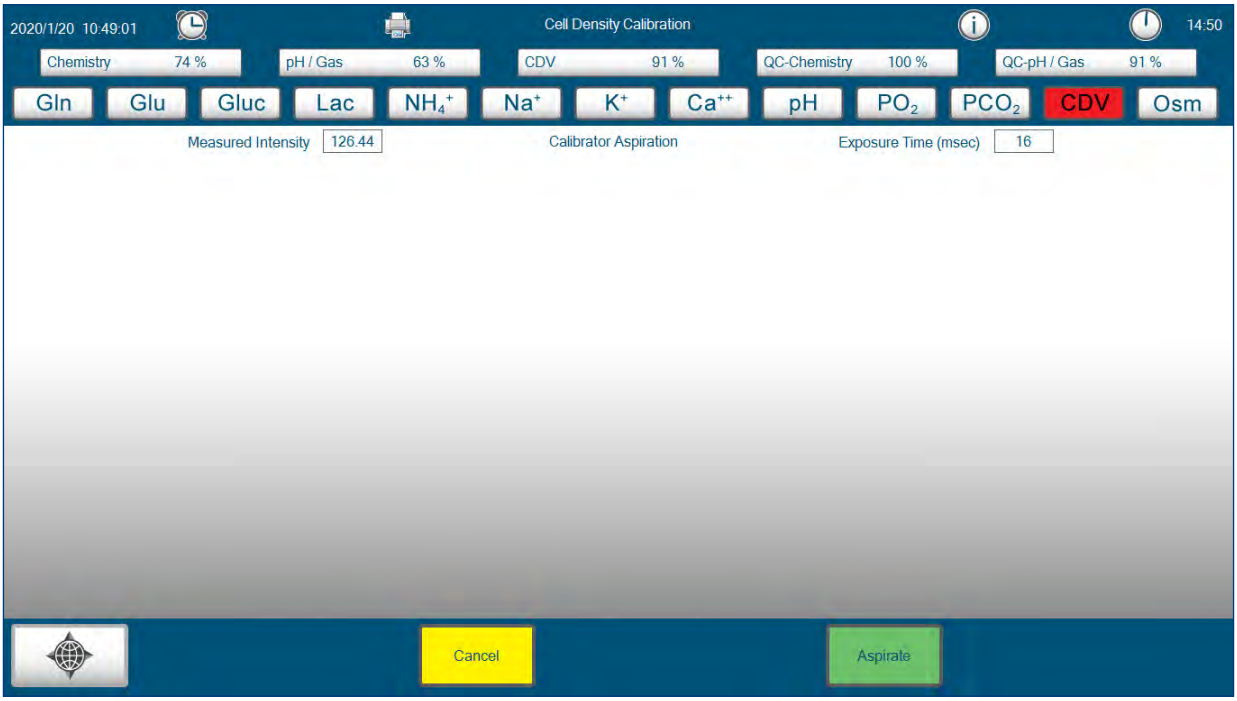
1. Prepare the Cell Density Calibrator Solution. If available, use a vortex to mix the ampule for 10 seconds just prior to analysis. If a vortex is not available, gently invert the ampule 10 times just prior to analysis. During inversion, allow fluid to empty from each portion of the ampule before turning. Before aspiration, make sure all of the fluid is in the bottom portion of the ampule.

Warning: ***Take care to avoid injury when opening glass ampules. Protect fingers with gauze or gloves when snapping open ampules for aspiration.***



3.25 *Vortex to Mix the Ampule*

2. Open the CDV Module Calibration screen by selecting one of the CDV buttons in the Status Bar and selecting **Calibrate**, or by selecting **Calibration** (Left Home screen), then CDV. The Cell Density Calibration screen will open and the top of the screen will display Calibrator Aspiration. The top of the screen also displays the Measured Intensity and Exposure Time (msec) result fields.



3.26 *Cell Density Calibration Screen*

3. Select **Cancel** to cancel the CDV calibration, if desired, or continue with the calibration.

4. The manual sampling position will be illuminated, and the sample probe will appear.

Warning: ***To avoid injury and system damage, always wait for the sample probe to extend fully before presenting the ampule to the probe.***

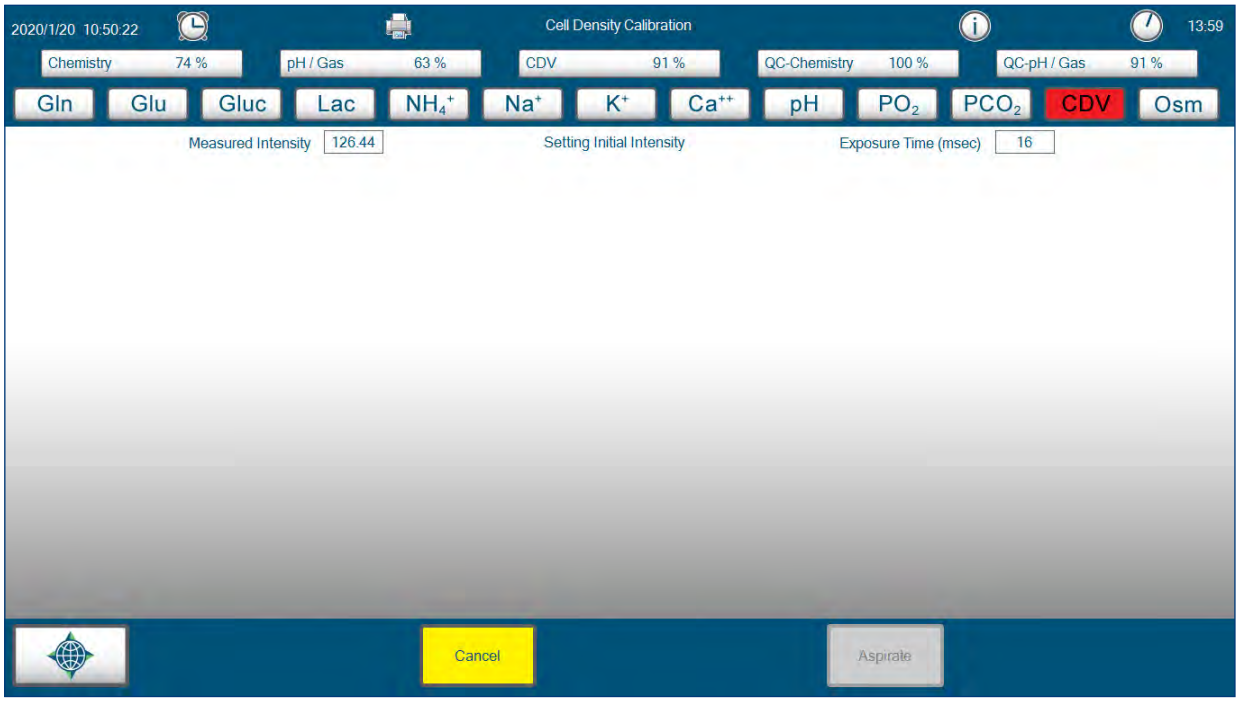
5. Crack open the ampule and present the ampule to the probe, then select **Aspirate** to aspirate the calibrator solution.

3.27 *CDV Calibrator Aspiration*

NOTE: *During aspiration, ensure that the tip of the sample probe does not make contact with the bottom of the ampule. Also ensure that tip of the probe remains below the surface of the solution to prevent short sampling.*

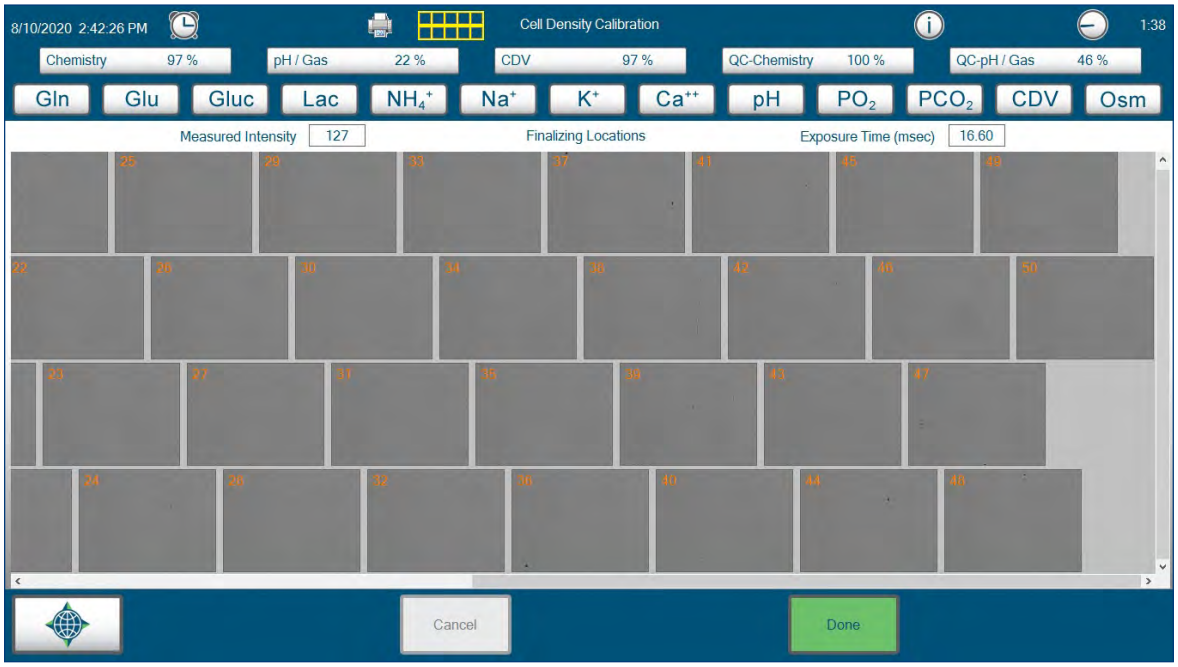
NOTE: *Once the calibration is progressing, do not navigate away from the calibration screen. There is no way to return to the calibration screen to review the images if this screen is exited.*

When aspiration is complete, the sample probe will retract and the screen will display Setting Initial Intensity, followed by Establishing Focus. During this process, each CDV image frame will appear with the beads going in and out of focus.



3.28 *Setting Intensity and Establishing Focus Screen*

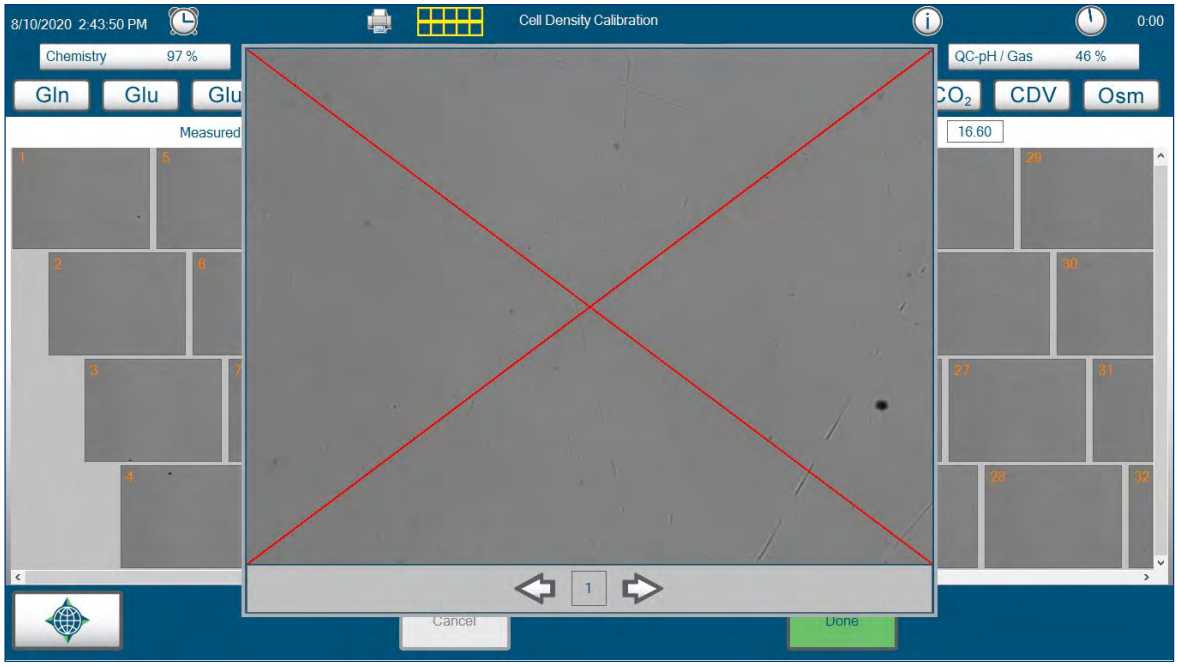
When the initial intensity and focus are established for each image frame, the screen will read Setting Final Intensity followed by Establishing Locations. During the Establishing Locations portion of the calibration, the screen will begin to display each of the 50 image frames as small picture tiles.



3.29 *CDV Image Frame Inspection/Deselection*

When all 50 image tiles have populated, the screen will read Finalizing Locations.

6. At this point each of the 50 image tiles should be inspected for dark spots, debris, or imperfections. Images containing any of these items can be deselected so that they will not be used when running CDV sample analyses, and will not apply to the CDV results. Up to 5 images can be deselected from the 50 available frames. Selecting any of the small tiles will expand the image to a larger viewing size.



3.30 *Omitting CDV Calibration Image*

The right and left arrow keys at the bottom of the image allow the operator to scan through each of the 50 possible image frames for inspection. Tapping on the image will place a RED X through it, indicating that it has been deselected.

7. When each calibration image has been inspected, select **Done** to complete the CDV module calibration.

NOTE: *Any CDV images deselected during a CDV module calibration will remain deselected until the next CDV module calibration is performed. End Users should take note of deselected images for future calibration cycles. If the CDV cuvette assembly shows signs of trapped debris, dark spots, and/or imperfections that are not removed by normal cleaning routines, contact Nova Biomedical Technical Support.*

3.3.8 OSMOMETER MODULE CALIBRATION

The calibration of the Osmometer is a manual calibration that requires the use of ampuled calibration solutions. Prior to initiating a calibration, check the configuration of your specific Osmometer (i.e. OSM20 or OSM48) and follow the applicable calibration sequence below.

WARNING: ***Take care to avoid injury when opening glass ampules. Protect fingers with gauze or gloves when snapping open ampules for aspiration.***

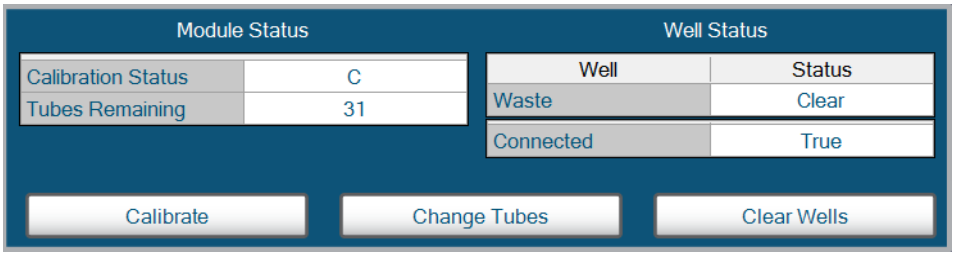
3.3.8.1 OSM48 CALIBRATION

The Osm48 calibration requires use of the 100 mOsm/kg and 900 mOsm/kg external calibration standards provided with PN 59856.

NOTE: *In order to perform an Osm48 calibration, 6 clean tubes must be available on the Osmometer Tray in any positions. If clean tubes are not available,* ***Calibrate*** *will not be available within the Osmometer Status Screen*

To begin an Osmometer calibration:

1. Verify that the required tubes are clean and available. If they are not available, perform the Change Tubes function from within the Osmometer Status window. (See **Section 4.4.1**)
2. Initiate the osmometer calibration by selecting **Osmometer** from the Calibration menu or by selecting **Osm** in the Status Bar followed by **Calibrate**.



3.31 *Osm48 Module Status Window*

3. Remove an ampule of the 100 mOsm/kg Osmo calibration solution from the packaging and mix the ampule thoroughly.

WARNING: ***To avoid injury and system damage, always wait for the sample probe to extend fully before presenting the ampule to the probe.***

4. Wait for the probe to appear and the manual sampling position to illuminate before presenting the ampule to the probe. Present the 100 mOsm/kg ampule to the probe and select **Aspirate 100**. The calibrator will be aspirated by the probe and delivered to the first 3 available tubes. Prepare to deliver the 900 mOsm/kg calibrator.

NOTE: *During aspiration, ensure that the tip of the sample probe does not make contact with the bottom of the ampule. Also ensure that the tip of the probe remains below the surface of the solution to prevent short sampling.*

5. Remove an ampule of the 900 mOsm/kg Osmo calibration solution from the packaging and mix the ampule thoroughly.
6. When the manual sampling position illuminates and the probe appears again, present the 900 mOsm/kg ampule and select **Aspirate 900**. The calibrator will be aspirated and delivered to the next 3 available tubes in the Osmometer tray.
7. The calibration will take approximately 15 minutes to complete.

NOTE: *There is no required calibration frequency for the Osm48. Nova Biomedical recommends that regular QC be run to determine when a calibration is necessary.*

3.3.8.2 Osm20 Calibration

The Osm20 calibration requires use of external calibration standards PN 42437 and PN 42438.

Note: *In order to perform an Osm20 calibration, clean tubes in all 20 positions and a new wiper ring must be available on the Osmometer tray. If clean tubes are not available in all 20 positions,* ***Calibrate*** *will not be available within the Osmometer Status Screen.*

To begin an Osmometer calibration:

1. Verify that the required tubes and wiper ring are clean and available. If they are not available (see **Section 4.4.2**), perform the Change Wiper and Tubes function from within the Osmometer Status window. Be sure to replace all 20 tubes and install a new wiper ring.
2. Initiate the osmometer calibration by selecting **Osmometer** from the Calibration menu or by selecting **Osm** in the Status Bar followed by **Calibrate**.

3.32 *Osm20 Module Status Window*

3. Remove an ampule of the 50 mOsm/kg Osmo calibration solution from the packaging and mix the ampule thoroughly.

Warning: ***To avoid injury and system damage, always wait for the sample probe to extend fully before presenting the ampule to the probe.***

4. Wait for the probe to appear and the manual sampling position to illuminate before presenting the ampule to the probe. Present the 50 mOsm/kg ampule to the probe and select **Aspirate 50**. The calibrator will be aspirated by the probe and delivered to the first 5 tubes of the Osmometer tray. Prepare to deliver the 850 mOsm/kg calibrator.

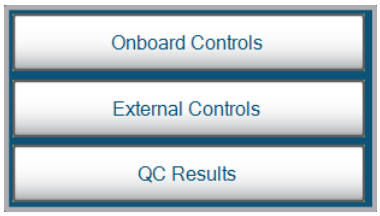
Note: *During aspiration, ensure that the tip of the sample probe does not make contact with the bottom of the ampule. Also ensure that the tip of the probe remains below the surface of the solution to prevent short sampling.*

5. Remove an ampule of the 850 mOsm/kg Osmo calibration solution from the packaging and mix the ampule thoroughly.
6. When the manual sampling position illuminates and the probe appears again, present the 850 mOsm/kg ampule and select **Aspirate 850**. The calibrator will be aspirated and delivered to tubes 6 – 10 in the Osmometer tray.
7. The calibration will take approximately 15 minutes to complete, during which time an audible “tap, tap, tap” will be heard every few minutes as each tube is measured.

Note: *The Osm20 calibration is completed on an as needed basis, as indicated by Quality Control testing.*

3.4 QUALITY CONTROL (QC)

By selecting QC (Left Home screen), the End User can choose to analyze Onboard Controls or External Controls or view QC Results.



3.33 *QC Menu*

3.4.1 ONBOARD CONTROLS

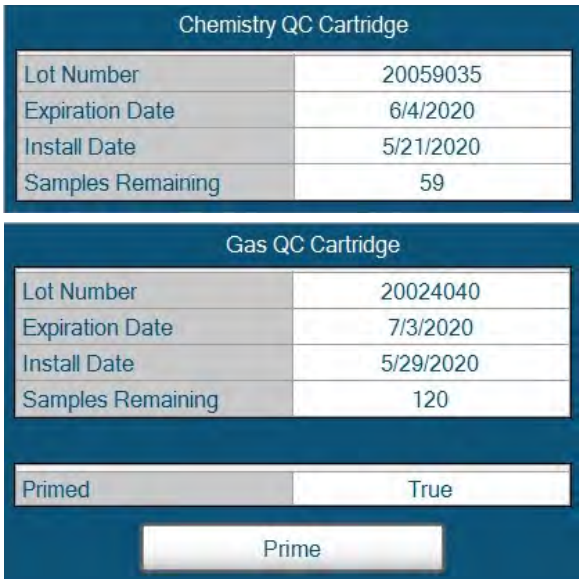
Using the BioProfile FLEX2 system's onboard quality control (**QC**) can save the End User time and QC can be scheduled to run automatically. There is onboard QC for the pH/Gas, Chemistry, and Osmometer modules, with a high and low QC solution to test for each module. QC for the osmometer is in the pH/Gas QC cartridge. The pH/Gas/Osmo and chemistry onboard QC operate independently. The access ports for the 2 modules are to the left of the 96-well plate, with the Chemistry QC bracket to the rear, and the 2 pH/Gas septa toward the front. Due to the stability of glutamine in the solution, the Chemistry QC cartridge is refrigerated onboard but must be stored frozen (**-15˚C**) and then thawed prior to its installation.

NOTE: *Scheduling for onboard QC is configured in Settings (Right Home screen), then under Scheduling. The onboard QC must be enabled before onboard QC analysis can be performed. * Requires 2.1.17118 software version or newer.*

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**.

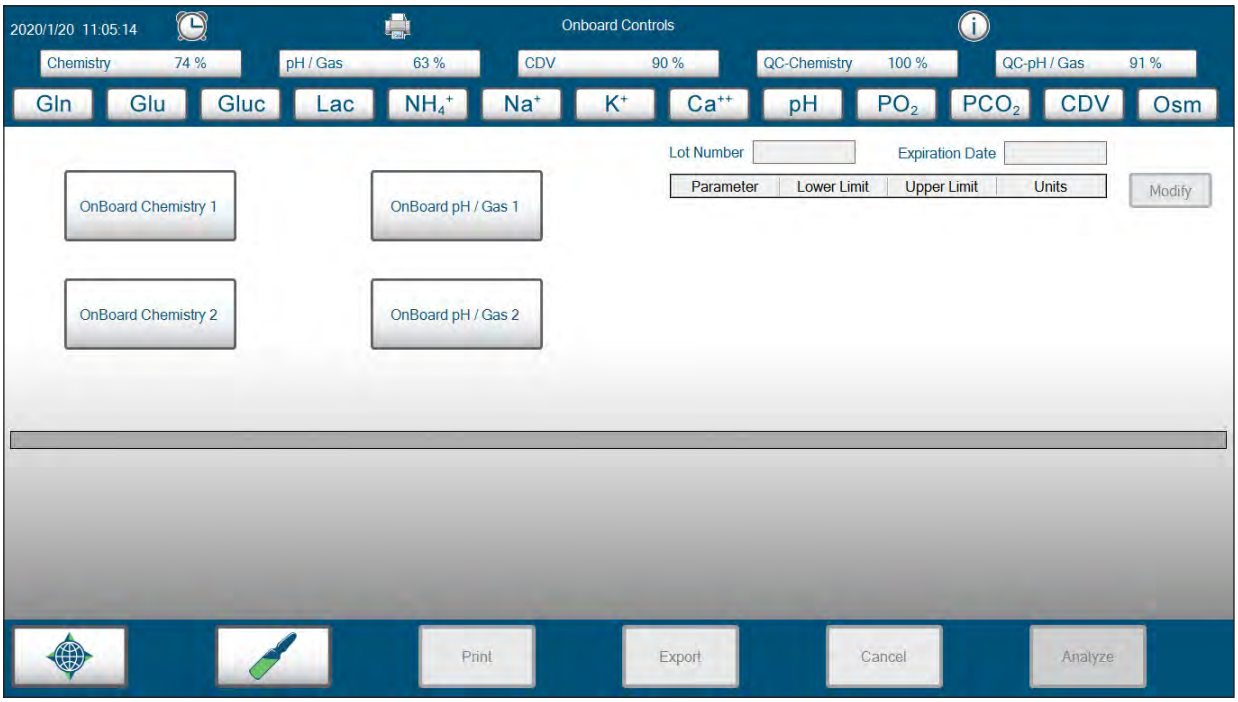
In the Status Bar, two additional status icons will appear: **Chemistry QC** and **pH/Gas QC**. By selecting either of these, a status window appears containing the date of QC cartridge installation, post-install expiration date, lot number and the number of samples remaining per cartridge. The status window for pH/Gas QC has a Prime option to prime the lines from the cartridge to the septa.



3.34 *Status Windows for Onboard QC*

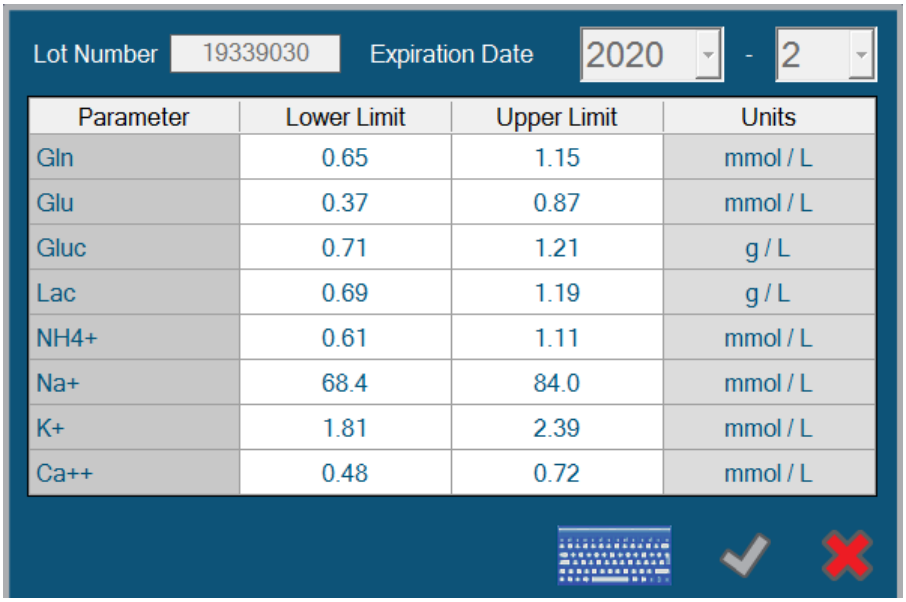
Running Onboard QC

Once Onboard QC is enabled in the settings menu the Onboard Controls button will be available in the QC sub menu. When selected, the Onboard Controls screen will be displayed.



3.35 *Onboard Control Screen*

An operator can select the desired QC module and level they would like to analyze. Once selected, the respective control lot number, expiration date, and control ranges will be displayed in a table on the right side of the screen. The control ranges for Onboard Controls will automatically populate to the table because the information is stored on the respective control pack's RFID tag. If required, the Lower Limit and Upper Limit ranges can be modified by selecting the modify button.

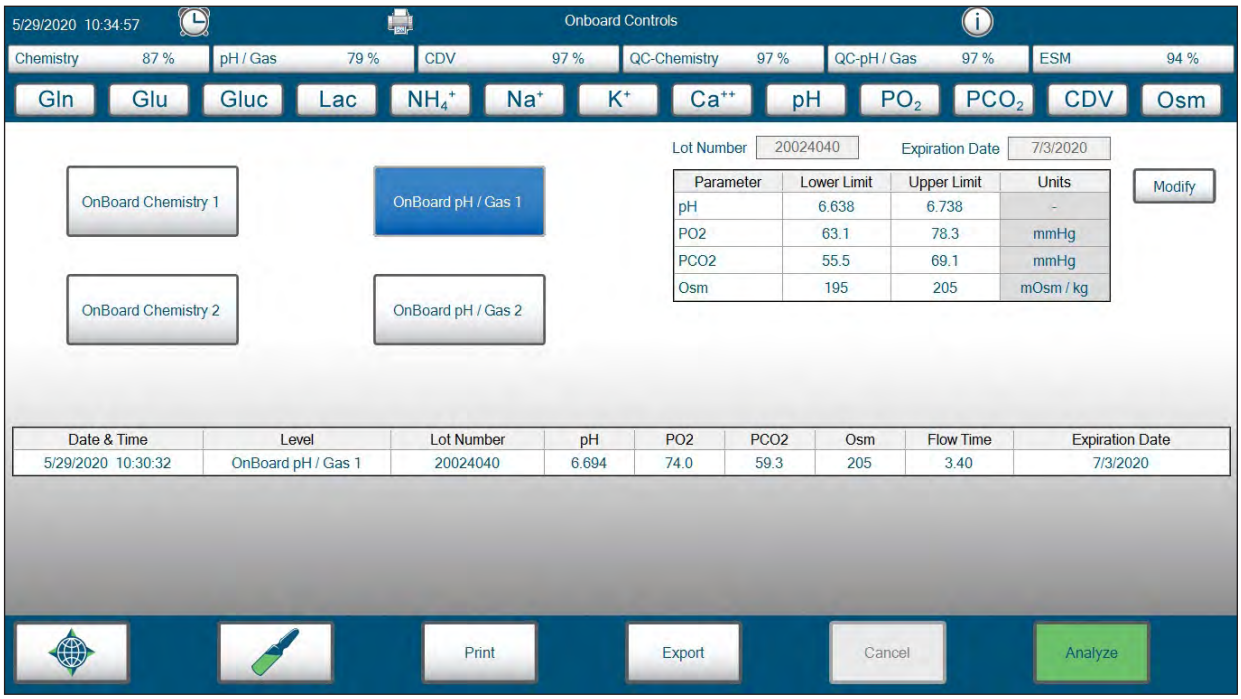


3.36 *Modify Onboard Control Range*

Nova Biomedical suggests using the default 2 SD ranges published on the QC package insert sheet unless otherwise instructed via an official Customer Information Bulletin.

Select **Analyze** to begin an Onboard QC analysis for the selected module and level. When the analysis completes the results will be displayed in the table at the bottom of the screen. Only the most recent QC result will be displayed on this screen. The operator can choose to Print a PDF report or export a .csv file of the highlighted QC result. To view historical QC data navigate to the QC Results screen using the QC button in the Command Bar.

NOTE: *For information on how to schedule onboard QC for automated analysis see* ***Section 3.5.4.1****.*



3.37 *Onboard Control Analysis Results*

3.4.2 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 ampuled control solutions.

When the QC lockout feature is enabled and any level of onboard QC reports a value outside of the specified QC range for a parameter, the parameter in question is **locked out** and its status icon will turn red. A locked-out parameter will remain as such until subsequent onboard QC testing produces results that are within range for all applicable levels of QCs that failed. The Calibration Status window will indicate **QC** in red text for the locked-out parameter along with the Level(s) that failed. Additionally, no sample result will be reported during regular sample analyses. 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.

QC Lockout can be enabled by a user with the appropriate privilege level from the General Settings screen.

To enable QC Lockout:

1. Select **Settings** followed by **General**.
2. Select the box next to Enable QC Lockout so that a check mark appears.
3. Select **Save**.

To disable QC Lockout uncheck the box in Step 2 and Select Save.

Calibration Status

Parameter	Status	Slope	Lower Limit	Upper Limit
Gln	C	33.47	5.00	100.00
Glu	C	31.33	5.00	100.00
Gluc	C	77.32	5.00	150.00
Lac	QC [L1,L2]	60.00	5.00	100.00
NH4+	C	11.22	8.50	12.50
Na+	C	10.22	8.50	12.50
K+	C	10.86	8.50	12.50
Ca++	C	10.64	8.50	12.50

3.38 *QC Lockout in Module Status Window*

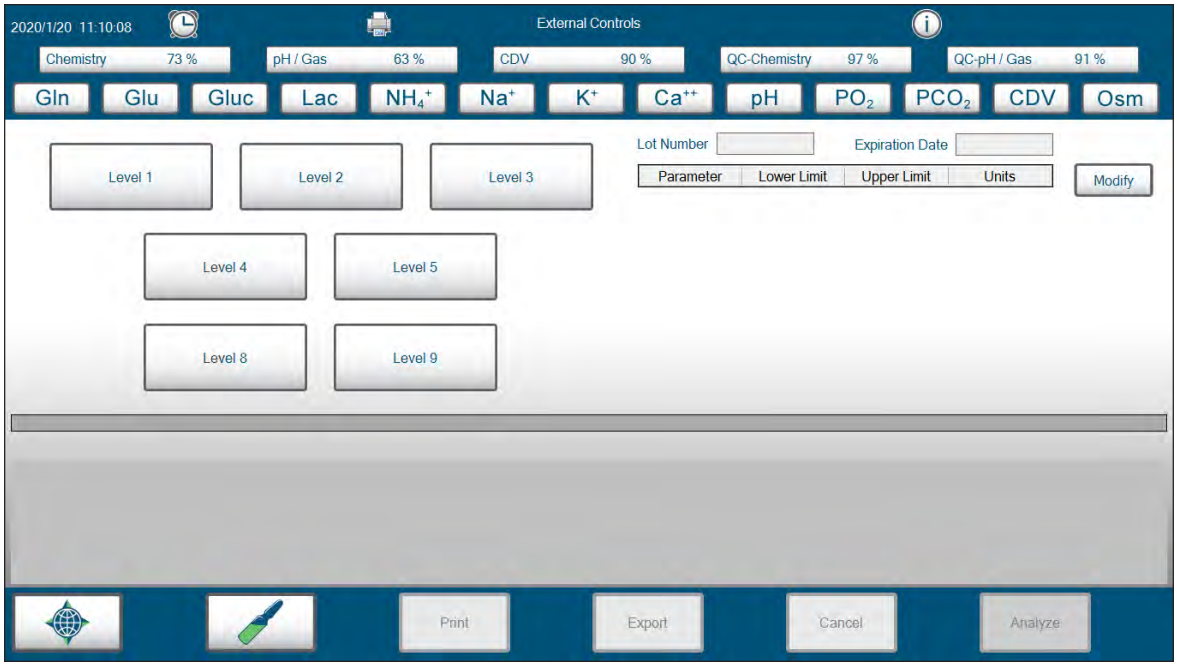
FLEX2 operators should note the following when using the QC Lockout feature:

- 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 on the Sample Results screen and Error Log.
  - If Ammonium is calibrated and available but Sodium and/or Potassium are locked out, no Ammonium result will be reported.
  - If pCO_2 is calibrated and available but pH is locked out, no pCO_2 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.

3.4.3 EXTERNAL CONTROLS

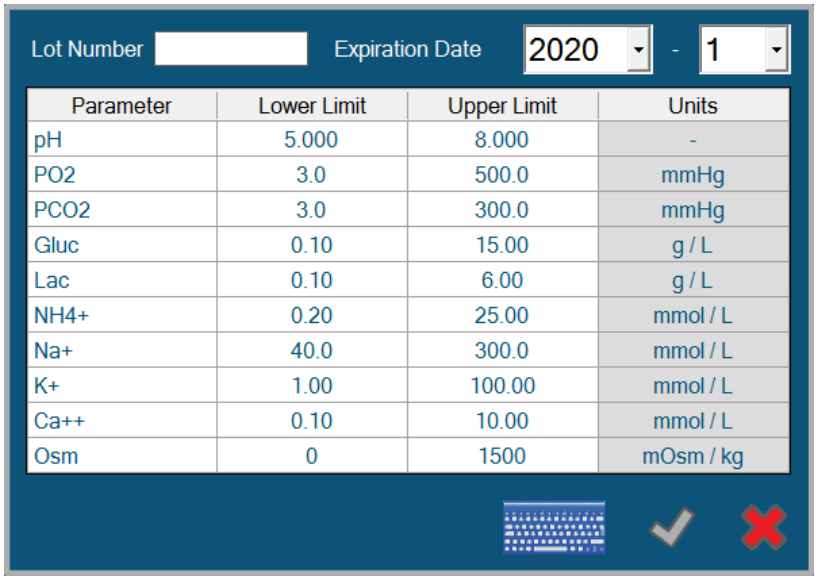
Select **External Controls** from the QC menu to open the External Controls screen. From this screen, an operator can program external control ranges from the BioProfile External Quality Control product insert sheets and analyze external QC. The product insert sheet information for the control level being analyzed must be entered before analysis can take place. It is important to note that the QC lockout feature does not apply to external quality control and that external QC cannot be scheduled to run automatically.



3.39 *External Controls Screen*

Entering External QC Ranges

An operator will not be able to analyze external controls if there is no range limit information entered for that level of QC or if the external controls expiration date has been surpassed. After opening the External Controls screen, select the desired level of control to highlight the button in blue, then select the Modify button. Enter the control lot number, expiration date, and parameter ranges as seen on the product insert sheet that accompanies the external control ampules. Select the green check mark to save the changes made or the red X to close the window.



Parameter	Lower Limit	Upper Limit	Units
pH	5.000	8.000	-
PO2	3.0	500.0	mmHg
PCO2	3.0	300.0	mmHg
Gluc	0.10	15.00	g / L
Lac	0.10	6.00	g / L
NH4+	0.20	25.00	mmol / L
Na+	40.0	300.0	mmol / L
K+	1.00	100.00	mmol / L
Ca++	0.10	10.00	mmol / L
Osm	0	1500	mOsm / kg

3.40 *Modify External Control Range*

Running External QC

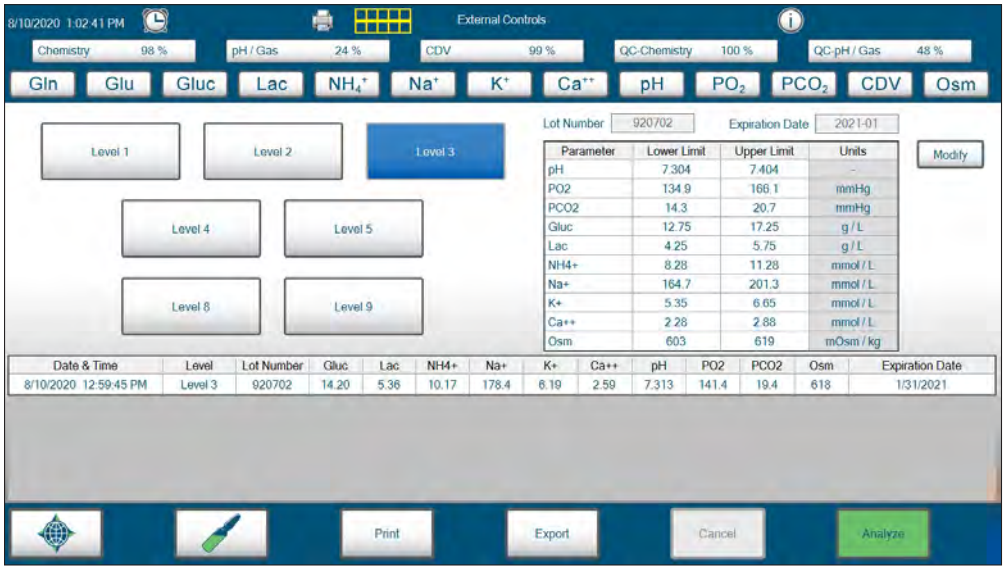
Select the desired level of external QC to highlight the button in blue, then press Analyze. The system probe will appear in the illuminated manual sampling port and the Analyze button text will change to Aspirate. Open the QC ampule, making sure to follow the recommended sample handling techniques listed on the product insert sheet, and present it to the sample probe. Press the green Aspirate button while making sure the probe stays below the fluid line throughout the duration of the aspiration sequence.

