BIOPROFILE®

pHOx®

Reference Manual

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Nova BioProfile® pHOx® Reference Manual

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Table of Contents

Table of Contents

1 Introduction

This manual provides all necessary instructions for the routine operation and maintenance of the BioProfile pHOx Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your BioProfile pHOx Analyzer.

WARNING: *Cell culture samples are a potential source of infectious agents. Handle all sample and flowpath components (waste-line, probe, flow cell, etc.) with care. Gloves and protective clothing are recommended.*

NOTE: *This International Caution Label appears on the rear of the pHOx Analyzer and means refer to the manual.*

This section introduces the BioProfile pHOx Analyzer and covers requirements, tests performed, procedural limitations, and sample handling.

1.1 Installation

This section covers the installation requirements and assembly procedures for the BioProfile pHOx Analyzer.

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

1.1.1 Requirements

Working Area Requirements:

Keep the working area around the system free of dirt, corrosive fumes, vibration, and excessive temperature changes. Ambient operating temperature is 15 °C to 30 °C (59°F to 86 °F). Operate at humidity of 0 to 85% without condensation.

Electrical Requirements:

A grounded, 3-wire receptacle within 5 feet of the system is required for operation. The U.S. models require a 120 Volt AC line at 50/60 Hz frequency. The analyzer can be operated at 100 - 120; 220 - 240 Volt AC 50/60 Hz.

Fuse requirements:

- 2 Amp Time Delay (SB 2A or T2A) at 100 - 120 Volt AC line.
- 1 Amp Time Delay (T1A) at 220 - 240 Volt AC line.

1.2 Intended Use and Tests Performed

Intended Use

The BioProfile pHOx Analyzer is intended for the quantitative determination of pH, PCO_2, PO_2.

Measured Parameters

pH, PCO_2, PO_2, and barometric pressure

Calculated Parameters

From the directly measured results, the calculated results are

- Bicarbonate level (HCO_3^-)
- Total Carbon Dioxide (TCO_2)
- Air Saturation
- CO_2 Saturation
- pH, PCO_2, PO_2 (corrected to Sample temperature)

1.3 The Sample

Samples from syringes, open tubes, small cups, and pipette tubes can be used on the BioProfile pHOx Analyzer. The sample size is 300 µL.

1.3.1 Handling Requirements

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

1.4 About This Reference Manual

This manual is for BioProfile pHOx Analyzer.

Throughout this manual, *NOTE:* indicates especially important information, ***CAUTION:*** indicates information that is critical to avoid instrument damage or incorrect results, and ***WARNING:*** indicates possible hazard to the operator.

2 Setup

This section describes how to setup the BioProfile pHOx Analyzer.

2.1 Installing the BioProfile pHOx

The analyzer is initially installed by a factory authorized representative.

> ***CAUTION:*** *The pHOx analyzer is designed to be left on with adequate fluids at all times. This is necessary to prevent crystallization of salts in the fluid lines. If it is to be shut down indefinitely, purge all fluid lines with distilled water and then with air. The purge sequence is selected from the Operational Menu.*

2.2 Power Up Procedure

The analyzer checks for error conditions each time it is turned on using an internal Power On Self Test (POST). During this time the analyzer displays the BioProfile pHOx Analyzer logo screen.
After POST completes, the Not Ready screen will be displayed showing the analyzer as warming up, then calibrate. Once the warm-up period has completed, the analyzer must first be calibrated before samples can be analyzed.

2.3 Using the Touch-Screen Display

Touch-Screen The touch-screen display provides prompts, menus, status information, error messages, results, etc. The top line gives the screen's name (e.g., Setup Menu) and in some screens the date and the time. The second line displays directions for the screen or additional information about the displayed data. The middle of the screen is for the menu items where you can select detailed direction for procedures, information, or electrode status.

Status Symbols There are a number of symbols that can appear after the results. The symbols have the following meanings:
↑ **(single up arrow),** ↓ **(single down arrow)** - The result is higher or lower than the defined reference range for the parameter.
↑ ↑ **(double up arrow),** ↓ ↓ **(double down arrow)** - The result is higher or lower than the defined alert range for the parameter.
↑ ↑ ↑ **(triple up arrow),** ↓ ↓ ↓ **(triple down arrow)** - The result is out of the analyzer's operating range.
X (an X through an analyte prefix) - The parameter is uncalibrated.
? (question mark) - Insufficient sample is detected during sample reading.

2.4 Overview of the User Interface

The format that allows the operator to change displays, enter data, and perform functions is generally referred to as the User Interface (controlled by software).

Here are some general rules for the user interface:

- To perform any operation, use the screen instructions to guide you.
- To go back to the Ready screen or the menu for a selected section (e.g., QC, Setup, etc.), press Home.
- To move back to the previous display, press Previous Page, if applicable.
- Press Cancel to terminate the current operation or sequence or to return to the previous display.
- Press Exit to return to the previous display.
- Analyzing a sample and performing calculations take precedence over the user interface. Therefore, you are temporarily locked out of accessing displays that can interfere with an ongoing sequence or operation.
- A status message indicates an error condition.

2.5 Adapting the Program to Your Laboratory Requirements with the Setup Menu

Use the Setup Menu to adapt the analyzer to your requirements.

2.6 Setup Options

The Setup Menu has the following setup options:

- System Password
- Operator Passwords
  - Password
  - Operator ID
  - Privilege Level (1, 2, 3)
- Results Configuration Menu
  - Reference and Alert Limits Setup
  - Result Units Setup
  - Biosensor Offsets
  - Result Suppression
  - Display Temp. Corrected: ON or OFF
  - Remote Review: ON or OFF
- Operation Configuration Menu
  - Analysis Configuration
    - Analysis Transmit Mode: Manual/Auto
    - Transmit Diagnostic Data: OFF/ON
    - Print Diagnostic Data: OFF/ON
    - Analysis Print Mode: Manual/Auto
    - Print Ref. & Alert Ranges: OFF/ON
  - Calibration Configuration
    - Set 2 Point Calibration Frequency: 2, 4, 6 hr.
    - Transmit Diagnostic Data :OFF/ON
    - Print Diagnostic Data: OFF/ON
    - Transmit Drift Data: OFF/ON
    - Print Drift Data: OFF/ON
  - System Configuration
    - Date and Time Set
    - Adjust Barometer
    - Set Date Format: DD/MM/YY, MM/DD/YY, YY/MM/DD
    - Set Time Mode: 24/12 hr. Mode
    - Set Analyzer ID Number
    - Set Tone Frequency (100-5000Hz): 3500 Hz
    - Measured BP
    - Corrected BP
  - Analysis Mode: A or B
  - STAT Mode: ON or OFF
- Lab Computer
  - Baud Rate (4800, 9600, 19200, OFF)
  - Data Bits (7, 8)
  - Parity (None, Even, Odd)
  - Stop Bits (1,2)
- Operator Passwords: ON or OFF

2.6.1 System Password

The system password is used to restrict access to the analyzer's Setup Menu. The default System Password is 0.

1. To change the system password, first press System Password.
2. Then press Password.
3. On the pop-up numeric keypad enter a new system password up to 4 numbers in length.
4. Press Enter.
5. Press Exit to return to the Setup menu or Home to go to the Ready screen.

2.6.2 Operator Passwords

Operator passwords are used to restrict use of the analyzer to those operators that have been entered into the analyzer's memory. Operators are assigned one of 3 privilege levels that restrict access to protected areas of the analyzer's software. Operator Passwords must be set to On in the Setup Menu once one or more passwords have been entered. Operator Passwords can be disabled by changing the setting to Off.

Privilege Level 1 Operators have access to all areas of the software except those protected by the existing system password. Level 1 operators are not subject to Remote Review if the feature is enabled. Level 1 operators may also override QC lockout if enabled.

Privilege Level 2 Operators have access to all areas of the software except those protected by the existing system password. Level 2 operators do require Remote Review but may override the feature if enabled. Level 2 operators cannot override QC lockout if enabled.

Privilege Level 3 Operators are restricted from all areas of the software except those related to performing a sample analysis. Level 3 operators do require Remote Review and cannot override the feature if enabled. Level 3 operators cannot override QC lockout if enabled.

Adding Operator Passwords

1. From the Ready screen, press Menu to access the Operation Menu screen.
2. Press Setup to display the Setup Menu.
3. A pop-up will be displayed prompting for the System Password. Enter the System Password (the default is 0) and press Enter to continue.
4. Press Operator Passwords to display the Operator Passwords screen.
5. Press Password to display a numeric keypad. Then enter a unique operator password from 1 to 9999 and press Enter.
6. Press Operator ID to display a numeric keypad. Then enter a unique operator ID of up to 15 digits and press Enter.
7. Press Privilege Level and select the privilege level for this operator.
8. Press Add/Modify to save the password to memory.

Using Find Password, Add/Modify and Delete

The list of operator passwords can be searched and edited using the Find Password, Add/Modify and Delete buttons in the Add Password screen.

To change an Operator ID or Privilege Level:

1. Press Password and enter the password on the pop-up numeric keypad.
2. Press Find Operator to display the Operator ID and Privilege Level assigned to that password.
3. Press Add/Modify and re-enter the Password, Operator ID, and Privilege Level (refer to above) or press Delete to delete the Password and Operator ID from memory.
4. Press Exit when done to return to the Setup Menu or Home to return to the Ready screen.

2.6.3 Results Configuration Menu

The Results Configuration Menu screen allows you to set reference and alert limits (low and high) for all analytes, to select units for temperature, pH, and gases, to adjust biosensor offsets for slope and intercept for all analytes, to suppress results for all analytes, to turn on/off the display for temperature correction, and to turn on/off remote review.

2.6.3.1 Reference and Alert Limits

Reference and Alert Ranges can be used to identify sample results that fall outside normal ranges. Results lower than the defined Reference value are displayed with a single down arrow ↓, results higher than the defined Reference range are displayed with a single up arrow ↑. Results lower than the defined Alert range are displayed with a double down arrow ↓ ↓. Results higher than the defined Alert range are displayed with a double up arrow ↑ ↑.

When entering Reference and Alert limits the Alert range is expected to be wider than the Reference range. The low Alert value for an analyte must be lower than the low Reference value for that analyte. The High Alert value for an analyte must be higher than the High Reference value for that analyte. Reference and Alert values must fall within the analyzer's measurement range for that analyte.

To set up Reference and Alert ranges:

1. From the Results Configuration Menu press Reference & Alert Limits
2. Press the Low Reference button for the desired analyte and enter the value using the numeric keypad. Press Enter to save the value.
3. Press the High Reference button for the desired analyte and enter the value using the numeric keypad. Press Enter to save the value.
4. Press the Low Alert button for the desired analyte and enter the value using the numeric keypad. Press Enter to save the value.

5. Press the High Alert button for the desired analyte and enter the value using the numeric keypad. Press Enter to save the value.
6. Press Exit to return to the Results Configuration Menu or Home to return to the Ready screen.

2.6.3.2 Result Units Setup

The Result Units Setup menu provides a means of changing the default unit of measure for specific parameters. The current unit of measure for each parameter is displayed on the drop-down button for that parameter. Here are the available parameters and units of measure:

Temperature °C, °F
Gases mmHg, kPa
pH

To change the units of measure for a parameter:

1. From the Results Configuration Menu, press Result Units Setup.
2. From the Result Units Setup menu, press the drop-down button for the desired parameter. Then select the unit of measure from the drop-down list.
3. When done, press Exit to return.

2.6.3.3 Biosensor Offsets

Biosensor Offsets may be used to modify the slope and offset of specific analytes in order to provide results that more closely resemble a reference analyzer. Slope and offset corrections should only be used after a comprehensive correlation study of sample results between a reference analyzer and the pHOx Analyzer to determine the slope and offset values for each analyte.

Allowable Slopes and Offsets for each analyte are shown below.

Analyte	Slope	Offset
pH	0.7000 – 1.300	-2.000 to 2.000
PCO_2	0.70 – 1.30	-20.0 to 20.0
PO_2	0.70 – 1.30	-30.0 to 30.0

To enter a slope and offset for an analyte:

1. From the Results Configuration Menu press Biosensor Offsets.
2. Press the Slope button for the desired analyte and enter the value using the numeric keypad. Press Enter to save the value.
3. Press the Offset button for the desired analyte and enter the value using the numeric keypad. Press Enter to save the value.
4. When done, press Exit to return to the Results Configuration Menu or Home to return to the Ready screen.

2.6.3.4 Result Suppression

Result suppression is used to prevent results from a suppressed analyte from being displayed, printed or transmitted. On the Ready screen, analytes that have been suppressed are displayed in light gray text. Some analytes are dependent on others for an accurate result. When a dependent analyte is suppressed results from the primary analyte are available if the dependent analyte remains calibrated. If the dependent analyte becomes uncalibrated the primary analyte will not be reported. Analytes that require results from at least one additional analyte are shown below.

Analyte Dependency

PCO_2 is dependent on pH.

To suppress an analyte:

1. From the Results Configuration Menu, press Result Suppression.
2. In the Result Suppression screen, press the drop-down button for the desired parameter and select Suppressed. Press Active to enable the analyte.
3. When done, press Exit to return to the Results Configuration Menu or Home to return to the Ready screen.

2.6.3.5 Display Temp. Corrected

Sample results for pH, PCO_2 and PO_2 are reported and measured at 37°C. Temperature corrected results are calculated if a sample temperature other than 37°C is entered in the Sample Information screen. Temperature corrected results are reported under the analyzer's calculated results as pHtc, PCO_2tc and PO_2tc. In some cases it may be desirable to display temperature corrected values regardless of the entered sample temperature. Display Temp. Corrected can be enabled (ON) or disabled (OFF) in the Results Configuration Menu.

2.6.4 Operation Configuration Menu

The Operation Configuration Menu screen allows you to setup the analysis output options, to configure calibration times, to configure printing and transmission options, to set the date, time, and barometric pressure, to change analysis mode (A or B), and to change STAT mode (OFF or ON).

2.6.4.1 Analysis Configuration

The Analysis Configuration Menu sets the Analysis Transmit Mode, Transmission of Diagnostic Data, Printing of Diagnostic Data, the Analysis Print Mode, and the Printing of Reference and Alert Ranges.

- Analysis Transmit Mode determines if sample results and information are transmitted to an LIS automatically. Press the Analysis Transmit Mode button and select either Manual or Automatic. Automatic will cause the analyzer to automatically transmit results at the completion of each analysis. Manual requires an operator to press transmit each time sample results are to be sent.
- Transmit Diagnostic Data sends additional diagnostic data on sensor performance to the LIS. This setting is normally disabled unless the analyzer is in a research setting. Transmit Diagnostic Data can be enabled (ON) or disabled (OFF) in the Analysis Configuration Menu.
- Print Diagnostic Data prints additional diagnostic data on sensor performance on the analyzer's printer. This setting is normally disabled unless the analyzer is in a research setting. Print Diagnostic Data can be enabled (ON) or disabled (OFF) in the Analysis Configuration Menu.
- Analysis Print Mode determines if sample results will be automatically printed on the analyzer's printer. Press the Analysis Print Mode button and select either Manual or Automatic. Automatic will cause the analyzer to automatically print results at the completion of each analysis. Manual requires an operator to press print each time sample results are to be printed.
- Print Reference and Alert Ranges determine if the reference and alert ranges (refer to Section 2.6.3.1) are printed on each sample report. Print Reference and Alert Ranges can be enabled (ON) or disabled (OFF) in the Analysis Configuration Menu. Press Exit to return to the Operation Configuration menu or Home to return to the Ready screen.

2.6.4.2 Calibration Configuration

The Calibration Configuration menu determines the frequency of 2 point calibrations, if diagnostic calibration data is transmitted or printed and if calibration drift data is transmitted or printed.

- Set 2-Point Calibration Frequency determines the frequency the analyzer performs a full 2-Point calibration. Select every 2, 4, or 6 hours from the Set 2-Point Calibration Frequency drop-down list.
- Transmit Diagnostic Data sends additional diagnostic calibration data on sensor performance to the LIS. This setting is normally disabled unless the analyzer is in a research setting. Transmit Diagnostic Data can be enabled (ON) or disabled (OFF) in the Calibration Configuration Menu.
- Print Diagnostic Data prints additional diagnostic calibration data on sensor performance on the analyzer's printer. This setting is normally disabled unless the analyzer is in a research setting. Print Diagnostic Data can be enabled (ON) or disabled (OFF) in the Calibration Configuration Menu.
- Transmit Drift Data sends additional diagnostic data on sensor performance to the LIS. This setting is normally disabled unless the analyzer is in a research setting. Transmit Diagnostic Data can be enabled (ON) or disabled (OFF) in the Calibration Configuration Menu.
- Print Drift Data prints additional diagnostic data on sensor performance on the analyzer's printer. This setting is normally disabled unless the analyzer is in a research setting. Print Diagnostic Data can be enabled (ON) or disabled (OFF) in the Calibration Configuration Menu. Press Exit to return to the Operation Configuration menu or Home to return to the Ready screen.

2.6.4.3 System Configuration

The System Configuration menu contains Set Date and Time, Adjust Barometer, configure the date and time format, set the analyzer ID number, and set the tone of the touch screen beep.

- Set Date displays a pop-up calendar. Select the current Month, Day, and Year then press OK to save the date or Exit to ignore any changes.
- Set Time displays a pop-up Set Time window. Press the Increase/Decrease Hour and Increase/Decrease Minute buttons to set the current time then press OK to save the time or Exit to ignore any changes.
- Adjust Barometer allows the analyzer's internal barometer to be adjusted to a local reference barometer. Use the pop-up numeric keypad to enter the desired barometric pressure and press Enter to save. The Measured BP displayed in the System Configuration screen displays the internal barometer reading. The Corrected BP shows the adjusted barometric pressure used in all calculations involving barometric pressure.

- Date Format allows the user to choose the date format used by the analyzer. From the drop-down window choose DD-MM-YYYY, MM-DD-YYYY or YYYYMM-DD.
- Time Mode allows the user to choose the time format used by the analyzer. From the drop-down window choose 12 Hour Mode or 24 Hour Mode.
- Analyzer ID allows the entry of a unique Analyzer ID of up to 10 digits. Press Analyzer ID and enter the ID number from the pop-up numeric keypad.
- Tone Frequency allows an operator to set the frequency of the tone used by the analyzer's touch screen. Press Tone Frequency to display a numeric keypad and enter a number between 100 and 5000. The higher the number the higher the tone pitch. Press Exit to return to the Operation Configuration menu or Home to return to the Ready screen.

2.6.4.4 Analysis Mode

Press Analysis Mode and select mode A or mode B.
I**n Mode A,** all analytes are checked for calibration drift every 30 minutes. This check is done by exposing the sensors to a known standard and comparing the value to the value obtained during the last 2-point calibration. A calibration drift error is generated if the difference exceeds the internally set limits. The flagged sensor will revert to an uncalibrated state.
In Mode B, analytes are checked for calibration drift during every sample analysis. This check is done by exposing the sensors to a known standard and comparing the value to the value obtained during the last 2-point calibration. A calibration drift error is generated if the difference exceeds the internally set limits. The flagged sensor will revert to an uncalibrated state.

2.6.4.5 Stat Mode

Stat Mode disables the Sample Information screen normally displayed after a sample analysis is initiated and immediately displays the Results screen. Sample information cannot be entered when the analyzer is in Stat Mode. Stat Mode can be enabled (ON) or disabled (OFF) from the Operation Configuration screen.

2.6.5 Lab Computer

The analyzer can be configured to transmit calibration and analysis data to a Laboratory Information System (LIS) from a serial COM port using an ASTM communications protocol. Detailed information on the ASTM communications protocol can be found in Section 7 Communications.

- Baud Rate should be set to match the receiving application's baud rate. Select the appropriate baud rate from the drop-down list. When OFF is selected the communications port is disabled.
- Data Bits should be set to match the receiving application's data bit setting.
- Parity should be set to match the receiving application's parity setting.
- Stop Bits should be set to the receiving application's stop bit setting. Press Exit to return to the Setup Menu or Home to return to the Ready screen.