External Control Storage and Sample Handling:

QC 1-3: Stored at room temperature

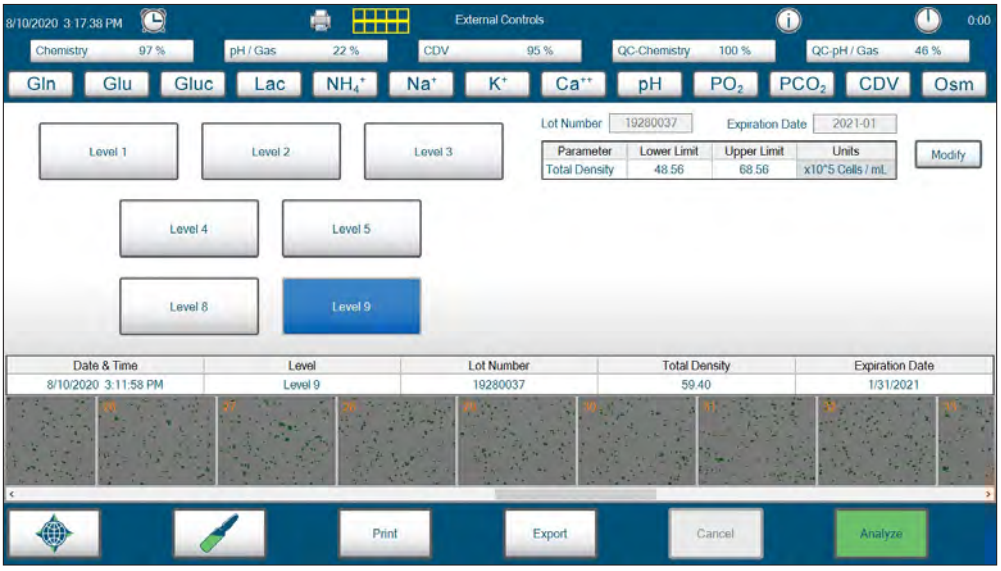
QC 4-5: Stored frozen, thaw before analyzing.

QC 8 & 9: Stored at room temperature. Vortex for 10s prior to analysis.



3.41 *External Control with Results*

When the analysis completes the values will be displayed in the results table at the bottom of the screen. For external cell density and viability QC (Level 8 and Level 9) the cell density images will also be displayed along with the total density value. Only the most recent QC result will be displayed on this screen. The operator can choose to print a PDF report or export a .csv file of the highlighted QC results in this screen by selecting the appropriate button in the Command Bar. To view historical QC data navigate to the QC Results screen.



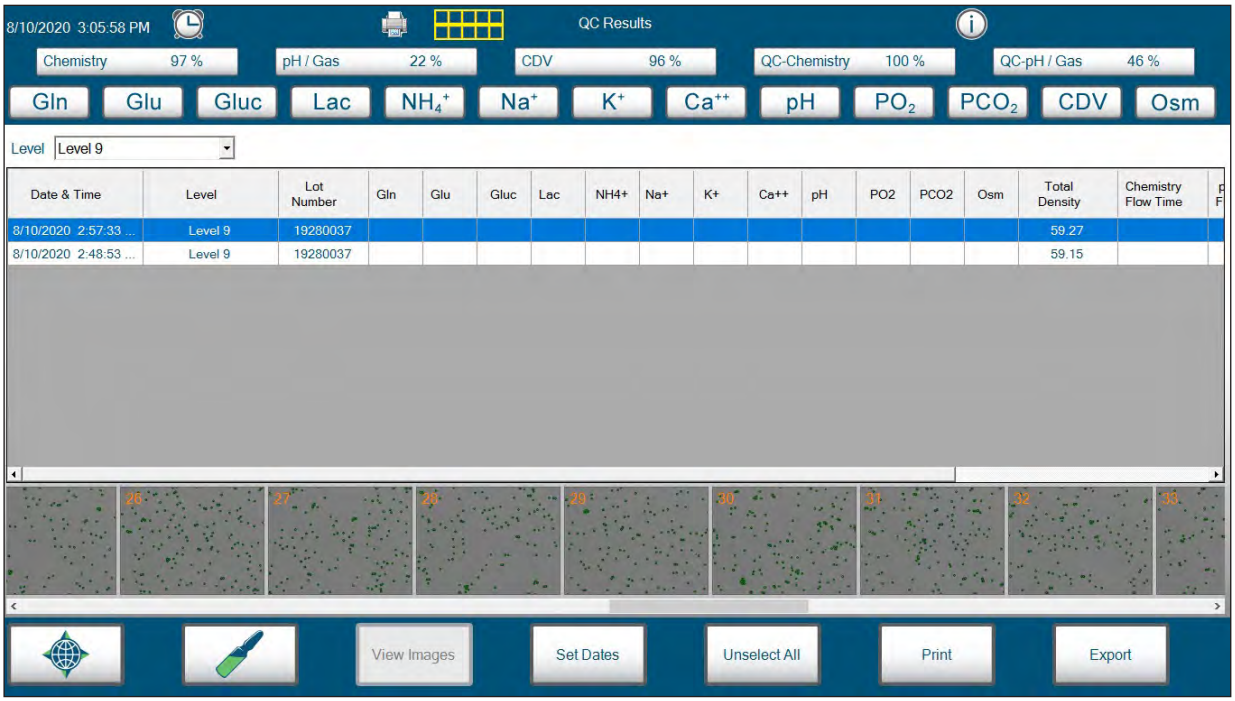
3.42 *External CDV QC Results*

3.4.4 QC RESULTS

Select QC Results from the QC sub-menu to open the QC Results screen. From this screen an operator can view historical Onboard and External QC data. The operator has the option to view all QC data or results for only a specific level of QC by using the Level dropdown menu. If an external cell density and viability QC (Level 8 and Level 9) result is highlighted, select View Images in the Command Bar to display the associated CDV image tiles at the bottom of the screen. To view full-sized QC images, select any image tile. By default, the QC results for the previous 7 days will be displayed, but a specific date range can be selected by using the Set Dates button in the Command Bar. The operator can choose to print a PDF report or export a .csv file of the highlighted QC results in this screen by selecting the appropriate button in the Command Bar.

NOTE: *For more information on Printing and Exporting data, see Exporting and Printing Historical Results in* ***Section 2.2.6.***

3.43 *QC Results Dropdown*

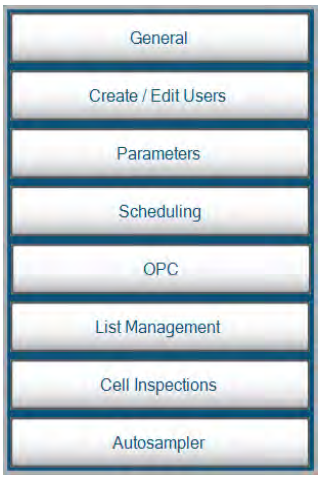


3.44 *QC Results Screen View Images*

3.5 Analyzer Settings

This section provides instructions on configuring the various analyzer settings of the BioProfile FLEX2 system. An operator with appropriate privileges can access each of the configuration menus detailed in this section by selecting **Settings** (Right Home screen), followed by the appropriate sub-menu.

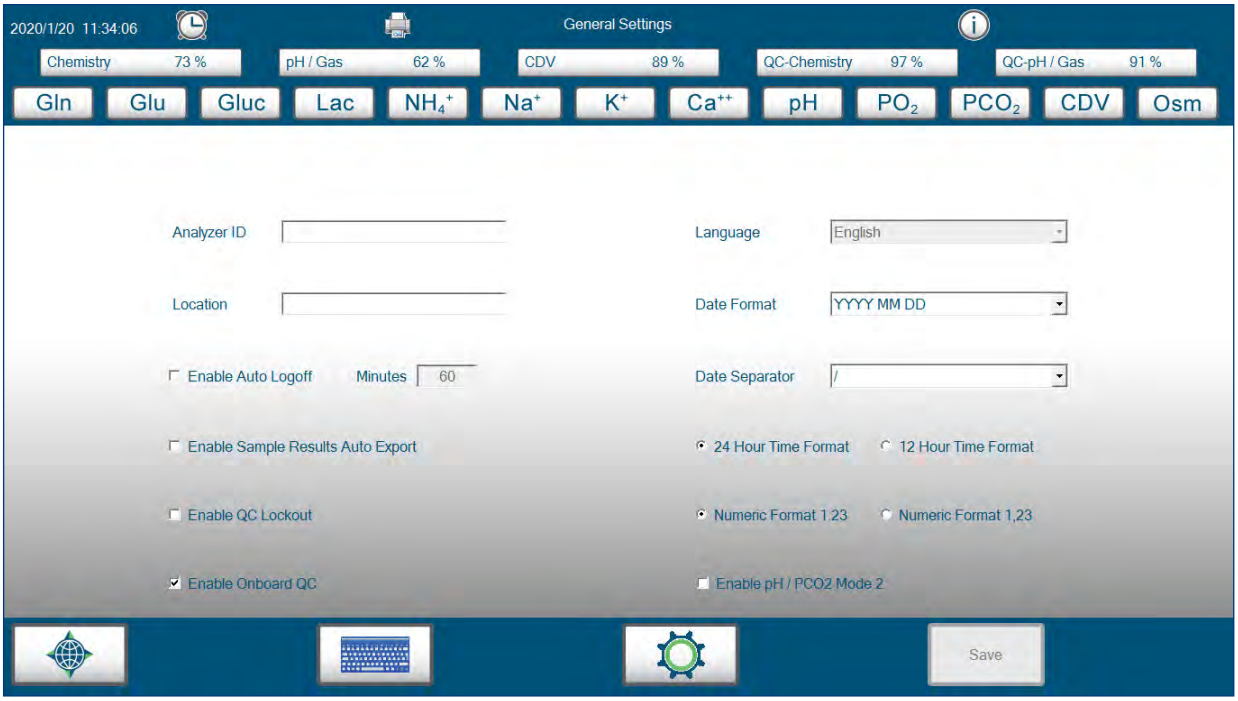
When an operator opens any of the submenu screens from within the Settings Menu, **Settings** is visible in the Command Bar. Select **Settings** to display each of the sub-menu options and navigate throughout the various Settings menus without having to return to the Home screen.



3.45 *Settings Menu with Autosampler*

3.5.1 General Settings

To access the General Settings menu, select **Settings**, followed by **General**.



3.46 *General Settings Screen*

3.5.1.1 Analyzer ID

In some cases it may be necessary to set an Analyzer ID for the BioProfile FLEX2 system. This is typically required when configuring the FLEX2 analyzer to communicate with a laboratory network.

To setup an Analyzer ID, perform the following steps:

1. Select **Settings** (Right Home screen), 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 alphanumeric characters including dashes (-) and underscores (_), but should not include any spaces or special characters (!,@,#,$,%,^,&,*,/,<).

3.47 *Analyzer ID*

3. Once the analyzer ID is entered, select **Save** in the Command Bar to save the analyzer ID.

Note: *The Analyzer ID will appear in the file name of printed reports and exported data.*

3.5.1.2 ANALYZER LOCATION

In some cases it may be necessary to input an analyzer Location for the BioProfile FLEX2 system.

To setup an Analyzer Location:

1. Select **Settings** (Right Home screen), 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 alphanumeric characters. Special characters are not allowed besides dashes or underscores.

3.48 *Analyzer Location*

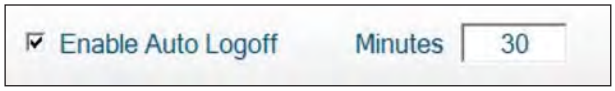
3. Once the analyzer location is entered, select **Save** in the Command Bar to save the analyzer location.

3.5.1.3 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/disable the Auto Logoff function:

1. Select **Settings** (Right Home screen), 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. Input the desired length of time 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.



3.49 *Enable/Disable Logoff*

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**.

3.5.1.4 ENABLE/DISABLE SAMPLE RESULTS AUTO EXPORT

When the **Enable Sample Results Auto Export** function is enabled, every sample result produced on the BioProfile FLEX2 will be automatically exported to the Shared Folder on the Bridge Computer, including onboard and external QC results. The results will be exported 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 for that month.

To enable/disable the automatic exportation of sample results to the Bridge Computer:

1. Select **Settings** (Right Home screen), then select **General** to open the General Settings Screen.
2. Select the empty box next to the words Enable Sample Results Auto Export. This will place a checkmark in the box.
3. Select **Save** in the Command Bar to save the Sample Results Auto Export configuration.

3.50 *Enable Sample Results Auto Export*

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**.

NOTE: *For more information on exporting sample results, see Exporting and Printing Historical Results in* ***Section 2.2.6*** *and* ***Section 2.3.3****- Exporting and Printing Data from the FLEX2.*

3.5.1.5 Enable pH/pCO_2 Mode 2

A user with Administrator privilege level may enable or disable pH/pCO_2 Mode 2. By default, pH/pCO_2 Mode 2 is disabled. Enabling pH/pCO_2 Mode 2 improves both pH and pCO_2 recovery when samples with pCO_2 concentrations greater than 100 mmHg are analyzed. Nova Biomedical recommends contacting Technical Support if you believe the system requires optimization or enabling of pH/pCO_2 Mode 2.

To Enable/Disable pH/pCO_2 Mode 2:

1. Select **Settings** (Right Home screen), then select **General** to open the General Settings Screen.
2. Select the empty box next to the words Enable pH/pCO_2 Mode 2. This will place a checkmark in the box.
3. Select **Save** in the Command Bar to save the new configuration.
4. To disable the pH/pCO_2 Mode 2, select the box next to the words Enable pH/pCO_2 Mode 2 to remove the checkmark, followed by **Save**.

3.5.1.6 Language Configuration

To configure the language of the BioProfile FLEX2 system, perform the following steps:

1. From the Right Home screen select **Settings**, then select **General** to open the General Settings Screen.
2. In the Language dropdown box, select the desired Language for the User Interface:

English	Japanese	French	Polish	Portuguese
Chinese	Korean	German	Spanish	Italian

3. Select **Save** in the Command Bar to save the configured language.

Note: *English is the default language of the BioProfile FLEX2 Analyzer. The ability to select additional languages is currently not available.*

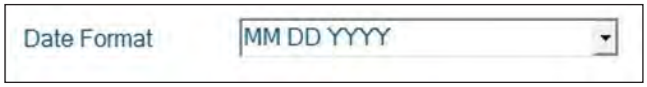
3.5.1.7 Date Format Configuration

The BioProfile FLEX2 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. Select **Settings** (Right Home screen), 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.



3.51 *Date Format*

3.5.1.8 Date Separator Configuration

The BioProfile FLEX2 has 3 different Date Separator options: (/), (-), and (.).

To configure the Date Separator, perform the following steps:

1. Select **Settings** (Right Home screen), 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. Select **Save** in the Command Bar to save the configured Date Separator.

3.52 *Date Separator*

3.5.1.9 TIME FORMAT CONFIGURATION

The BioProfile FLEX2 can be configured for 24 Hour Time Format or 12 Hour Time Format.

3.53 *Time Format 24 or 12 Hour*

Select the desired format, then select **Save** in the Command Bar to save the configured Time Format.

3.5.1.10 NUMERIC FORMAT CONFIGURATION

The BioProfile FLEX2 has 2 different Numeric Format options for sample results reporting:

3.54 *Numeric Format*

To configure the Numeric Format, perform the following steps:

1. Select **Settings** (Right Home screen), 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. Select **Save** in the Command Bar to save the configured Numeric Format.

3.5.1.11 ENABLE ONBOARD QC

By selecting **Enable Onboard QC**, the analyzer can perform manual and/or automated QC analysis using the onboard QC cartridges for both the Chemistry and pH/Gas modules. If Enable Onboard QC is not selected, no QC icons will appear in the Status Bar, and no QC can be scheduled to run. Onboard QC is discussed further in **Section 3.4.1**.

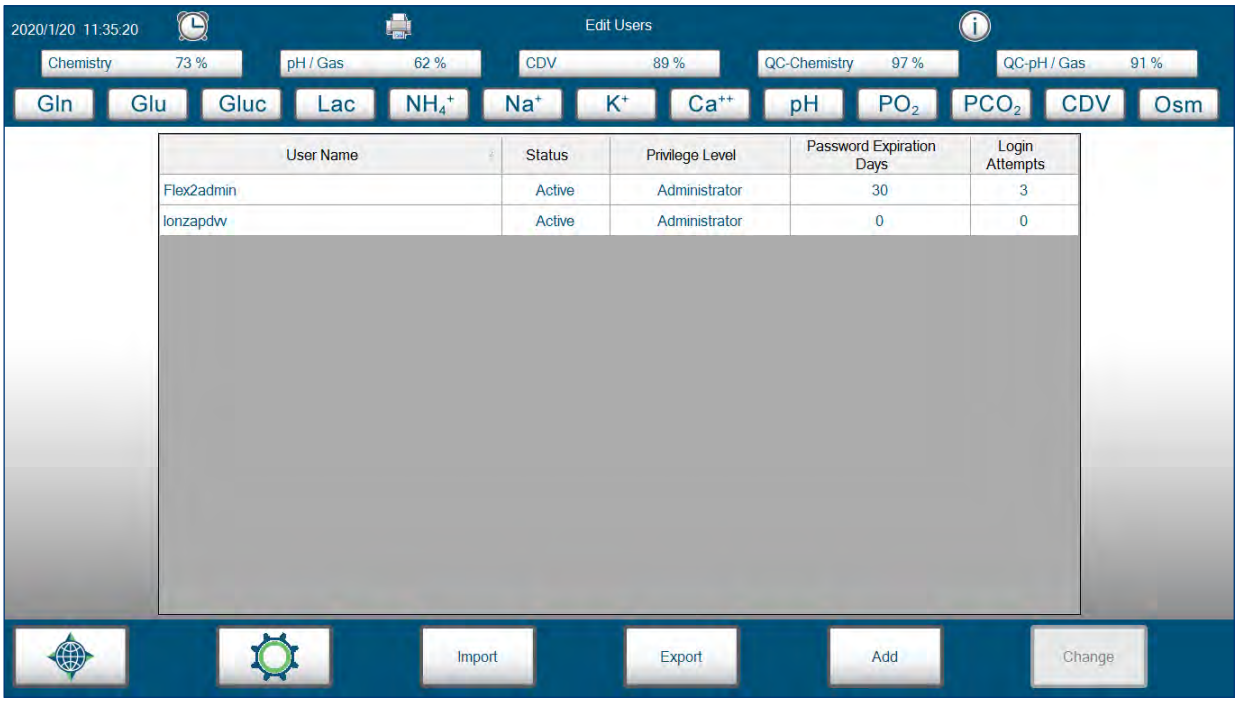
3.5.2 CREATE/EDIT USERS

The BioProfile FLEX2 allows an operator with Administrator privileges to create and edit User Accounts for other system operators. Each User Account must have a unique User Name and an associated Password. 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 for the number of failed log-in attempts for each user.

When initially setting up the FLEX2, use the default administrator account to login and create additional users. The default administrator username and password is U: Flex2admin P: Password1. After initial login to the default administrator account the system will require the password be changed.

3.5.2.1 Creating a User Account

1. Select **Settings** (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, 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.



3.55 *Edit Users Screen*

3. Enter a User Name in the box provided. User Names must be 3-25 alphanumeric characters and are not case sensitive. User names can include dashes (-) and underscores (_) but no spaces or special characters (!,@,#,$,%,^,&,*,/,<).
4. Enter a Password for the User Account. Passwords must be 8-25 alphanumeric characters and are case sensitive. The password must include at least 1 capital letter, 1 lowercase letter, and 1 number. Passwords can include dashes (-) and underscores (_) but no spaces and no special characters (!,@,#,$,%,^,&,*,/,<).

3.56 *Add User Account Window*

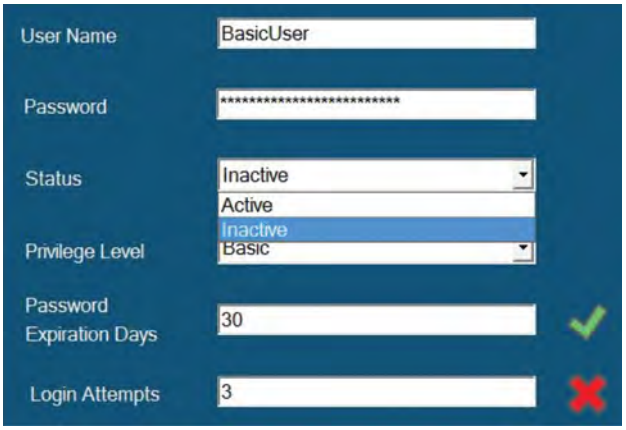
Note: *The alert icon will appear and flash next to the User Name and Password entry boxes when entering in these items. The alert icon will be visible until the User Name and Password criteria have been met. When adding a new User Account, the system will not let the operator enter any information into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

5. 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.

3.57 *Alert Icon Next to Inadequate User Name*

6. Select the Privilege Level for the User Account (**Basic**, **Intermediate**, **Advanced**, or **Administrator**).
7. Set the number of days after which the password will expire.

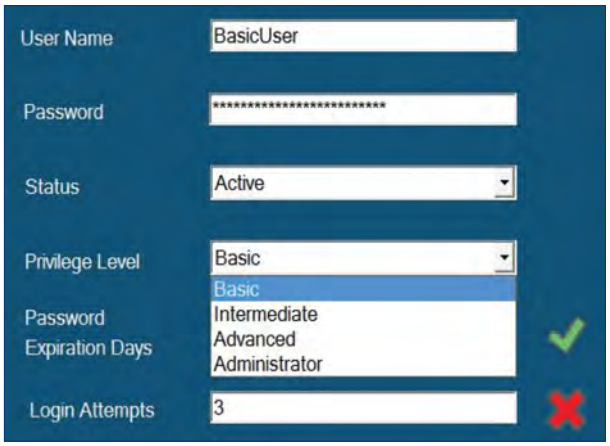
   For example, if this number is set to 30 days, the password will expire every 30 days. The end user will be required to create a new password every 30 days upon logging in to the system. The same password cannot be used twice. If this number is set to 0, the password will have no expiration for this User Account.



3.58 *User Account Status*

8. 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.



3.59 *Privilege Level Selection*

9. 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.

3.5.2.2 CHANGING A USER ACCOUNT

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

1. 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.
2. 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.
3. Make all necessary edits to the User Account information, then select the green checkmark to save the changes. Select the red X to cancel changes.

NOTE: *In V 4.2 and newer software, an operator with administrator privileges can disable the Nova Service User Account to help enhance analzyer security. If your facility is considering this option, please contact Technical Support prior to disabling this.*

3.5.2.3 IMPORTING & EXPORTING USER ACCOUNTS

The BioProfile FLEX2 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 analyzers. An operator with Administrator privileges can perform an import or export of User Accounts.

To Export/Import User Accounts:

1. Insert a USB drive into either open port on the back of the FLEX2 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 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 configured on that system.

Note: *Any users configured on the analyzer you are importing a list of users to will be overwritten by the imported users.*

7. Select **Import** from the Command Bar, then select the drive you wish to import the User Accounts from.

3.5.2.4 User Account Privilege Levels

This section details the available User Account privilege levels for the BioProfile FLEX2 Analyzer and the specific functions that can be performed at each level.

Menu	Privilege	Basic	Intermediate	Advanced	Admin
Analysis Menu	Run Manual Sample Analysis	✓	✓	✓	✓
	Cancel Manual Sample Analysis	✓	✓	✓	✓
	Run Load-and-Go Sample Analysis	✓	✓	✓	✓
	Cancel Load-and-Go Sample Analysis	✓	✓	✓	✓
	Run 96-Well plate Sample Analysis	✓	✓	✓	✓
	Cancel 96-Well Plate Sample Analysis	✓	✓	✓	✓
	Run Autosampler Sample Analysis	✓	✓	✓	✓
	Cancel Autosampler Sample Analysis	✓	✓	✓	✓
	View Sample Information	✓	✓	✓	✓
	Enter Sample ID	✗	✓	✓	✓
	Enter Batch ID	✗	✓	✓	✓
	Enter Vessel ID	✗	✓	✓	✓
	Enter Cell Type	✗	✓	✓	✓
	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 O_2% (Defaulted to 20.9%)	✗	✓	✓	✓
	Change the Pre-dilution Multiplier (Defaulted to 1.0x)	✗	✓	✓	✓
	Select/deselect the pH/Gas Module	✗	✓	✓	✓
	Select/deselect the Chemistry Module	✗	✓	✓	✓
	Change Chemistry Dilution Ratio	✗	✓	✓	✓
	Select/deselect CDV Module	✗	✓	✓	✓
	Change CDV Dilution Ratio	✗	✓	✓	✓

Menu	Privilege	Basic	Intermediate	Advanced	Admin
	Change the Cell Inspection Type	✗	✓	✓	✓
	Select/deselect the Osmolality Module	✗	✓	✓	✓
Historical Results Menu	View, Export, and Print Historical Results	✓	✓	✓	✓
Calibration Menu	Run pH/Gas & Chemistry Calibration	✓	✓	✓	✓
	Run CDV Calibration	✗	✓	✓	✓
	Run Osmometer Calibration	✗	✓	✓	✓
QC Menu	Run Onboard/External QC	✓	✓	✓	✓
	Export/Print QC Results	✓	✓	✓	✓
	View QC Results	✓	✓	✓	✓
	Cancel QC Analysis	✓	✓	✓	✓
	Modify Onboard/External QC	✗	✗	✓	✓
User Menu	Change Password	✓	✓	✓	✓
	Log Out of Current User	✓	✓	✓	✓
Maintenance Menu	Run Module Depro	✓	✓	✓	✓
	Run Depro Wells	✓	✓	✓	✓
	Change Syringe	✓	✓	✓	✓
	Change Probe	✓	✓	✓	✓
	Change Pump Tubing	✓	✓	✓	✓
	Initialize Carousel Tray	✓	✓	✓	✓
	Long-Term Shutdown	✓	✓	✓	✓
	Clean Cell Density Flowcell	✓	✓	✓	✓
	Intensive Clean Cell Density Flowcell	✓	✓	✓	✓
General Settings	Modify General Settings	✗	✓	✓	✓
	Create/Edit Users	✗	✗	✗	✓
	Modify Parameters	✗	✗	✓	✓
	Modify Scheduling (Automatic Maintenance)	✗	✓	✓	✓
	Modify OPC	✗	✗	✗	✓
	Modify List Management	✗	✓	✓	✓
	Modify Cell Inspection Type Settings	✗	✗	✓	✓
	Enable pH/pCO_2 Mode 2	✗	✗	✗	✓
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	✓	✓	✓	✓

Menu	Privilege	Basic	Intermediate	Advanced	Admin
	View Warranty Logs	✓	✓	✓	✓
	Print Warranty Logs	✓	✓	✓	✓
	Export Warranty Logs	✓	✓	✓	✓
	Export Diagnostic Logs	✓	✓	✓	✓
Database Menu	Backup	✗	✗	✗	✓
	Restore	✗	✗	✗	✓
Shutdown Menu Button	Shutdown Analyzer	✗	✓	✓	✓
Chemistry Module Status Window	Run Chemistry Calibration	✓	✓	✓	✓
	Run Clear Wells	✓	✓	✓	✓
	Run Prime	✗	✓	✓	✓
pH/Gas Module Status Window	Run pH/Gas Calibration	✓	✓	✓	✓
	Run Prime	✓	✓	✓	✓
pH/Gas QC Window	Prime pH/Gas QC	✓	✓	✓	✓
CDV Module Status Window (If Applicable)	Run CDV Calibration	✗	✓	✓	✓
	Run Clear Wells	✓	✓	✓	✓
	Run Prime	✓	✓	✓	✓
	Run Auto-Intensity	✓	✓	✓	✓
OSMO Module Status Window (If Applicable)	Run Osmo Calibration	✗	✓	✓	✓
	Change Wiper and Tubes	✓	✓	✓	✓
	Run Clear Wells	✓	✓	✓	✓
Warranty Issues Window	Claim Failed Sensors	✗	✓	✓	✓
	Claim Failed Sensor Card	✗	✓	✓	✓
Print Icon Status Window	Access Print Icon Status Window	✓	✓	✓	✓
	Access Remote Desktop	✗	✗	✗	✓
Time/Date Window	Change Analyzer Date and Time	✗	✗	✗	✓
Information Button	Access Video Help	✓	✓	✓	✓
Autosampler Configuration	Access Autosampler Configuration	✗	✗	✓	✓
Autosampler Maintenance	Prime Reactor	✓	✓	✓	✓
	Prime Pack	✓	✓	✓	✓
	Initialize RSM	✓	✓	✓	✓
	Change Syringe	✓	✓	✓	✓
	Clean Sample Line	✓	✓	✓	✓
	Intensive Clean Sample Line	✗	✓	✓	✓
	Intensive Clean Reactor Line	✗	✓	✓	✓
	Long Term Shutdown	✗	✓	✓	✓
Autosampler Scheduling	Access Autosampler Scheduling	✗	✓	✓	✓

3.5.3 PARAMETERS SETTINGS

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

3.5.3.1 CONFIGURING UNITS OF MEASURE

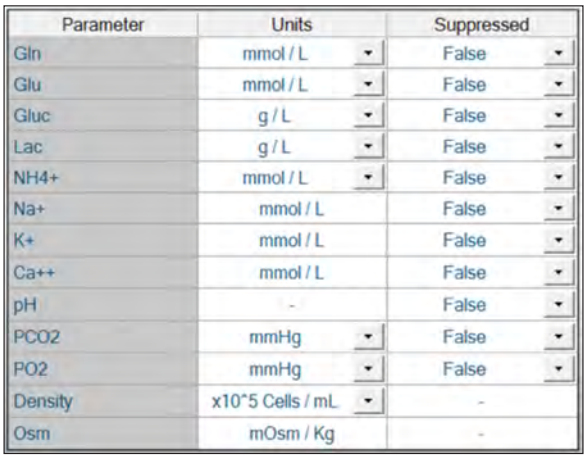
The FLEX2 Analyzer uses the following units of measure for each test parameter:

Directly Measured 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
Cell Density (TCD/VCD)	**x10^5 Cells/mL**, or x10^6 Cells/mL
Osmolality	**mOsm/kg H_2O**

Calculated Parameters	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** (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
Density	x10^5 Cells / mL	-
Osm	mOsm / Kg	-

3.60 *Parameters Settings Menu*

3.5.3.2 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.

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

- *pCO_2 is dependent on pH*
- *Glutamine (Gln) is dependent on Glutamate (Glu)*
- *Ammonium (NH_4^+) is dependent on Sodium (Na^+) and Potassium (K^+)*

3.5.4 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 (Right Home screen), then select **Scheduling** to open the Scheduling Menu.

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

- Onboard Quality Control (QC)
- Chemistry/pH/Gas Calibration Time
- Depro Wells
- Cell Density (CDV)
- Database Backup
- ESM (if installed)
- Autosampler (if installed)

3.5.4.1 Onboard QC Scheduling

Select **QC** to display 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.

3.61 *Scheduling Menu*

Note: *Onboard QC must be enabled through the Settings menu before any onboard QC can be scheduled. See **Section 3.4.1** Onboard Controls for more information.*

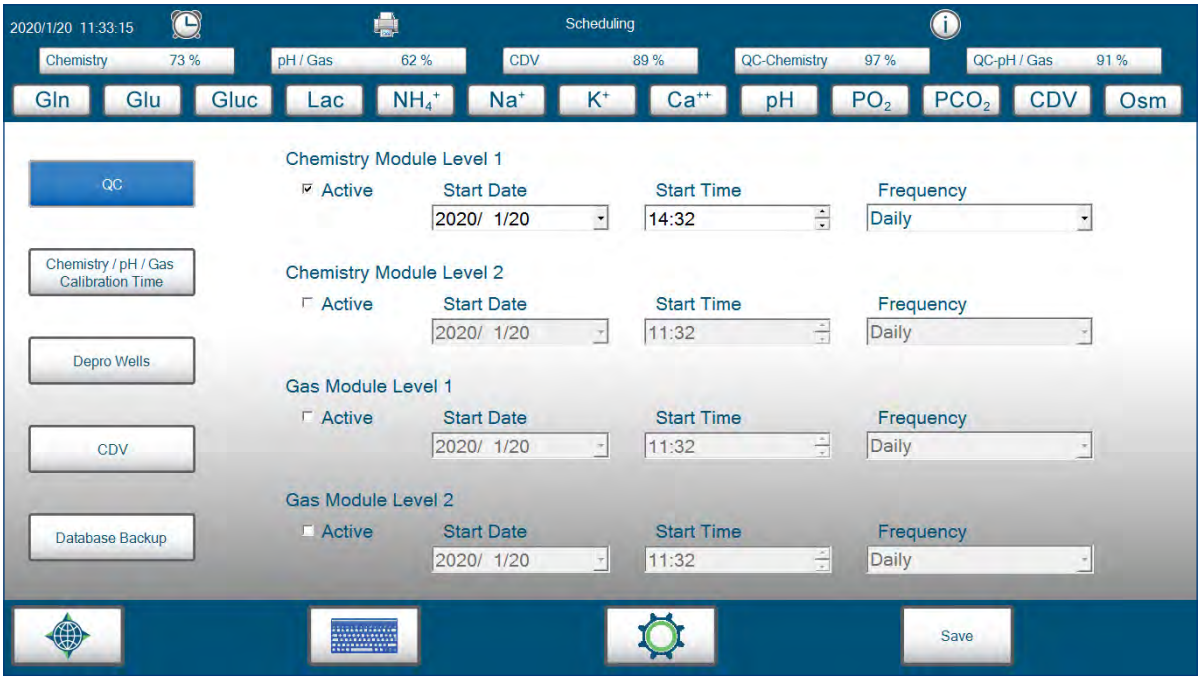
To schedule onboard QC to run:

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 Next Scheduled Event icon in the Status Bar, or via the Scheduling menu.



3.62 *QC Scheduling Menu*

3.5.4.2 pH/Gas and Chemistry Automatic Calibration

Select **Chemistry/pH/Gas Calibration Time** to display 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.

3.63 *Chemistry/Gas Calibration Scheduling Options*

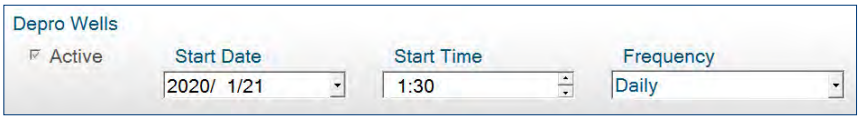
NOTE: *Automatic pH/Gas and Chemistry calibrations will occur every two hours regardless of the time selected.*

3.5.4.3 Depro Wells Scheduling

Select **Depro Wells** to display the configuration menu for setting the automatic onboard Depro of the Waste Well and CDV Well. By default, Depro wells will be scheduled to occur daily and cannot be deactivated.

To change the schedule of automatic Depro cycles for these wells:

1. Select a Start Date for the Depro Wells function.
2. Select a Start Time for the Depro Wells function.



3.64 *Depro Wells Scheduling Options*

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 analyzer will not be used.*

3.5.4.4 Cell Density Maintenance Scheduling

Select **Cell Density** to display the configuration menu for setting up automatic onboard maintenance of the Cell Density Module. From within this menu, an operator can configure the Adjust Intensity and Clean Cell Density Flowcell sequences.

3.65 *Cell Density Maintenance Scheduling Options*

Adjust Intensity

The Cell Density Module uses the Trypan Blue exclusion assay to determine Total Cell Density, Viable Cell Density, and cell Viability. Trypan Blue Dye is known to precipitate as it ages. The dye can become lighter or darker depending on the volume remaining in the cartridge and the amount of precipitation that occurs while the pack is installed. The light intensity that creates the background for cell imaging in the Cell Density flowcell assembly needs to remain constant for consistent CDV analysis. The LED light that provides the background light intensity can be adjusted to normalize this setting as the Trypan Blue ages or changes color. The BioProfile FLEX2 will automatically run an Adjust Intensity sequence whenever a new CDV Reagent Cartridge is installed and when the module is calibrated, but the Adjust Intensity sequence should also be run regularly.

To schedule regular automatic Adjust Intensity sequences:

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

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 Adjust Intensity schedule configuration.

Note: *A weekly Adjust Intensity cycle is recommended. Adjust Intensity requirements will vary based on system usage. When the Adjust Intensity function is running, the Cell Density Module will be temporarily unavailable for sampling. If possible, schedule this function to occur during times of the day when the BioProfile FLEX2 analyzer will not be used.*

Clean Cell Density Flowcell

The CDV Reagent Cartridges include cleaning solutions that are used to clean the CDV well, flow path tubing, and flowcell assembly between sampling to remove cellular debris and prevent sample-to-sample cross contamination. Additional cleaning cycles of the CDV flowcell can be configured to run automatically on a scheduled basis to help maintain the cleanliness of the flowcell.

To schedule regular automatic Clean Cell Density Flowcell sequences:

1. Check the **Active** box to activate the Clean Cell Density Flowcell scheduling function.
2. Select a Start Date for the Clean Cell Density Flowcell function.
3. Select a Start Time for the Clean Cell Density Flowcell function.
4. Select a Frequency (Daily, Weekly, Bi-Monthly, Monthly) for the Clean Cell Density Flowcell function.

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 Clean Cell Density Flowcell schedule configuration.

Note: *A daily Clean Cell Density Flowcell sequence is recommended. Cleaning requirements will vary based on system usage. When the cleaning function is running, the Cell Density Module will be temporarily unavailable for sampling. If possible, schedule this function to occur during times of the day when the BioProfile FLEX2 analyzer will not be used.*

3.5.4.5 ESM Depro Scheduling

Select **ESM** to display the configuration menu for setting the automatic onboard Depro of the ESM module. This option will only display if you have an ESM module installed. For more information, please see the ESM Instructions for Use Manual (PN: 59698).

3.5.4.6 Autosampler Scheduling

Select **Autosampler** to display the configuration menu for the On-Line Autosampler module. This option will only display if you have an OLS module installed. For more information, please see the On-Line Autosampler Instructions for Use Manual (PN: 63623).