2.7 Operator Passwords ON/OFF

Operator passwords (refer to Section 2.6.2) can be enabled (ON) or disabled (OFF) from the Setup Menu.

2.7 QC Setup

To access the QC Setup screen, press QC on the Ready screen. Then press Setup QC Levels to display the QC Setup screen. For External Controls, first select the level from the Level drop-down box then enter the Lot Number, the Expiration Date, the Daily Analysis Times (up to 3 times per control per day), and the Ranges of each control. For Internal Controls, the Lot Number, the Expiration Date, and the Control Ranges are automatically read from the control pack when the QC Auto Cartridge is installed. The Daily Analysis Times (up to 3 times per control per day) must be manually entered. For Automatic QC mode to perform, turn Automatic QC Analysis ON in the Quality Control screen.

2.7.1 QC Lockout

QC Lockout can be enabled in one of 2 modes or disabled (OFF) from the QC Setup screen (a password protected screen). Press the QC Lockout Mode drop-down box and select Off, Mode A or Mode B. When QC Lockout is set to Mode A or Mode B and QC is due, all tests that are scheduled for QC will be locked out. A QC analysis must be performed for a locked out test before an analysis can be performed for that test.

2.8.2 Analyte Lockout

An analyte will be locked out when it does not pass a QC level. The analyte appears with a strike-through it. This analyte will not report results unless a password overrides it. When all analytes become locked out, the analyzer displays the Not Ready screen.

NOTE: *If the QC Lockout feature is OFF, the analyzer will internally keep track (Mode A) of the analytes that would be locked out if the QC Lockout feature was ON. If the QC Lockout feature is turned ON, all those analytes will now become locked out.*

2.8.3 Level Lockout

QC level lockout is enforced for both Mode A and Mode B. If a QC level is not run and QC Lockout is enabled, all analytes in that QC level will become locked out. These analytes remain locked out until the QC analysis cycle of that level is run. A message is displayed on the Ready/Not Ready screen that a QC analysis is due for a particular level.

NOTE: *If the QC Lockout feature is OFF, the analyzer will internally keep track of all analytes in this level that would be locked out if the QC Lockout feature was ON. If the QC Lockout feature is turned ON, all those analytes will now become locked out.*

2.8.4 QC Lockout Activation

QC Lockout is activated by selecting either Mode A or Mode B.
Mode A QC lockout locks or unlocks analytes based on the last QC level run. A locked out analyte is displayed with a strike-through the analyte name. Results for a locked out analyte are not calculated. If more than one QC level is run for the QC cycle, only the last QC level run for an analyte determines whether the analyte will be locked or unlocked. If 3 levels were run and the analyte passed the first 2 levels

but failed the last, the analyte will be locked out. To be unlocked, this analyte must pass that last level: passing the first 2 does not count. If the reverse happened and the analyte failed the first 2 levels but passed only the last level, the analyte will not be locked out.

Mode B QC lockout locks or unlocks analytes based on the last QC run for all levels. A locked out analyte is displayed with a strike-through the analyte name. Results for a locked out analyte are not calculated. If an analyte fails any level run in a QC cycle, the analyte will be locked. To be unlocked, the analyte must pass all levels that it failed.

QC Lockout OFF

When the QC lockout mode is set to OFF, the analyzer internally tracks the lock-out state for each analyte. The tracking uses the Mode A lockout. If QC lockout is enabled by selecting either Mode A or Mode B, any number of the tracked analyte can now become locked out. QC Lockout is password protected, and a password override (Level 1 operators only) is provided with a pop-up screen. Analysis can be initiated for all analytes in a lockout state, but results will be displayed with the message "Scheduled QC Not Run" and printed with this error message. For Automatic QC mode to perform, turn Automatic QC Analysis ON in the Quality Control screen. Messages displayed on the Ready/Not Ready screen detail the reason for the QC lockout. These messages are only displayed if QC lockout is enabled (Mode A or Mode B). The following are the messages and their meanings.

Level Lockout Ready/Not Ready Screen Messages

Internal L(n) Not Run: Internal L(n) missed a scheduled QC cycle. All analytes are locked out for that level. Results for the locked out analytes will not be reported. Internal QC level (n) must be run to unlock the analytes.

External L(n) Not Run: External L(n) missed a scheduled QC cycle. All analytes are locked out for that level. Results for the locked out analytes will not be reported. External QC level (n) must be run to unlock the analytes.

Mode A Ready/Not Ready Screen Messages

QC Lockout: All analytes are locked out. Analysis cannot be run without a password override. Any QC level that is run will unlock the analytes.

Mode B Ready/Not Ready Screen Messages

QC Lockout: All analytes are locked out. Analysis cannot be run without a password override. QC samples must be run for the specific control level(s) that failed to unlock the system.

3 Operation

The BioProfile pHOx Analyzer is pictured below with its components.

Figure 3.1 Nova BioProfile pHOx Components

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

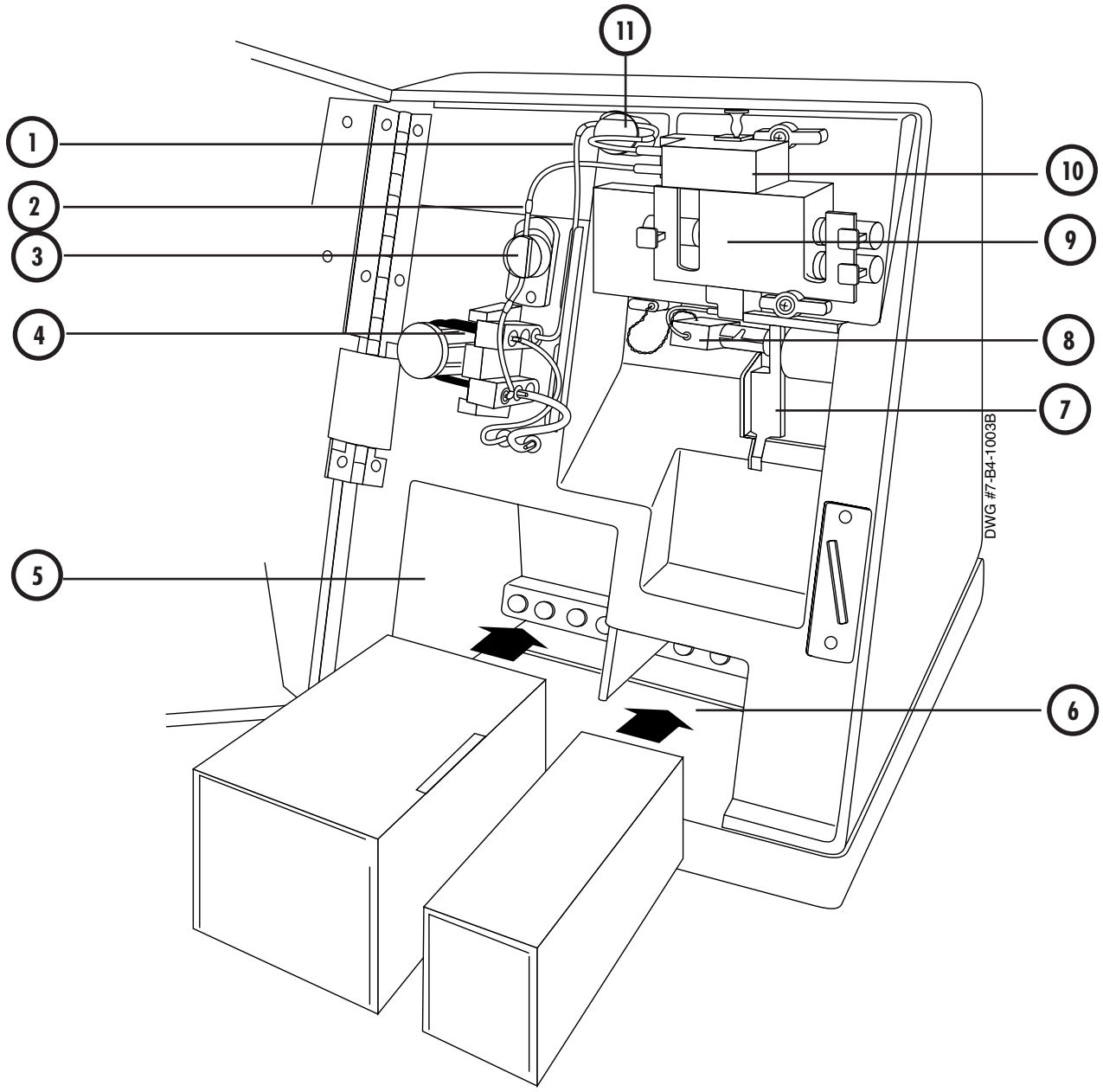


Figure 3.2 Analytical Compartment

1. Waste Line
2. Reference Line
3. Pinch Valve (Reference)
4. Pump and Pump Tubing
5. Calibrator Cartridge Opening
6. Control Cartridge Opening
7. Sampler
8. Air Detector
9. Sensor Module With Sensors
10. Reference Sensor
11. Pinch Valve (Waste)

3.1 Display and Door

The display is a touchscreen, liquid crystal display (LCD). Prompts, menus, status information, error messages, results, etc. are displayed on the screen.
The door may be opened to access the analytical compartment of the system. There is an inside magnetic latch that is easily released when you pull at the bottom right side of the door.

3.2 Printer

The internal printer is able to print sample results, list the analyzer's setup information, error log, etc.

3.3 Sampler

The sampler allows for the aspiration of the sample. The sampler has 2 sampling positions: horizontal for the aspiration of a sample from a pipette tube and inclined for the aspiration of the sample from a syringe. No special adapters are required to aspirate a sample from a pipette tube. The pipette or syringe positions are selected by pressing the Pipette button or the Syringe button.

3.4 Sensor Module

The sensor module includes the preheater and flow cell. The preheater heats samples and controls to 37°C. In addition, it contains 2 air detectors.
The sensor module geometry is an interlaced configuration with the reference electrode at the top of the sensor module, 1 sensor on the left side, 2 sensors on the right side. There are 4 sensors: Reference electrode, PCO_2, pH, and PO_2.