3.5.4.7 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 (with the exception of CDV image files).
- 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 and the number of CDV images, 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 3.8** Database.*

3.5.5 OPC

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

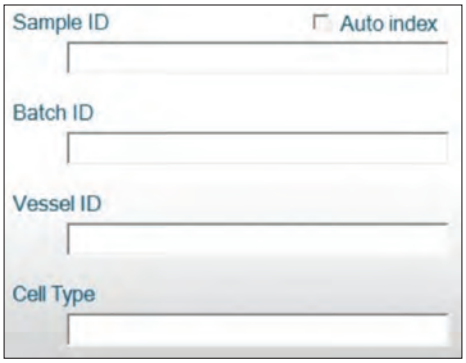
For information on how to purchase an OPC server and license for an existing FLEX2 analyzer, contact your regional Nova Biomedical Account Manager or authorized distributor. For information on setting up your OPC Server and licensing, please refer to the OPC Manual (PN 60644) or contact Nova Biomedical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

NOTE: *The OPC functionality is only available on FLEX2 systems with software version 3.2.18138 or later. A software update may be necessary to address this and any re-validation is ultimately up to the end user's discretion.*

3.5.6 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



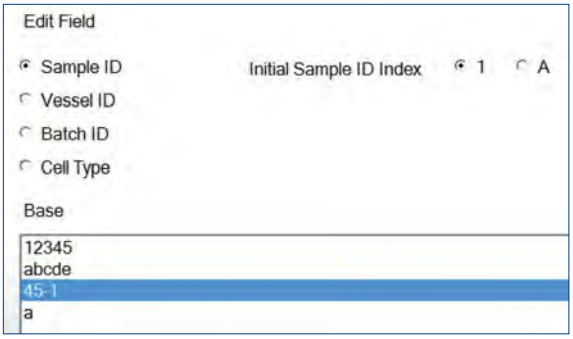
3.66 *Sample Information Entry Fields*

Each time new information is entered into these sample information fields, the BioProfile FLEX2 saves and keeps a running list of each identifier for future use.

Whenever a new sample is configured, the sample information fields 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.



3.67 *List Management Settings Menu*

3.5.6.1 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 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.
2. Select the desired identifier in the base list to highlight it in blue.
3. Once the identifier is highlighted, select **Delete** in the Command Bar to remove it from the list.
4. Select **Save** in the Command Bar to save all changes to the sample list settings.

3.5.6.2 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.

3.5.7 CELL INSPECTIONS

Cell Density and Viability (**CDV**) is the measurement of the total number of cells in suspension and a proportional determination of live and dead cells within suspension. To best understand how results are calculated and the parameters that affect CDV measurement, it helps to have an overview of how the cell density module works.

1. A sample is aspirated and dispensed into the CDV well.
2. The sample is mixed with Trypan Blue and advanced to the imaging cuvette where the cells are allowed to settle.
3. The imaging cuvette is indexed from 45 to 50 locations for analysis.
4. The sample is discarded as waste. The well, lines, and imaging cuvette are cleaned in preparation for the next sample.
5. The analysis is done by the onboard imaging system, and the raw images are stored in the system memory.
6. At the completion of the imaging process, the BioProfile FLEX2 presents the operator with virtual slides that can be enlarged for closer inspection.

These images are subjected to analysis using Cell Inspection Parameters. As digital images, they are not subject to degradation and can be reanalyzed with new parameters at any time within 30 calendar days of imaging. The BioProfile FLEX2 applies the parameters to the images and presents the user with both a graphical and numerical representation of the results. An operator can configure 10 parameters that include brightness thresholds, size, focus, and settling time.

NOTE: *If the Focus Offset and/or Settling Time values are changed for a Cell Inspection Type, a new sample must be run in order for those values to take effect on the images that are produced. If any of the remaining 8 parameters are changed, the images can simply be re-analyzed for the changes to take effect.*

NOTE: *After 30 days the image format is compressed to save space. The images are stored and can be reviewed, but the compression does not allow for reanalysis.*

Capabilities and Reporting

The Cell Density Cell Viability module is integrated into the FLEX2 with both hardware and software functionality. Presenting a sample for CDV analysis occurs in the same manner as other analyses (Manual, Load-and-Go, and Tray modes) and runs concurrently with other modules.

Results are presented in the **Historical Results** screen, along with any other results from other selected modules.

The FLEX2 utilizes a portion of the total volume of presented sample and from this calculates the following:

- Viable Density
- Total Density
- Viability
- Total Live Count
- Average Live Diameter
- Live Standard Deviation

3.5.7.1 Live or Dead Cell Identification

Trypan Blue Exclusion

The Trypan Blue Exclusion assay is used to determine the number of viable cells present in a cell suspension. It is based on the principle in which, unlike dead cells, live cells possess intact cellular membranes that exclude Trypan Blue dye. A cell suspension mixed appropriately with Trypan can be visually examined to determine whether individual cells take up or exclude dye. Viable cells have clear cytoplasm whereas nonviable cells have blue cytoplasm.

Programmed Cell Death

Apoptosis is typically a passive, degenerative process, which is characteristically different from cell necrosis in morphology and biochemistry. Apoptosis results in the condensation of the nucleus and decrease in cellular volume, eventually leading to the fragmentation and blebbing of the cell. These smaller constituents (apoptotic bodies) may be confused for individual small dead or live cells. The life cycle within a properly maintained cell culture typically follows natural cell growth and death via apoptosis. Observable cellular morphology coupled with Trypan exclusion allows the FLEX2 to correctly ascertain the differences between live and dead cells. The results can be visualized and are quantified using the FLEX2's integrated optics and calculations within the CDV module.

Configuring the Cell Density Module

An operator with appropriate privileges can customize the CDV module to include individual settings for specific cell types, growth stages, and study preferences. The FLEX2 has built-in inspection types that allow for quality control measurements (QC) and Standard CHO.

Cell Inspection Types

The FLEX2 provides 10 configurable parameters that can refine how the sample images are processed.

These parameters include:

Live Cell Brightness Threshold

- Live Cell Brightness is measured from 0 to 255 on a scale where zero is black and 255 is white. The normal background of a Trypan Blue stained slide is around 127.
- Changing this parameter results in changes to the minimum allowable brightness threshold of a live cell.
  For example, a slightly dark live cell may not be counted at a setting of 200 but is counted correctly at a setting of 180.

Live Cell Minimum Size (Diameter)

- Changing this parameter increases or decreases the minimum size allowable (0.00 – 100.00 µm) to distinguish a live cell.
- Using your knowledge of your own cell lines, set this number to the size you feel is adequate for a small live cell.
  For example, if the average CHO cell is 12.5 µm, you may find a setting of 8-9 may work best to include small viable cells while excluding smaller apoptotic bodies.
- Decrease this number if live cells are bright, slightly small and not counted as live during an initial analysis.

Dead Cell Brightness Threshold

- Dead Cell Brightness is measured from 0 to 255 on a scale where zero is black and 255 is white. This setting sets the upper limit for dead cell brightness.
- Increase this number if dead cells are light in color and are not counted as dead.

Dead Cell Minimum Size (Diameter)

- This parameter sets the minimum size (0.00 – 100.00 µm) a cell needs to be in order to be distinguished as dead.
- If debris from lysed cells is counted as dead cells, increasing this number excludes the smaller non-cell items.
- Decrease this number if small dead cells are not counted.

Dead Cell Aggregate Area

- This parameter sets the minimum area (0 – 1x10^5 µm^2) the FLEX2 counts as an aggregate of dead cells.
- This number approximates the area taken by 2 or more dead cells in a clump.
- Increase this number if single dead cells are counted as multiple dead cells.

NOTE: *Clumps of dead cells are identified with orange numbers where the number represents estimated number of dead cells within the aggregate.*

Average Dead Cell Diameter.

- This number is used to calculate the number of dead cells in an aggregate clump (1 – 100.00 µm).
- Typically this number is 2-3 µm smaller than the average live cell diameter for the 12.5 µm CHO cell.
- Change this number if aggregate clumps of dead cells are not being counted correctly.

  For example, if you have a clump made up of what appears to be 10 dead cells, yet the orange aggregate count is 25 you need to increase the Average Dead Cell Diameter.

Debris Size Threshold

- This number sets the minimum area (0 – 1x10^5 µm^2) the FLEX2 counts as debris. An image with large debris present will be excluded from the analysis.
- Increasing this number allows smaller debris to be present without excluding the image from the analysis.

NOTE: *Images with a red X through them have been excluded from the analysis.*

Focus Offset

- This parameter is the focus setting for the cell type.
- Changing this number changes the distance between the objective lens and the cuvette flowcell stage.
- A more positive number decreases the distance between the objective lens and the cuvette.
- A properly focused image has all of the cells in that image in crisp focus with well-defined nuclei and cell membranes.

NOTE: *The Focus Offset value must be determined before any other parameters are adjusted.*

Settling Time

- This parameter changes the amount of time (seconds) the cells are allowed to settle before beginning the imaging process (15 - 240 seconds).
- Increase this number if cells appear in multiple planes.
- The settling time clock is initiated once the entire sample has been delivered to the cuvette.

NOTE: *Increasing the Settling Time value increases the overall analysis time of the sample.*

Cell Density Multiplier

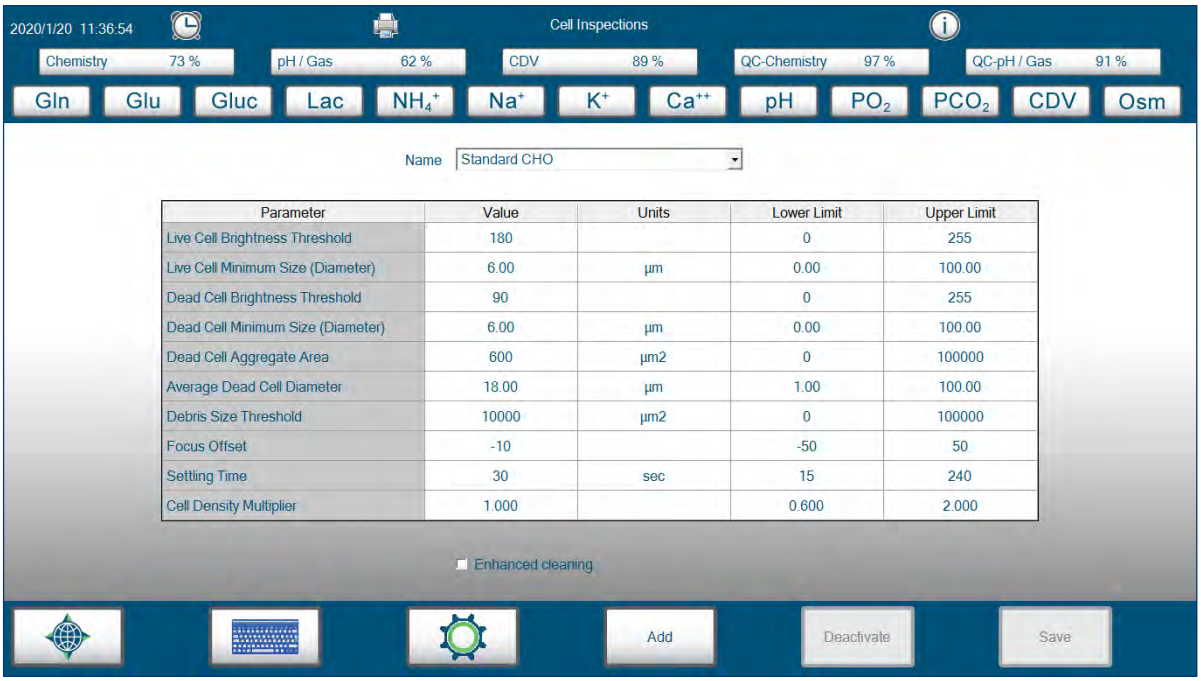
- This parameter allows the user to set a multiplier (0.6 - 2.0x) that adjusts the total and viable densities when correlating to a reference analyzer.

All parameters except for Focus Offset and Settling Time can be readjusted and used to reanalyze prior images to allow for optimum cell inspection configuration. It is important to note that although the Focus Offset and Settling Time can be adjusted at any time, these changes are not applied until a new sample is run.

3.5.7.2 Creating and Modifying Cell Inspection Types

Review or create new Cell Inspection Types by the following method:

1. Select **Settings** (Right Home screen).
2. Select **Cell Inspections** to bring up the Cell Inspections menu.
3. From the Cell Inspections Name dropdown menu, scroll down through the **Inspection Types** that are saved in the system. With the proper user privileges, all of these inspection types can be modified.



3.68 *Configure Cell Inspections Screen (Default Standard CHO Settings)*

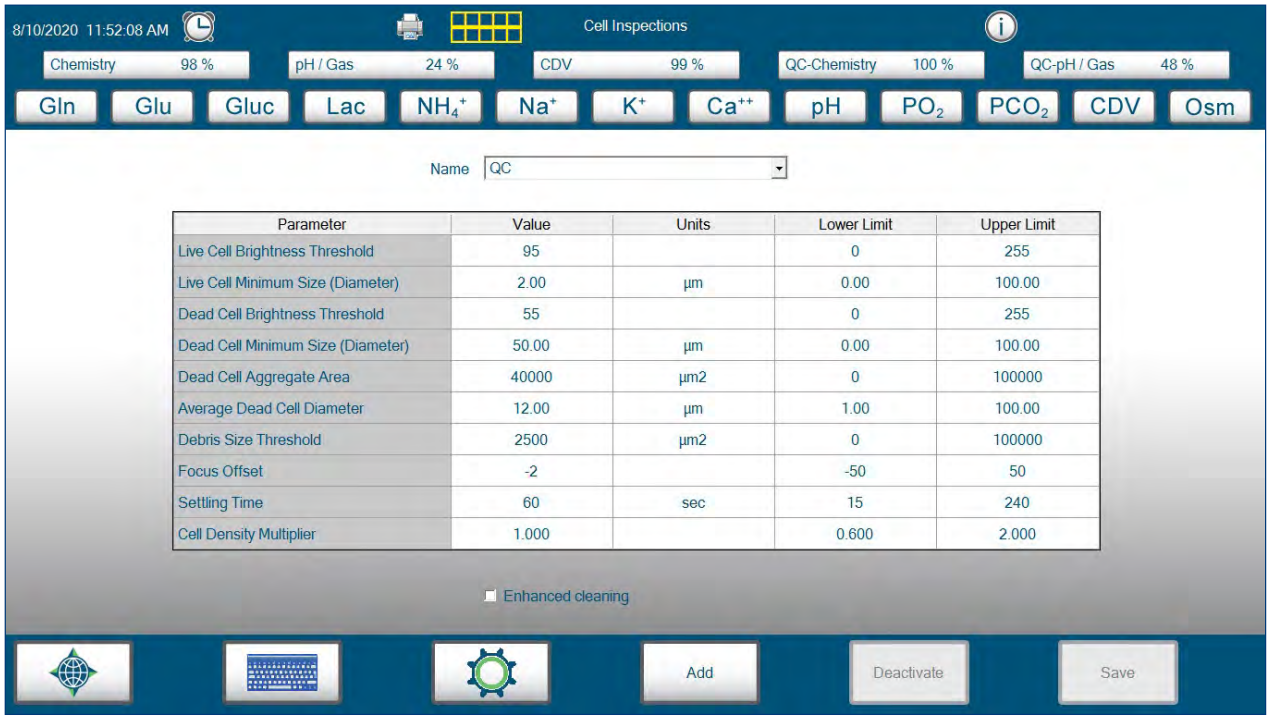
4. New inspection types can be created by selecting **Add** in the Command Bar. Selecting **Add** prompts the operator to enter the Name for the new inspection type in the **Name** box. Existing cell inspections can be modified by selecting them from the dropdown.
5. Configure the Cell Inspection parameters based on the cell line being analyzed.

Note: *The Focus Offset value must be determined before any other parameters are adjusted.*

6. After all values have been entered for the inspection criteria, select **Save** in the Command Bar to save the inspection type.

The **Standard CHO** Cell Inspection Type (pictured above) was based on numerous cell lines tested by Nova Biomedical. While this is a good starting point, Standard CHO may not be the most optimal inspection type for individual usage. Customization of an inspection type will greatly improve cell counting accuracy. For assistance with optimizing and customizing Cell Inspection Types, please contact Nova Biomedical Technical Support.

The **QC** Cell Inspection Type is optimized for counting of the polystrene beads in suspension within the ampuled CDV calibrator and controls (L8 & L9). These default settings (below) should not be modified.



3.69 *QC Cell Inspection Type Settings*

Cell Inspection Deactivation

Once a Cell Inspection Type has been created, it is stored permanently within the FLEX2 system database. A Cell Inspection Type can be edited but not deleted. However, a Cell Inspection Type can be deactivated by an operator with appropriate privileges. When an inspection type is deactivated it can no longer be selected from the sample configuration screen during sample analysis. When deactivating Cell Inspection Types be sure to also modify any Sample Types that may have been created using the Cell Inspection Type that was deactivated. A Sample Type with a deactivated Cell Inspection Type cannot be used as long as the Cell Inspection Type is deactivated.

To Deactivate a Cell Inspection Type:

1. Select **Settings** from the Right Home screen.
2. Select **Cell Inspections** to open the Cell Inspections menu.
3. In the Name dropdown box, select the desired Cell Inspection Type.
4. Select **Deactivate** to deactivate the Inspection Type.
5. Select **Save** to save the changes to the Cell Inspections configuration.

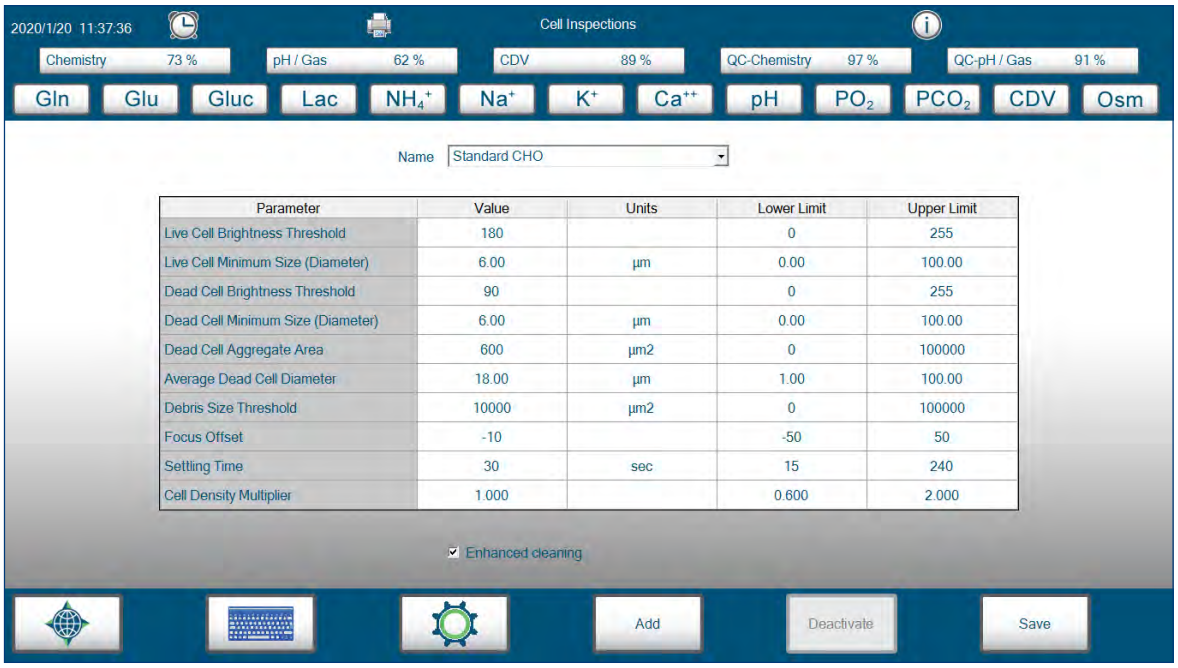
Enhanced Cleaning

When configuring a Cell Inspection Type, the operator has the option to activate the Enhanced Cleaning function. When Enhanced Cleaning is programmed for an Inspection Type, the system flushes the CDV module flow path and flowcell with additional cleaning solution whenever that inspection type is used for sample analysis. Enhanced cleaning is recommended for Cell Inspection Types that will be used to analyze cell culture samples that are particularly sticky, clumpy, or viscous.

NOTE: *Turning on Enhanced Cleaning for a Cell Inspection Type will add an additional 20 seconds to each sample analysis when that inspection type is used.*

To turn On or Off the Enhanced Cleaning function:

1. Select **Settings** from the Right Home screen.
2. Select **Cell Inspections** to open the Cell Inspections menu.
3. In the Name dropdown box, select the desired Cell Inspection Type.
4. To turn on Enhanced Cleaning, check the box next to Enhanced Cleaning.
5. Select **Save** to save the changes to the Cell Inspections configuration.



3.70 *Cell Inspection Type with Enhanced Cleaning*

3.5.8 Autosampler

This option will only be available on systems interfaced with the BioProfile FLEX2 On-line Autosampler. In the Autosampler Settings menu an operator can modify RSM configuration and schedule online sampling.

For more information, please reference the BioProfile FLEX2 On-line Autosampler Instructions for Use Manual.

3.6 RUNNING AN ANALYSIS

3.6.1 SELECT MODE

The BioProfile FLEX2 offers 3 default methods of sampling: Manual sampling, 24 position Load-and-Go carousel tray sampling, and 96-well Microtiter Plate sampling.

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 Load-and-Go samples, then 96-well Microtiter plate samples.

- 96-well Microtiter plate analysis can be suspended and placed on hold to schedule and execute Load-and-Go samples.
- Load-and-Go sampling can be suspended and placed on hold to execute Manual sampling.

Each level of sampling can resume when the sample mode with the higher priority has completed.

Manual Sampling

To configure and run sample(s), select **Analysis** (Left Home screen).

Select the **Manual Analysis** icon to display the Manual sample analysis screen.

3.71 *Manual Analysis Screen*

From the Manual Sample Analysis screen, the operator can configure the sample and begin the analysis. A manual sample can be configured to run any combination of test modules or a pre-configured Sample Type can be selected.

Once a sample has been fully configured with the desired

-Sample Type

-Parameter Panels

-Dilution Ratios

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

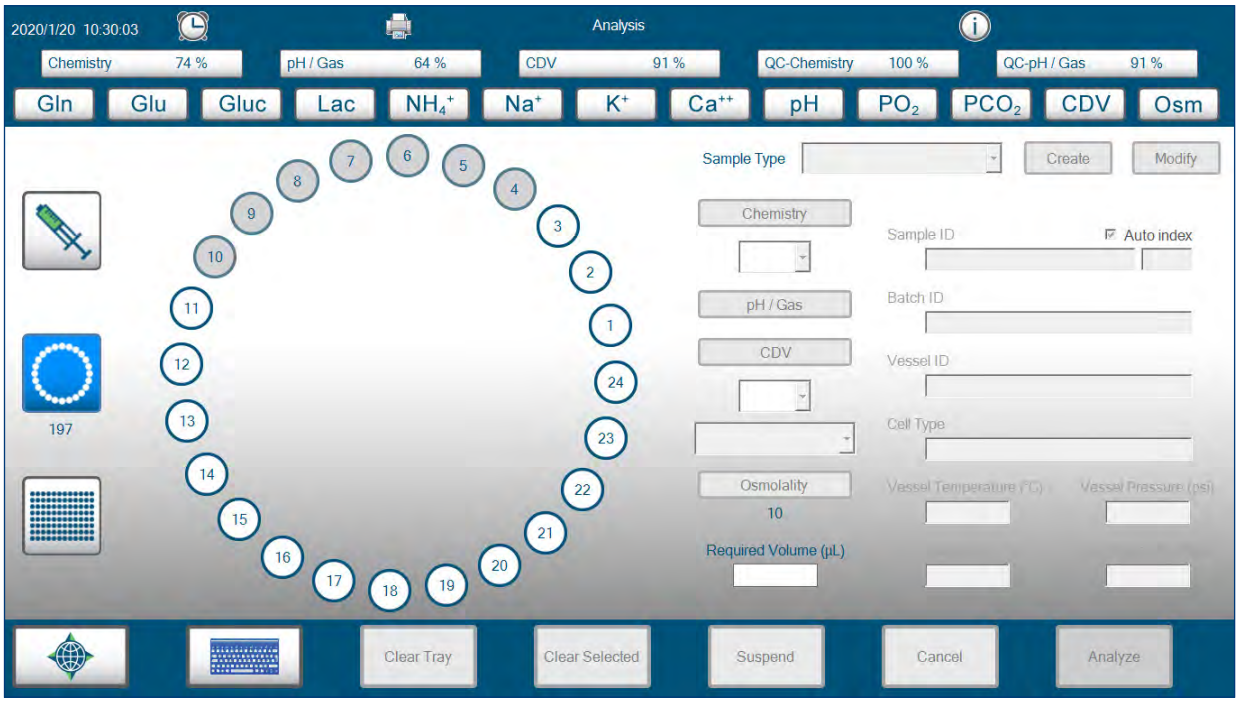
-Vessel Temperature, Pressure, Sparging O_2%, Pre-Dilution Multiplier

Select Analyze to begin the sample analysis. The **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.

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.***

Load-and-Go Sampling

Selecting the **Load-and-Go Analysis** icon displays the Load-and-Go sample analysis screen.

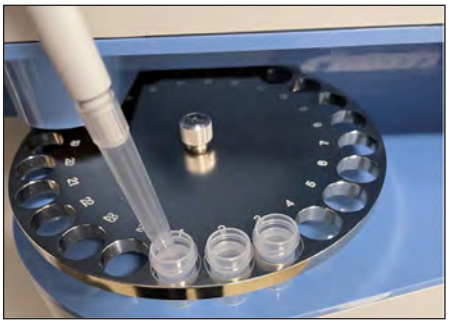


3.72 *Load-and-Go Analysis Screen*

Load-and-Go sampling requires sample cups be loaded into one or more of the available cup locations. To ensure optimal sample results, the operator should pipet 400 µL of sample into each sample cup.

When dispensing solution into the cup, sample droplets may sides of the cup, resulting in air gaps in the sample. To prevent these air gaps and subsequent analysis errors, perform the following steps:

1. Ensure the tip of the pipette is positioned at the bottom of the cup before dispensing.
2. In a slow and fluid movement, dispense the solution into the cup confirming that no air bubbles have been introduced into the solution.



3.73 *Pipet Sample into Each Sample Cup*

NOTE: *For optimal sample performance and to prevent analyzer damage, Nova Biomedical recommends the use of Nova Biomedical FLEX2 Sample Cups (PN 58275) when sampling from the FLEX2 Load-and-Go carousel.*

CAUTION: *The FLEX2 Load-and-Go carousel rotates clockwise. To prevent analyzer damage or bodily injury, avoid sticking any body parts or foreign objects into the Load-and-Go carousel.*

To configure a Load-and-Go analysis, an operator must select one or more of the available cup locations on the Load-and-Go carousel cup map.

When a cup location is selected, the location will change color. If a cup location is selected but no test modules have been configured, the cup background will appear yellow alerting the operator that at least one test module must be configured before that cup can be run. A tray sample can be configured to run any combination of test modules or a pre-configured Sample Type. When at least one test module is selected for a cup, the cup location will turn light blue. If the operator selects **Analyze** or selects another cup location, the previous cup turns dark blue indicating it is ready for analysis.

NOTE: *Load and Go sampling will only support 1:2 and 1:6 Cell Density Dilution Ratios.*

Additional cups can be added to the Load-and-Go carousel at any time, even while the system is running an analysis. If an operator selects a new cup location and a Load-and-Go analysis is running, the tray becomes suspended. **Resume** in the Command Bar must then be selected to continue the Load-and-Go testing.

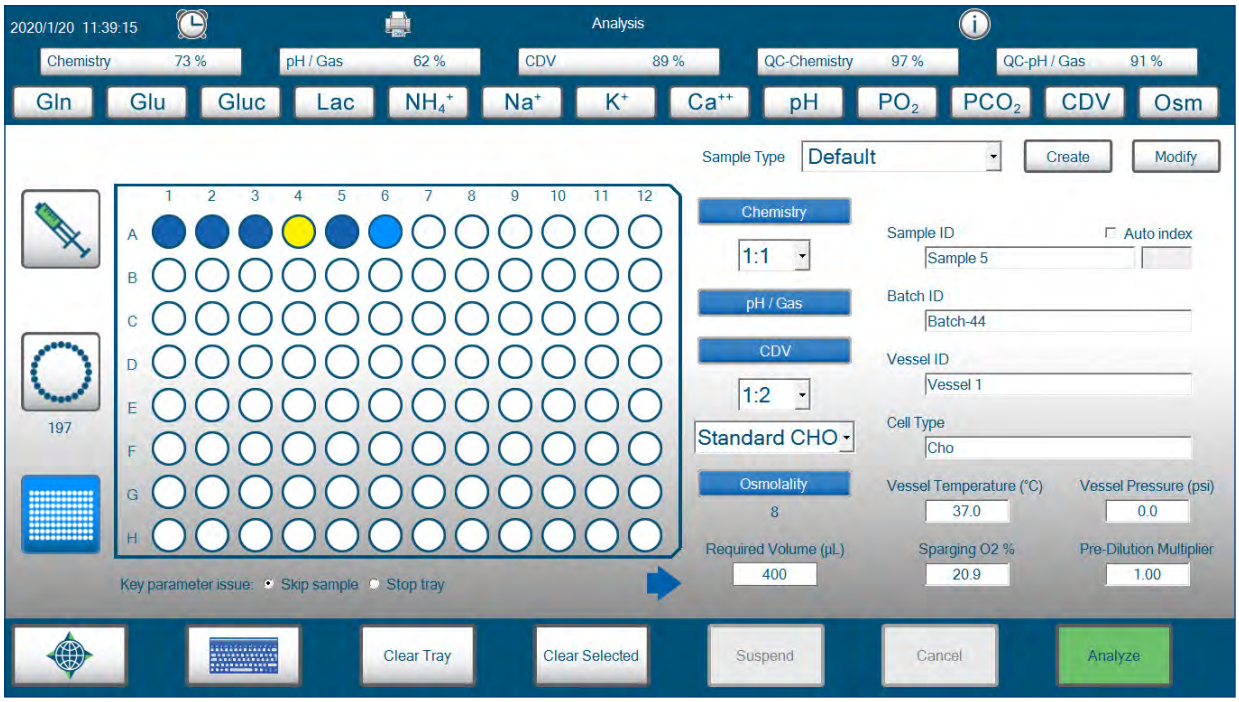
Clear Tray will clear all cup location configurations. To clear an individual cup location, select the desired cup, then select **Clear Selected**.

Load-and-Go sampling requires a minimum of 400 µL per cup. When the CDV module is selected, the system will attempt to re-suspend the sample before analysis, and this sample volume prevents short sampling. When the operator does not require results from the CDV module, the system will not attempt to re-suspend the sample.

NOTE: *Carousel samples are exposed to room air and exposure to the atmosphere will cause varying degrees of pO_2 equilibration. End Users must use discretion when considering the accuracy of gas values generated from samples run on the Load-and-Go carousel. For optimal pO_2 and pCO_2 results, Manual sampling from a syringe or sealed tube/cup is recommended.*

96-Well Plate Sampling

Select the **Tray Analysis** icon to display the 96-well Microtiter plate sample analysis screen.



3.74 *Microtiter Plate Sample Analysis Screen*

To configure a Microtiter plate analysis, an operator must select one or more of the available well locations on the Microtiter plate map.

From within the 96-well plate sample analysis screen, an operator can configure one or up to 96 wells for sample analysis. Similar to the Load-and-Go carousel, when a well location is selected, the location will change color. Each well can be configured to run any combination of test modules or a pre-configured Sample Type. A well must be configured to run at least one module. If a well location is selected but no test modules have been configured, the well background will appear yellow alerting the operator that at least one test module must be configured before that well can be run. When at least one test module is selected for a well, the well location will turn light blue. If the operator selects **Analyze** or selects another well location, the previous well turns dark blue. Sampling will begin at well A1 and will follow the order A1, A2, A3,…H12.

Note: *96-Well Plate sampling will only support a 1:2 or 1:6 Cell Density Dilution Ratio.*

When configuring 96-well plates using a Sample Type that utilizes Key Parameters, the operator has the option of programming the plate 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 96-well plate map screen. One of the options must be selected for the analysis.

Note: *For more information on Key Parameters see* ***Section 3.6.2****.*

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

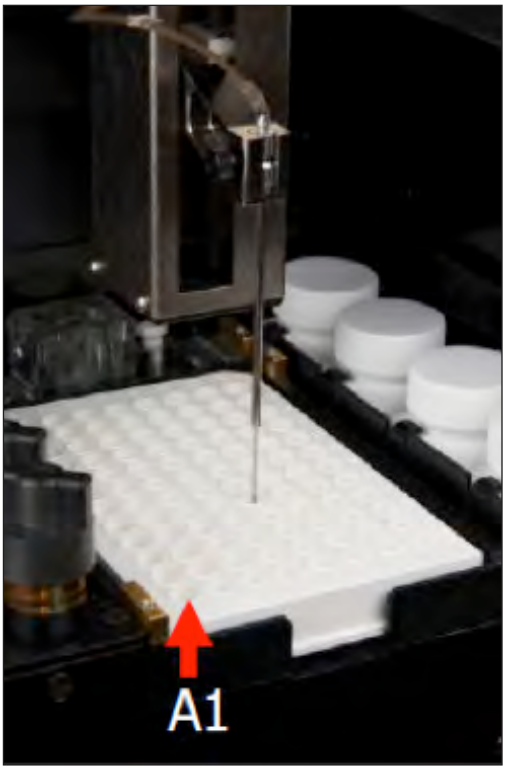
96-well plate sampling requires a minimum of 400 µL per well. When the CDV module is selected, the system will attempt to re-suspend the sample before analysis. This sample volume prevents short sampling. For optimal performance, Nova Biomedical recommends the following criteria with respect to 96-well plate type and fill volume:

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 µL
Profile:	U-Shape, 8 mm Diameter
Fill Volume:	400 µL (nominal pipette tolerance)

CAUTION: *Failure to supply a minimum volume of 400 µL per well may result in **No Sample** errors or less accurate results when using a 96-well plate.*

When the operator does not require results from the CDV module, the system will not attempt to re-suspend the sample. The operator can use any low profile 96-well plate with the wells filled to at least 400 µL (volume can be overfilled and is not as critical without CDV selected).

For ease of configuration, the 96-well plate 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. Use the notches and arrow depicted on the 96-well plate analysis screen to help orient the tray correctly when placing it inside the user domain.



3.75 *96-Well Plate Orientation*

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

In order to program additional 96-well plate samples, the current tray analysis must be suspended and the tray configuration must be cleared by selecting **Clear Tray**. Unlike the Load-and-Go carousel, you cannot continuously load samples into a 96-well tray.

NOTE: *A 96-well plate analysis may take several hours to complete. The samples are exposed to room air and exposure to the atmosphere will cause varying degrees of pO_2 equilibration. End Users must use discretion when considering the accuracy of gas values generated from samples run on the 96-well plate. For optimal pO_2 and pCO_2 results, Manual sampling from a syringe or sealed tube/cup is recommended.*

3.6.2 Select Sample Type

Create/Modify Sample Types

For easier sample configuration, the BioProfile FLEX2 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 comes pre-configured with the following Sample Type:

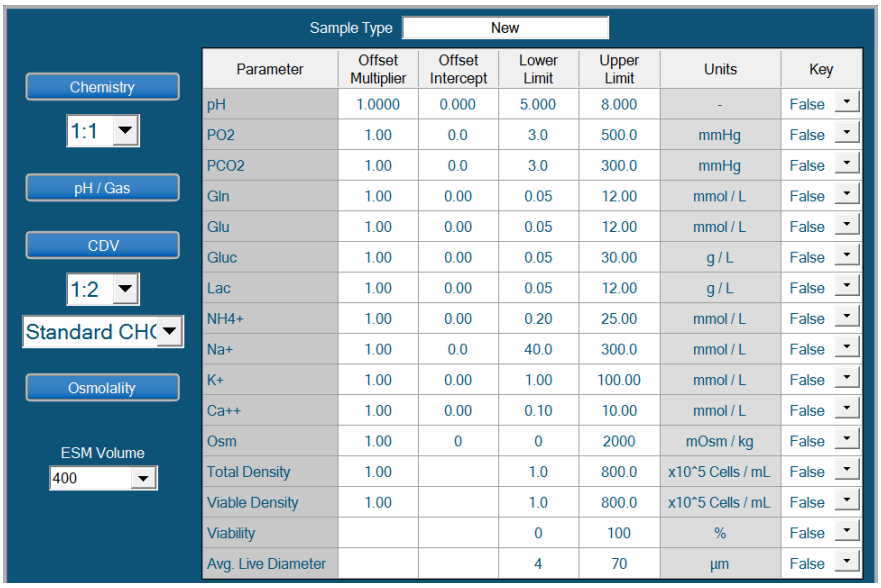
- Default
  - All modules selected
  - Standard CHO Cell Inspection Type
  - 1:1 Chemistry dilution ratio
  - 1:2 CDV dilution ratio

To Create a Sample Type:

1. From within any of the Sample Analysis screens, select **Create** next to the Sample Type dropdown menu.

3.76 *Create Button*

   This will open the Create New Sample Type Window.



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
Osm	1.00	0	0	2000	mOsm / kg	False
Total Density	1.00		1.0	800.0	x10^5 Cells / mL	False
Viable Density	1.00		1.0	800.0	x10^5 Cells / mL	False
Viability			0	100	%	False
Avg. Live Diameter			4	70	µm	False

3.77 *Create New Sample Type Menu*

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. If the Cell Density module is selected for this Sample Type, configure the desired dilution ratio and Cell Inspection Type from the dropdown windows.
6. To configure correlation factors for each individual parameter for the Sample Type, set the Offset Multiplier and Offset Intercept to the desired values.
7. To configure a specified process range for each parameter, set the Lower Limit and Upper Limit to the desired values. The process ranges established in any given Sample Type function independently from the analytical range limits of the system.
   - If a parameter's value is outside of the analytical range, an error will be logged into the error log indicating [parameter] Analytical Range High/Low.
   - If a parameter's value is outside the process range established in the Sample Type used for that particular analysis, no error will be logged into the error log. Instead, the status column for that parameter will be marked as Low or High on the sample result screen.

NOTE: *When creating process limits or interpreting results flagged Low/High, It is important to consider how each parameter's analytical range changes depending on the dilution ratio selected for that analysis.*

8. Configure Key Parameters (see below for more information).
9. Save the Sample Type by selecting the green checkmark at the bottom right or select the red X to cancel the setup.

Key Parameters

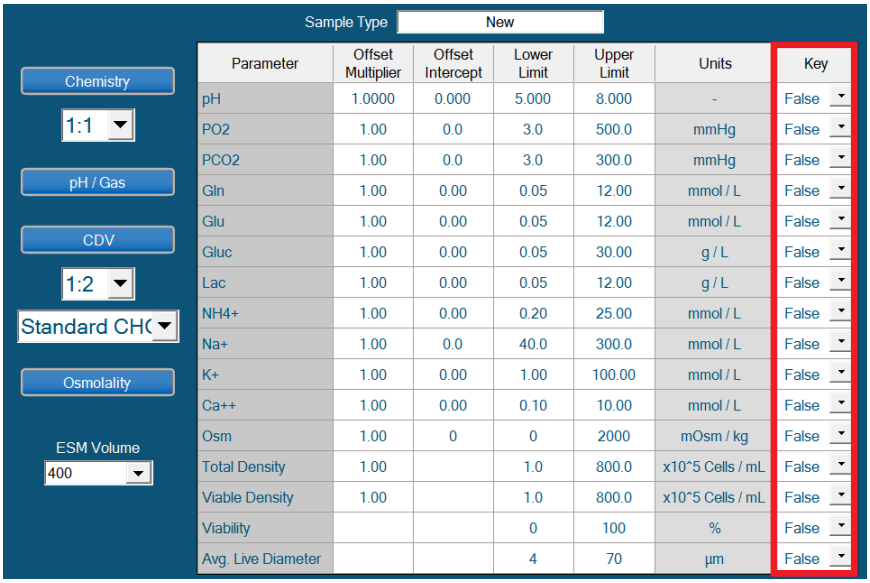
Key Parameters provide a means to suppress analysis of samples when specific **key** parameters are not available for any reason. An operator has the option of identifying which parameters are **key** when creating or modifying a Sample Type. The Key Parameters function only applies to samples supplied to the FLEX2 by the External Sampling Module (**ESM**), FLEX2 Online Autosampler (**OLS**), or when running a 96-well plate sample. The Key Parameters function does not apply to the manual or Load-and-Go carousel sampling modes.

To Configure Key Parameters:

1. From the Sample Type window, select **True** from the dropdown in the column labeled **Key**.
2. Press the green checkmark to save the Sample Type.

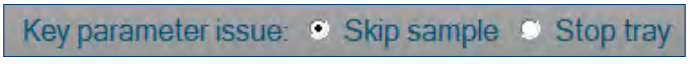
When running a sample with a Sample Type that has Key Parameters configured, the Key Parameters must be available for the sample to be analyzed. If a key parameter is unavailable for any reason (QC Lockout included) the FLEX2 will not run the sample. This feature prevents the loss of sample material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

In addition, if key parameters in a Sample Type are enabled but are unavailable, the text for that Sample Type will turn red to indicate that a key parameter is not available.



3.78 *Configure Key Parameters Window*

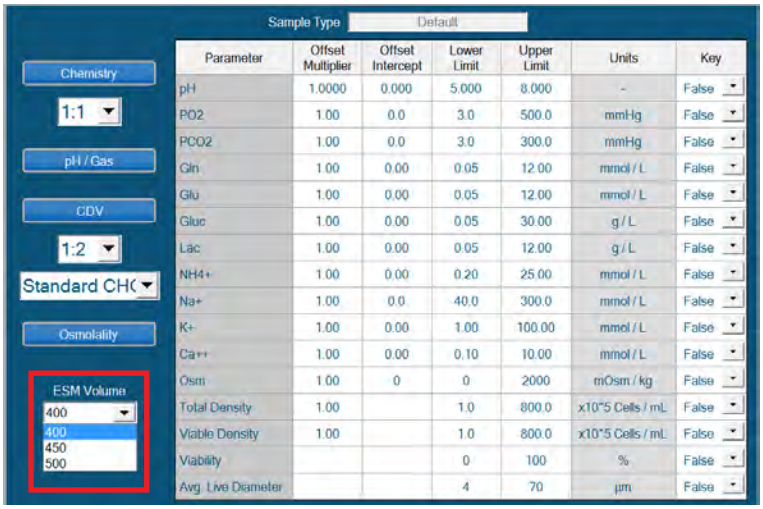
When configuring 96-well plate analyses using a Sample Type that utilizes Key Parameters, the operator has the option of programming the plate analysis to skip a sample well if a Key Parameter is not available or to have the system stop the entire tray from running any further. These options appear as buttons at the bottom of the of the 96-well plate map screen. One of the options must be selected for the analysis.



3.79 *Buttons at Bottom of Well Map*

ESM Sampling Volume

In the bottom left corner of the Sample Type window is a dropdown menu labeled ESM Volume. For FLEX2 systems that are integrated with an External Sampling Module (**ESM**), this volume is the acquisition volume from the microbioreactor system. Three volumes can be chosen (ambr15 only): 400 µL, 450 µL or 500 µL. For systems integrated with an ambr250 system, the default volume is 675 µL.



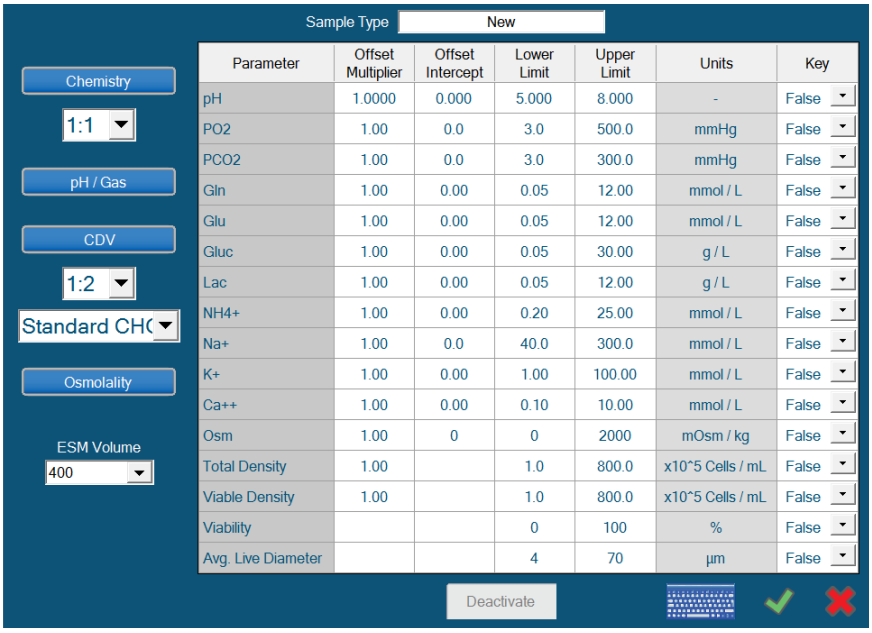
3.80 *ESM Sampling Volume*

Note: *To determine which volume is optimal for sampling, Nova Biomedical recommends performing a correlation study to test similarity of results between manual sampling and ESM sampling at the 3 volumes (ambr15 only).*

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 two Sample Types cannot have the same name even if one is deactivated.*

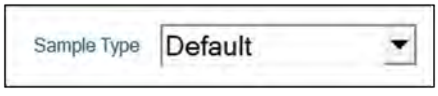


3.81 *Modify Sample Type Menu*

3.6.3 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.

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



3.82 *Sample Type Dropdown*

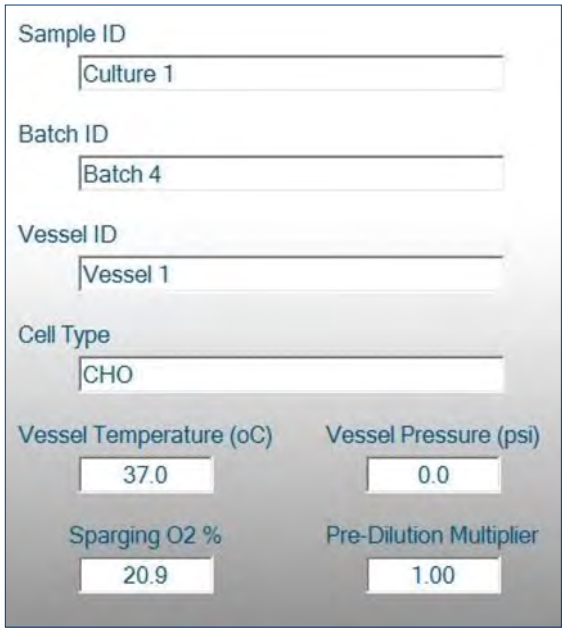
Alternately, you can select the desired test parameters from the available buttons. Selected modules will turn blue. If the Chemistry module is selected, you can select the desired dilution ratio (1:1, 1:2 or 1:4). If the CDV module is selected, you can select the desired dilution ratio (1:1, 1:2 or 1:6) and the desired Cell Inspection Type.

Note: *For both Load-and-Go and 96-well plate Samples, the CDV Dilution Ratio is limited to the 1:2 or 1:6 dilutions.*

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

3.6.4 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.



3.83 *Sample Information Fields*

Calculated Values

The operator also has the option to configure the Vessel Temperature (°C), Vessel Pressure (psi), Sparging O_2%, and the Pre-Dilution Multiplier if the reactor conditions differ from the default values or an external dilution was applied.

When samples are tested on the BioProfile FLEX2, the raw data is always determined with the default Vessel Temperature of 37 °C, Vessel Pressure of 0.0 psi, and Sparging O_2% 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.

Vessel Temperature defaults to 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 for pH/Gas parameters at the vessel 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 O_2 and CO_2 saturation values.

The Sparging O_2% value should be changed to the composition of the oxygen sparge inside the reactor. If ambient air is sparged, this value can remain at 20.9%, reflecting ambient air's O_2 composition. A change to this value will change the O_2 Saturation values in the Calculated Parameters field.

The **Pre-Dilution Multiplier** will only impact CDV results. The Pre-Dilution Multiplier should be used when an external dilution has been made to a sample prior to it being tested on the BioProfile FLEX2. If a value other than 1.00 is entered for the Pre-Dilution Multiplier, the system will multiply the CDV sample results by that value.

For example, an external 1:2 dilution would warrant a Pre-Dilution Multiplier of 2.0.

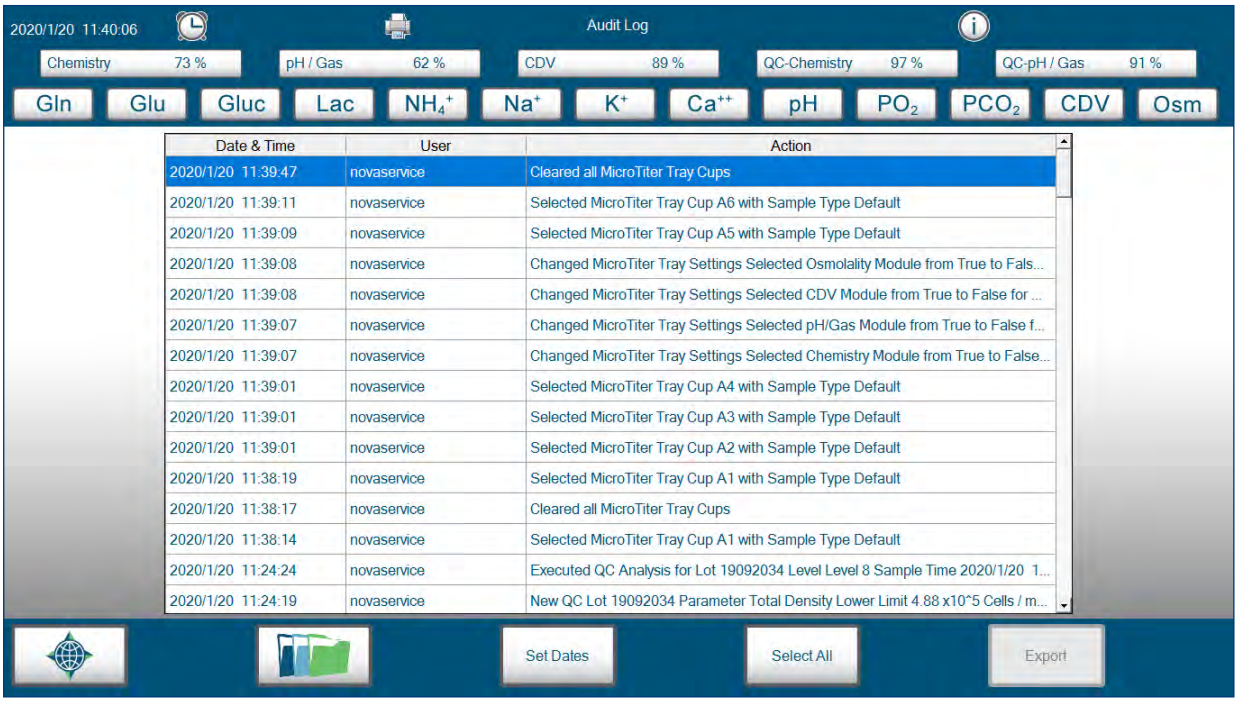
All sample information fields have sticky properties. This means that the information from the previously configured sample will remain in the entry fields for the next configured sample.

NOTE: *Calculated values are reviewed by scrolling to the right within the Historical Results screen.*

3.7 Logs

3.7.1 Audit Log

The Audit Log serves as an electronic trail of the changes and/or updates made to the setup of the BioProfile FLEX2 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** from the 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.



3.84 *Audit Log*

An operator can export audit log entries by selecting a time frame using the Set Dates button in the Command Bar, highlighting the entries of interest (or pressing Select All), and then pressing the Export button. The Audit Log can be exported to the Bridge computer Shared Folder or a USB drive as a .csv file.

The following is a list of actions stored in the Audit Log if performed by a BioProfile FLEX2 Operator:

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}
Change to Sample Type Settings: Cell Inspection	Changed {sample_type_name} Cell Inspection from {old_value} to {new_value}
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 of the system	User {user_name} logged out
Change to Cell Inspection Settings	Changed {cell_inspection_name} {field_name} from {old_value} to {new_value}
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}

Action	Output
Analysis Canceled	Canceled Sample Analysis Sample ID {sample_ID} Reason: {reason}
Execute ESM Analysis Run	Executed ESM Sample Analysis Sample ID {sample_ID} Sample Time {sample_time}
Autosampler Analysis Run	Executed Sample Analysis RSM {rsm_name} Sample ID {sample_ID} Sample Time {sample_time} Sample Type {sample_type} Batch ID {batch_ID} Vessel ID {vessel_ID} Cell Type {cell_type}
Autosampler Configuration Edited	Changed RSM {rsm_name} {field_name} from {old_value} to {new_value}
Unconfigured RSM	Unconfigured RSM {rsm_name}
Analysis Results Edited	Changed Sample Time {sample_time} {field_name} from {old_value} to {new_value}
Analysis Results Image Re-Analysis	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}
Change to Analyzer Information	Changed Analyzer Information {field_name} from {old_value} to {new_value}
Change to QC Configuration: Expiration Date	Changed Expiration Date in Lot {lot_number} Level {level} from {old_date} to {new_date}.
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}
Change to QC Configuration: Created New Lot	Created new QC Lot {lot_number} in External Controls Level {level} Expiration Date {expiration_date}
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}
Enter Flowpath Service	Flow Path Service Start
Exit Flowpath Service	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}
Modification to Bridge Computer Time	Changed 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

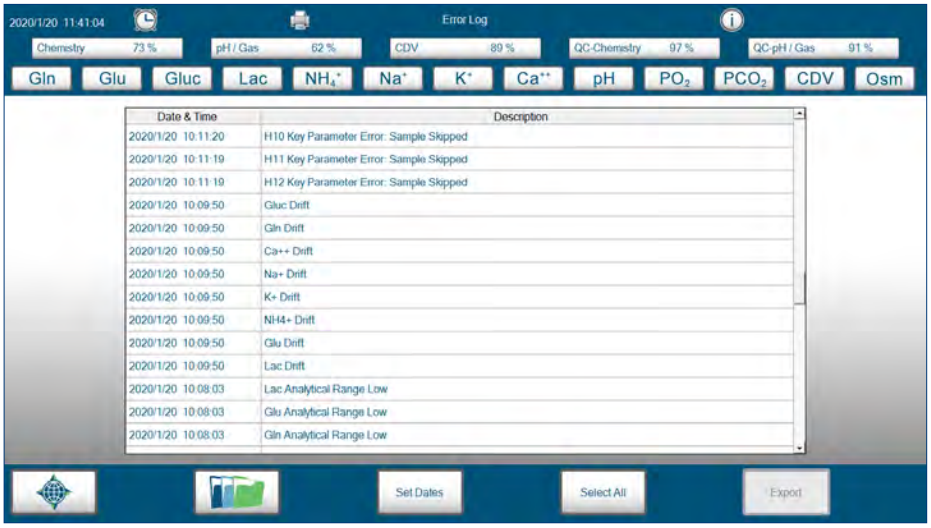
Action	Output
Execute System Shutdown	System Shut Down
Execute Calibrate Chemistry	Calibrate Chemistry
Execute Calibrate Gas	Calibrate pH/Gas
Execute Calibrate CDV	Calibrate CDV
Execute Calibrate Osmometer	Calibrate Osmometer
Activated Temporary OPC License	Activated Temporary OPC License
OPC License Requested	OPC License Requested
Installed OPC License	Installed OPC License
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: ESM Volume	Changed {sample_type_name} ESM Volume from {old_value} to {new_value}
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: CDV Dilution Ratio	Changed CDV 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
Exported Growth Calculation	Exported Growth Calculation with BatchID {batch_ID} Parameter {parameter} Elapsed Time Unit {elapsed_time_unit}
Execute Calibrate Gas & Chemistry	Calibrate pH/Gas and Chemistry
Execute File Restore	Database Restore
Execute Change Tubes and/or Wiper Ring	Change Tubes and Wiper Ring
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}
Manual Analysis Settings Changed: CDV Dilution Ratio	Changed Manual Sample Analysis Settings CDV Dilution Ratio from {old_value} to {new_value}
Manual Analysis Settings Changed: Cell Inspection	Changed Manual Sample Analysis Settings Cell Inspection 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}

Action	Output
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}
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}
Printed Sample Profile Report	Printed Sample Profile Report for Sample Time {sample_time}
Printed Live Cell Histogram Report	Printed Live Cell Histogram Report for Sample Time {sample_time}
Printed Cell Density Image Report	Printed Cell Density Image Report for Image Number {image_number} Sample Time {sample_time}

3.7.2 Error Log

The Error Log serves as an electronic trail of the errors generated and reported by the BioProfile FLEX2 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**.



3.85 *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.

An operator can export Error Log entries by selecting a time frame using the Set Dates button in the Command Bar, highlighting the entries of interest (or pressing Select All), and then pressing the Export button. The Error Log can be exported to the Bridge computer Shared Folder or a USB drive as a .csv file.

3.7.3 Calibration Log

The Calibration Log serves as an electronic trail of all manually initiated and automatic pH/Gas & Chemistry module calibrations performed by the FLEX2 analyzer. The Calibration Log documents 2-point calibration data used in the determination of a parameter's slope value. An operator cannot delete or modify the Calibration Log. Entries in the Calibration Log can be sorted by any column header if selected.

To view the Calibration Log select **Logs** (Right Home screen) then select **Calibration Log**.

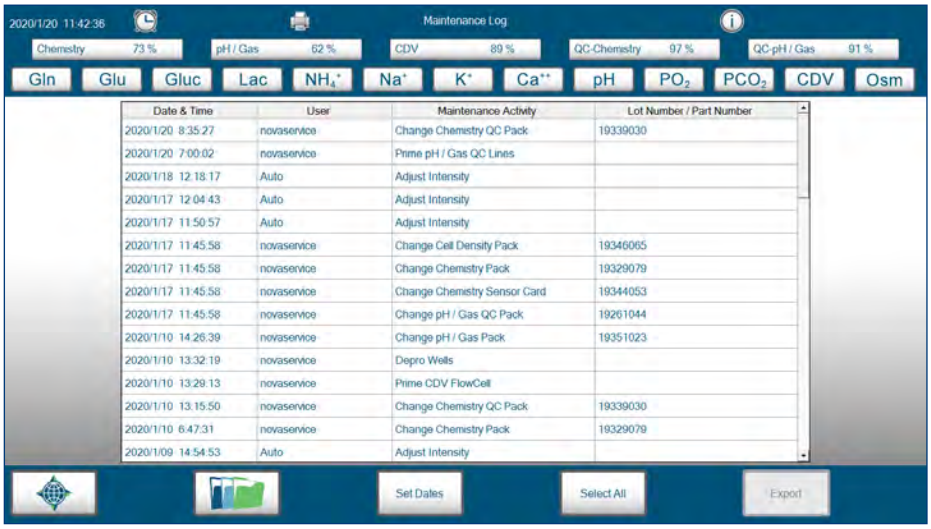
An operator can export Calibration Log entries by selecting a time frame using the Set Dates button in the Command Bar, highlighting the entries of interest (or pressing Select All), and then pressing the Export button. The Calibration Log can be exported to the Bridge computer Shared Folder or a USB drive as a .csv file.

3.86 *Calibration Log*

3.7.4 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*).

The Maintenance Log 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.



3.87 *Maintenance Log*

An operator cannot delete or modify the Maintenance Log. Notations in the Maintenance Log can be sorted by Date & Time, User, Maintenance Activity, or Lot/Part Number if the applicable column header is selected.

An operator can export Maintenance Log entries by selecting a time frame using the Set Dates button in the Command Bar, highlighting the entries of interest (or pressing Select All), and then pressing the Export button. The Maintenance Log can be exported to the Bridge computer Shared Folder or a USB drive as a .csv file.

3.7.5 WARRANTY LOG

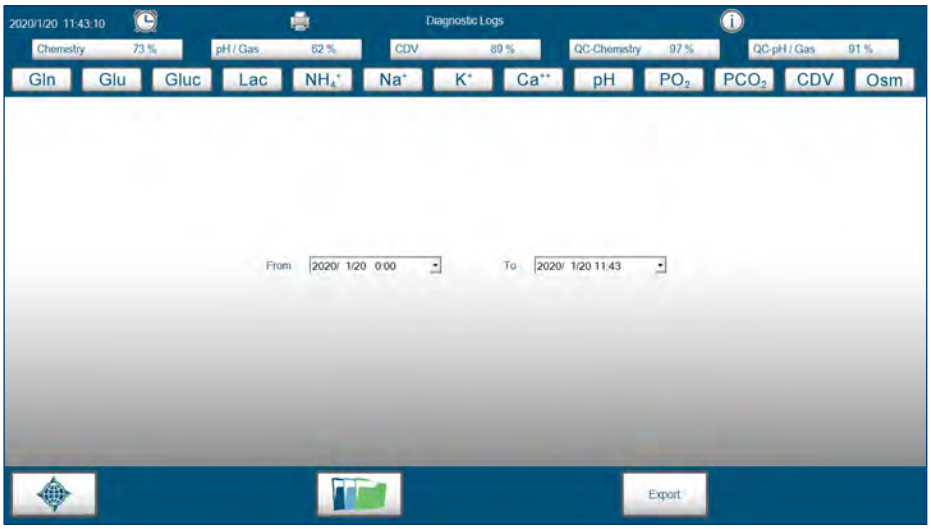
The Warranty Log displays the list of warranty codes that have been claimed through **Warranty Support**. For more detail regarding Warranty support, see **Section 3.3.6**. An operator cannot delete or modify the Warranty Log. Notations in the Warranty Log can be sorted by Date & Time, Lot Number, or Code if the column header is selected.

3.88 *Warranty Log*

An operator can export or print Warranty Log entries by selecting a time frame using the Set Dates button in the Command Bar, highlighting the entries of interest (or pressing Select All), and then pressing the Export or Print button. The Warranty Log can be exported to the Bridge computer Shared Folder or a USB drive as a .csv file.

3.7.6 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.



3.89 *Diagnostic Log*

To export the Diagnostic Logs:

1. Select **Logs** (Right Home screen).
2. Select **Diagnostic Logs**. This will open the Diagnostic Logs Screen.
3. Select the Date and Time Range.
4. Insert a USB drive into an available port on the back of the FLEX2 analyzer.
5. Select **Export** then select an Export Location
6. Select the green checkmark to begin the file export

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.*

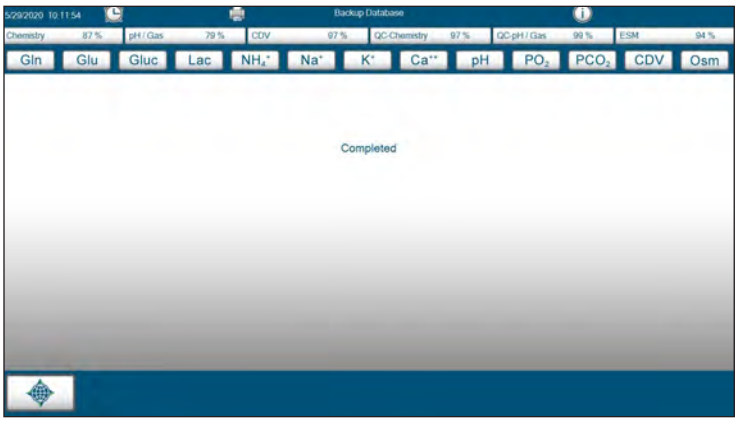
3.8 DATABASE

After selecting **Database** (Right Home screen), the End User has the option to either **Backup** or **Restore** the FLEX2 database. When using the Database function, the database is backed up to and restored from the Bridge Computer. Backup can also be scheduled to occur automatically at regular intervals through the Settings menu (See **Section 3.5.4.7**).

NOTE: *Archive Database is not yet available.*

3.8.1 BACKING UP THE DATABASE

Backing up the database will create a group of encrypted files that store the following information in the event a database becomes corrupt or needs to be replaced.



3.90 *Backup Database Screen*

-Sample/QC Analysis Data

-CDV Images

-Audit Logs

-All other logs

-User Accounts

-Sample Types

-Cell Inspection Types

-Scheduled Maintenance and Tasks

-General Settings

The database will be backed up to the **C:\Export\Database** directory of the FLEX2 Bridge Computer.

Select Backup from the Database menu to begin the backup process. During a backup, several text strings are displayed on the screen:

1. Initializing
2. Creating Backup file
3. Copying images X of Y
   (Systems with CDV only)
4. Completed

On the Bridge Computer, the **C:\Export\Database** folder will now contain a folder titled "Backup_YYYY-MM-DD_HHMMSS" for the time and date the backup was generated. This sub directory contains a **DatabaseBackup.dbb** file, a Persist.dbb file, and an Images directory (for CDV images). The Images directory does not apply to systems without the CDV module.

The DatabaseBackup.dbb file, Persist.dbb, and images directory folder must be kept together within their respective backup folder. Any existing backup files will be overwritten with the newest backup. Nova Biomedical recommends regularly moving or copying backups from the Bridge computer to a secure network location for redundancy.

3.8.2 Restoring the Database

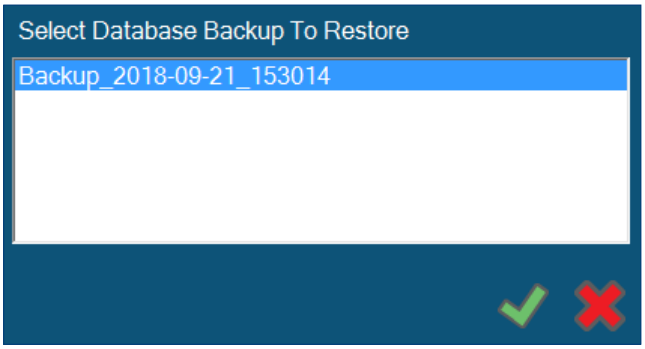
Select **Restore** from the Database menu to open the **Select Database Backup to Restore** window

If no database has been previously backed up, or there is no backup folder inside the C:\Export\ Database location on the Bridge, 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 images X of Y (Systems with CDV only)
3. Copying database
4. Completed
5. Restarting



3.91 *Database Restore Window*

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 (with the exception of CDV image files).
- CDV image file backup directories contain the .jpg images and associated .xml files produced during the sample analysis.
- 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 folder (Backup_YYYY-MM-DD_HHMMSS) must reside within the C:\Export\Database location on the Bridge computer and must contain the DatabaseBackup.dbb file, Persist.dbb file and Images directory (CDV analyzers only) for a restore to be successful.

4 MAINTENANCE

The following sections provide detailed information and directions to operate and maintain the BioProfile FLEX2 analyzer.

WARNING: ***Cell culture samples are potential sources of infectious agents. Handle all sample and flowpath 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.*

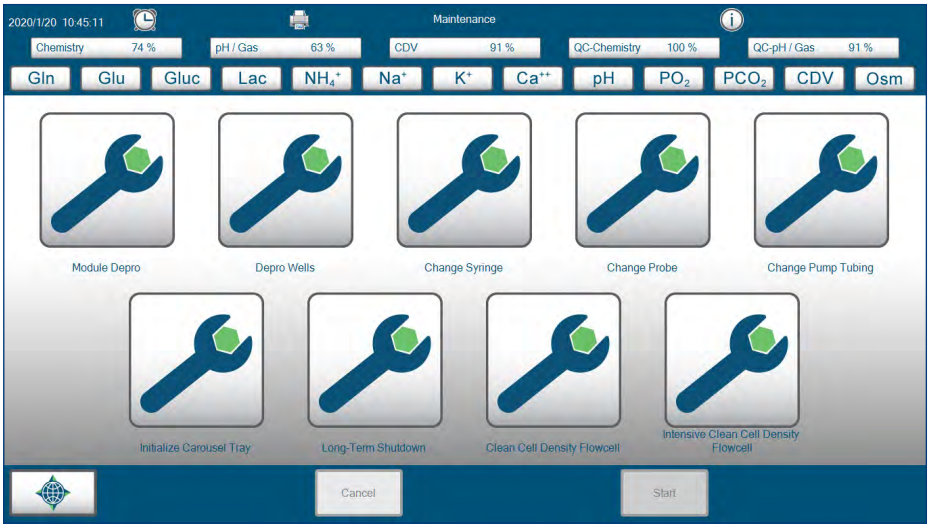
NOTE: *Select the Information icon in the Status Bar at any time to display the FLEX2 training video portal. Select the desired training module to watch an instructional video while performing any maintenance task.*

4.1 SYSTEM MAINTENANCE SCREEN

Select **Maintenance** (Left Home screen), to display the Maintenance sub-menu

This sub menu includes:

- Module Depro
- Depro Wells
- Change Syringe
- Change Probe
- Change Pump Tubing
- Initialize Carousel Tray
- Clean Cell Density Flowcell
- Intensive Clean Cell Density Flowcell
- Long-Term Shutdown



4.1 *Maintenance Menu*

NOTE: *If you have an ESM or OLS system added to your FLEX2 device configuration, you will have an additional option displayed at the bottom of the Maintenance Menu. For additional information on the ESM or Autosampler Maintenance sub-menus, please see the ESM Instructions for Use Manual (PN: 59698) or the On-Line Autosampler Instructions for Use Manual (PN: 63623).*

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 sensor card from the pH/Gas and Chemistry sensor modules.
2. Install Depro cards into the pH/Gas and/or 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/or Chemistry MicroSensor Cards.

Note: *Nova Biomedical recommends that the Module Depro be run monthly at a minimum.*

4.1.2 Depro Wells

The Depro Wells function allows an operator with appropriate privileges to Depro the Waste and CDV wells. The Depro Wells function will soak these wells with Depro solution for 5 minutes. The Depro Wells sequence, by default, is scheduled to occur on a daily basis and cannot be deactivated. The time and frequency at which Depro Wells executes can be modified within the Settings menu. The sequence can also be initiated manually.

Note: *This function does NOT Depro the Chemistry well.*

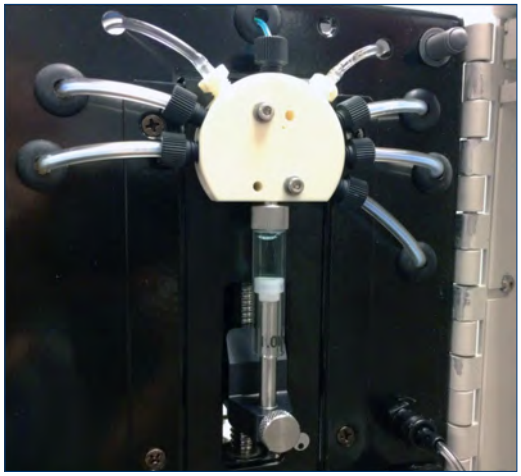
Note: *A valid chemistry Reagent Cartridge set must be installed and all wells must be clear in order to initiate a Depro Wells sequence.*

To perform a Depro Wells sequence:

1. Select **Maintenance** (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

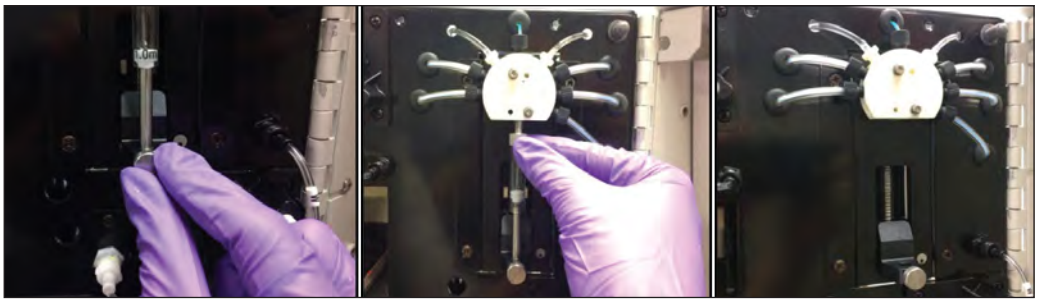
The **Change Syringe** function allows an operator with appropriate privileges to replace the plunger and barrel of the syringe pump assembly.



4.2 *Syringe Pump*

To change the syringe:

1. Select **Maintenance** (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 the plunger at the bottom of its axis.
5. When the syringe plunger is all the way down and the Continue button appears, remove the syringe by loosening the thumb screw at the bottom, then unthread the syringe from the valve assembly to remove it.



4.3 *Syringe Barrel & Plunger Removal*

6. Install the new syringe making sure to secure the threaded connections.
7. When the new syringe is installed, select **Continue** to prime the syringe pump.

4.1.4 CHANGE PROBE

The Change Probe function allows an operator with appropriate privileges to change the S-line Probe assembly.

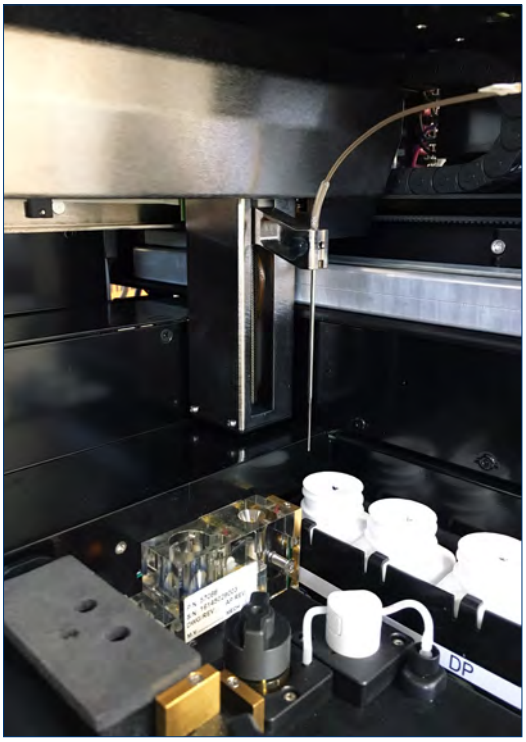
NOTE: Before attempting to change the probe, make sure all of the gold teach-points inside the FLEX2 cabinet are clean and free of debris. Thoroughly cleaning the teach-points with 70% IPA and a swab is recommended.

To change the Sample Probe:

1. Select **Maintenance** (Left Home screen) to display the Maintenance menu.
2. Select **Change Probe**.

CAUTION: Before starting the Change Probe sequence, make sure any 96-well plate that might be installed on the FLEX2 is removed to avoid probe damage.

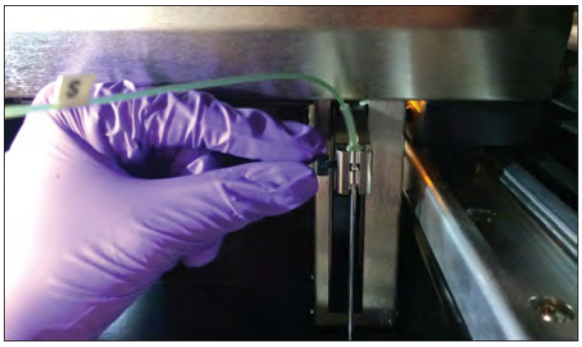
3. Select **Start** in the Command Bar to begin the Change Probe sequence.
4. Enter the Lot/Part number of the new S-line probe assembly into the textbox and press the green check mark to begin the Change Probe sequence. The analyzer will move the Sample Probe to its Home position. When **Start** changes to **Continue**, it is safe to open the main door and remove the Sample Probe and S-Line.



4.4 *Sample Probe in Home Position*

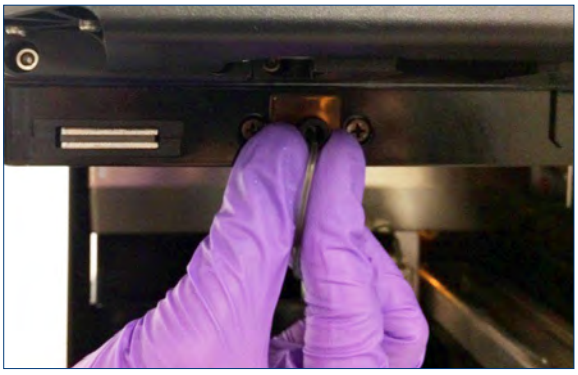
CAUTION: Do not attempt to remove the probe until it is in the Home position.

5. Remove the Sample Probe by loosening the set screw that holds it into the Z-axis of the probe transport arm.



4.5 *Probe Set Screw*

6. Remove the S-line tubing by unscrewing the threaded fitting from the sample line port beneath the pH/Gas module.

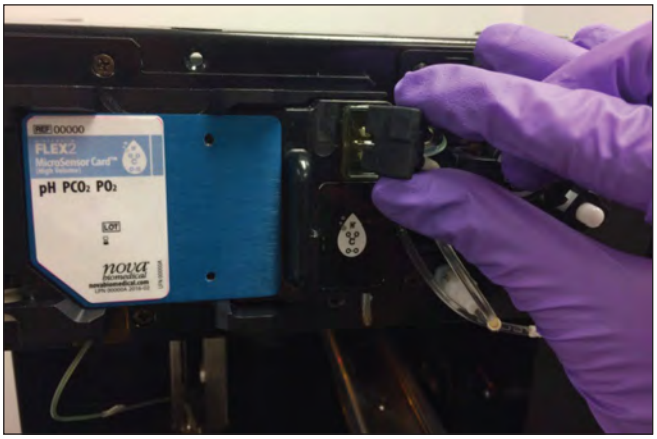


4.6 *Sample Line Port*

7. Install the new sample probe and S-line tubing. Thread the new sample line tubing into the sample line port. Tighten the probe set screw to make sure that it cannot fall out of place. Ensure all connections are tightly secured and that the probe is fully seated within the probe arm
8. Close the analyzer door and select **Continue**. The probe will teach itself all required positions using the probe alignment targets inside the analyzer.

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.