3.5 Sensors

The Sensors housed in the sensor module are the core of the BioProfile pHOx Analyzer. The methodology used by each sensor are

Electrode	Methodology
pH	Hydrogen ion-selective glass electrode
PCO_2	Severinghaus-type electrode
PO_2	Polarographic Clark-type electrode

The sensors clip into the sensor module, and electrical contact is automatically made.

3.6 Reference Electrode

The Reference Electrode is mounted above the sensor module. It is a solid-state Ag/AgCl electrode and provides the reference voltage for comparison to sample voltages. The exit port of the flow path is located on this electrode.

3.7 Barometric Pressure Module

The Barometric Pressure Module, located on an internal printed circuit board, continuously monitors the barometric pressure. This barometer can be calibrated against an external barometer, if desired, through the software.

3.8 Pinch Valves

There are 2 pinch valves: one is used to control the flow of the reference fluid and the other one is used to control the flow of fluids through the sensor module.

3.9 Peristaltic Pump

The pump is a 6-roller peristaltic pump driven by a stepper motor.

3.10 Reagent Cartridge

The reagent cartridge contains 6 flexible bags in a cardboard carton. One of these is a waste bag to collect the used reagents, controls, and samples. The other 5 bags contain standard reagents: A, B, C, D, and R. Each bag includes a fitment with a septa. The exposed bag fitments are arranged in a line along the rear of the cartridge. The septa are pierced during insertion of the cartridge. The lot number and expiration date are printed on the front of the pack.
The Reagent Management System (RMS) of the reagent cartridge automatically enters the calibration values, the lot number, the fluid volumes, and the expiration date to the analyzer's computer after installation of the reagent cartridge.

3.11 Movement of Fluids

To begin an analysis, press the Pipette or Syringe key to move the sampler to either the pipette or syringe position. Present the sample to the probe and press Aspirate. The Aspirate button allows for the aspiration of 300 µL of sample. The sample is aspirated by the peristaltic pump until the leading edge is detected by the air detector. After the aspiration is completed, there is an audible beep and a pop-up display that prompts you to press Analyze after removing the syringe or pipette. The sample is advanced until the leading edge is properly located in front of the electrodes. Once all measurements have been completed, the sample is pumped to the waste and the flow path is washed.

3.12 Operational Overview

The BioProfile pHOx Analyzer is a stand-alone, microprocessor-based instrument for analyzing cell culture samples. The analyzer measures pH, PCO_2, and PO_2. The analyzer additionally calculates the parameters listed in Section 1.2.
The software allows the control of the following functions:

- Calibration
- Sample analysis
- Quality Control
- Diagnostic and maintenance functions
- System configurations
- Communication interface with external devices
- Storage and retrieval of sample records

After the analyzer is set up and calibrated, it is ready to begin analyzing samples. Samples can be aspirated from syringes, open tubes, small sample cups, or ampules. After sample acceptance, sample data can be entered. A limited number of sample records (96) is stored in a "circular" buffer. Once the buffer is full, each new saved record overwrites the oldest record.

3.13 Ready to Analyze

When the Ready screen is displayed, the analyzer is ready to run samples.

The following information is displayed on the screen:

- All calibrated analytes - Uncalibrated analytes are X'd out.
- Next QC time (if selected in Setup)
- Next Calibration time
- Remaining reagent volume (A bar graph is displayed for fluid volumes greater than 10% of the original volume.)
    - Calibrators
    - Controls

3.14 Calibrating the Analyzer

The analyzer uses a 2-point calibration to measure pH, PCO_2, and PO_2 electrode slopes and to verify electrode performance. This 2-point calibration occurs automatically at regular intervals, or, if desired, calibration can be manually initiated. The options are listed in the Calibration screen. If an electrode fails to calibrate for any reason, an appropriate error code is generated. An operator can cancel a calibration in progress from the keypad to run a stat analysis. If this is done, the previous calibration slopes are used for the analysis calculations.

3.14.1 Two-Point Calibration (Automatic and Manual)

The analyzer performs an automatic 2-point calibration at 2, 4 or 6 hour intervals (as selected in Setup). These Auto-Cal intervals can be extended as follows:

Auto-Cal Extension: System Busy when Auto-Cal scheduled to run
If the system is busy when an Auto-Cal is scheduled to run, the request is held in a queue until the current sequence is completed. The system presents the operator with a pop-up that allows the delay of a 2-point calibration sequence for an additional 10 minutes. The 2-point calibration sequence may be delayed indefinitely.

3.14.2 User Initiated Calibration

User initiated calibrations may be performed to calibrate any uncalibrated electrodes or calibrate the system after maintenance. Press the soft key for Calibrate on the Home screen. The 2-point Calibration screen is displayed with options for calibration. Press Calibration to start the calibration sequence.

3.15 Quality Control

The Quality Control screen is accessed from the Home screen by pressing the QC button. Times for running QC can be set through the QC Setup. This menu also allows access to reports and Levy-Jennings Charts and allows the manipulation of daily, monthly, cumulative data.

Definitions:

Daily Statistics - All QC samples stored since the last Move Daily Data to Month-to-Date was performed. Daily data accumulation begins at 12:00 AM of the current day.

Monthly Statistics - Cumulative statistics for the last 30 days. Monthly statistics are simply cumulative statistics.

Cumulative Statistics - A running accumulation of mean, SD (standard deviation), and CV% (coefficient of variance in percent) for all stored QC samples. Although these statistics are based on the total number of samples, the (n) on the screen and on the printout indicates the number of days. The Cumulative Statistics cannot be reset except by changing to a new lot of control.

3.15.1 Running QC Samples

From the Home screen, press the QC button to display the Quality Control (QC) screen. Press Analyze QC, select the level to be analyzed from the Level drop down window then press Analyze. Follow the instructions on the screen.

NOTE: *If the mandatory QC mode is selected (i.e., QC times have been entered) and you choose to delay or not run the QC, a message is displayed indicating that QC was not run. If the QC lockout mode is selected and a scheduled QC is not allowed to run, the analyzer becomes Not Ready. Pressing the Pipette or Syringe buttons automatically displays the Quality Control (QC) screen.*
If you power up without QC scheduled and QC Lockout off, the analyzer will boot up in control.

NOTE: *To use the Auto QC mode, set the times for the 3 control levels in the Setup QC Levels screens, then turn Automatic QC Analysis ON in the Quality Control (QC) screen.*

3.16 Analyzing Samples

Samples can be analyzed from pipettes of various sizes and glass or plastic syringes from 1 cc to 10 cc. Samples are aspirated from a horizontal position for pipette tubes through a built-in adapter or at a 30° angle from the horizontal position for syringes and ampule control samples.

3.16.1 Analyzing from a Syringe or an Ampule

From the Home screen (Ready), press the syringe key (for syringe or ampule samples) to position the probe. To aspirate the sample, press Aspirate. Follow the directions on the screen.

NOTE: *For other functons, follow the screen instructions.*

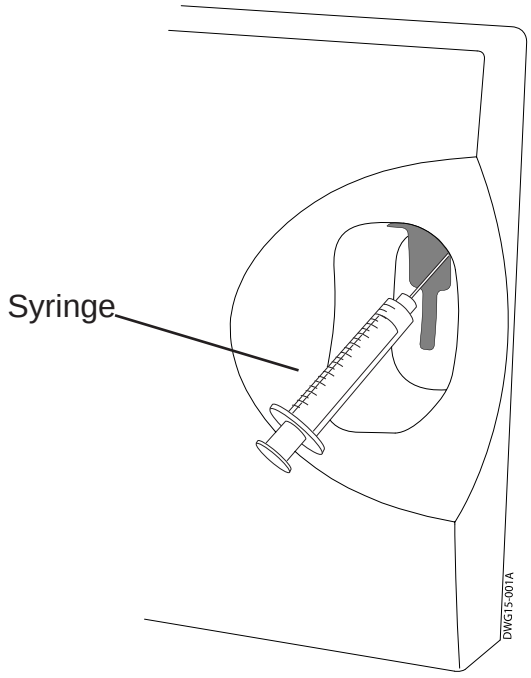


Figure 3.3 Analyzing from a Syringe

3.16.2 Analyzing from a Pipette Tube

From the Home screen (Ready), press the Pipette key to position the probe. To aspirate the sample, press Aspirate. Follow the directions on the screen.

NOTE: *For other functions, follow the screen instructions.*

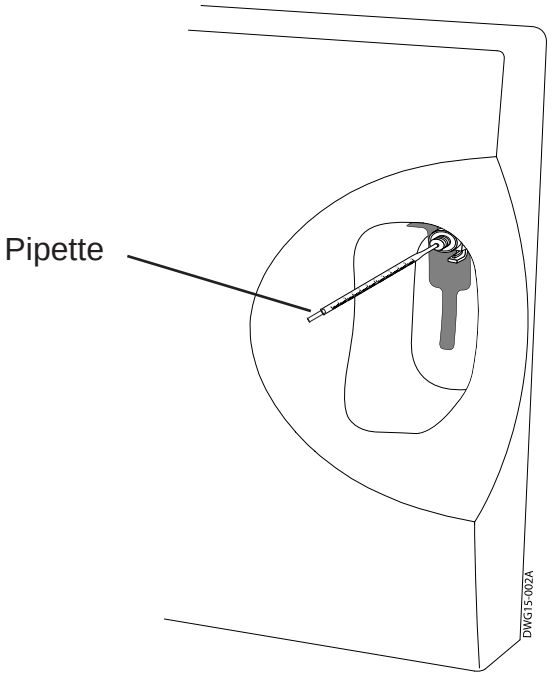


Figure 3.4 Analyzing from a Pipette

3.17 Results Recall

Previously analyzed samples can be recalled for viewing only. These records are stored in a circular buffer. When the buffer becomes full (greater than 96 analyses), the oldest record in the buffer is overwritten. The record is automatically saved by the analyzer when the analysis is successfully completed. The results are cataloged by Date, Time, Accession Number, and Test Number. These results are accessed through the Ready screen.