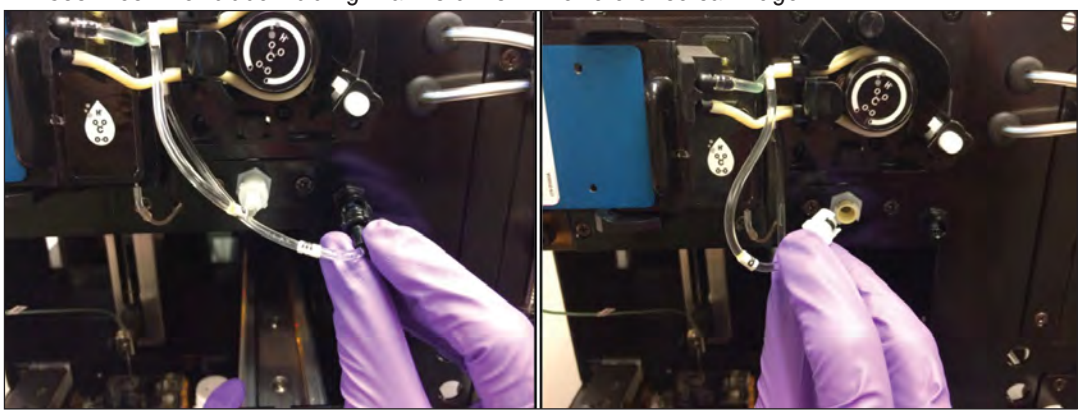


4.7 *Disconnect Pump Tubing Manifold*

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

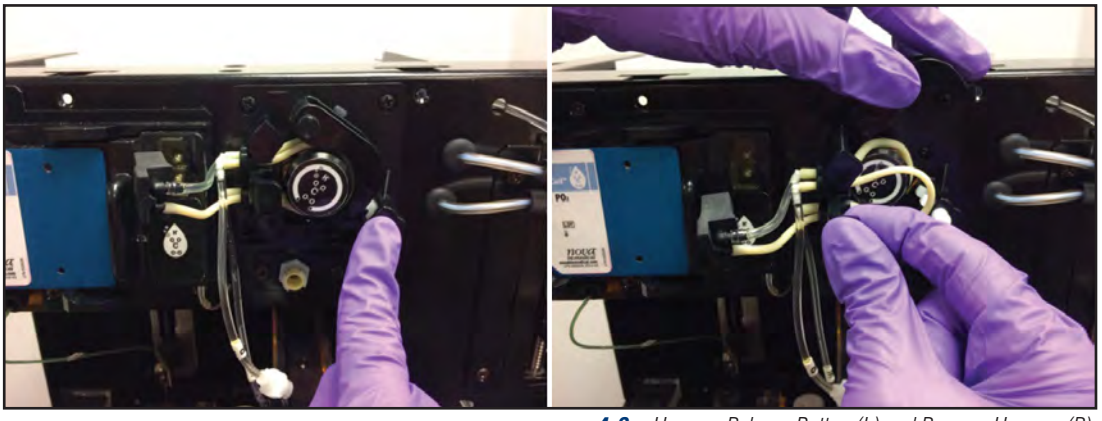
To change the Pump Tubing:

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 open the main door and remove the Pump Tubing Assembly.
5. Disconnect the Waste tubing fitting from the port on the chassis by turning the twist-lock connector 1/8-turn counterclockwise.
6. Disconnect the Reference tubing fitting from the port on the chassis by turning the twist-lock connector 1/8-turn counterclockwise.
7. Disconnect the rubber tubing manifold from the reference cartridge.



4.8 *Waste Tubing Fitting (L) and Reference Tubing Fitting (R)*

8. Push the white button on the pump tubing retaining clip to release the tension on the tubing harness and remove the tubing harness assembly.



4.9 *Harness Release Button (L) and Remove Harness (R)*

9. Install the new pump tubing harness by stretching the pump tubing around the peristaltic pump. Make sure the two pieces of pump tubing are not touching once positioned on the pump.
10. Clamp down the pump tubing retaining clip (You will hear an audible click). Reconnect the Waste and Reference line twist-lock connectors and the tubing manifold to the Reference Sensor.
11. 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 INITIALIZE CAROUSEL TRAY

The Initialize Carousel Tray function allows an operator with appropriate privileges to initialize or **Home** the Load-and-Go carousel when required.

To Initialize the Carousel Tray:

1. Select **Maintenance** (Left Home screen) to display the Maintenance menu.

NOTE: *Be sure to remove any loaded samples prior to initializing the carousel for risk of them being discarded.*

2. Select **Initialize Carousel Tray**.
3. Select **Start** in the Command Bar to begin the sequence. If the carousel tray initializes properly, the cup 1 location should be in the 6 o'clock position (closest to the operator).

4.1.7 CLEAN CELL DENSITY FLOWCELL

The Clean Cell Density Flowcell function allows an operator with appropriate privileges to clean the CDV module cuvette flowcell assembly, and can be scheduled to run automatically at regular intervals in Settings. This function should be used if residual debris or any foreign object is observed in CDV sample images that does not appear to be washing away during normal CDV sampling. The Clean Cell Density Flowcell function performs a CDV Module wash using the internal cleaning solution from the CDV Reagent Cartridge. When the wash is complete, the function also primes the CDV flowcell.

To perform a Clean Cell Density Flowcell sequence:

1. Select **Maintenance** (Left Home screen) to display the Maintenance menu.
2. Select **Clean Cell Density Flowcell**.
3. Select **Start** in the Command Bar to begin the Clean Cell Density Flowcell sequence.

NOTE: *A valid CDV Reagent Cartridge must be installed and the CDV Well must be clear to initiate a Clean Cell Density Flowcell sequence.*

4.1.8 INTENSIVE CLEAN CELL DENSITY FLOWCELL

The Intensive Clean Cell Density Flowcell function allows an operator with the appropriate privileges to perform a more intensive clean of the CDV module flow path and cuvette flowcell. This function can be used when a Clean Cell Density Flowcell sequence fails to remove trapped debris or foreign objects observed in the CDV flowcell. The Intensive Clean sequence will soak the CDV flowcell for 30 minutes with the external cleaning solution. When the soak is complete, the function also primes the CDV flowcell.

To perform an Intensive Clean Cell Density Flowcell sequence:

1. Select **Maintenance** (Left Home screen) to display the Maintenance menu.
2. Select **Intensive Clean Cell Density Flowcell**.
3. Select **Start** in the Command Bar to begin the Intensive Clean Cell Density Flowcell sequence.
4. When the manual sampling position illuminates and the sample probe appears, present an ampule of the Cell Density Viability Advanced Cleaning Solution (PN 63940) to the probe and select **Aspirate**.

Note: *If the Intensive Clean Cell Density Flowcell function does not work to remove the debris or foreign object(s) from the CDV flowcell images, the CDV module should be recalibrated and those affected images should be deselected. This will prevent any impact to sample cell counts. Up to 5 CDV images can be deselected. Nova Biomedical also recommends contacting Nova Technical Support to request that the CDV flowcell be cleaned or replaced.*

4.1.9 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 will be powered off or left with expired/empty Reagent Cartridges 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 to resolve.

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 a long-term shutdown in accordance with this procedure.***

Long-Term Shutdown Cartridges

FLEX2 analyzers operating with software version 4.0 or newer can utilize the Long-term Shutdown Cartridges to properly shutdown the system for extended periods of inactivity. The Shutdown Cartridges are one-time use and will need to be discarded after the long-term shutdown process.

Long-term shutdown via the Shutdown Cartridges requires the following, depending on module configuration:

- PN 60608 pH/Gas Module Shutdown Cartridge
- PN 60610 Chemistry Module Shutdown Cartridge
- PN 60611 CDV Module Shutdown Cartridge
- PN 60612 ESM Shutdown Cartridge (if applicable)
- PN 60613 pH/Gas Auto QC Shutdown Cartridge

Note: *In order for the Long-Term Shutdown sequence to initiate, shutdown cartridges for all available modules must be installed. The pH/Gas Auto QC Cartridge is not required to initiate the sequence. The ESM Shutdown Cartridge is only required if an ESM is connected.*

Note: *A Chemistry Auto QC Shutdown Cartridge is not required/offered for long-term shutdown.*

To perform a Long-Term Shutdown with Shutdown Cartridges:

1. Open the main door and remove all Reagent Cartridges, bottle packs, and QC cartridges from the BioProfile FLEX2. All MicroSensor cards, reference sensors, and pump tubing must remain installed.
2. Install all shutdown cartridges into the respective pack bays (the pH/Gas QC Shutdown Cartridge and ESM Shutdown Cartridge are optional). Ensure the fitments on the rear of each pack are fully engaged with the needle shrouds at the rear of the pack bays.
3. Close the main door and the shutdown sequence will automatically begin. Shutdown solution will be pumped from the cartridges into all internal fluid lines and then purged with air. After approximately 8 minutes, the User Interface will turn black.
4. Once the User Interface screen is dark, wait one minute and power down the FLEX2 by toggling the power switch on the rear right side of the unit to the OFF position. Remove both the Chemistry and pH/Gas Pump Tubing and leave the Reference Sensors and MicroSensor Cards installed on the unit.

Warning: ***Failure to properly switch off power to the FLEX2 following the Long-Term Shutdown procedure could result in analyzer damage.***

Long-Term Shutdown Flush Fixtures

If the Long-Term Shutdown Cartridges are not available, the FLEX2 Flush Fixtures can be utilized to perform the Long-Term Shutdown sequence manually.

Long-Term Shutdown via the Flush Fixtures requires the following, depending on module configuration:

- PN 58355 Flush Fixture 6 Port (x2) (pH/Gas Calibrator and Chemistry Reagent Cartridge)
- PN 59121 Flush Fixture 4 Port (CDV Reagent Cartridge)
- PN 57530 Flush Fixture 2 Port (Chemistry Calibrator)
- 2 – 3 Beakers/Bottles with at least 250 mL of DI H_2O
- 2 – 3 Empty Beakers/Bottles (capable of holding 250 mL of water waste)

NOTE: *No Flush Fixture is required/offered for the pH/Gas Auto QC Cartridge bay for performing long-term shutdown.*

To perform a Long-Term Shutdown and Flowpath Purge with Flush Fixtures:

1. Remove all Reagent Cartridges, bottle packs, and QC cartridges from the BioProfile FLEX2. All MicroSensor Cards, Reference Sensors, and pump tubing must remain installed.
2. Install the two 6 port Flush Fixtures into the Chemistry Reagent Cartridge bay and the pH/Gas Calibrator Cartridge pack bay. Make sure that the needle fitments at the rear of each fixture fully engage with the needle shrouds at the rear of the pack bays.
3. Install the 4 port Flush Fixture into the CDV Reagent Cartridge bay. Make sure the needle fitments at the rear of the fixture fully engage with the needle shrouds at the rear of the pack bay.
4. Install the 2 port Flush Fixture into the Chemistry Calibrator Cartridge pack bay. Make sure the needle fitments at the rear of the fixture fully engage with the needle shrouds at the rear of the pack bay.
5. If applicable, line the pH/Gas Auto QC pack bay with dry lint-free wipes to collect all spent fluids. The sample probe will flush fluid through the onboard pH/Gas Auto QC lines. This will cause a small amount of fluid to build up in the pH/Gas Auto QC pack bay and should be cleaned at the end of the long-term shutdown procedure.
6. Locate the length of tubing labeled “W” (Waste) on each fixture and place the end of each waste tubing into an empty beaker/bottle to collect the waste.
7. Gather all of the remaining lengths of tubing on each fixture and place them into a beaker/bottle containing at least 250 mL of DI, WFI, or RO H_2O. Make sure the ends of each piece of tubing are completely submerged in the H_2O and will remain submerged during the entire shutdown procedure.
8. On the FLEX2 Graphical User Interface (GUI), navigate to the Maintenance menu found on the second Home screen. Select **Long-Term Shutdown** and then select **Start** to begin the Flowpath Purge sequence. During the Flowpath Purge sequence, the analyzer will drain all residual reagent from its internal tubing and will flush each flowpath with the supplied water for several minutes. The waste reagent and water used for the flushing processes will drain into the supplied empty beakers/bottles.
9. When the first purge is complete, remove each piece of flush fixture tubing from the DI, WFI, or RO H_2O beaker/bottle and leave the “W” tubing in the beakers/bottles for waste collection.
10. Select **Start** again to purge the residual DI, WFI, or RO H_2O from the internal flowpaths and flush each internal line with air.

11. When *Step 9* is complete, remove all flush fixtures and power down the analyzer by navigating to the second Home screen of the GUI and selecting the Shutdown button. Once the User Interface screen is dark, wait one minute and power down the FLEX2 by toggling the power switch on the rear right side of the unit to the OFF position. Remove both the Chemistry and pH/Gas Pump Tubing and leave the Reference Sensors and MicroSensor Cards installed on the unit.

Warning: ***Failure to properly switch off power to the FLEX2 following the Long-Term Shutdown procedure could result in analyzer damage.***

Start-Up Procedure After a Long-Term Shutdown

Start-up after a long-term shutdown requires the following, depending on module configuration:

- PN 57510/57526 (x1) pH/Gas MicroSensor Card LV/HV
- PN 57512/57528 (x1) Chemistry MicroSensor Card LV/HV
- PN 57957/58102/54507 (x1) pH/Gas Calibrator Cartridge LV/MV/HV
- PN 58003/58101/53937 (x1) Chemistry Calibrator and Reagent Cartridges LV/MV/HV
- PN 55297 (x1) CDV Reagent Cartridges
- PN 55281 (x1) Chemistry Module Tubing Harness
- PN 55283 (x1) pH/Gas Module Tubing Harness
- PN 58644 (x1) Chemistry Module Deproteinization Card
- PN 58645 (x1) pH/Gas Module Deproteinization Card

To perform the Start-Up Procedure:

1. Ensure the FLEX2 is powered OFF, place both the pH/Gas and Chemistry Module Deproteinization Cards and new Reagent Cartridges, bottle packs, and QC Cartridges in the unit.
2. Install the pH/Gas and Chemistry Module Tubing Harnesses and ensure that the FLEX2 doors are closed.
3. Toggle the power button located in the rear right corner of the FLEX2 to the ON position. The User Interface screen will illuminate and ask for the operator to log in.
4. Once the operator has logged in, the user will have access to the FLEX2 User Interface screen. The unit will be going through several start-up sequences, including a pH/Gas and Chemistry module priming and CDV adjust intensity if applicable, and may take up to 8 minutes. The countdown timer will be displayed in the top right corner of the User Interface screen during the start-up sequence.
5. When the start-up sequence is complete and the countdown timer is no longer displayed in the top right corner of the screen, navigate to the second Home screen and select **Maintenance**. In the Maintenance menu, run a Module Deproteinization Sequence, which will take about 12 minutes to complete.
6. When the Module Depro Sequence has finished, remove the pH/Gas and Chemistry Module Deproteinization Cards from the unit and replace them with the pH/Gas and Chemistry MicroSensor Cards.

Note: *The pH/Gas and Chemistry Deproteinization Cards are reusable.*

7. The unit will hydrate both the pH/Gas and Chemistry MicroSensor Cards for the next 2 hours simultaneously. During this time, the pH/Gas and Chemistry modules will not be available for sample analysis.
8. Perform a CDV module calibration and/or an Osmometer module calibration using the external Cell Density and Osmo calibration standards if applicable.

9. When the pH/Gas and Chemistry MicroSensor Card hydration period is complete and all modules have been calibrated, test all applicable levels of Quality Control (QC) to verify analyzer performance for each test parameter. Once QC testing is complete, the analyzer will be ready for sample analysis.

4.2 pH/Gas Module

4.2.1 Installing pH/Gas Calibrator Cartridge

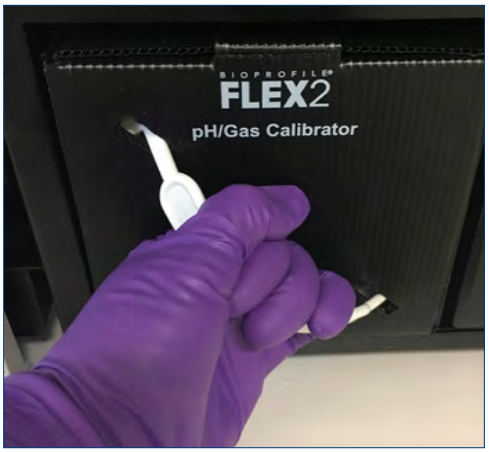
The BioProfile FLEX2 Analyzer Reagent Cartridges are equipped with smart installation technology. Once a new Reagent Cartridge is installed in the analyzer and the door is closed, the unit will automatically prime and install the cartridge. If the user presses the Module Status icon (*e.g pH/Gas 98%*), the Calibration Status, Well Status, Flow Time, Sensor Card, and Pack Information will all be displayed in the pH/Gas module status window.

For all Reagent Cartridges, selecting the desired module's reagent indicator will display the lot number, expiration date, installation date of the cartridge, and the number of sample tests remaining for the cartridge.

4.10 *pH/Gas Calibrator Cartridge*

To install a new pH/Gas Calibrator Cartridge:

1. Open the BioProfile FLEX2 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.



4.11 *Remove Old Cartridge*

Warning: ***The needle fitments inside the pack bay are sharp. To avoid injury, never stick your hands inside the pack bay.***

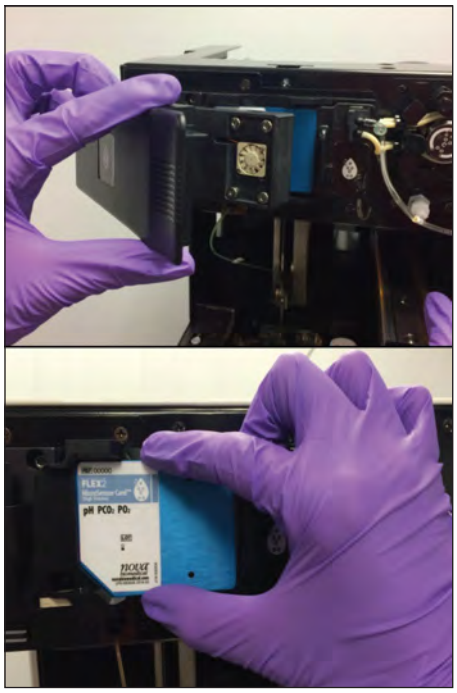
4.2.2 Installing pH/Gas Sensor Card

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 front panel door.
2. Open the pH/Gas Module door, located in the top left of the analyzer chamber.
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 and attempt to pass calibration and QC. This process takes about 90-120 minutes to complete.*



4.12 *Open Sensor Module Door and Install New Sensor Card*

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.

Note: *Nova Biomedical recommends replacement of the Reference Sensor every 12 months. This frequency may vary depending on analyzer usage.*

To install a new pH/Gas Reference Sensor:

1. Open the BioProfile FLEX2 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. Disconnect the pH/Gas Pump Tubing Manifold from the Reference Sensor.
5. Remove the pH/Gas MicroSensor Card and then remove the pH/Gas Reference Sensor by gripping the tab and sliding to the right.
6. Remove the new reference sensor from its packaging and install it into the pH/Gas Sensor Module by sliding it to the left.
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.

4.13 *Disconnect Sample Line Tubing*

4.14 *Disconnect Tubing Manifold*

4.2.4 INSTALLING ONBOARD pH/GAS CONTROLS

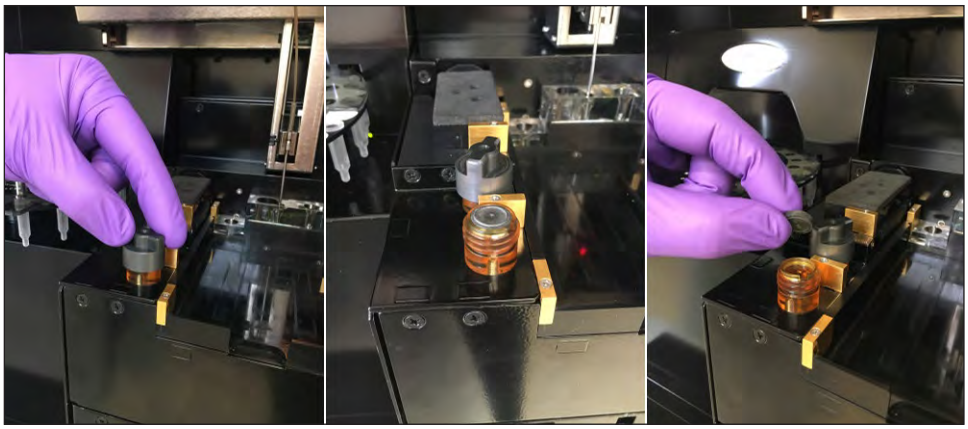
To install the onboard pH/Gas Auto QC Cartridge:

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.

4.15 *pH/Gas Auto QC Cartridge*

Failure to install a new pH/Gas Osmo QC septa with each new cartridge may result in onboard QC Sampling errors.

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



4.16 *Changing Rubber Septa for pH/Gas Auto QC*

3. Invert the cartridge a few times. Then insert the cartridge into its respective port, and ensure the needle fitments pierce the rubber fitments at the back of the cartridge. The cartridge should be flush with the chassis.

4.17 *pH/Gas Auto QC Cartridge Flush with Chassis*

4. Close the analyzer door. The Smart Maintenance feature will read the RFID and prime the cartridge as needed.

4.3 Chemistry Module

4.3.1 Installing Chemistry Calibrator and Reagent Cartridges

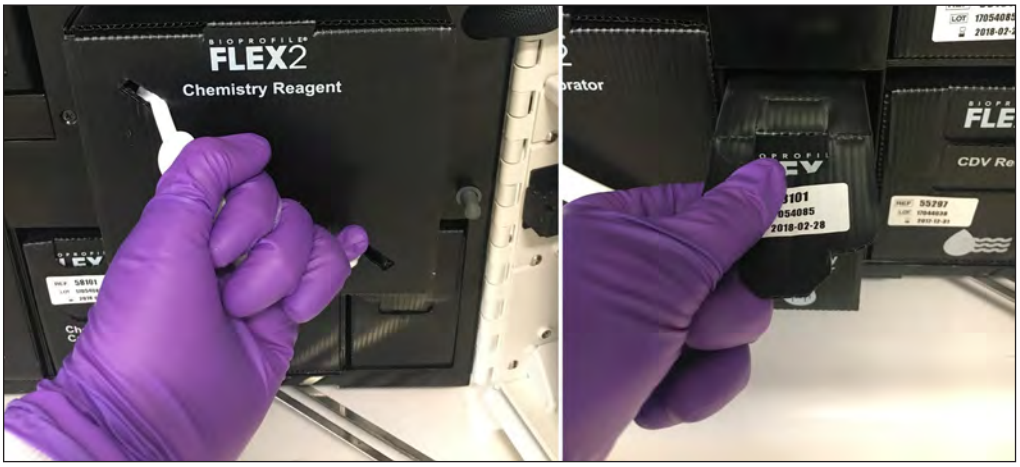
The BioProfile FLEX2 Analyzer reagent cartridges are equipped with smart installation technology. The Chemistry Module Reagent Cartridge set includes 2 separate cartridges that must be replaced together. The set consists of a larger Reagent Cartridge, and a smaller Calibrator Cartridge. The smaller Calibrator Cartridge must be activated prior to installation on the FLEX2 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.

4.18 *Chemistry Reagent and Calibrator Cartridges*

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 the chemistry module status icon *(e.g., Chemistry 98%*), the Calibration Status, Well Status, Flow Time, Sensor Card, and Pack Information will all be displayed in the Chemistry Module status window. For all Reagent Cartridges, selecting desired Reagent Cartridge indicator will indicate the lot number, expiration date, and installation date of the pack.

To install new Chemistry Calibrator & Reagent Cartridges:

1. Open the FLEX2 front panel door.
2. Remove the old Chemistry Calibrator Cartridges by pulling on the handle on the larger pack and the pull tab on the smaller pack.



4.19 *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.

4.21 *Remove Tape/ Lift Tabs*

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.
6. 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.*

7. Gently slide the new Chemistry Calibrator and Reagent Cartridges into their pack bays. There will be 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.

4.20 *Properly Installed Chemistry Calibrator and Reagent Cartridges*

8. Close the analyzer door. The system will automatically recognize the new Reagent Cartridges and will prime and calibrate the Chemistry module.

WARNING: ***The needle fitments inside the pack bays are sharp. To avoid injury, never stick your hands inside the pack bays.***

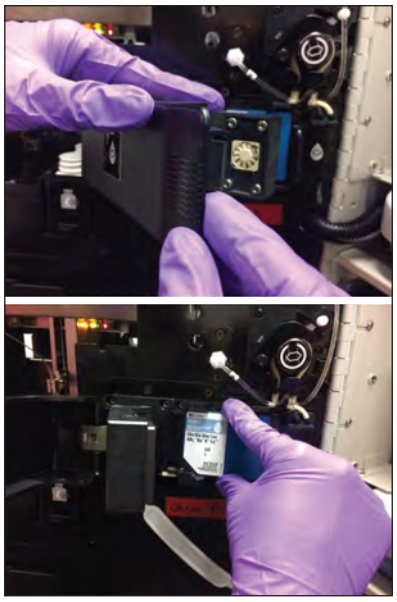
4.3.2 Installing Chemistry MicroSensor Card

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

To install a new MicroSensor Card:

1. Open the BioProfile FLEX2 front panel door.
2. Open the Chemistry Sensor Module door, located at the middle right of the analyzer chamber
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 Chemistry Module.

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



4.22 *Open the Chemistry Sensor Module Door and Install New Sensor Card*

4.3.3 Installing the Chemistry Reference Sensor

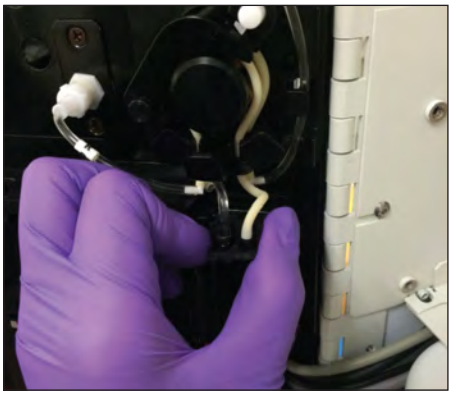
The Chemistry Reference Sensor provides the reference voltage required by the Chemistry Module. This assembly is part of the Chemistry module and is connected to the Chemistry MicroSensor Card and Pump Tubing Harness when installed.

Note: *Nova Biomedical recommends replacement of the Reference Sensor every 12 months, or as needed.*

To install a new Chemistry Reference Sensor:

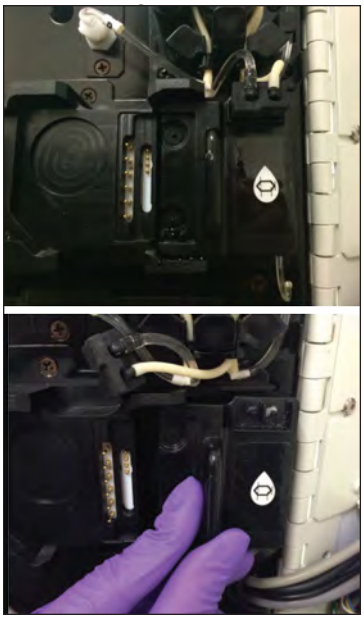
1. Open the BioProfile FLEX2 front panel door.
2. Open the Chemistry Sensor Module door, located at middle right of the analyzer chamber
3. Disconnect the Chemistry Sample Line tubing from the bottom of the Reference Sensor.
4. Disconnect the Chemistry Pump Tubing Manifold from the Reference Sensor.

4.23 *Disconnect Sample Line Tubing*



4.24 *Disconnect Tubing Manifold*

5. Remove the Chemistry MicroSensor Card and then remove the Chemistry the tab and sliding to the right.
6. Remove the new reference sensor from its packaging and install it into the Chemistry Sensor Module by sliding it to the left.
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.



4.25 *Remove Sensor Card & Reference Sensor*

4.3.4 INSTALLING ONBOARD CHEMISTRY CONTROLS

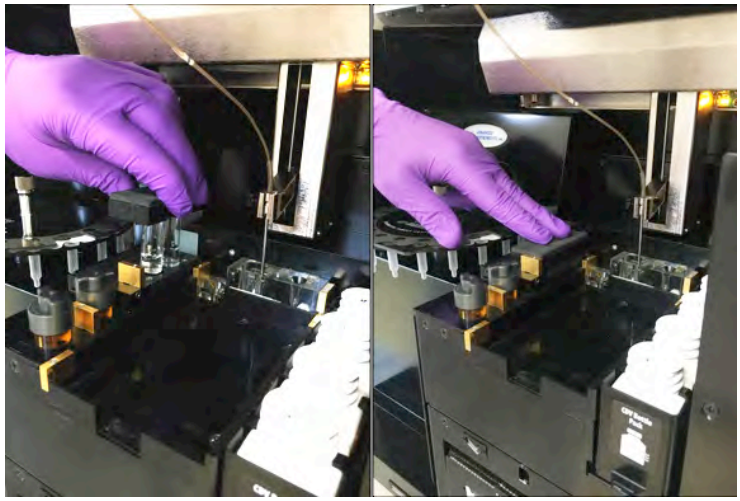
To install the onboard Chemistry Auto QC Cartridge:

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.*

4.26 *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.



4.27 *Installing and Seating Chemistry Auto QC Cartridge*

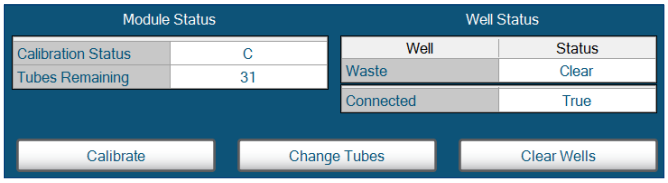
4.4 Osmometer Module

There are two osmometers compatible with the BioProfile FLEX2 analyzer. The 48-Position Osmometer (**Osm48**) manufactured by Nova Biomedical, and the 20-Position Osmometer (**Osm20**) manufactured by Advanced Instruments. Be sure to identify the osmometer configuration on your FLEX2 system before completing the maintenance procedures outlined in this section.

Caution: *Using incorrect Micro Sample Tubes on the Osmometer will cause system damage. The Osm48 requires PN 59859 tubes while the Osm20 requires PN 42435 tubes.*

4.4.1 Osm48 Change Tubes

To change the tubes for the Osm48, select Osm in the Status Bar.



4.28 *Osm48 Module Status Window*

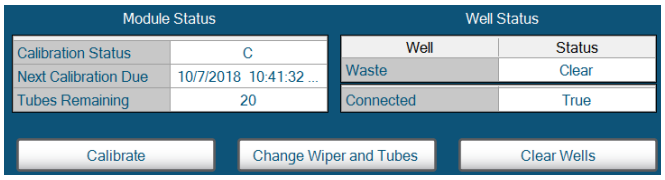
1. Select **Change Tubes** on the Osmometer Module status window. This will initiate the Change Tubes sequence and home the Osmometer Tray so it can be removed.
2. Gently remove the Osmometer Dust Cover.
3. Turn the set screw, located in the center of the Osmometer tray, counterclockwise and pull gently upwards until free.
4. Slide the tray away from the Osmometer and lift up to completely remove it.
5. Discard the old tubes.
6. Install 49 new tubes into the slots.
7. Install the Osmometer Tray back into the Osmometer by lifting the set screw and sliding the tray forward until it will go no further. Tighten the adjustment screw.

Note: *The tray is designed to only fit one way. Use the arrow and target printed on the tray to guide it into position.*

8. Install the Osmometer Dust Cover and ensure the magnet engages to hold it in place.
9. Select **Continue** in the Command Bar. The sequence will align the Osmometer Tray and count the newly installed tubes.

4.4.2 Osm20 Change Wiper Ring and Tubes

To Change the tubes and wiper ring for the Osm20, select OSM in the Status Bar.



4.29 *Osm20 Module Status Window*

1. Select **Change Wiper and Tubes** on the Osmometer Module Status Window. This will initiate the Change Wiper and Tubes sequence and home the Osmometer Tray so it can be removed.
2. Remove the Osmometer Tray by turning the set screw located in the center of the tray, counterclockwise and pull gently upwards until free.
3. Slide the tray away from the Osmometer to completely remove it.
4. Gently remove the Osmometer Dust Cover.
5. Discard the old tubes and wiper ring.
6. Install 20 new tubes and a new wiper ring.
7. Install the Osmometer Tray back into the Osmometer by lifting the set screw and sliding the tray forward until it will go no further. Tighten the adjustment screw.

Note: *The tray is designed to only fit one way.*

8. Install the Osmometer Dust Cover.
9. Select **Continue** in the Command Bar. The sequence will count the newly installed tubes.

4.5 CDV MODULE

4.5.1 INSTALLING THE CDV REAGENT CARTRIDGE

The BioProfile FLEX2 Analyzer Reagent Cartridges are equipped with smart installation technology. The CDV Module Reagent Cartridge includes 2 separate cartridges that must be replaced together. The set consists of a larger CDV Reagent Cartridge, and a smaller Bottle Pack.

CAUTION: *The bottle caps must be removed from all 4 bottles of the Bottle Pack prior to installation. Failure to remove the bottle caps will result in damage to the analyzer.*

4.30 *CDV Reagent Cartridge & Bottle Pack*

Similarly to the pH/Gas & Chemistry Calibrator Cartridges, once a CDV Reagent Cartridge is installed in the analyzer and the door is closed, the unit will automatically prime and install the pack. If the user presses the Cell Density module status icon (*e.g. CDV 98%*), the Calibration Status, Well Status, Flow Time, and Pack Information will all be displayed in the CDV module status window. For all Reagent Cartridges, clicking the desired Reagent Cartridge indicator will indicate the lot number, expiration date, and installation date of the cartridge.

To install a new CDV Reagent Cartridge:

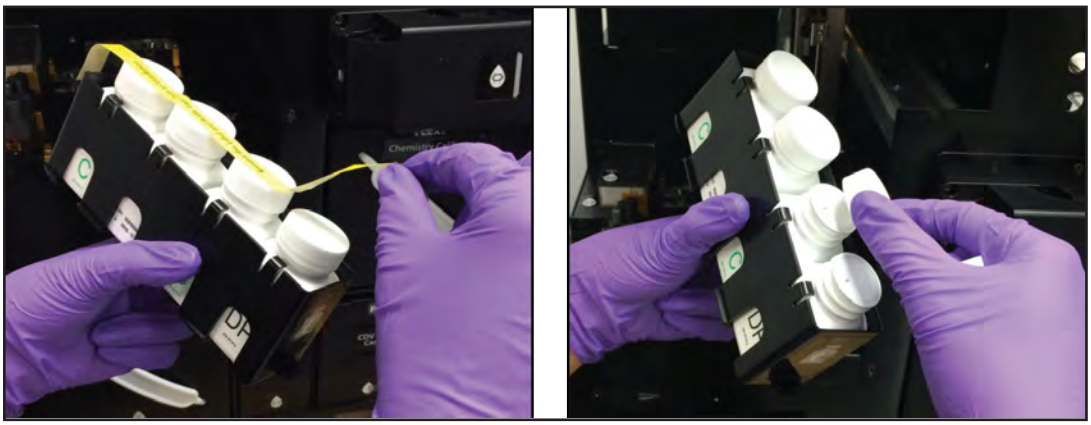
1. Open the BioProfile FLEX2 front panel door.
2. Remove the old CDV Reagent Cartridges by pulling on the tab on the larger pack and the pull tab on the bottle pack.

4.31 *Remove Old Cartridges*

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

NOTE: *Make sure the Lot number of the bottle pack matches the Lot number of the larger Reagent Cartridge.*

4. Remove all 4 bottle caps, but not the white seals from each of the bottles on the bottle pack.



4.32 *Remove Bottle Caps*

Caution: *Failure to remove all 4 bottle caps from the CDV Bottle Pack will result in system damage.*

5. Install the new bottle pack by sliding it into the bottle pack location until it clicks into place.
6. Gently slide the new CDV Reagent Cartridge into its pack bay. There will be 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 analyzer chassis.
7. Close the analyzer door. The system will automatically recognize the new Reagent Cartridges, prime the CDV module, pierce the reagent bottles, and run an Adjust Intensity procedure.

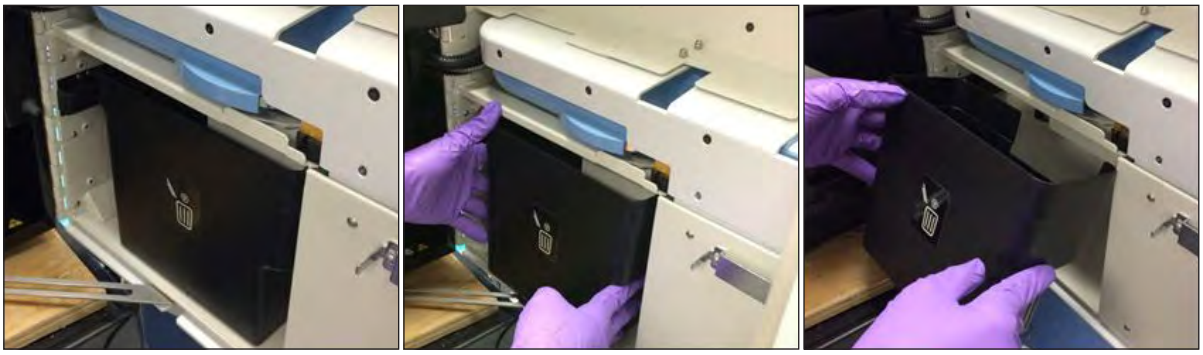
4.33 *Pack Flush with Analyzer Chassis*

Warning: ***The needle fitments inside the pack bays are sharp. To avoid injury, never stick your hands inside the pack bays.***

Warning: ***The CDV Reagent Cartridges contain Trypan Blue Dye which is a known carcinogen. Avoid direct contact with skin. Gloves, protective clothing, and safety glasses are recommended when handling these Reagent Cartridges. Used cartridges will contain residual Trypan Blue Dye and should be disposed of in accordance with state and local regulations.***

4.6 EMPTYING THE LOAD-AND-GO WASTE CONTAINER

After each carousel analysis, the spent cup is deposited into the waste container located behind analyzer the door. The waste container can hold up to 200 discarded cups. To empty, remove the container and discard the cups.

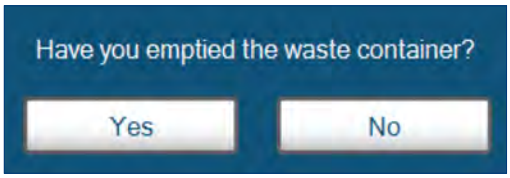


4.34 Removal/Replacement of the Waste Container

CAUTION: *When the waste container is reinstalled and the door is closed, a prompt will ask if the waste container has been emptied. Selecting* **Yes** *will reset the waste container cups back to 200 remaining.*

NOTE: *If the waste container is not present, Load-and-Go sampling will not be available .*

WARNING: ***Used cups are considered a biohazard and should be disposed of in accordance to your institution's standard operating procedure.***



4.35 Waste Container Prompt

4.7 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 analyzer. Selecting the **Service** button 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 on-site 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. Administrators will have access to the Flowpath Service, the RFID Test, a Resource Issues section, an Auto Log, and the PSoCs Test.