1. From the Ready screen, press Results.
2. Select the desired results.
3. Press VIEW to display the selected results.

4 Operating Procedures

The following sections provide detailed information and directions to operate the Bio-Profile pHOx Analyzer at peak efficiency. From the Home screen, press the Menu key. From the Operational Menu screen, the following options can be performed:

- Set Sample Number Counter
- Change the Calibrator Cartridge
- Change the Control Cartridge
- Flowpath/Probe maintenance: change tubing, sensors, purge, etc.
- Flowpath Cleaning
- Sensor Conditioning
- Standby Mode

WARNING: *Cell culture samples are a potential sources of infectious agents. Handle all sample and flowpath components (waste-line, probe, flow cell, etc.) with care. Gloves and protective clothing are recommended.*

A **Maintenance Log** that includes performance records and a maintenance checklist is supplied with your instrument. Use this log to record data for long-term performance verification and to document maintenance.

4.1 Sample Number Counter

The screen allows you to check and/or to change the Sample Number Counter, but the Total Samples Accepted number, the Total Internal QC Samples Accepted number, and the Total Samples and Internal QC number are read only.

4.2 Scheduled Maintenance

It is important to perform preventive maintenance as scheduled. The **Maintenance Log** (PN 33578) gives suggested schedules based on sample volume. Space is provided for slopes and control results in the **Maintenance Log.**

4.2.1 Reagent Cartridge and Control Cartridge Replacement

The reagent cartridge and/or control cartridge should be changed when the system indicates the cartridge is empty. From the Operation Menu screen, select Change Calibrator Cartridge or Change Control Cartridge. **Mix the cartridge thoroughly by inverting several times.** Then follow the directions on the screen to replace the cartridges and the pipette adapter.

WARNING: *When the reagent cartridge or control cartridge is removed, keep your fingers and hands away from the back of the cartridge compartment. There are sharp needles that can cause injury, and the waste needle is also a biohazard.*

NOTE: *The reagent or the control cartridge must be replaced through the Operation Menu screens. If you remove and replace a cartridge (even if it is the same cartridge) outside these screens, you will not be able to prime the analyzer, and you will not be able to calibrate or to analyze samples (Reagent Cartridge) or to analyze internal controls (Control Cartridge). If you have removed and replaced a cartridge outside these screens, go to the appropriate screen and press the Install/ Prime (soft key).*

NOTE: *The pipette adapter comes in the reagent cartridge box. As you put on the new adapter, make sure the probe goes through the center hole of the adapter.*

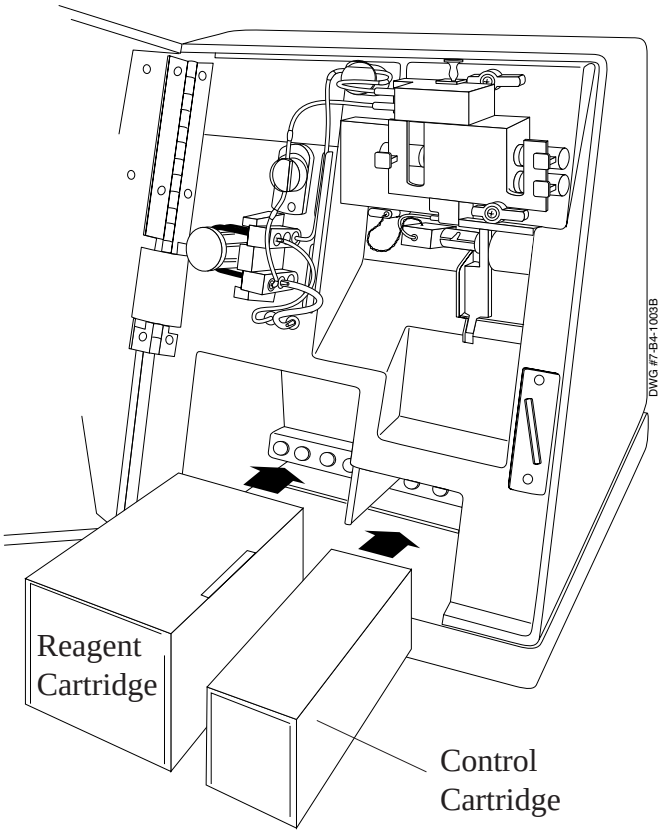


Figure 4.1 Replacing the Reagent Cartridge and the Control Cartridge

4.2.2 Flowpath/Probe Maintenance

The Flowpath/Probe Maintenance option removes fluid from the flow path, so that tubing, sensor, or probe changes, or other maintenance can be performed without fluids leaking or pumping into the analyzer. After all replacements are made, press Continue (soft key) to prime the flow path. The analyzer will prime and give you the option to calibrate now or later.

4.2.3 Standby Mode

This option allows you to place the analyzer into a standby mode and allows you to reactivate the analyzer out of the mode at a programmed time and date. The standby mode will use less reagents and controls because the analyzer will not run its automatic calibration cycles. Calibration will be lost. Standby mode ends after the set time is elapsed; if you turn Standby off; or if you initiate a calibration. The analyzer automatically performs 2 calibrations or a second calibration after Standby mode ends.

The following is the procedure to set the Standby Mode:

To place the analyzer in Standby:

- Select ON from the Standby Mode drop-down list in the Operation Menu. The analyzer is automatically configured to exit standby in 7 days at midnight (00.00 hours).
- To change the date the analyzer will exit standby press the Exit Standby Date button and select a new date using the pop-up calendar.
- To change the time the analyzer will exit standby press the Exit Standby Time button and set a new time using the Set Time pop-up window.

To bring the analyzer out of Standby:

- Select OFF from the Standby Mode drop-down menu or press Calibrate from the Ready screen. The analyzer automatically runs 2 full calibrations as it exits standby. If QC lockout is used analytes may be locked out until QC has been run.

4.2.4 pH Sensor Replacement

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door and locate the pH sensor.
3. Remove the sensor from the sensor module by pinching the front and rear of the sensor clip.
4. Clean the sensor module flow cell with a lint-free wipe.
5. Shake down the sensor to degas it.
6. Insert the new sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
7. Press Prime. Please wait until the time bar completes.
8. Calibrate the sensor 2 times.

4.2.5 PCO_2 Sensor or Membrane Replacement

The following procedure explains how to replace the PCO_2 sensor and membrane.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door.
3. Locate the PCO_2 sensor.
4. Remove the PCO_2 sensor by pinching the front and rear of the sensor clip and sliding it out of the sensor module. Be careful not to touch the electrical contacts.
5. Unscrew the used membrane cap from the sensor body and discard it.

> ***NOTE:*** *If installing a new sensor, carefully remove the shipping cap before installing a new membrane cap. Do not touch the electrical contacts of the sensor.*

6. Take a new PCO_2 Membrane Cap (PN 25048) that is prefilled with internal filling solution. Hold the shipping plug end of the membrane cap and shake it gently, as if shaking down a thermometer, to ensure that the air bubble is at the threaded end of the membrane cap.

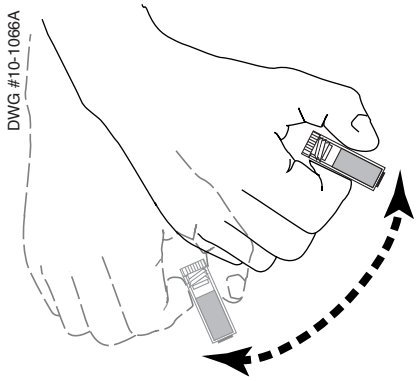


Figure 4.2 Shaking Down Membrane Cap

7. Unscrew the black shipping plug from the cap. Screw the cap onto the sensor. Discard the black shipping plug. Do not tilt the membrane cap when installing onto the sensor; the internal filling solution may drip out.

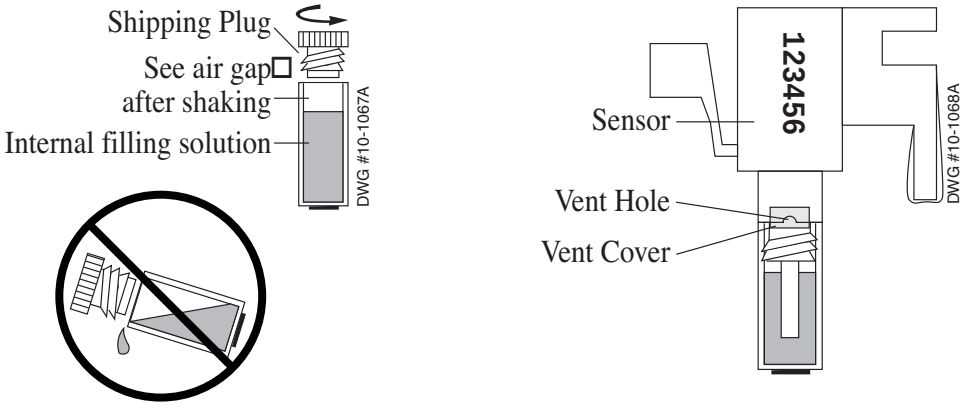


Figure 4.3 The PCO_2 Membrane Cap (With Shipping Plug and Attached to Sensor)

NOTE: *The prefilled PCO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the sensor's performance.*

8. Degas the sensor as follows:
    a. Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
    b. With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.

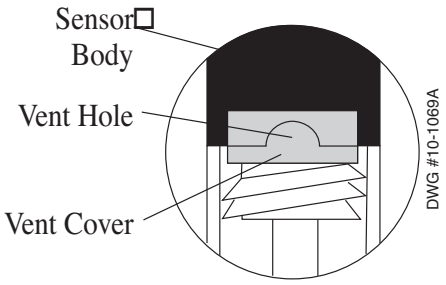


Figure 4.4 Vent Cover on Membrane Cap

9. Wipe the sensor body and cap dry. Remove a single blue vent cover from the backing and place over the vent hole (see Figure 4.4). Press firmly to ensure a good seal.
10. Clean the sensor module flow cell with a lint-free wipe.
11. Insert the sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
12. Press Prime.
13. Please wait until the time bar completes.
14. Calibrate the sensor 2 times.
15. If the sensor does not calibrate due to slope errors, remove air bubbles as follows:
    a. Perform a flowpath purge and open the door.
    b. Remove the sensor and shake down the sensor with a wrist-snapping motion to move air bubbles to the back of the sensor.
    c. Reinsert the sensor into the sensor module and close the door.
    d. Recalibrate.

4.2.6 PO_2 Sensor, Polishing, and Membrane Replacement

The following procedure explains how to polish and to replace the PO_2 sensor and/or to replace the membrane cap.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door and locate the PO_2 sensor.
3. Remove the PO_2 Sensor by pinching the front and rear of the sensor clip and sliding it out of the sensor module.
4. Unscrew the used PO_2 cap from the PO_2 body and dispose of it.
5. **If polishing the sensor is unnecessary, go to Step 7 to replace the PO_2 cap.**
6. Polish the sensor as follows:
    a. Take a polishing paper from kit PN 21795 and place a couple of drops of deionized water onto it.
    b. Hold the PO_2 polishing paper so that the tip of your index finger provides light pressure against the back of the paper.
    c. Gently polish the sensor tip on the paper, move the tip in a circular motion for about 10 seconds. Discard the polishing paper.
    d. Wipe the sensor tip with a lint-free tissue soaked in deionized water.

    CAUTION: *Never polish the sensor tip on a hard surface such as a bench top.*

7. Take a new PO_2 Premembraned Cap (PN 21795) that is prefilled with internal filling solution, and shake it gently to ensure that the solution is away from the threaded end and at the membrane end. Unscrew and discard the shipping plug from the cap.
8. Insert the sensor body straight down (vertical position only to ensure no loss of internal filling solution) into the filled cap and screw the cap onto the sensor body. (See Figure 4.5.)

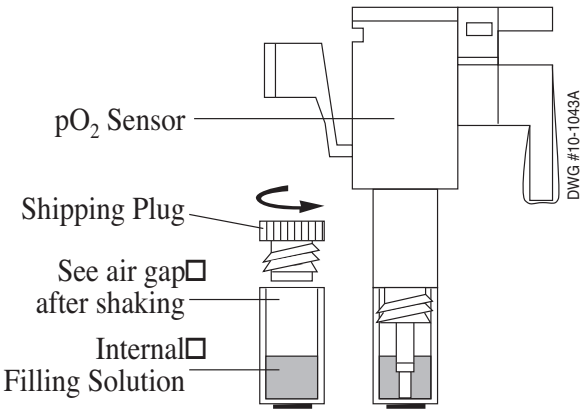


Figure 4.5 Installing the PO_2 Membrane Cap

NOTE: *The prefilled PO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the sensor's performance.*

9. Degas the sensor as follows:
    a. Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
    b. With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.
10. Dry the sensor with a lint-free tissue. Take care not to touch the tip.
11. Clean the sensor module flow cell with a lint-free wipe.
12. Insert the sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
13. Close the door and press Prime.
14. Please wait until the time bar completes.
15. Calibrate the sensor 2 times.
17. If the sensor does not calibrate due to slope errors, remove air bubbles as follows:
    a. Perform a flowpath purge and open the door.
    b. Remove the sensor and shake down the sensor with a wrist-snapping motion to move air bubbles to the back of the sensor.
    c. Reinsert the sensor into the sensor module and close the door.
    d. Recalibrate.

4.2.7 Reference Electrode Replacement

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door.
3. Disconnect the W and R-lines from the reference electrode.
4. Pull up the retaining screw.

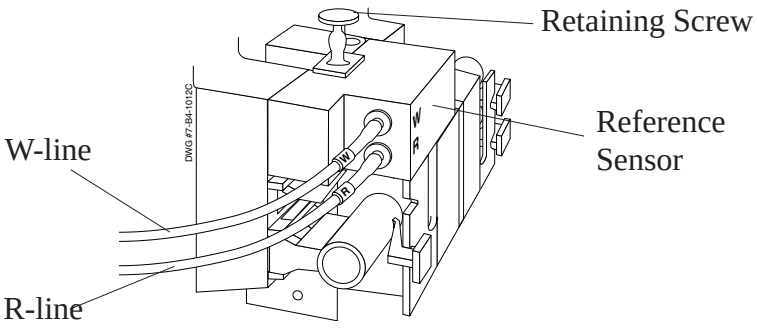


Figure 4.6 Disconnecting the Reference Electrode

5. Lift the used reference electrode up and out of the way of the sensor module.
6. Place the new Reference Electrode (PN 21520) on top of the sensor module, align the electrode sides with the backplate sides. Ensure that the reference electrode connector is seated properly on the sensor module interconnect tubing.

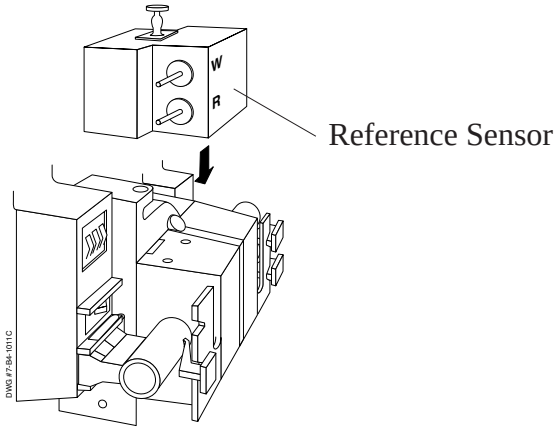


Figure 4.7 Placing New Reference Electrode onto Sensor module

7. Push down on the retaining screw.
8. Attach the W/R-lines to the reference electrode and press Prime.
9. Please wait until the time bar completes.
10. Recalibrate.

4.2.8 Pump Tubing Replacement

The pump tubing should be replaced at intervals prescribed in the maintenance log. Replace the tubing that goes around the pump as follows.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door.
3. Disconnect the R-line and W-line (the tubings that go through the pinch valves) from the pump manifold.
4. Disconnect the R and W-pump tubing lines from the labeled outlets that are below the pump manifold.
5. Slide the top and bottom tube manifolds out
6. Discard the used tubing and manifolds.
7. On the new pump tubing, Locate the half circle on one of the manifolds. This is the top manifold.

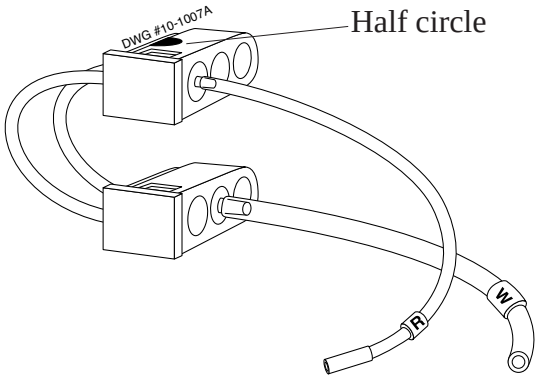


Figure 4.8 Pump Tubing

8. Slide the top pump tubing manifold into its slots. The top manifold's half circle should line up with the half circle on the slot.
9. Stretch the pump tubing around the pump and slide the bottom manifold into its slots.
10. Connect the R-pump tubing line to the R-labelled outlet below the pump manifold (see Figure 4.9).
11. Connect the W-pump tubing line to the W-labelled outlet below the pump manifold (see Figure 4.9).

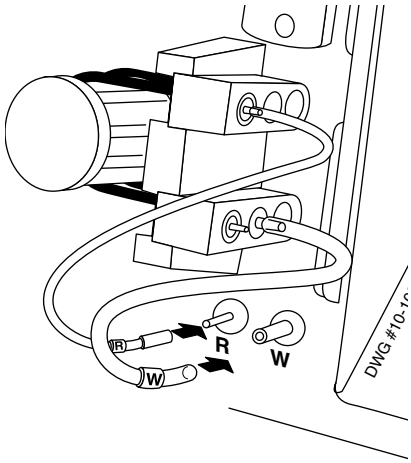


Figure 4.9 Connecting the Pump Tubing W and R-lines

12. Reconnect the R-line and W-line (the tubings that go through the pinch valves) to the pump manifold.
13. Close the door and press Prime.
14. Please wait. A time bar to completion will appear.
15. Recalibrate.

4.2.8.1 Waste Line Replacement

The waste line should be replaced at intervals prescribed in the maintenance log. The W-line connects at the middle of the top pump manifold, travels through the waste pinch valve, and connects to the top W-labelled outlet on the reference electrode. The W-line can be replaced by following this procedure.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door.
3. Disconnect the W-line from the pump manifold, pinch valve, and reference electrode. Discard the used tubing.
4. Attach the new W-line starting with the pinch valve. At the pinch valve segment of the W-line (elastic segment), stretch the segment and slide it into the pinch valve.
5. Connect the line to the W-labelled outlet of the reference electrode and the middle of the top pump manifold. (See Figure 4.10.)

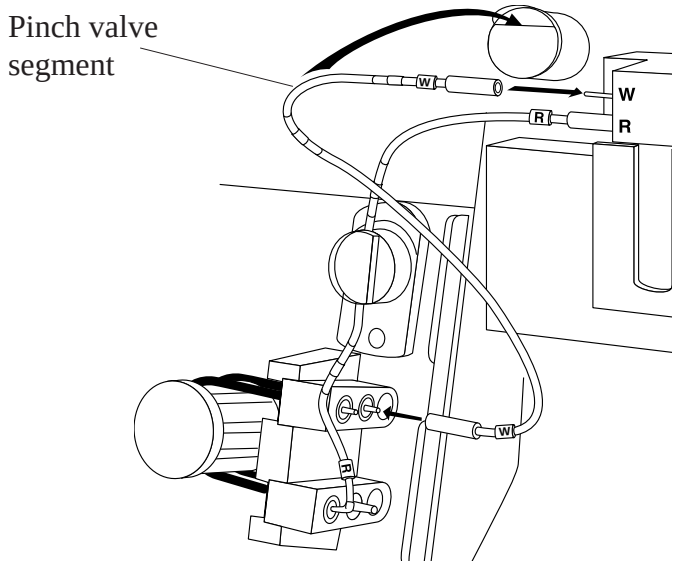


Figure 4.10 Connecting the W-line

6. Close the door and press Prime.
7. Please wait. A time bar to completion will appear.
8. Recalibrate.

4.2.8.2 Reference Line Replacement

The reference line should be replaced at intervals prescribed in the maintenance log. The R-line connects at the outside of the bottom pump manifold, travels through the reference pinch valve, and connects to the bottom R-labelled outlet on the reference electrode. The R-line can be replaced by following this procedure.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door.
3. Disconnect the R-line from the pump manifold, pinch valve, and reference electrode. Discard the used tubing.
4. Attach the new R-line starting with the pinch valve. At the pinch valve segment of the R-line (elastic segment), stretch the segment and slide it into the pinch valve.
5. Connect the line to the R-labelled outlet of the reference electrode and the outside of the bottom pump manifold. (See Figure 4.11.)