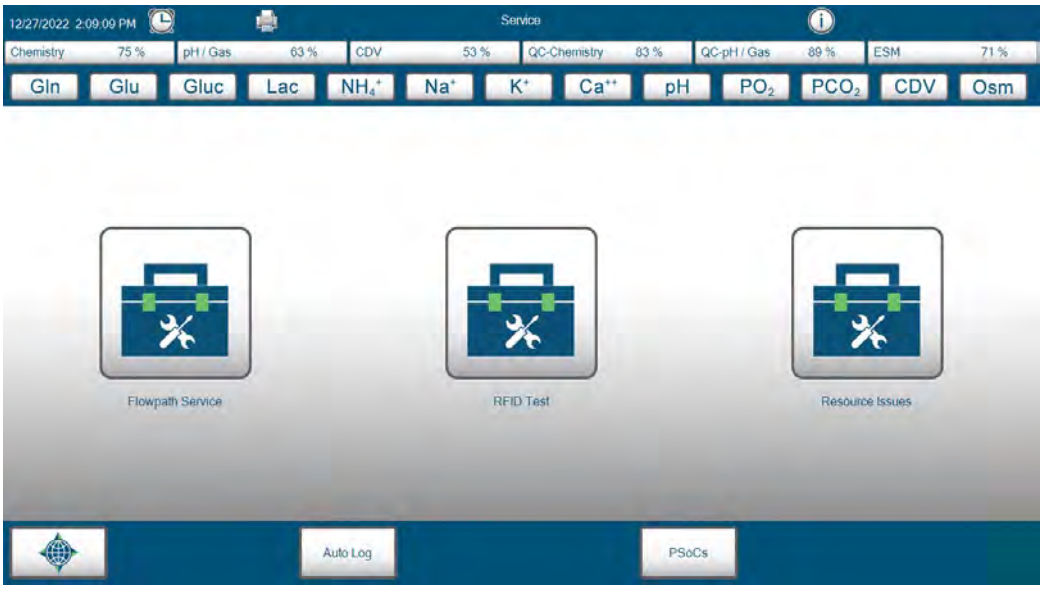
4.7.1 RFID TEST

The RFID Test is used to confirm that the RFID within each consumable pack and MicroSensor Card is communicating properly with your FLEX2. 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. Click the **Service** button, then select the **Customer Service** menu.
2. Click **RFID Test**.
3. Click **Start**.
4. Let the test run and review the results. For initial readings of pack performance, click **Cancel** after 5 minutes.

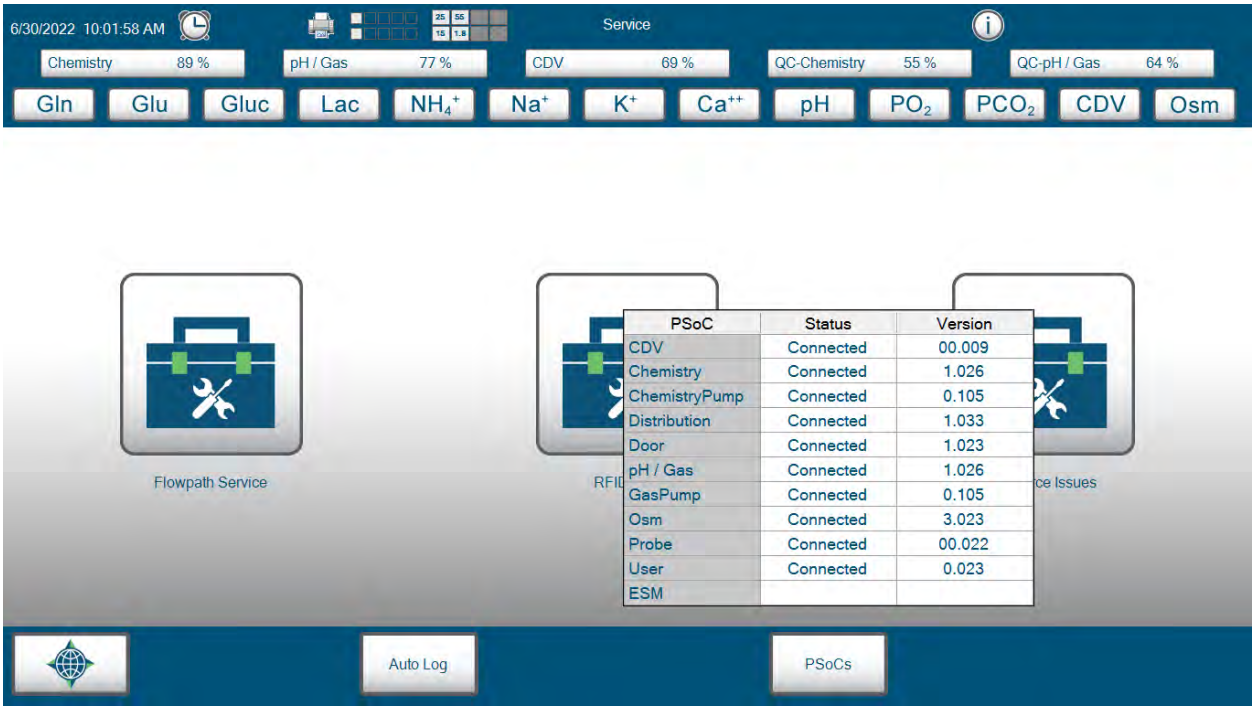
5. The results will be presented. The right-hand column, Pass, indicates whether the RFID successfully communicated to the FLEX2. True indicates proper communication; False indicates a failure in communication.
6. Contact Technical Support for any communication failure from the RFID Test.



4.36 *RFID Test*

4.7.2 PSoCs Test

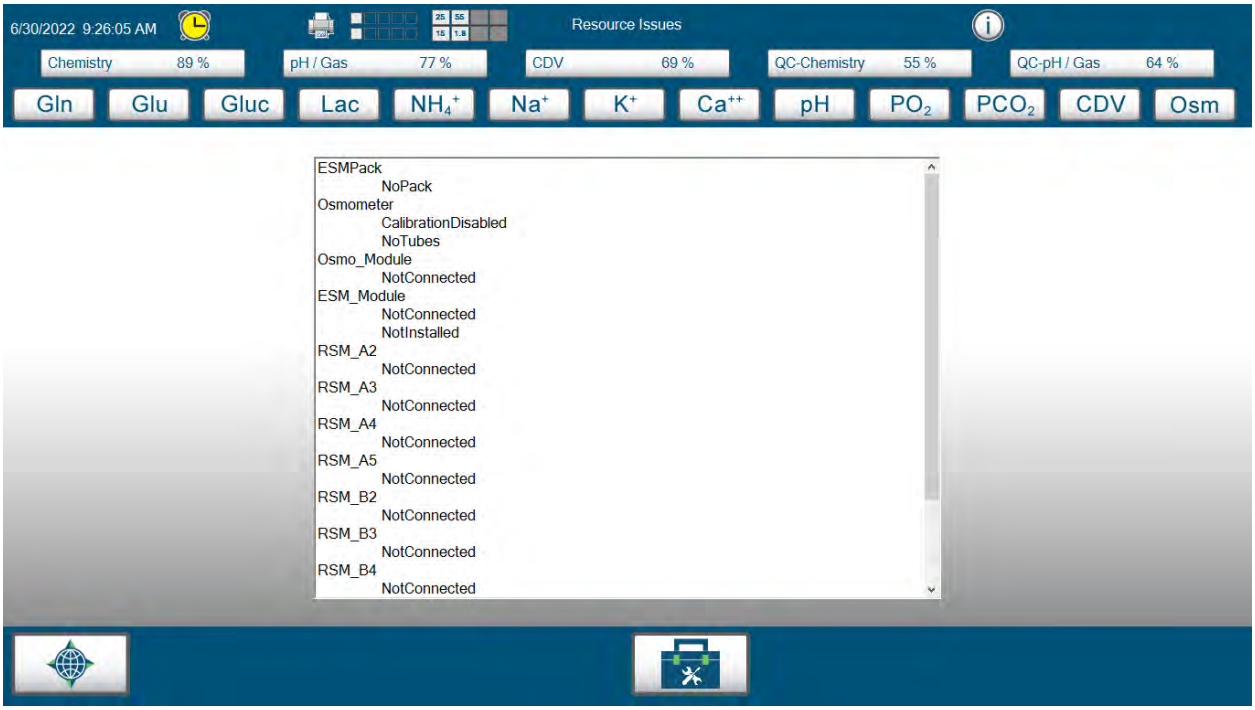
The PSoCs Test pings the programable system on a chip, the PSoC board, for each module within the FLEX2. The test results will display the status of the PSoC communication link and version number. Successful communication between the Host computer and PSoCs board indicates that the FLEX2 is properly 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.



4.37 *PSoCs Test*

4.7.3 RESOURCE ISSUES

The Resource Issues button will search your FLEX2 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.



4.38 *Resource Issue*

4.7.4 AUTO LOG

The Auto Log option will provide a detailed list of logs from your FLEX2 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 device, see* ***Section 5****.*

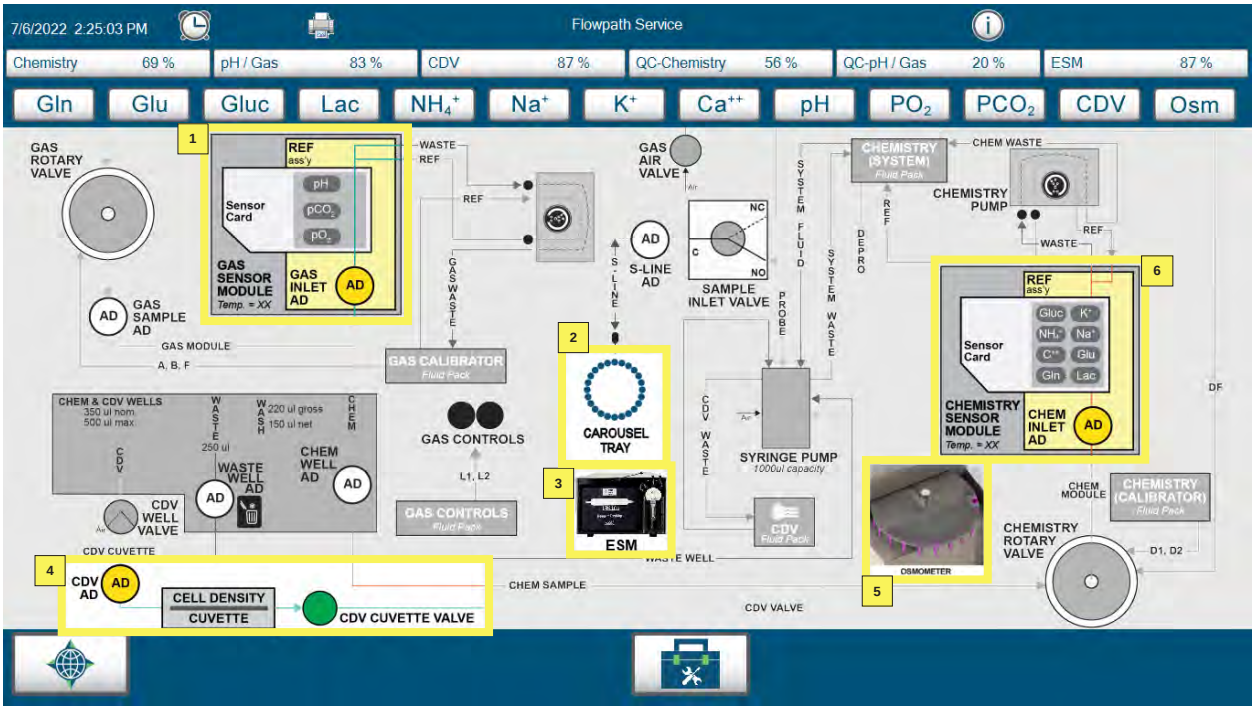
4.7.5 FLOWPATH SERVICE

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.

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 flowpath. The following options can be selected on the Flowpath Service screen depending on which modules are installed on your machine:

1. **Gas Sensor Module**
2. **Carousel Tray**
3. **ESM Module**
4. **CDV Module**
5. **Osmometer**
6. **Chemistry Sensor Module**

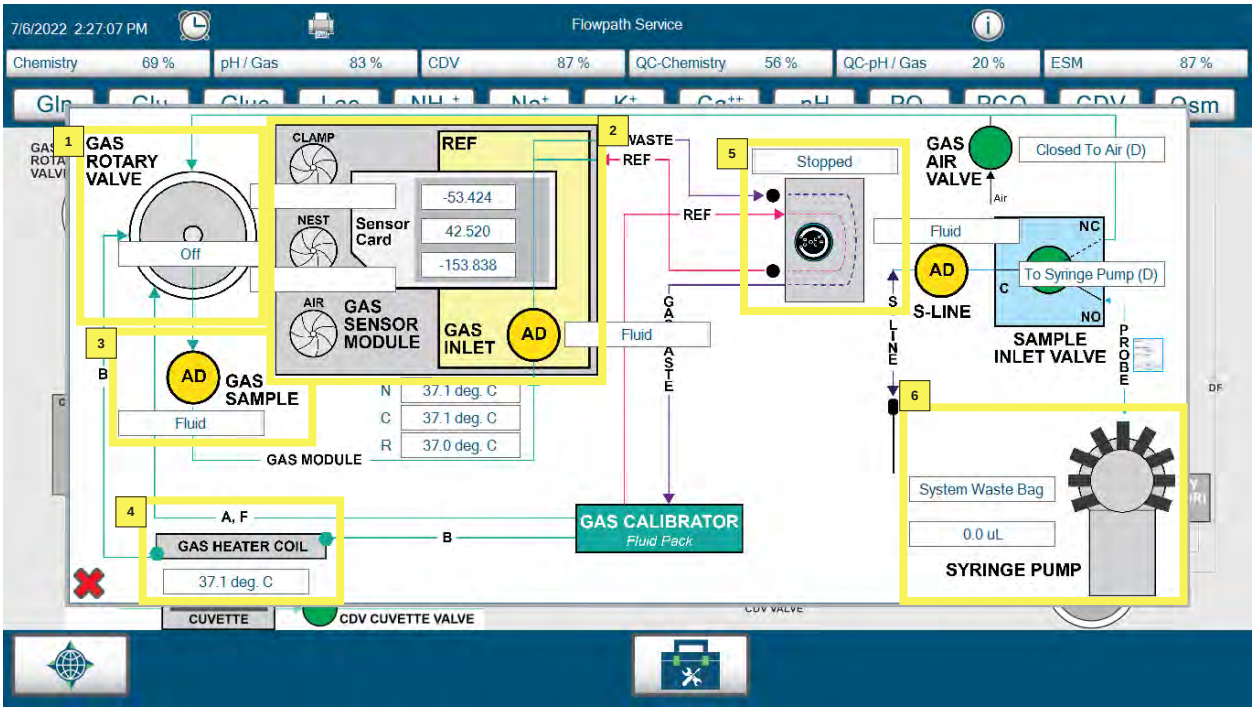


4.39 *Flowpath Service Modules*

4.7.5.1 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:

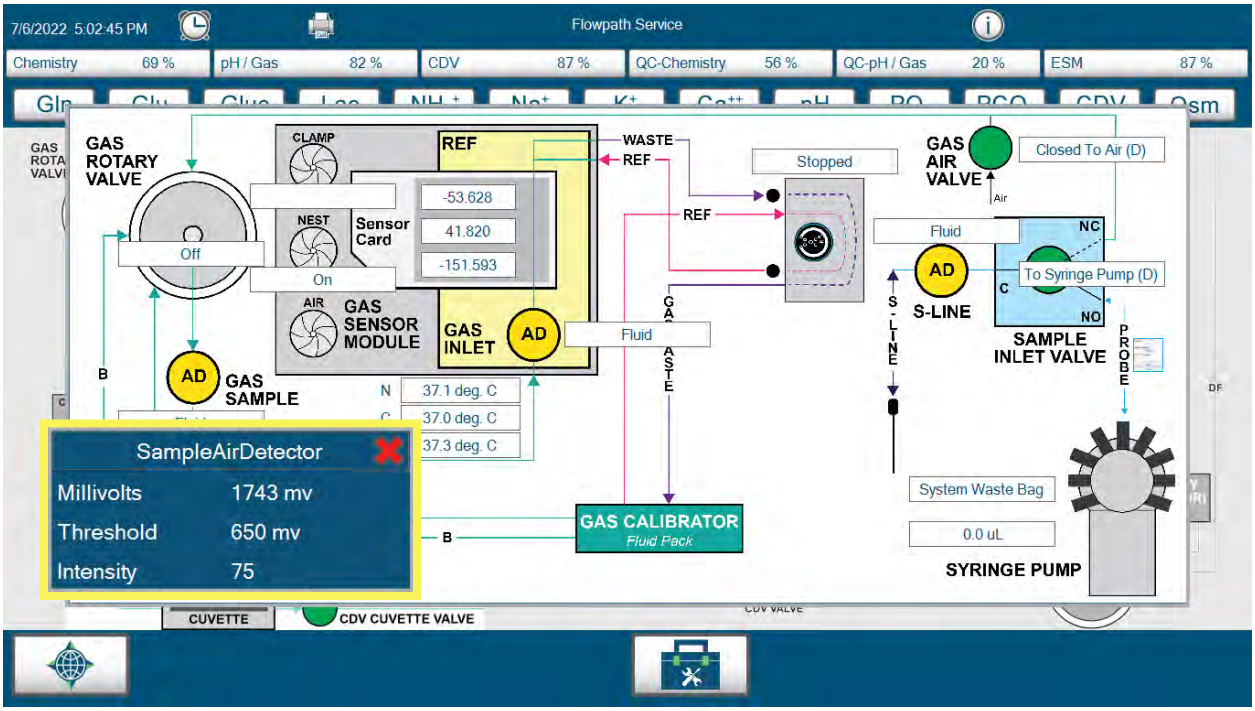
1. **Gas Rotary Valve** displays the rotary valve status and allows for device control.
2. **Gas Module Sensor** displays information from the Gas Module and allows operators to control the Gas Module Sensor.
3. **Gas Module Air Detector.** The air detectors display (air/fluid) based on the current sensor 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.



4.40 *Gas Module Control Window*

Gas Sample Air Detector

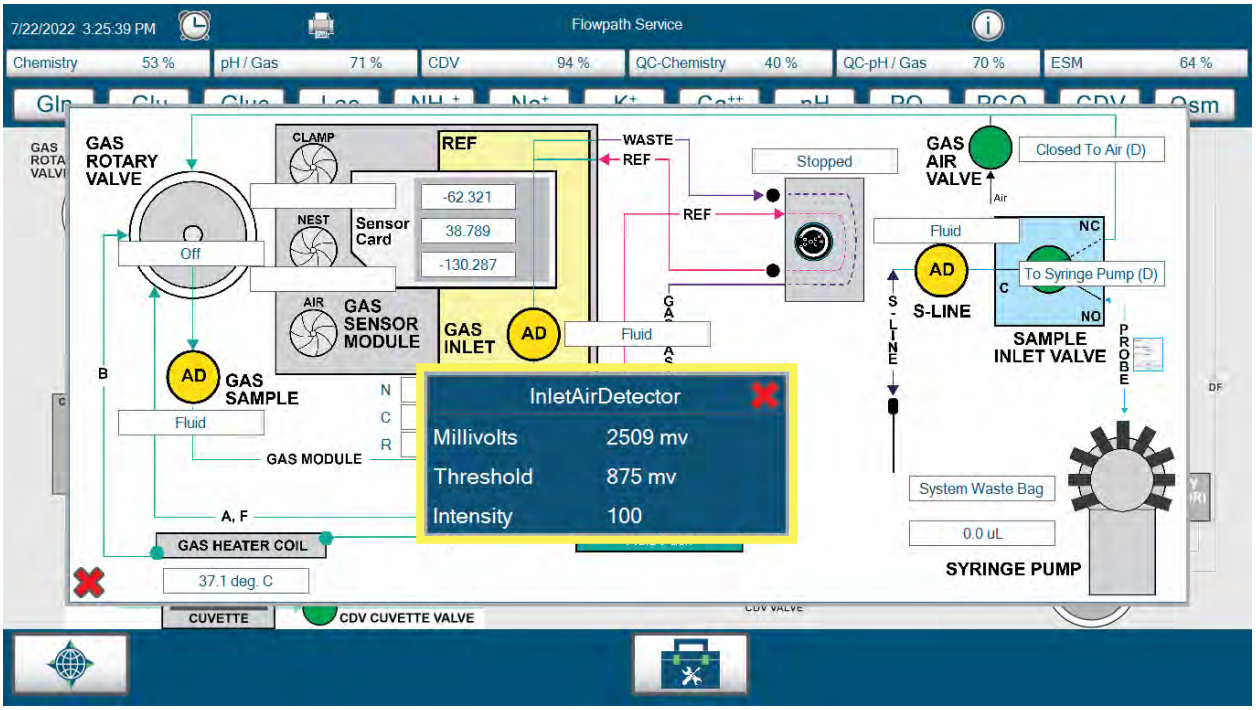
This air detector is in the common line tube of the Gas Rotary Valve. Select the information box below the air detector to see the associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value are all displayed.



4.41 *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.



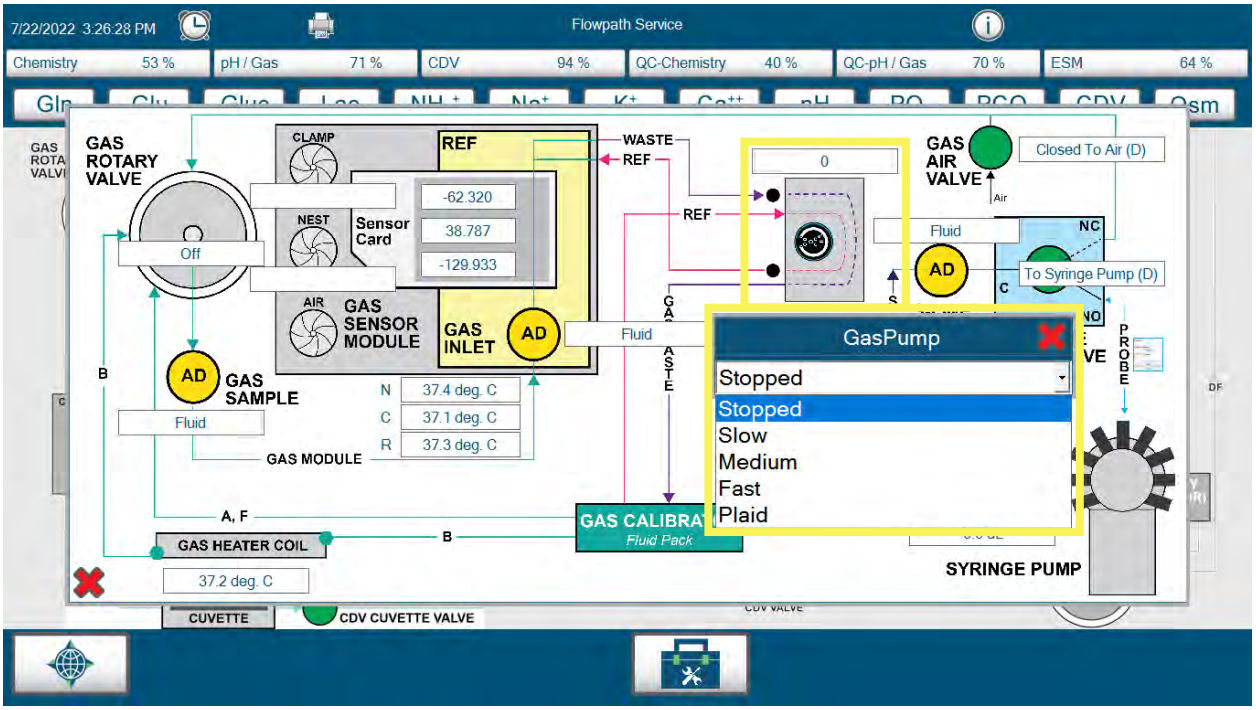
4.42 *Gas Inlet Air Detector*

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.*

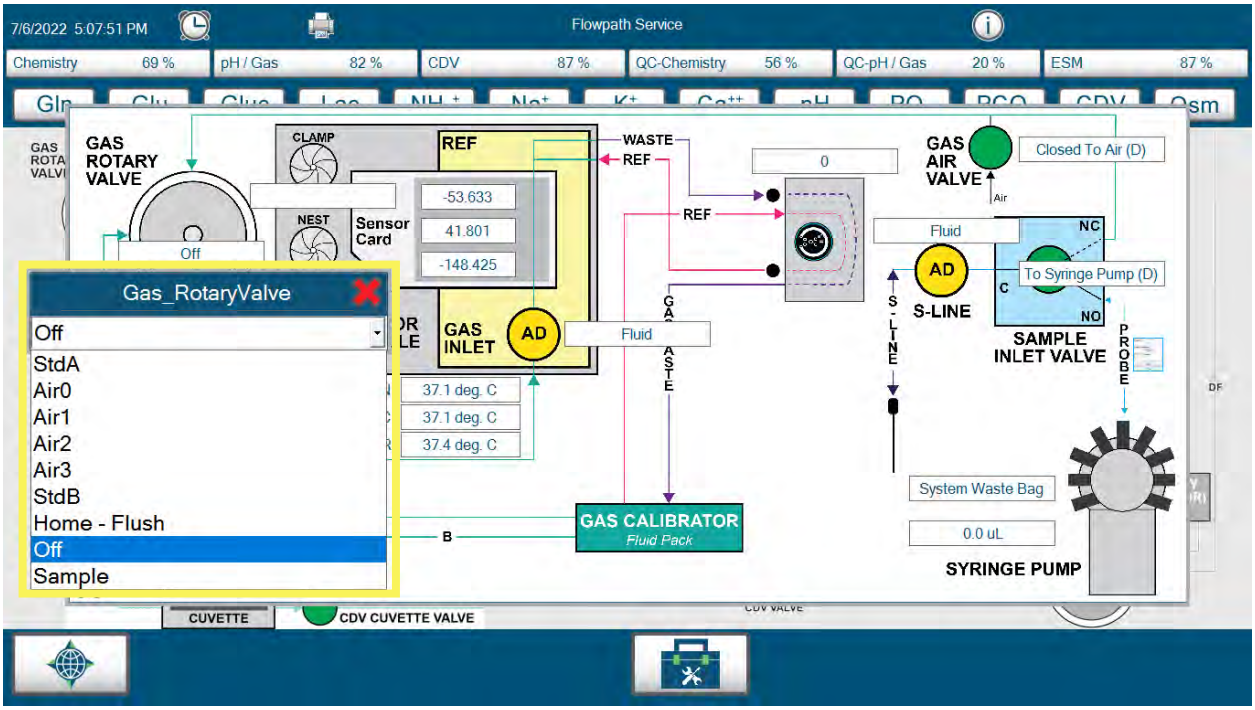


4.43 *Gas Module Peristaltic Pump Control*

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.



4.44 Gas Module Pump Control

4.7.5.2 Carousel Tray

Administrators can also move the carousel and control the light above the sample position through Flowpath Service.

To move the Load & Go Carousel:

1. Select the **Carousel Tray** from Flowpath Service.
2. Select the position.
3. Click **Initialize**.

To turn the light above the sample position on:

1. Select the **Carousel Tray** from Flowpath Service.
2. Select either **Tray LED On** or **Tray LED Off**.

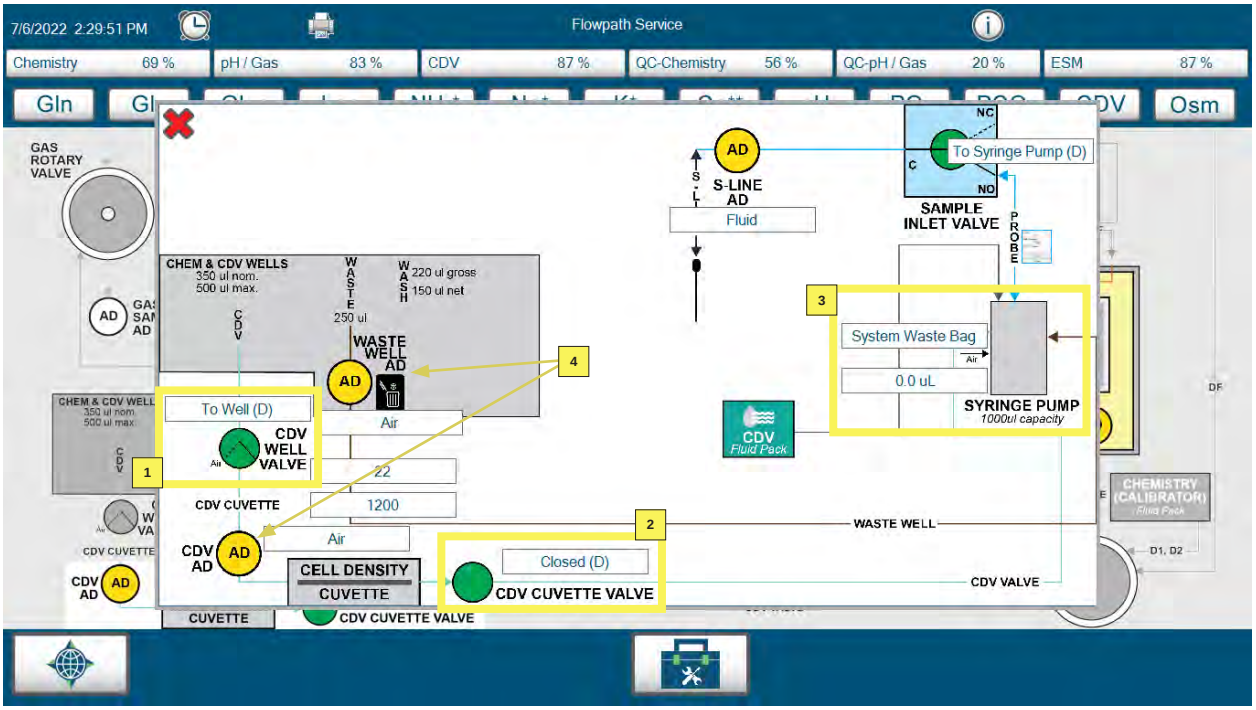
Note: *Be sure to remove any sample cups from the carousel tray prior to using this feature to avoid the loss of sample material.*

4.45 *Carousel Control and Cup Alignment*

4.7.5.3 Cell Density Viability Module

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

1. **CDV Well Valve** displays the CDV Well Valve status and allows for device control.
2. **CDV Cuvette Valve** displays the CDV Cuvette Valve status and allows for device control.
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. **Waste Well and CDV Cuvette Inlet Air Detectors**. The air detectors display (air/fluid) based on the current sensor signal strength. Selecting the reading brings up the sensor label.

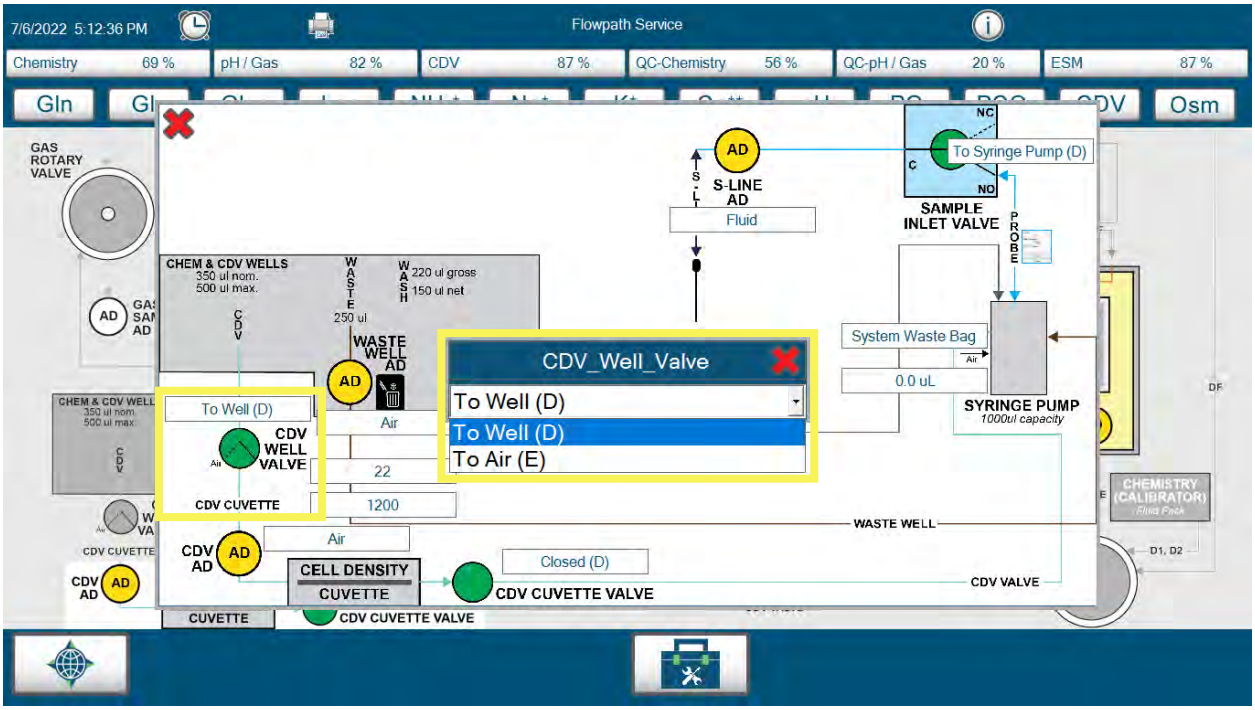


4.46 *CDV Module Window*

Cell Density Viability Well Valve

To control the Cell Density Viability Well Valve:

1. Select the information box above the Cell Density Viability Well Valve that displays its current position.
2. In the drop-down menu, you can change the position of the Well Valve to control the fluid flow to the Cell Density Viability Well. Observe the flow of fluid in the CDV well and listen for movement of the valve to help troubleshoot flow issues.

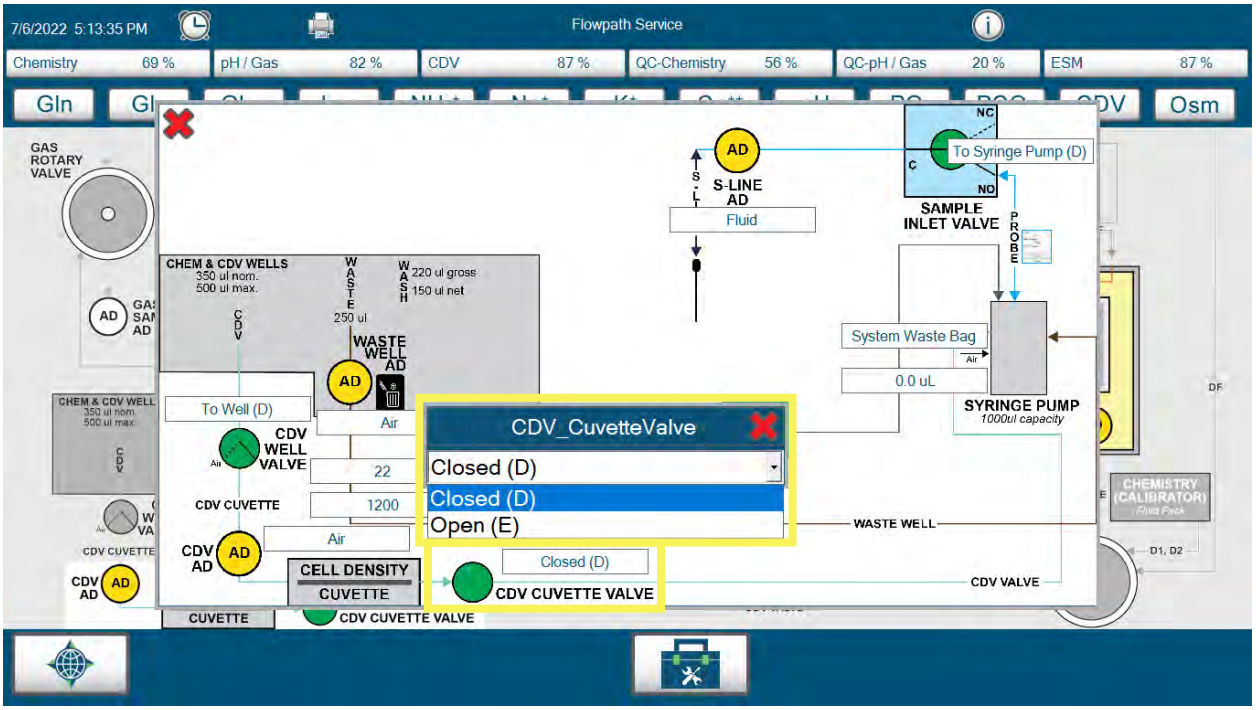


4.47 *CDV Well Valve Control*

Cell Density Viability Cuvette Valve

To control the Cell Density Viability Cuvette Valve:

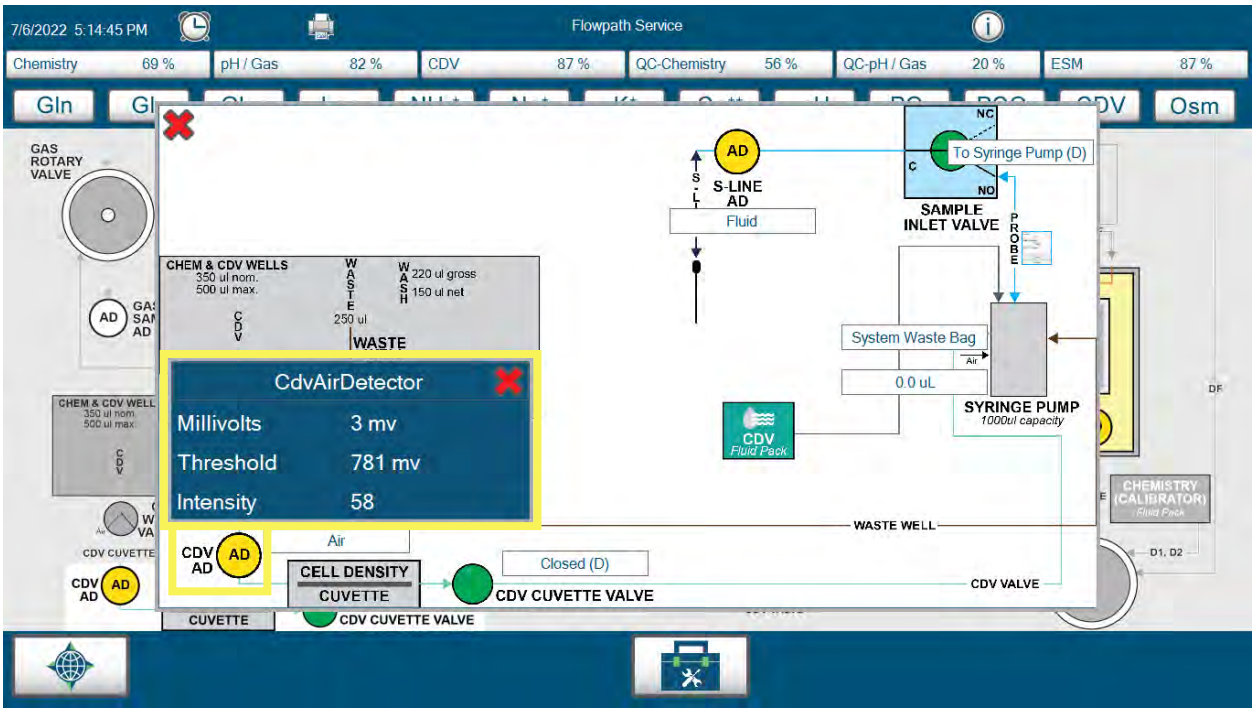
1. Select the information box on the Cell Density Viability Cuvette Valve that displays its current position.
2. In the drop-down menu, you can change the position of the Cuvette valve to control the fluid flow to the Cell Density Viability Cuvette. Listen for movement of the valve or control the fluid flow through the cuvette to help troubleshoot flow issues.



4.48 *CDV Cuvette Valve Control*

Cell Density Viability Air Detector

The Cell Density Viability Air Detector is located along the module flowpath in the cuvette inlet tubing. 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 are all displayed.



4.49 *CDV Air Detector*

Pierce Bottles

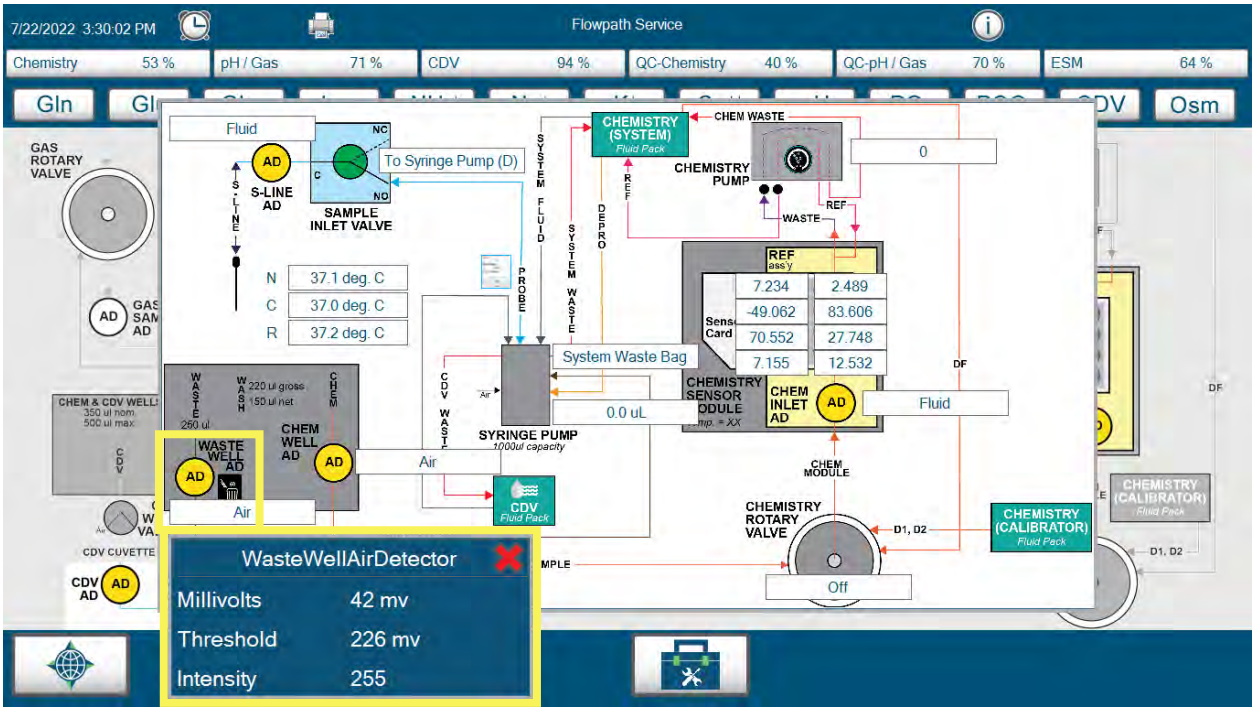
Pierce Bottles starts a routine to pierce all the CDV bottles. This is necessary if the CDV pack was not installed correctly or if the bottles were not pierced correctly.

To move the System Probe to pierce the the CDV bottle packs:

1. Open the System Probe control menu by clicking the image next to the word **PROBE**.
2. Select **Pierce Bottles** in the System Probe control window.

Waste Well Air Detector

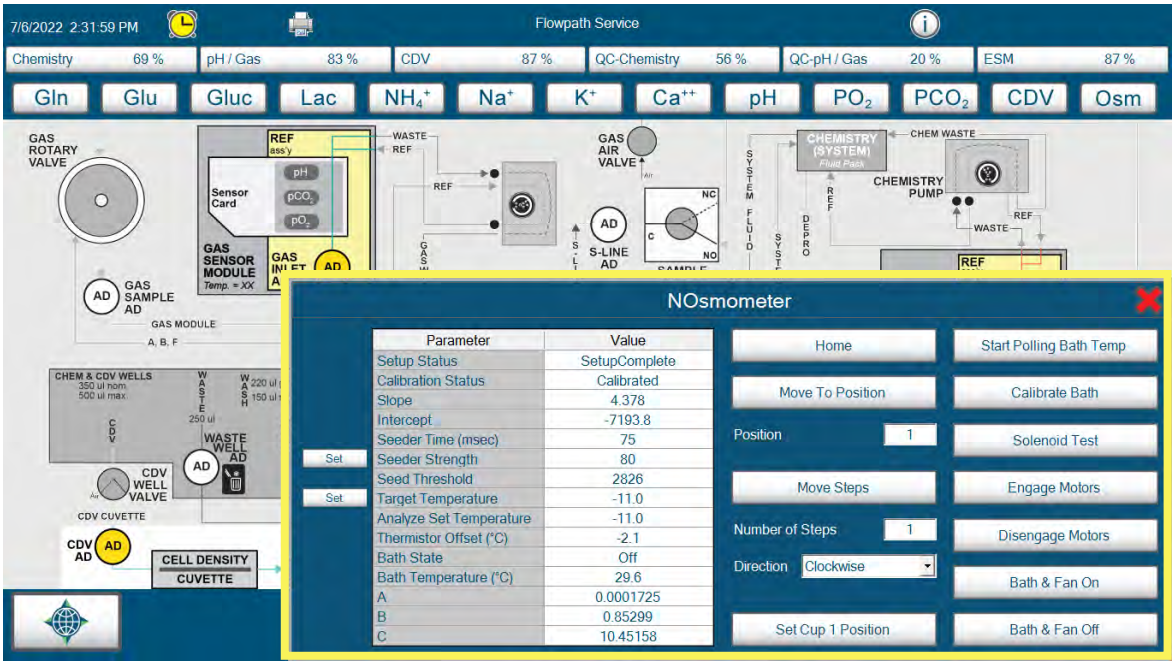
The Waste Well Air Detector information can be accessed through either the Cell Density Viability Module or Chemistry Module Windows. Select the information box to the right of the air detector to view its associated signal levels. The current signal strength, the threshold for Fluid, and the intensity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



4.50 *Waste Well Air Detector*

4.7.5.4 Osmometer

The Osmometer Module window allows operators to control the Osmometer manually and troubleshoot errors associated with the Osmo Module. **This option should only be used when under the guidance of Nova Technical Support Personnel.**

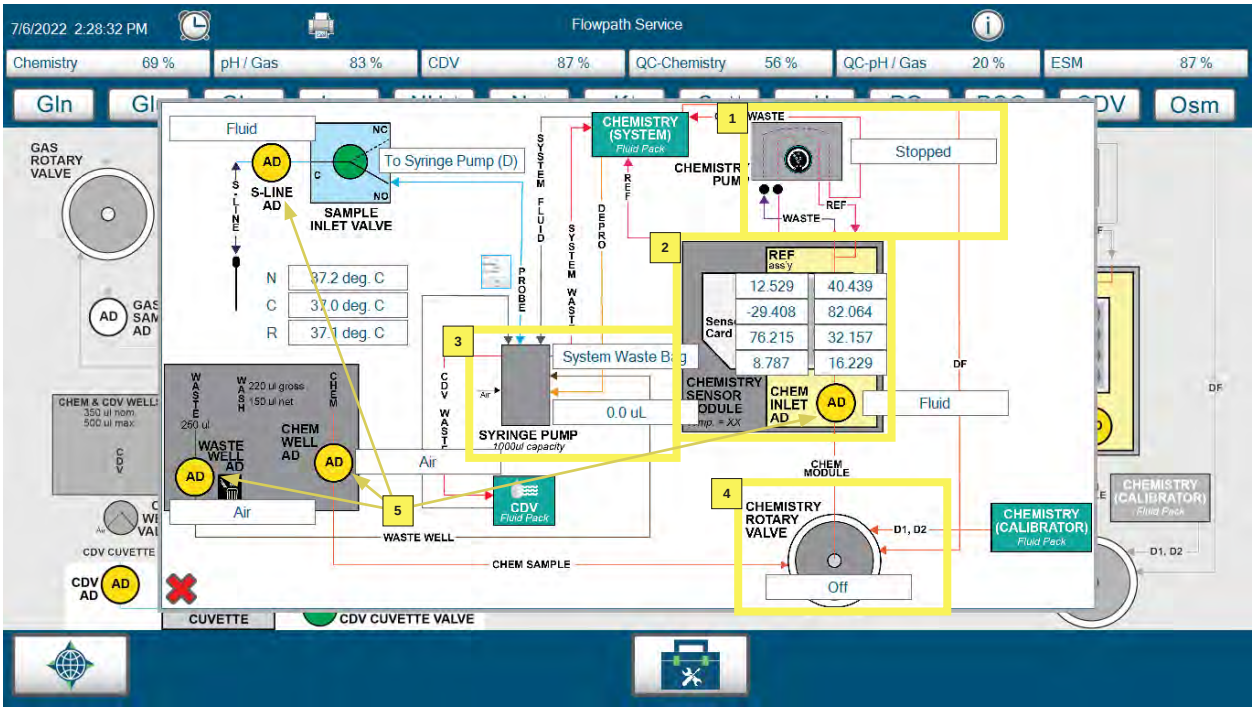


4.51 *Osmometer Module Window*

4.7.5.5 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:

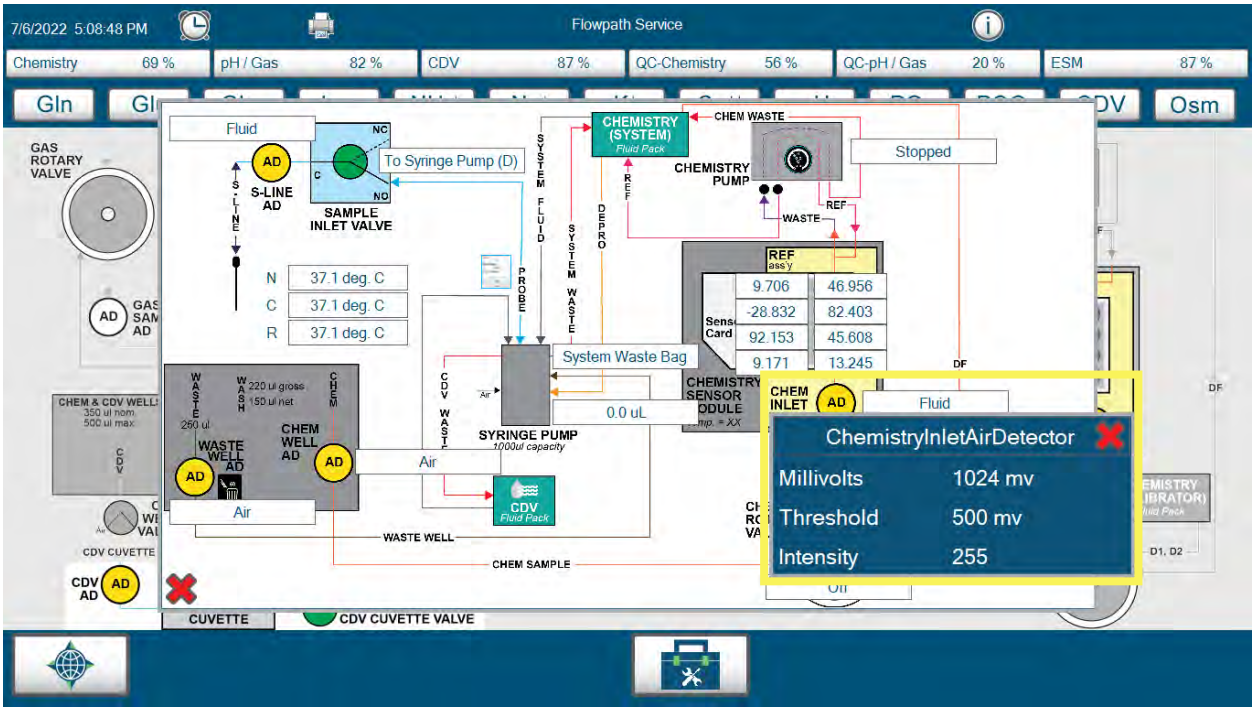
1. **Chemistry Peristaltic Pump** displays the status of the peristaltic pump and allows for device control.
2. **Chemistry Sensor Module** displays the current sensor signal strength. Selecting the reading brings up the sensor label.
3. **Syringe pump** displays the current syringe pump position and 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.



4.52 *Chemistry Module Submenu Screen*

Chemistry Inlet Air Detector

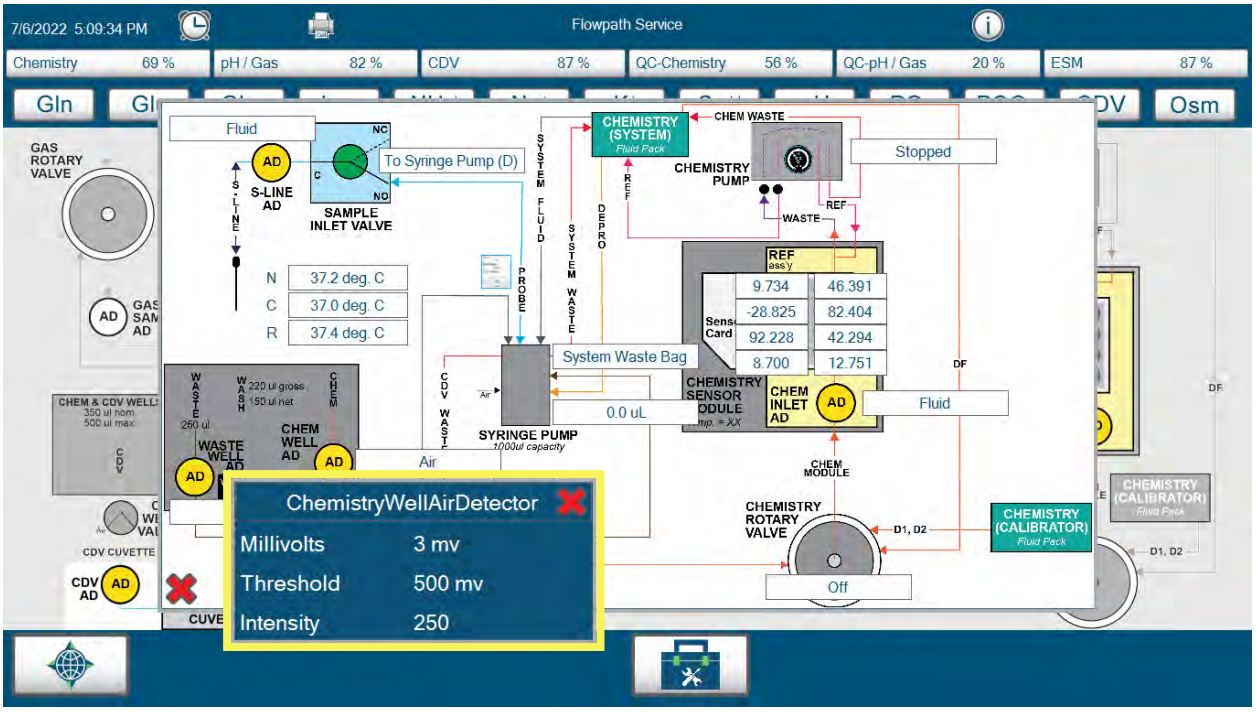
The Chemistry Inlet Air Detector is in the reference sensor. Select the information box to the right of the air detector to see the associated signal levels. The current signal strength, the threshold for Fluid, and the intensity value are all displayed.



4.53 *Chemistry Inlet Air Detector Information*

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.



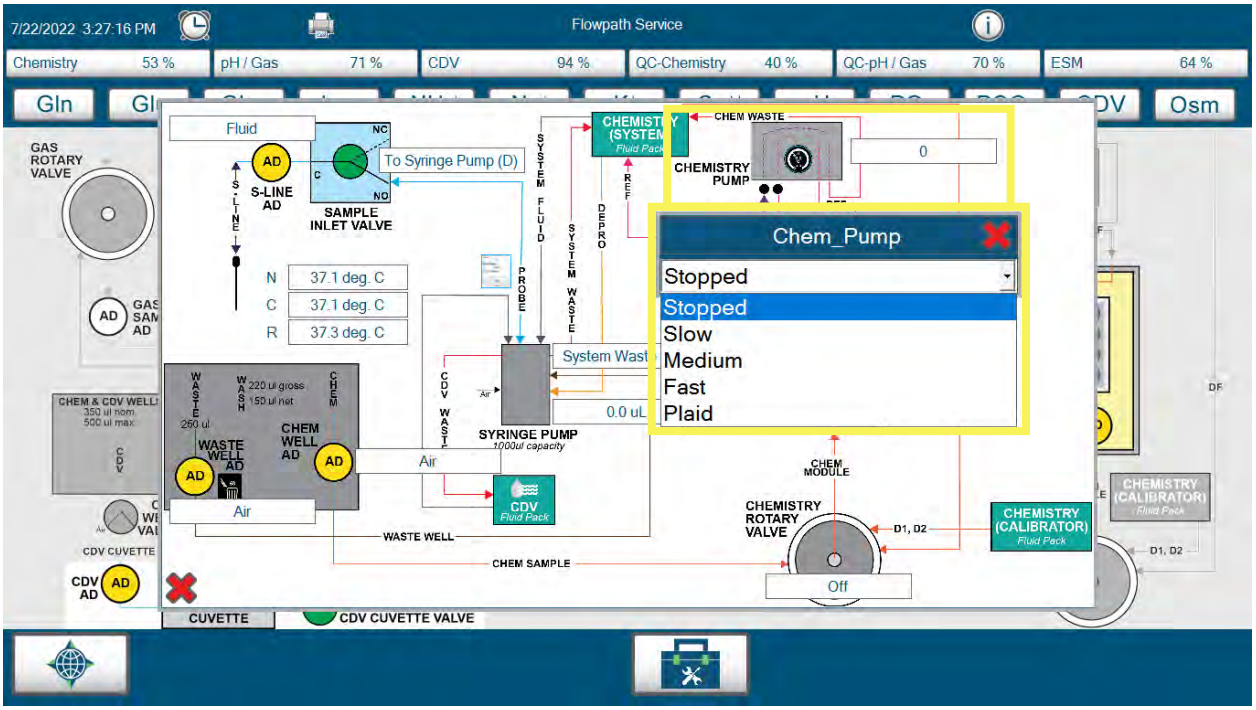
4.54 *Chemistry Well Air Detector*

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 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.*

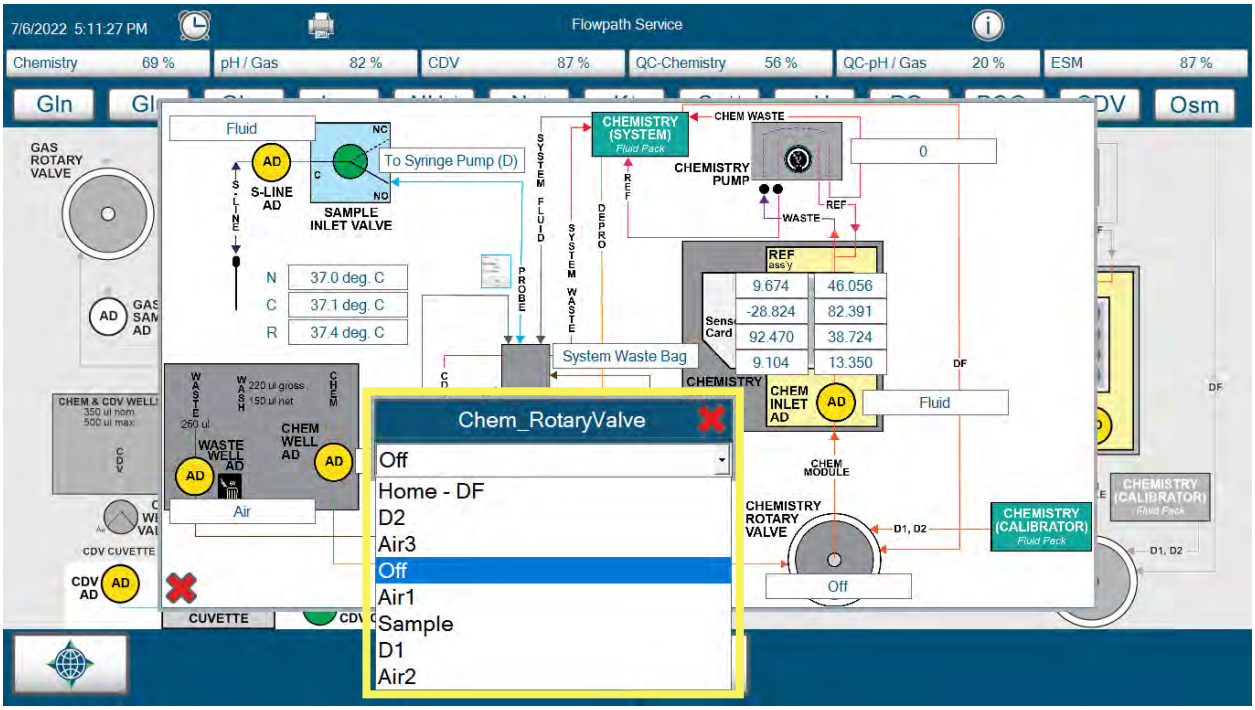


4.55 *Chemistry Peristaltic Pump Control*

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.



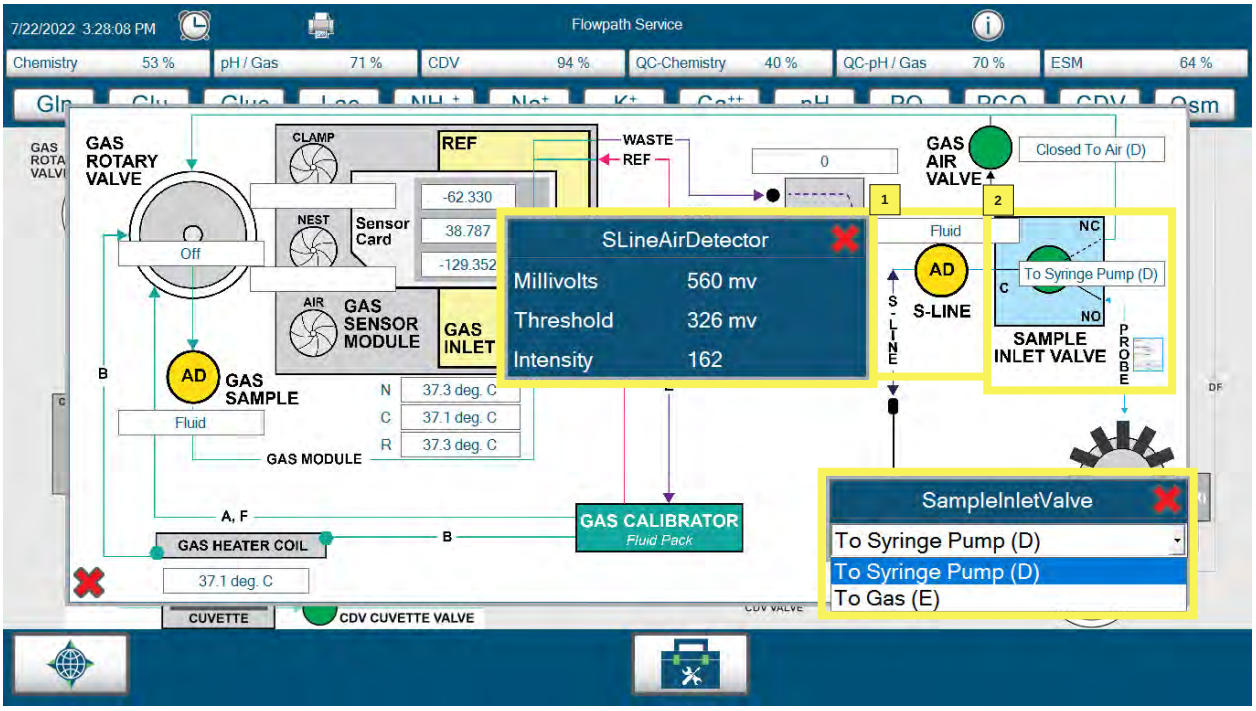
4.56 *Chemistry Rotary Valve Control*

4.7.5.6 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.



4.57 *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.

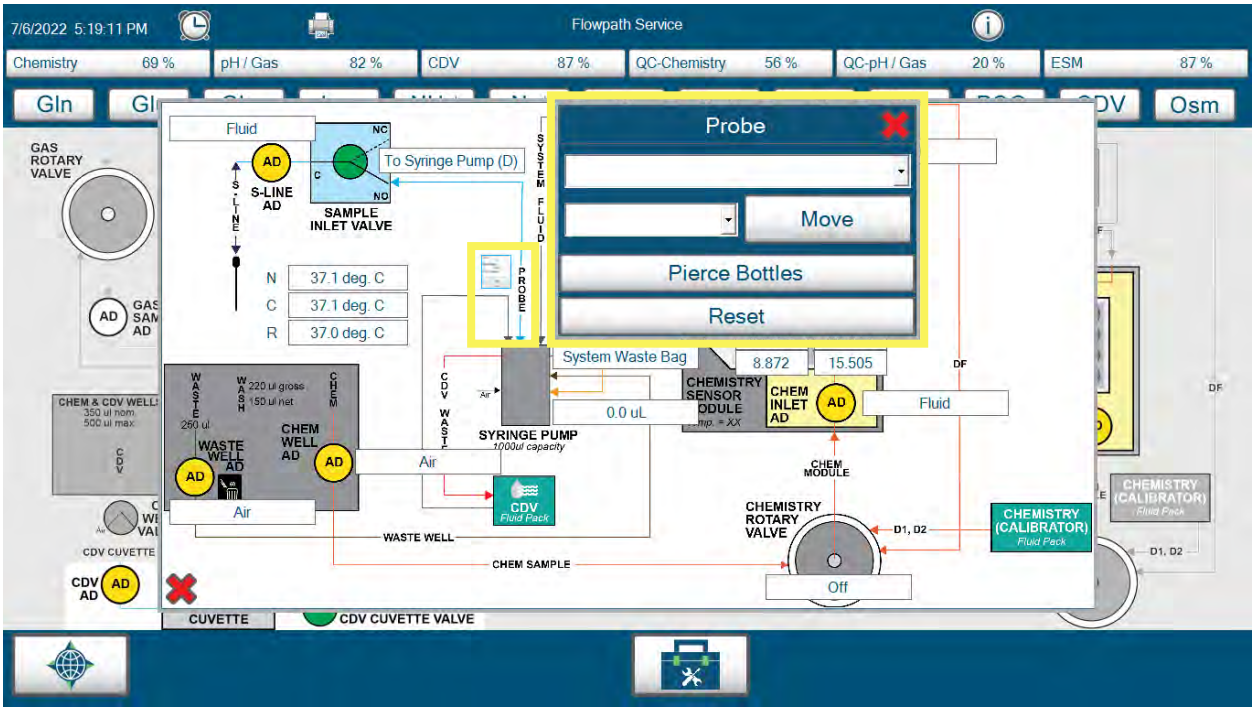
System Probe Control

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, and it can also perform a CDV Pierce Bottles sequence.

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.*



4.58 *System Probe Control Menu on the Chemistry Module Window*

Syringe Pump

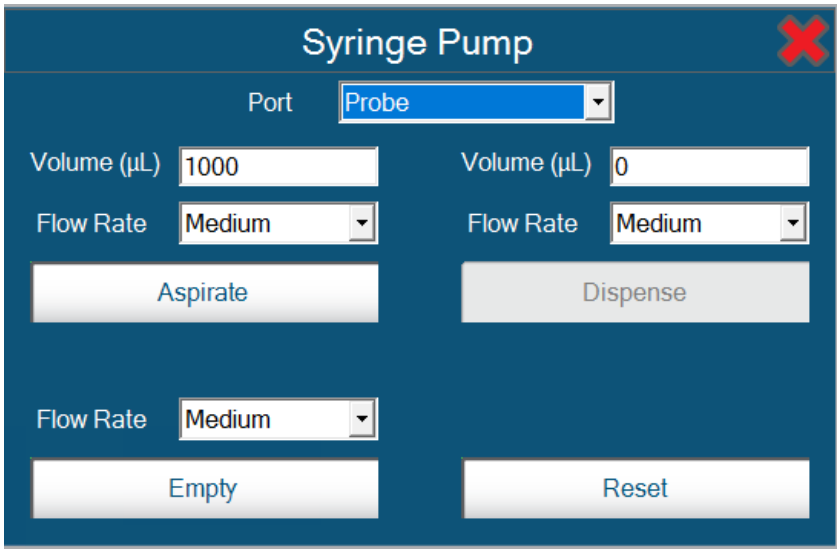
In Flowpath Service, the Syringe Pump can be controlled to help flush certain wells, confirm flow from certain reagents, or flush different flow paths. The following steps contain details on how to perform basic actions with the Syringe Pump to aspirate and dispense reagents from the different module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

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.



4.59 *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:*

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

4.8 Cleaning FLEX2 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.

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®.

Note: *Residual alcohol on any Osmometer Module surface may result in elevated osmolality readings.*

Warning: ***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.***

5 TROUBLESHOOTING

This section describes the errors and explains the troubleshooting procedures for the BioProfile FLEX2.

WARNING: ***Cell culture samples are potential sources of infectious agents. Handle all sample and flowpath 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.

Error Codes

A

C

D

E

A

Auto Focus Failure

During the CDV calibration, the auto focus sequence did not complete successfully.

Recommended Solutions:

1. If no other errors are present, repeat the calibration.
2. If there are other errors present or the error persists, contact Nova Biomedical Technical Support.

Auto Intensity Failure

During the CDV calibration, the adjustment for the intensity of the light on the CDV module was outside specifications.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
2. If the error persists, contact Nova Biomedical Technical Support.

C

Ca^{++} Analytical Range High

During the last analysis, the measured result exceeded the upper limit of the Ca^{++} sensor's 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's 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.

Carousel Tray Position Error

During the last Carousel Tray analysis, the tray *home* sensor was unable to verify the tray position.

Recommended Solutions:

1. Initialize the Carousel Tray from the Maintenance Screen.
2. Contact Nova Biomedical Technical Support.

CDV Flow Fast

During the last analysis, calibration, or maintenance sequence, the cell density 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 CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
2. Contact Nova Biomedical Technical Support.

CDV Flow Slow

During the last analysis, calibration, or maintenance sequence, the cell density 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 CDV Reagent 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 Cell Density 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 Depro Wells from the Maintenance screen.
4. Run a Clean Cell Density Flowcell from the Maintenance screen.
5. Run an Intensive Clean Cell Density Flowcell from the Maintenance screen.
6. Contact Nova Biomedical Technical Support.

CDV Flow Time

During the last analysis, calibration, or maintenance sequence, the cell density 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 CDV Reagent 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 Cell Density 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 Depro Wells from the Maintenance screen.
4. Run a Clean Cell Density Flowcell from the Maintenance screen.
5. Run an Intensive Clean Cell Density Flowcell from the Maintenance screen.
6. Contact Nova Biomedical Technical Support.

CDV Found Fluid When Expected Air

During the last analysis, calibration, or maintenance sequence, the cell density 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 CDV Reagent 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 Cell Density 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 Clean Cell Density Flowcell from the Maintenance screen.
4. Contact Nova Biomedical Technical Support.

CDV Image Dark

During the last analysis, calibration, or maintenance sequence, the cell density image exceeded the maximum intensity.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
2. Run the Adjust Intensity sequence from the Cell Density module status screen.
3. Run an Intensive Clean Cell Density Flowcell from the Maintenance screen.
4. Contact Nova Biomedical Technical Support.

CDV Image Light

During the last analysis, calibration, or maintenance sequence, the cell density image exceeded the minimum intensity.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
2. Run the Adjust Intensity sequence from the Cell Density module status screen.
3. Run an Intensive Clean Cell Density Flowcell from the Maintenance screen.
4. Contact Nova Biomedical Technical Support.

CDV No Air

During the last analysis, calibration, or maintenance sequence, the air detector failed to see air when expected.

Recommended Solutions:

1. Run a Prime from the Cell Density module status screen.
2. Contact Nova Biomedical Technical Support.

CDV No Depro

During the last analysis or maintenance sequence, the Deproteinizing solution was not aspirated properly.

Recommended Solutions:

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

CDV No Diluent

During the last analysis or maintenance sequence, the diluent was not aspirated properly.

Recommended Solutions:

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

CDV No Mucasol

During the last analysis or maintenance sequence, the mucasol cleaning solution was not aspirated properly.

Recommended Solutions:

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

CDV No System Fluid

During the last analysis or maintenance sequence, the system fluid was not aspirated properly.

Recommended Solutions:

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

CDV No Trypan Blue

During the last analysis or maintenance sequence, the trypan blue was not aspirated properly.

Recommended Solutions:

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

CDV Not Available

During the last analysis, the Cell Density module was not available for analysis.

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
2. Run the Clear Wells sequence from the Cell Density module status screen.
3. Calibrate the Cell Density module.
4. Contact Nova Biomedical Technical Support.

CDV Pack No Samples Remaining

The CDV Reagent Cartridge Set has reached its use life expiration.

Recommended Solutions:

1. Replace the CDV Reagent Cartridge Set.
2. Contact Nova Biomedical Technical Support.

CDV Trypan Blue Bottle Empty

During the last analysis or maintenance sequence, trypan blue was not detected when expected.

Recommended Solutions:

1. Replace the CDV Reagent Cartridge Set.
2. Contact Nova Biomedical Technical Support.

CDV Well Blocked

During the last analysis, the Cell Density 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 CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
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. On the Home page, run Clear Wells from the Cell Density module status 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/deproteinize the CDV Well through Flowpath Service. For intructions on how to perform this step, see **Section 5.3.6**.
6. Run a Clean Cell Density Flowcell from the Maintenance screen.
7. Contact Nova Biomedical Technical Support.

CDV Well Flow Time

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

Recommended Solutions:

1. Verify the percent remaining in the CDV Reagent 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 Cell Density 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 Depro Wells from the Maintenance screen.
4. Run a Clean Cell Density Flowcell from the Maintenance screen.
5. Run an Intensive Clean Cell Density Flowcell from the Maintenance screen.
6. Contact Nova Biomedical Technical Support.

Cell Density No Sample

During the last analysis, the cell density sample volume was not sufficient.

Recommended Solutions:

1. Repeat the analysis.
2. Verify the percent remaining in the CDV Reagent Cartridge Set. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the set.
3. 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.

E

ESM Air Detector Calibration Failed

During the last ESM analysis or maintenance procedure the ESM top-plate air detector failed to calibrate properly.

Recommended Solutions:

1. Verify the percent remaining in the ESM Reagent Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge, septum and pinch valve tubing.
2. Verify the ESM septum and pinch tubing are properly seated and Prime the ESM.
3. Run an ESM Initialize sequence through the ESM status bar.
4. Contact Nova Biomedical Technical Support.

ESM Line Not Primed

The ESM is not primed properly.

Recommended Solutions:

1. Run a Prime sequence through the ESM status bar.
2. Verify the percent remaining in the ESM Reagent Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge, septum and pinch valve tubing.
3. Verify the ESM septum and pinch tubing are properly seated.
4. Run an ESM Depro through the Maintenance menu and run a Prime sequence through the ESM status bar.
5. Contact Nova Biomedical Technical Support.

ESM No Sample Detected

During the last analysis sequence the ESM air detector did not detect the presence of a sample when expected.

Recommended Solutions:

1. Confirm delivery of the ambr sample to the ESM cup.
2. Run an Initialize sequence through the ESM status bar.
3. Verify the percent remaining in the ESM Reagent Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge, septum and pinch valve tubing.
4. Contact Nova Biomedical Technical Support.

ESM Issue

During the last ESM analysis or maintenance procedure the ESM was unable to complete the sequence.

Recommended Solutions:

1. Run an Initialize sequence through the ESM status bar.
2. Verify the percent remaining in the ESM Reagent Cartridge. If there is less than 10% remaining or a cartridge is within 1 day of expiration, replace the cartridge, septum and pinch valve tubing.
3. 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

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.

NH_4^+ Analytical Range High

During the last analysis, the measured result exceeded the upper limit of the NH_4^+ 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.

NH_4^+ Analytical Range Low

During the last analysis, the measured result exceeded the lower limit of the NH_4^+ 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.

NH_4^+ Dependency

During the last analysis or calibration, a successful NH_4^+ sensor reading could not be obtained. Without a successful Na^+ and/or K^+ measurement, the NH_4^+ 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.

NH_4^+ Drift

During the last analysis sequence, the 1-point calibration reading of the NH_4^+ 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 NH_4^+ 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.

NH_4^+ Instability

During the last calibration or analysis sequence, the NH_4^+ 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.

NH_4^+ No Reading

During the last analysis or calibration, a successful NH_4^+ 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.

NH_4^+ Not Calibrated

During the last analysis, the NH_4^+ 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.

NH_4^+ Overload

During the last calibration or analysis sequence, the NH_4^+ 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.

NH_4^+ Slope

The measured difference between the NH_4^+ 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 NH_4^+ 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.

O

Osmometer No Plateau

During the last calibration or analysis, the Osmometer was unable to detect a freeze plateau and failed to report a result.

Recommended Solutions:

1. Retest sample or run the Clintrol™ 290 Reference Solution to see if result is as expected.
2. For the Osmo 20 only, clean the Osmometer probe tip with a lint-free applicator.
3. Contact Nova Biomedical Technical Support.

Osmometer Recalibration Needed

This message indicates the Osmometer needs to be recalibrated as a result of loss of calibration data in the instrument.

Recommended Solutions:

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

Osmometer Sample Error

During the last analysis or calibration, the Osmometer sample result was outside of the analytical range.

Recommended Solutions:

1. Repeat the analysis.
2. Calibrate the Osmometer module.
3. Analyze external or on-board QC material and confirm the results are within the specified insert range.
4. Contact Nova Biomedical Technical Support.

Osmometer Sample Pre-Freeze

During the last analysis or calibration, the Osmometer sample froze before reaching the seed temperature threshold.

Recommended Solutions:

1. Repeat the analysis.
2. Replace the osmometer tubes with new tubes.

3. For the Osmo 20 only, clean the Osmo well using a swab moistened with 70% IPA or reagent alcohol. Ensure the well is dry before initiating another analysis.
4. Ensure there is no equipment that would cause vibration on the same bench as the FLEX2.
5. Contact Nova Biomedical Technical Support.