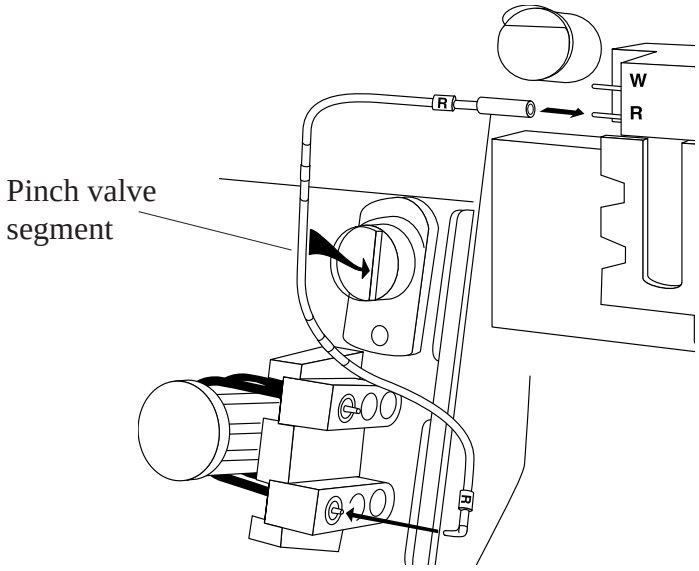


Figure 4.11 Connecting the R-line

6. Close the door and press Prime.
7. Please wait. A time bar to completion will appear.
8. Recalibrate.

4.2.9 Flowpath Cleaning/Deproteinizing

Nova recommends the use of Deproteinizing Solution (PN 12704) when **routine cleaning** is required. Use, for example, if flow problems persist, if air detectors become uncalibrated, or if PO_2 results are consistently low. To clean the sample preheater, the analyzer aspirates Deproteinizing Solution, a specially formulated solution, into the sample preheater, where the solution dissolves protein buildup. The following are more detailed instructions than displayed on the screen.

> ***NOTE:*** *Terminating a flow path cleaning will trigger a flush sequence before the Ready screen is displayed.*

1. From the Operational Menu screen, select Flowpath Cleaning.
2. Wait for the pump to stop.
3. Immerse the probe into an ampule of Deproteinizing Solution. Then press Aspirate.
4. After the tone, remove the probe from the ampule. Then press Continue.
5. Wait for the flow path cleaning cycle to complete. (To stop the cycle, press Cancel.)
6. Recalibrate.

4.2.10 Printer Paper Replacement

1. Open the printer cover.
2. Remove the depleted roll of paper.
3. Insert a new roll of paper. The loose end of the paper should feed from the bottom of the roll.
4. Feed paper past the cover. Then close the printer cover.

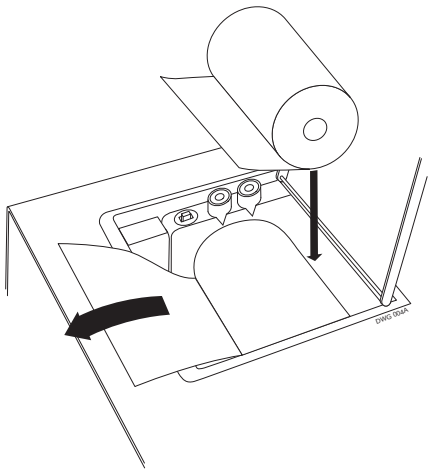


Figure 4.12 Replacing the Printer Paper

4.2.11 Probe and Air Detector Replacement

If the probe or air detector becomes damaged, replace it. Use the following procedure to replace the probe or the air detector.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.

   NOTE: *If you are only changing the air detector, skip to Step 4.*

2. Press Move Probe. Open the door.
3. Remove the pipette adapter from the front of the probe by gently pulling.
4. Disconnect the air detector's sample line from the sensor module.
5. Disconnect the 2-prong cable of the air detector from the analyzer.
6. If changing the probe, push the air detector down and pull the air detector with probe out of the sampler assembly.
   If changing only the air detector, push the air detector down and pull the air detector out. Replace with new air detector and skip to Step 9. DO NOT remove the probe if only the air detector is to be changed.

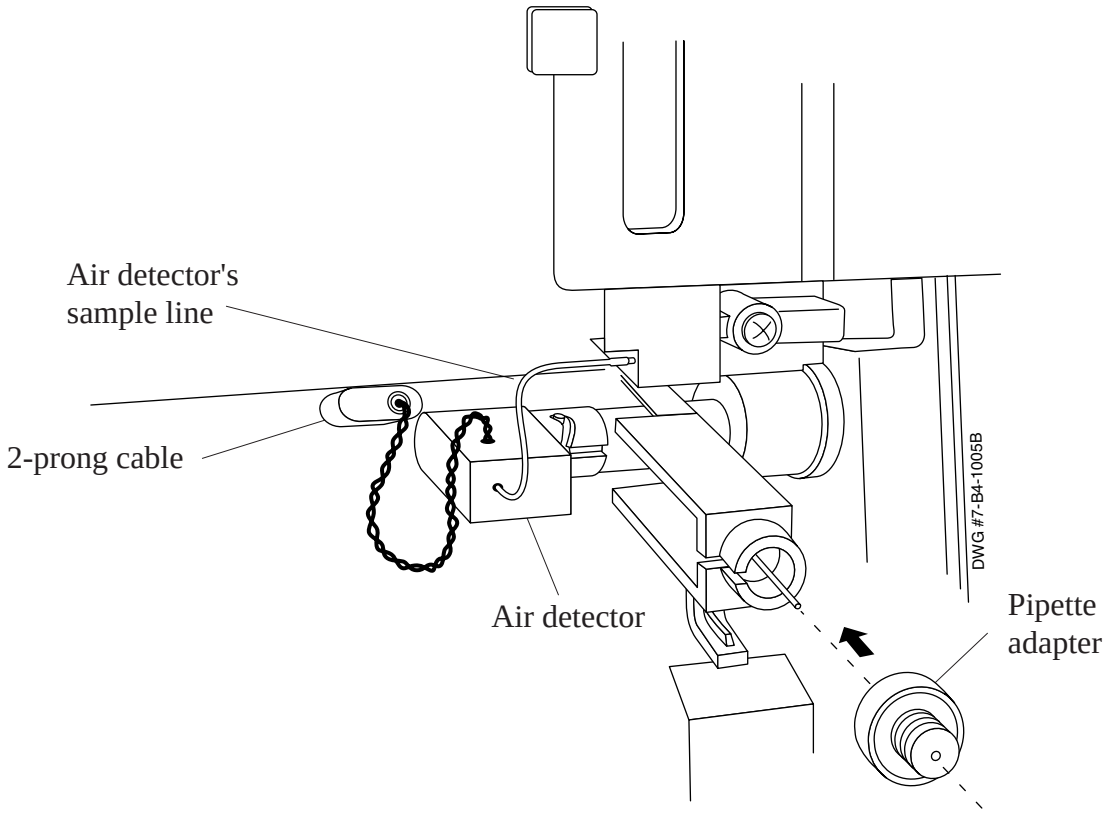


Figure 4.13 Removing Pipette Adapter

7. Discard the used probe.
8. Place a new probe into the air detector and slide both into the sampler assembly.
9. Push the air detector up to lock the probe and air detector into the sampler assembly.