Osmometer Sample Probe Open/Block Probe Open

Indicates that the Osmo sample probe resistance measurement greatly exceeds the coldest possible temperature for the unit.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

Osmometer Sample Did Not Freeze

During the last analysis or calibration, the Osmometer sample did not freeze when it was supposed to.

Recommended Solutions:

1. Repeat the analysis.
2. Replace the osmometer tubes with new tubes.
3. For the Osmo 20 only, clean the Osmo well using a swab moistened with 70% IPA or reagent alcohol. Ensure the well is dry before initiating another analysis.
4. Contact Nova Biomedical Technical Support.

Osmometer Standards Reversed

During the last calibration, the instrument detected that the low and high calibration standards were introduced in the wrong sequence.

Recommended Solutions:

1. Retry the calibration; being sure to follow the displayed prompts and presenting the correct standard at the appropriate time.
2. Contact Nova Biomedical Technical Support.

Osmometer Test Time Out

During the last analysis, the instrument was unable to complete the test within the allotted time. This is indicated with 8 audible solenoid hits and then 3 beeps.

Recommended Solutions:

1. Confirm that the sample is within the test range of instrument.
2. For the Osmo 20 only, clean the Osmometer sample probe and cooling well with a lint-free applicator and run the Clintrol™ 290 Reference Solution.
3. Contact Nova Biomedical Technical Support.

Osmometer Tube Not Present

During the last analysis or calibration, there were not enough Osmometer tubes present.

Recommended Solutions:

1. Replace the Osmometer tubes by running a Change Tubes or Change Tubes and Wiper Ring sequence.
2. Contact Nova Biomedical Technical Support.

Osmometer Results not Repeatable (too scattered)

Poor repeatability is usually the result of poor sample delivery.

Recommended Solutions:

1. For the Osmo 20 only, check the Osmometer wiper ring to make sure that the probe is properly piercing it and that there are not multiple wiper rings installed.
2. Recalibrate the Osmometer.
3. Contact Nova Biomedical Technical Support.

Osmometer Motor Errors

Osmometer motors may be stuck or hanging up due to dirt, dust, or debris build-up on the worm gears or assembly rails.

Recommended Solutions:

1. Contact Nova Biomedical Technical Support.

P

pCO_2 Analytical Range High

During the last analysis, the measured result exceeded the high limit of the pCO_2 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.

pCO_2 Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the pCO_2 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.

pCO_2 Dependency

During the calibration or analysis, a successful reading from the pCO_2 sensor could not be obtained. Without a successful pH calibration or measurement, the pCO_2 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.

pCO_2 Drift

During the last analysis sequence, the 1-point calibration reading of the pCO_2 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 pCO_2 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.

pCO_2 Instability

During the last calibration or analysis sequence, the pCO_2 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.

pCO_2 No Reading

During the last analysis or calibration, a successful pCO_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.

pCO_2 Not Calibrated

During the last analysis, the pCO_2 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.

pCO_2 Overload

During the last calibration or analysis sequence, the pCO_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.

pCO_2 Slope

The measurement difference between the pCO_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 PCO_2 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.

pO_2 Analytical Range High

During the last analysis, the measured result exceeded the high limit of the pO_2 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.

pO_2 Analytical Range Low

During the last analysis, the measured result exceeded the low limit of the pO_2 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.

pO_2 Drift

During the last analysis sequence, the 1-point calibration reading of the pO_2 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 pO_2 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.

pO_2 Instability

During the last calibration or analysis sequence, the pO_2 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

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.

T

Thickness Out Of Range, Original Thickness Will Persist

The programmed thickness of the CDV cuvette exceeded specifications. Thickness will default to previous setting.

Recommended Solutions:

1. Verify the data entry in the open fields.
2. 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.

5.3 Troubleshooting Steps for Flowpath Service

Note: *Access to the Service menu requires an Administrator privilege level.*

5.3.1 Waste Well Blocked

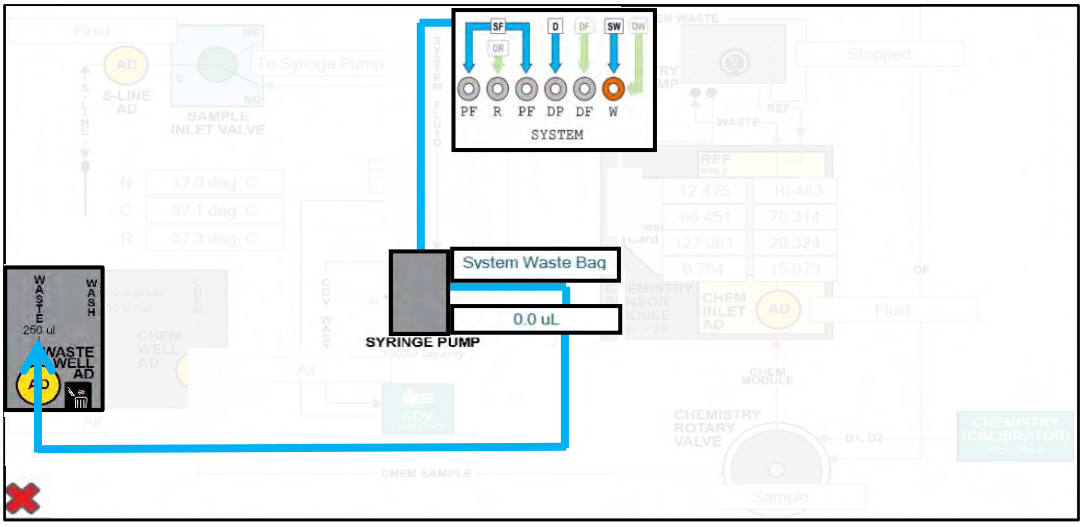
A well blockage will inhibit analysis of the respective module and will also disable the Depro Wells function. If the Waste Well is still blocked after performing the steps in **Section 5.2**, Flowpath Service provides a convenient way to manually flush/deproteinize the wells.

To clear a Waste Well blockage through Flowpath Service:

1. Select **Service**.
2. Select **Customer Service**.

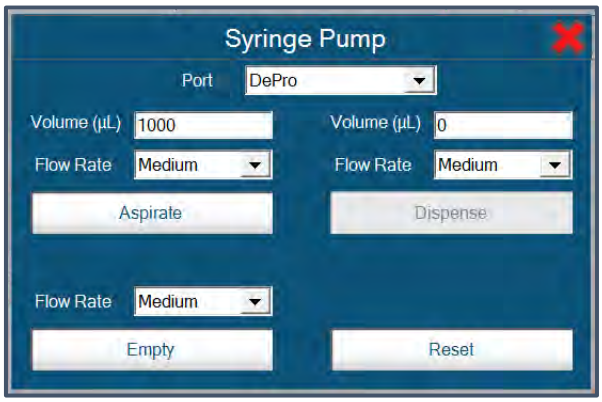
Note: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

3. Select **Flowpath Service**.
4. Select either the **CDV Module**, the **Gas Sensor Module**, or the **Chemistry Sensor Module**.



5.1 *Chemistry Sensor Module Flowpath*

5. Select the **Syringe Pump Information box** from an applicable model overlay to open the Syringe Pump menu. This is the text box to the side of the Syringe Pump above the volume information box.



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:

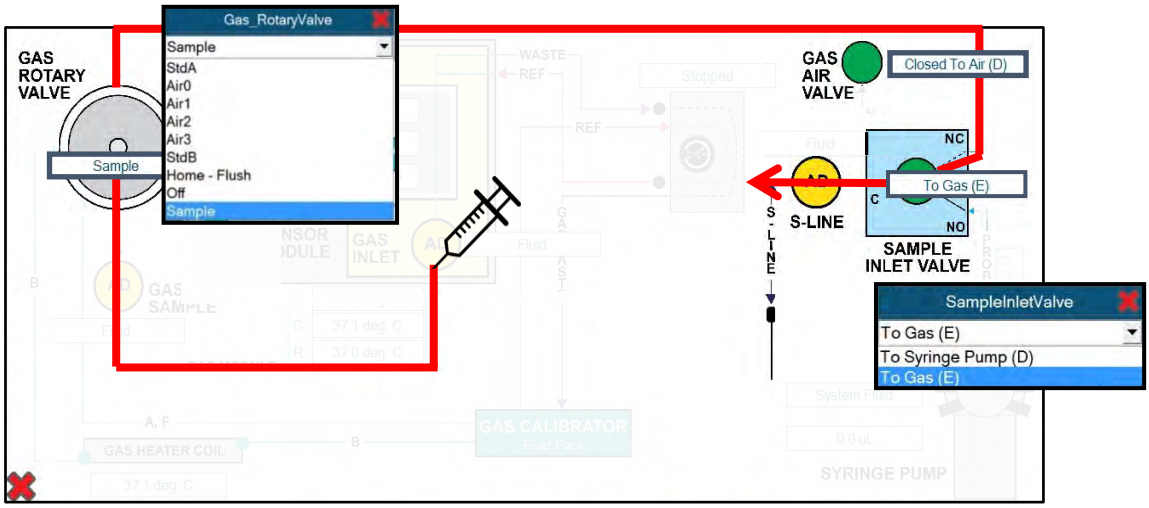
1. Kimwipes®
2. Blunt needle tip syringe
3. Deionized water

To flush the Sample Inlet Manifold through the Sample Inlet Valve:

1. Select **Service**.
2. Select **Customer Service**.

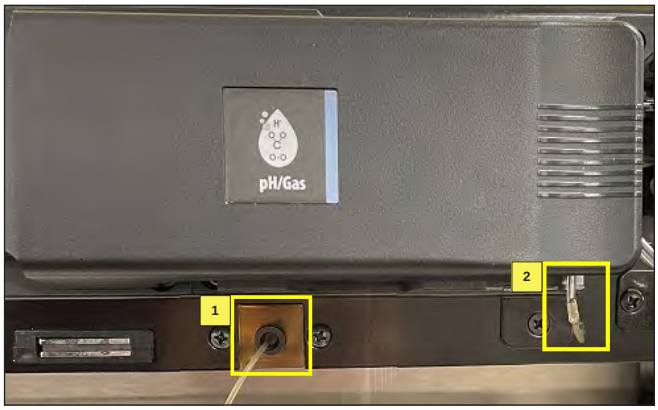
Note: *If you do not see a Customer Service option and are prompted to enter a password, contact Technical Support for further assistance. You will need a daily coded password to continue.*

3. Select **Flowpath Service**.
4. Select the **Gas Sensor Module** in *Flowpath Service*.



5.3 *Sample Inlet Valve and Gas Rotary Valve Menus*

5. On the *Sample Inlet Valve*, select **To Gas (E)** (Figure 5.3).
6. On the *Gas Rotary Valve*, select **Sample** (Figure 5.3).
7. On the *Gas Air Valve*, select **Closed to Air (D)** (Figure 5.3).
8. Open the door of the FLEX2 and unscrew the S-Line Tubing from the Sample Inlet Valve (Figure 5.4).
9. Place a Kimwipe® at the Sample Inlet Manifold where the S-Line Tubing was unscrewed from.
10. 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)*

11. Fill a blunt needle tip flushing syringe with 5 mL of DI water.
12. Connect the flushing syringe to the pH/Gas Sample Inlet Tubing (do *not* connect to the Reference Sensor).
13. Flush the pH/Gas Sample Inlet Tubing and check for flow at the Sample Inlet Manifold.

14. Repeat steps 11-13 to help clear any obstruction.
15. Fill a blunt needle tip flushing syringe filled with 5mL of air.
16. Connect the flushing syringe to the pH/Gas Sample Inlet Tubing (do *not* connect to the Reference Sensor).
17. Flush the pH/Gas Sample Inlet Tubing with air.
18. Reconnect the S-Line Tubing to the Sample Inlet Valve and repeat *Steps 11-17* to flush the S-Line Probe Tubing.
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 on the **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.*

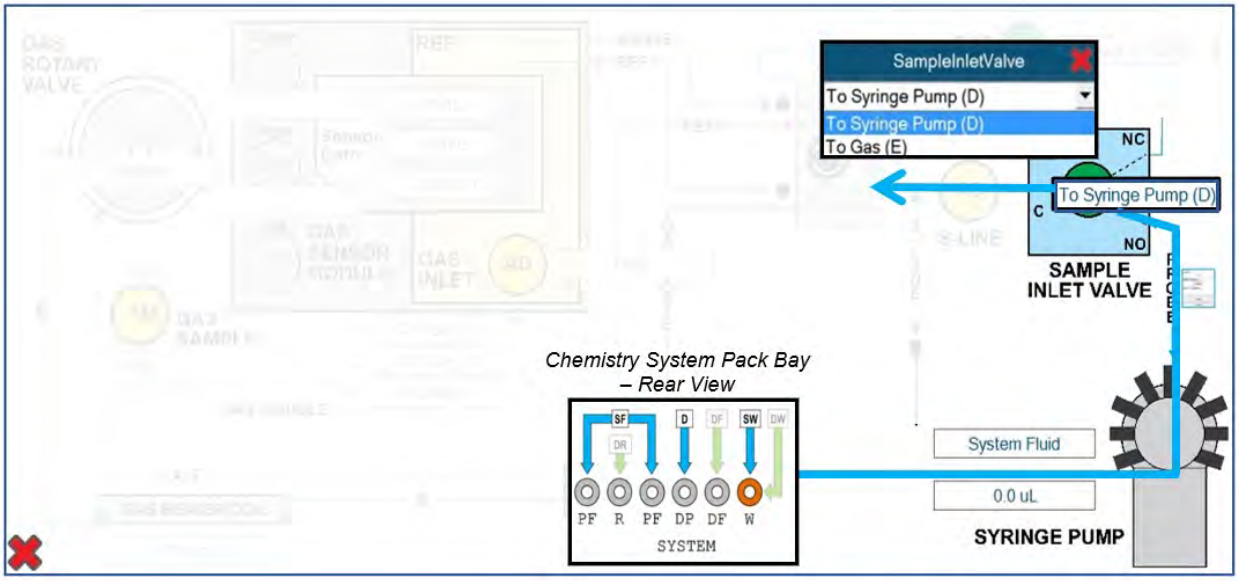
23. Run QC to confirm if the sample is properly acquired.

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:

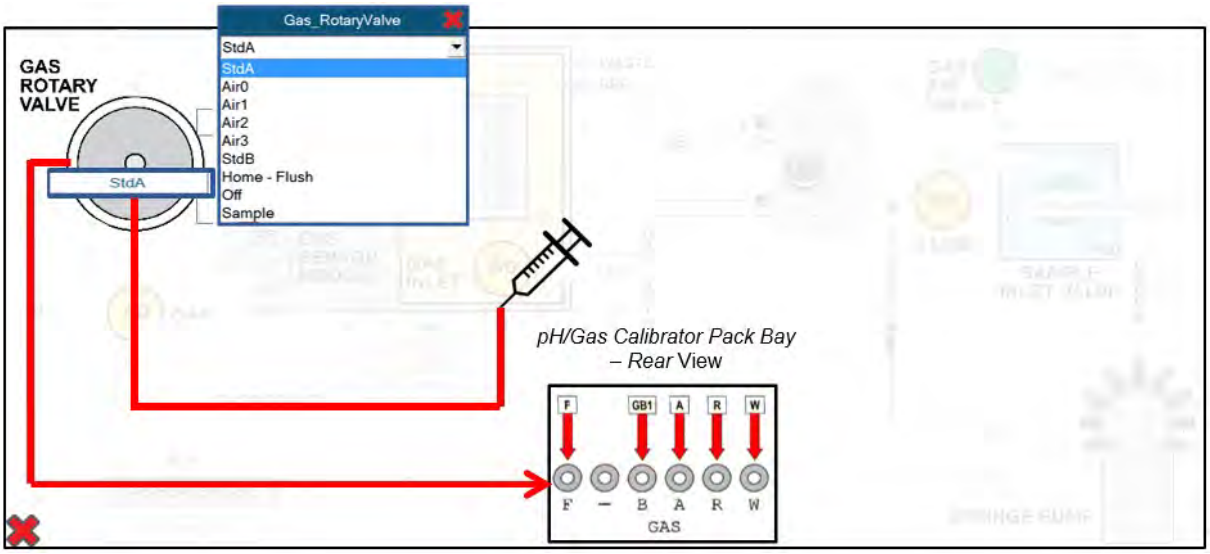
1. Kimwipes®
2. Blunt needle tip syringe
3. Deionized water

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.
11. Disconnect the flushing syringe from the pH/Gas Sample Inlet Tubing and reconect 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 **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.*

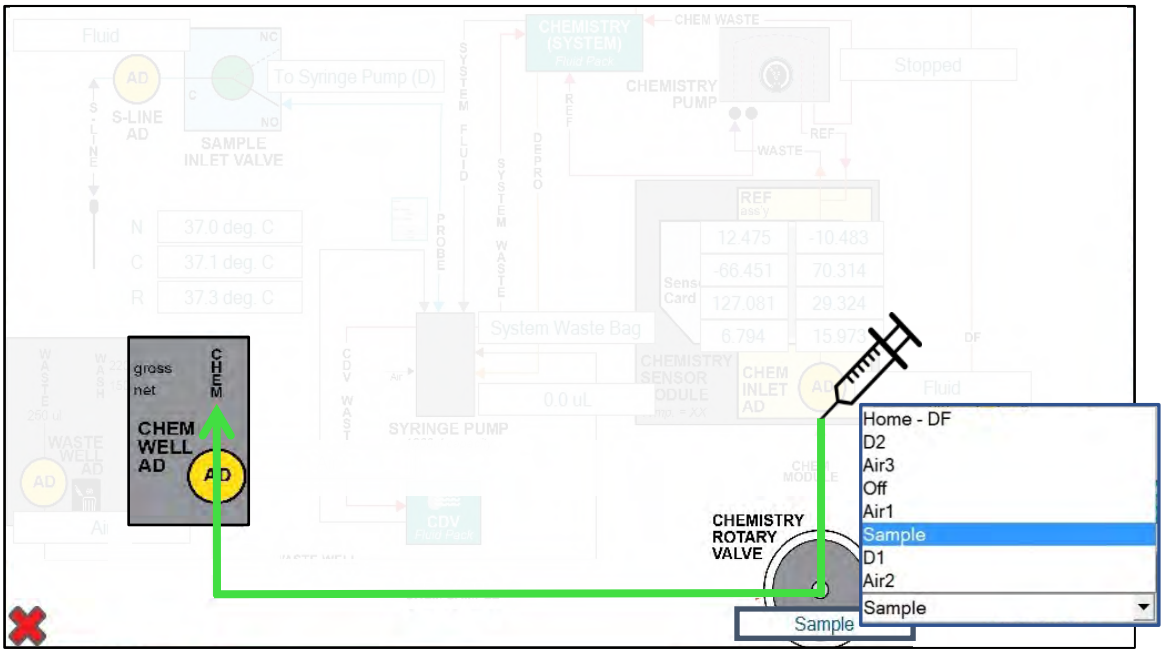
4. Deionized water or Depro solution

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:* ***500µL***

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. Pipet 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 on the **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.*

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:

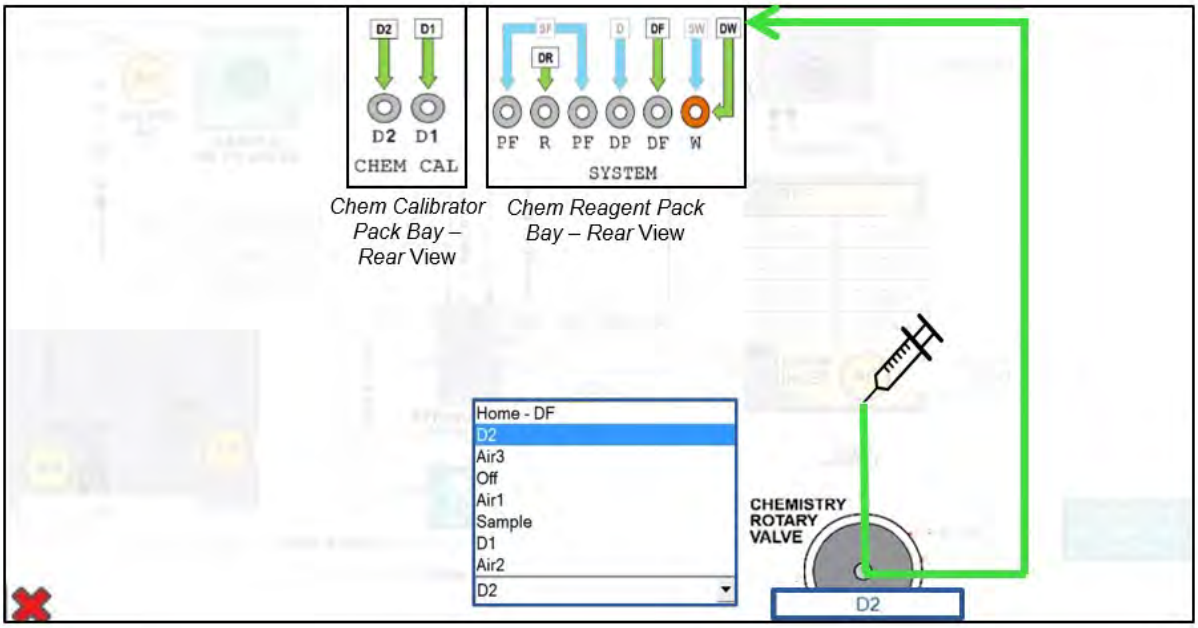
1. Kimwipes®
2. Blunt needle tip syringe
3. Deionized water

To flush Internal Chemistry Reagent Tubing:

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. Open the door of the FLEX2 and remove the Chemistry Calibrator Cartridge and the Chemistry Reagent Cartridge.
6. 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*

7. Disconnect the Sample Inlet Tubing from the port on the bottom right of the Chemistry Reference Sensor (Figure 5.8).
8. 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.
9. Flush the Chemistry Sample Inlet Tubing. Check for a steady flow from the needle shroud in the back of the pack bay.
10. 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.
11. Disconnect the flushing syringe and reconnect the Chemistry Inlet Tubing to the bottom right of the Chemistry Reference Sensor.
12. Clean up the fluid flushed into the Chemistry pack bays.
13. Re-install the Chemistry Reagent Cartridge and Chemistry Calibrator Cartridge in the analyzer.
14. Exit *Flowpath Service* and navigate back to the **Home** screen.
15. Select on **Chemistry Parameter** on the *Home* screen.
16. 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.*

17. Select **Calibrate** on the *Chemistry module*.

5.3.6 CDV Well Blocked

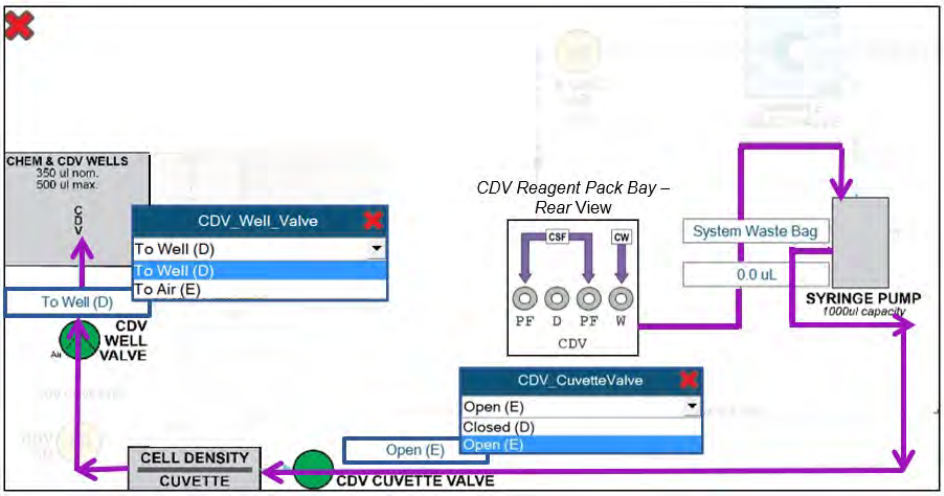
When presented with a CDV Well blocked error or if the CDV will not prime, the flowpath may need to be flushed to ensure there are no obstructions. If the error persists after the steps in **Section 5.2**, there may be a blockage in the flowpath that will need to be flushed through Flowpath Service.

To flush the CDV Flowpath to the CDV 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 **CDV module** on the bottom left corner of Flowpath Service.



5.10 *Cell Density Module Flowpath*

5. Select the information box above the *CDV Cuvette Valve* and set this to **Open** (Figure 5.10).
6. Select on the information box above the *CDV Well Valve* and select **To Well (D)** (Figure 5.10).
7. Select the **Syringe Pump information box** from an applicable module overlay to open the *Syringe Pump* menu (see Figure 5.2). This is the text box to the side of the syringe pump above the volume information box.
8. 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 500µL.
   c. Select **Aspirate** on the left-hand side.
   d. Select **CDV Cuvette** from the *Port* drop-down menu.
   e. Select **Dispense** on the right-hand side.
   f. With the *Port* menu still set to **CDV Cuvette**, repeat steps 8b-8e multiple times to help clear any obstructions.
   g. After selecting **Dispense** during the last repetiton of steps 8b-8e, enter a volume of 500µL on the left-hand side.
   h. Select **Aspirate** on the left-hand side.
   i. Select **System Waste Bag** from the *Port* drop-down menu.
   j. Select **Dispense** on the right-hand side.
9. Exit *Flowpath Service* and navigate back to the **Home** screen.
10. 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 be available.*

11. Select **Depro Wells**.

A INSTRUMENT SPECIFICATIONS

This section includes instrument specifications for the Nova BioProfile FLEX2.

A.1 INSTRUMENT SPECIFICATIONS

Measurement Range:

Parameter	Units	Alt. Units	Low End	High End	Dilution Ratio
Glutamine	mmol/L	g/L	0.10 0.20 0.40	6.00 12.00 24.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Glutamate	mmol/L	g/L	0.10 0.20 0.40	6.00 12.00 24.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Glucose	g/L	mmol/L	0.10 0.20 0.40	15.00 30.00 60.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Lactate	g/L	mmol/L	0.10 0.20 0.40	6.00 12.00 24.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Ammonium	mmol/L	g/L	0.20 0.40 0.80	25.00 50.00 100.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Sodium	mmol/L	N/A	40.0 80.0 160.0	300.0 600.0 1200.0	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Potassium	mmol/L	N/A	1.00 2.00 4.00	100.00 200.00 400.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
Calcium	mmol/L	N/A	0.10 0.20 0.40	10.00 20.00 40.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:4
pH	N/A	N/A	5.000	8.000	N/A
pO_2	mmHg	kPa	3.0	500.0	N/A
pCO_2	mmHg	kPa	3.0	300.0	N/A
Total and Viable Cell Density*	$1x10^5$ cells/mL	$1x10^6$ cells/mL	0.10 0.20 0.60	35.00 80.00 160.00	Dil. Ratio = 1:1 Dil. Ratio = 1:2 Dil. Ratio = 1:6
Viability	%	N/A	0	100	N/A
Live Cell Diameter	microns	N/A	4	70	N/A
Osm20	mOsm/kg H_2O	N/A	0	1500	N/A
Osm48	mOsm/kg H_2O	N/A	0	2000	N/A

**Default CDV analytical ranges are $1x10^5$ vc/mL. Low-End and High-End limits in this table are provided in $1x10^6$ vc/mL alternate units.*

Analysis Rate:

Test Panel	Manual Analysis Time	Carousel/Tray Analysis Time
Chemistry	110 seconds	110 seconds
Gas	110 seconds	110 seconds
Chem and Gas	110 seconds	110 seconds
CDV	220 seconds	250 seconds
CDV (Enhanced Cleaning)	245 seconds	275 seconds
Gas and CDV	235 seconds	265 seconds
Gas and CDV (Enhanced Cleaning)	260 seconds	290 seconds
Chem and CDV	235 seconds	265 seconds
Chem and CDV (Enhanced Cleaning)	260 seconds	290 seconds
All Modules	275 seconds	305 seconds
All Modules (CDV Enhanced Cleaning)	300 seconds	330 seconds

Sample Volume:

Test Panel	Volume	with Osm20	with Osm48
Chemistry	135 µL	135 µL	145 µL
Gas	265 µL	265 µL	275 µL
Chem and Gas	265 µL	265 µL	275 µL
CDV (Dilution Ratio 1:1)	220 µL	220 µL	230 µL
CDV (Dilution Ratio 1:2 or 1:6)	135 µL	135 µL	145 µL
Gas and CDV (Dilution Ratio 1:1)	350 µL	350 µL	360 µL
Gas and CDV (Dilution Ratio 1:2 or 1:6)	265 µL	265 µL	275 µL
Chem, CDV, and Osmo (Dilution Ratio 1:1)	N/A	220 µL	230 µL
Chem, CDV, and Osmo (Dilution Ratio 1:2 or 1:6)	N/A	135 µL	145 µL
All Modules (CDV Dilution Ratio 1:1)	350 µL	350 µL	360 µL
All Modules (CDV Dilution Ratio 1:2 or 1:6)	265 µL	265 µL	275 µL
Carousel (Any module configuration)	400 µL	400 µL	400 µL
96-well plate (Any module configuration)	400 µL	400 µL	400 µL

Reagents: Multiple Calibrator and Reagent Cartridges

Analytical Specifications:

Parameter	Units	Within Run CV%	Within Run SD	Day-To-Day CV%	Day-To-Day SD
pH	-	-	0.007	-	0.018
pO_2	mmHg	5.0	3.0	7.0	4.2
pCO_2	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
NH_4^+	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

NOTE: *Imprecision specifications are determined with a minimum n=10 samples.*

Osmolality Module (OSM20/OSM48) Specifications:

Measurement	Precision Specification
0 - 400 mOsm/kg H2O	+/- 3 mOsm/kg H2O (equivalent to 1 Standard Deviation)
400 – 2,000 mOsm/kg H2O	+/- 0.75% (equivalent to 1 Standard Deviation)
Calculation	With respect to the mean of 5 or more valid test results

Parameter Offset and Multiplier Specifications:

Parameter	Offset Multiplier		Offset Intercept (default units)		Offset Intercept (alternative units)	
	Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
pH	0.5	1.5	-2.0	2.0		
pO_2	0.3	1.7	-50.0	50.0	-6.7	6.7
pCO_2	0.3	1.7	-30.0	30.0	-4.0	4.0
Gln	0.3	1.7	-1.0	1.0	-0.15	0.15
Glu	0.3	1.7	-3.0	3.0	-0.44	0.44
Gluc	0.3	1.7	-6.0	6.0	-33.3	33.3
Lac	0.3	1.7	-1.2	1.2	-13.32	13.32
NH_4^+	0.3	1.7	-5.0	5.0	-0.093	0.093
Na^+	0.3	1.7	-30.0	30.0		
K^+	0.3	1.7	-1.0	1.0		
Ca^{++}	0.3	1.7	-1.0	1.0		
Density	0.5	2.0				
Osmo	0.95	1.05	-5.0	5.0		

Electrical Requirements:		
Operating Voltage Range	90-264	VAC
Operating Frequency	47-63	Hz

Electrical Compliance: Conforms to 73/23/EEC, Low Voltage Directive, 89/336/EEC, EMC Directive, EN61010-1-2001, EN 61010-2-081:2002, Measurement, Control, and Laboratory Equipment

Power Consumption:		
Without Osmometer Option	480	Watts
With Osmometer Option	590	Watts
Fuses (2)	SB 8A or T8A/250V	

Temperature Thermostatting: 37ºC ± 0.1ºC

Ambient Operating Temperature: 15°C to 30°C (59°F - 86°F)

Operate at Humidity: 20 – 85% without condensation

Dimensions:

Measurement	Without Osmometer	With Osmometer
Height	23.5 in (59.69 cm)	23.5 in (59.69 cm)
Width	16.75 in (42.55 cm)	24.75 in (62.86 cm)
Depth	25.0 in (63.50 cm)	25.0 in (63.50 cm)
Weight*	less than 125 lb (56.7 kg)	less than 145 lb (65.8 kg)

*With reagents installed

A.2 BioProfile FLEX2 Spare Parts & Supplies List

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 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 CDV Reagent Cartridges 55297

Cell Density Module Consumable

Cell Density Module Calibration Solution (30 ampules/box) 43034
Cell Density Viability Advanced Cleaning Solution 63940

Internal QC

BioProfile FLEX2 pH/Gas Auto QC Cartridge 56073
BioProfile FLEX2 Chemistry Auto QC Cartridge 57035

External QC

BioProfile Control Level 1 (30 ampules/box) 22600
BioProfile Control Level 2 (30 ampules/box) 22601
BioProfile Control Level 3 (30 ampules/box) 22602
BioProfile Control Level 4 (30 ampules/box– Contains Gln,Glu,Gluc, Lac) 24617
BioProfile Control Level 5 (30 ampules/box– Contains Gln,Glu,Gluc,Lac) 24619
BioProfile Control Level 8 (30 ampules/box– Contains Cell Density Control) 43472
BioProfile Control Level 9 (30 ampules/box– Contains Cell Density Control) 43473

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

Osmometer Module Consumables

Osm20

Tube Micro Sample Osmometer 500/box 42435
Wiper Rings 50/Package 42436
50 mOsm/Kg Calibration Standard 10/Box 42437
850 mOsm/Kg Calibration Standard 10/Box 42438

Osm48

Micro Tubes 59859
Calibration Standards (Includes 100 mOsm/Kg and 900 mOsm/Kg ampules) 59856

Osm20 & Osm48

290 mOsm/Kg Reference Standard 10/Box 42439
Cleaner Kit, PKG/50 Swabs 43717

Accessories

BioProfile FLEX/FLEX2 Flush Fixture 6 Port 58355
BioProfile FLEX/FLEX2 Flush Fixture 4 Port 59121
BioProfile FLEX2 Flush Fixture 2 Port 57530
FLEX2 pH/Gas Shutdown Cartridge 60608
FLEX2 Chemistry Module Shutdown Cartridge 60610
FLEX2 CDV Module Shutdown Cartridge 60611
FLEX2 pH/Gas Auto QC Shutdown Cartridge 60613
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 instal) 59942
BioProfile FLEX2 Instructions for Use Manual 57960
Deproteinizing Solution 12704

ESM

ESM Reagent Cartridge 56227
ESM Syringe Replacement 60018
ESM Tubing Line Replacement 59209
Pre-Pierced Septum (for ESM, Gas QC, and EOLS) 59228
ESM Swivel Adapter Kit 61326
ESM Sample Cup (ambr™15/250) 59975
ESM Sample Cup (ambr™15+Analysis Module) 60094
FLEX2 ESM Shutdown Cartridge 60612

On-Line Autosampler (OLS) Consumables

Reagent Cartridges

FLEX2 Online Autosampler Fluid Cartridge (2/pack) 62450
FLEX2 STM Waste Bottle Pack w/ Septa (4/pack) 46400

Tube Sets

FLEX2 20 Ft Autosampler Line Set 61376
FLEX2 Autosampler RSM Air Detector Assembly 62849
FLEX2 Autosampler STM Replacement Tubing Harness 61372
FLEX2 Autosampler STM Waste Tubing Harness 61371
FLEX2 Reactor Line Assembly - 24 inch 1/4-28 fitting 61370
External Waste Line Kit (for remote waste) 62878
Reactor Line Adapter 63274
External RSM Cleaning Line Assembly PN 62877

Bioreactor Connection Options

10mm Head Plate, 7 inch Dip Tube Assembly 47456
10mm Head Plate, 9 inch Dip Tube Assembly 50251
10mm Head Plate, 15 inch Dip Tube Assembly 47457
7 inch 10 mm Barbed Dip Tube Assy 55505
9 inch 10 mm Barbed Dip Tube Assy 55506
5.63 inch 10 mm Barbed Dip Tube Assy 55885
15 inch 10 mm Barbed Dip Tube Assy 55881
8.88 inch 12 mm Barbed Dip Tube Assy 55887
7.75 inch 12 mm Barbed Dip Tube Assy 55882

Accessories

FLEX2 Autosampler Communications Cable - 10ft 62563
FLEX2 Autosampler Tightening Tool 62590
FLEX2 RSM Replacement Syringe 46915

B THEORY

This section explains instrument theory of the BioProfile FLEX2 Analyzer.

B.1 pH/Gas and Chemistry Sensor Calibration

B.2 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.3 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.4 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+, NH4+, iCa, Gluc, Lac, Gln, and Glu) on the Chemistry MicroSensor Card.

B.5 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.6 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.7 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.8 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.9 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.10 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.11 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.12 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.12.1 TEMPERATURE CORRECTION FOR MEASURED VALUES

The BioProfile FLEX2 Analyzer allows you to enter the sample temperature when this differs from 37 °C. The pH, pCO_2, and pO_2 sample values, at the sample's actual temperature, are then calculated as follows:

Equation 1

$$pH_{(corrected)} = pH + [- 0.0147 + 0.0065 (7.400 - pH)](T - 37)$$

Equation 2

$$pCO_2(corrected) + pCO_2 \times e\,(0.04375(T - 37))$$

Equation 3

$$pO_{2(corrected)} = pO_2 \times 10^{U}$$

where:

$$U = \left(\left[\frac{(5.49\times10^{-11})\,Y + 0.071}{(9.72\times10^{-9})\,Y + 2.30}\right] \times (T - 37)\right) \text{ and } Y = e[3.88 \times \ln(pO_2)]$$

B.12.2 CALCULATED PARAMETERS

B.12.2.1 O_2 SATURATION %

Equation 4

$$O_2 \text{ Saturation \%} = \frac{pO_2 \text{ mmHg}}{(\text{BP* mmHg} - 47) \times 0.209} \times 100\%$$

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 $p0_2$ 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 O_2%.

B.12.2.2 CO_2 Saturation %

Equation 5

$$CO_2 \text{ Saturation \%} = \frac{pCO_2 \text{ mmHg}}{(\text{BP* mmHg} - 47)} \times 100\%$$

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 pCO_2 value

BP adds additional vessel pressure value entered to the barometric pressure reading taken at the time of sampling*

B.12.2.3 Calculated Bicarbonate Concentration [HCO_3-]

Bicarbonate Concentration (mmol/L) is calculated using the Henderson-Hasselbalch equation:

Equation 6

$$pH = pK + \log \frac{[HCO_3^-]}{\alpha(pCO_2)}$$

where pH and pCO_2 are measured.

$pK = 6.091$

$\alpha = 0.0307$ = solubility coefficient of CO_2 in water at 37 °C

Rearranging Equation 6 gives:

Equation 7

$$\text{Log}_{10}[HCO_3^-] = pH + \log_{10} pCO_2 - 7.604$$

B.13 Cell Density

The BioProfile FLEX2 measures cell density and cell viability using the Trypan Blue Dye Exclusion method. Live cells with intact cell membranes are selective in the compounds that can pass through the membrane. In a viable cell, Trypan Blue is not absorbed, and the cells appear unstained. However, it traverses the membrane in a dead cell, and the cells stain a distinctive blue color.

This analyzer automates the Trypan Blue Dye Exclusion method and acquires digital images at 10x optical magnification. The cells are counted, measured, and categorized as live or dead, using sophisticated image processing software.

B.14 WARRANTY

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

1. The 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 Cartridges, 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.