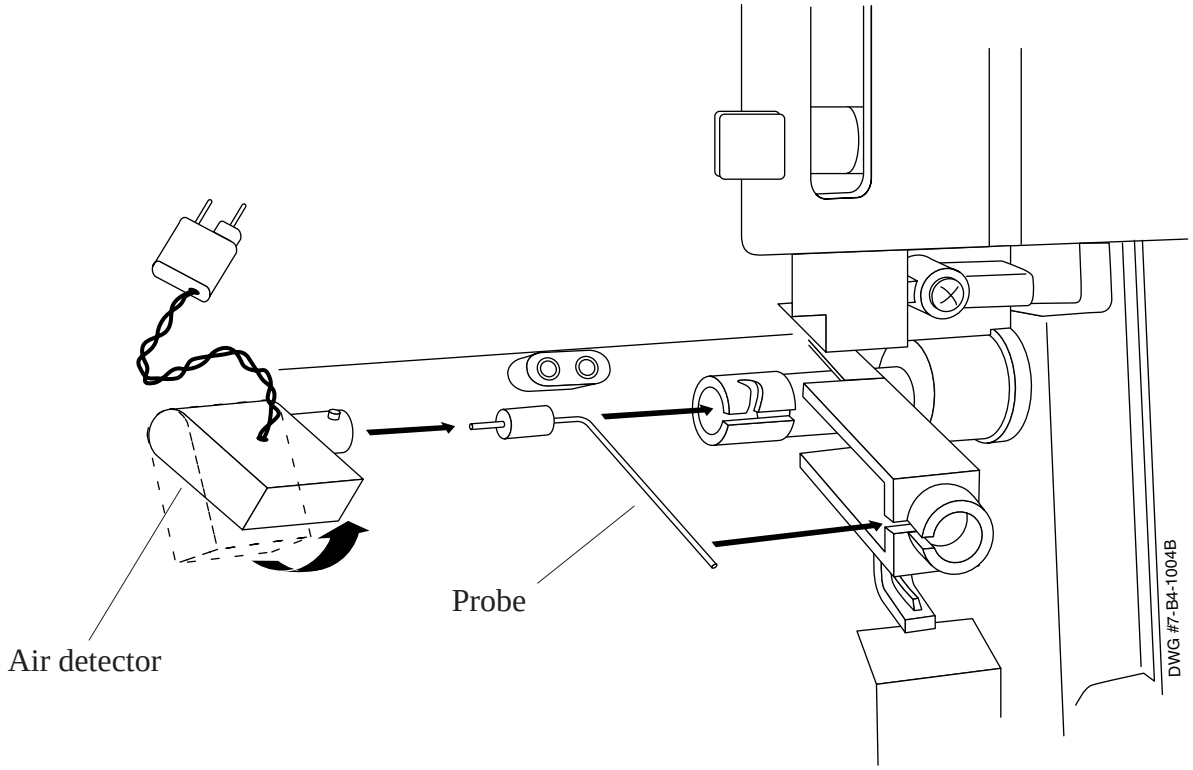


Figure 4.14 Replacing Probe and Air Detector

10. **If changing the probe, do this step; if not skip to next step.** Replace the pipette adapter over the end of the probe. To make the operation easier, push the probe arm back so that the probe extends (1/2 in or 12 mm) beyond the edge. The probe must go through the center hole of the adapter to work properly.
11. Reconnect the air detector's sample line to the sensor module.
12. Reconnect the 2-prong cable back into outlet.
13. Close the door and press Move Probe.
14. Press Prime and wait for timing bar to complete.

4.2.12 Sensor Module Replacement

If the sensor module becomes damaged, replace it. Use the following procedure when you need to replace it.

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. When the cycle is completed, **POWER DOWN THE ANALYZER**. Open the door.
3. Remove the reference electrode (see Section 4.2.7) and the air detector's sample line (see Section 4.2.11).
4. Press the tabs on the sensors to remove them.

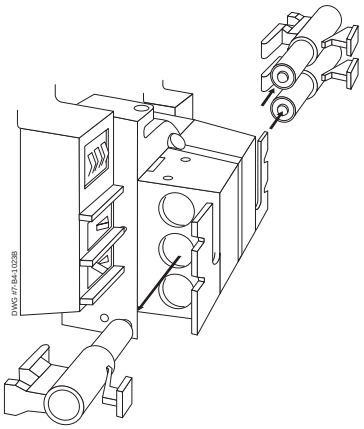


Figure 4.15 Removing the Sensors

5. Disconnect the air detector's sample line.
6. Push the 2 locking levers to the vertical position.

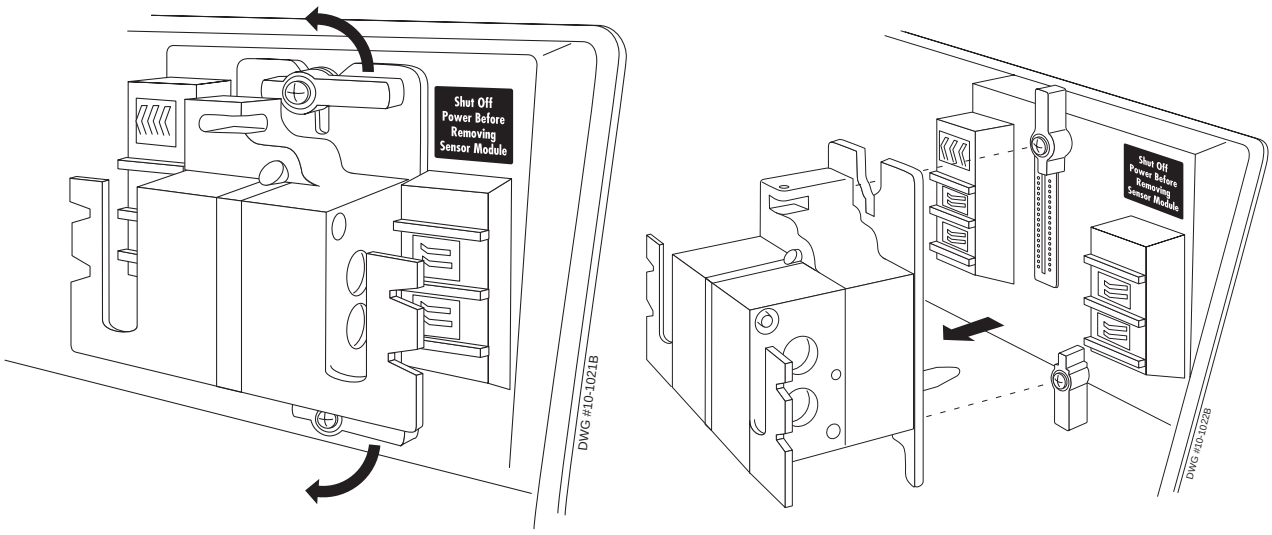


Figure 4.16 Unlocking and Removing the Sensor Module

7. Remove the sensor module; pull it straight out.
8. Guide the new sensor module into place so that it fully engages (Figure 4.17).
9. Push the 2 locking levers to the horizontal position.
10. Replace sensors back into their appropriate place in the sensor module; each sensor clicks into position (Figure 4.18).

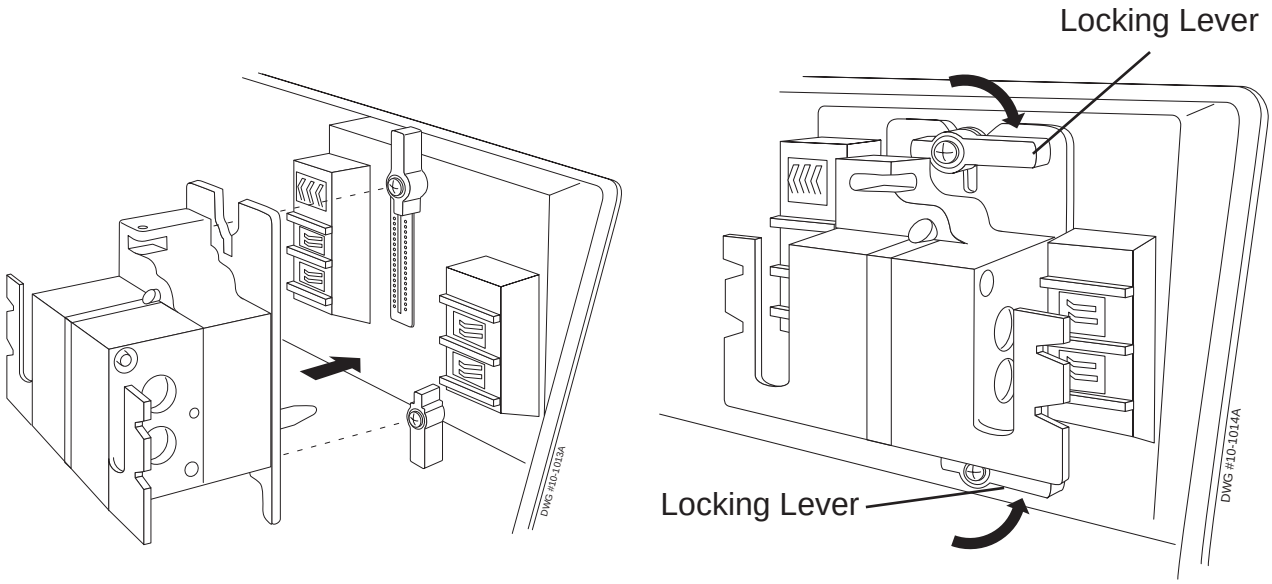


Figure 4.17 Replacing and Locking the Sensor Module

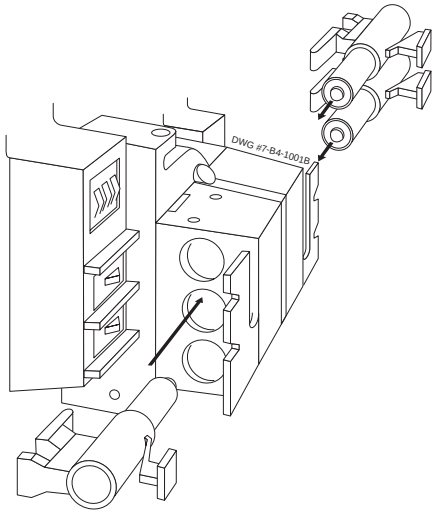


Figure 4.18 Replacing the Sensors

11. Replace the reference electrode (see Section 4.2.7) and the air detector's sample line (see Section 4.2.11).
12. Close the door.
13. Power up the analyzer.
14. Calibrate the analyzer.

4.3 Display/Cabinet Cleaning

Cleaning the Display: Clean the display screen with a damp (not wet) lint-free cloth. For a heavy buildup, use a liquid glass cleaner sprayed onto a lint-free cloth first, never spray directly onto the display. If available, prepackaged screen wipes can also be used.

Cleaning the Cabinet: Clean the cabinet with a damp (not wet) lint-free cloth. Do not use aerosol sprays, solvents, or abrasives that might damage the finish.

5 Troubleshooting

This section describes the status screens, error codes, and Service Menu and explains the troubleshooting procedures for the BioProfile pHOx Analyzer.

WARNING: *Cell culture samples are a potential sources of infectious agents. Handle all sample and flowpath components (waste-line, probe, flow cell, etc.) 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 set up in a block format which lists groups of steps to perform in order to restore operation. The steps are also organized to prevent unnecessary parts replacement, such as sensors and tubing, until the more common causes for an error have been checked.

In the case of multiple error codes, those errors which apply to flow are at the top of the hierarchy. In most cases, when you resolve the flow error codes, the other errors will be resolved as well.

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 TOLL FREE:

1-800-545-NOVA

5.2 BioProfile pHOx 2-Point Calibration Sequence

The calibration sequence is outlined in Table 5.1 according to the order in which the various calibration standards are brought into the system for slope determinations, flow checks, etc.

Table 5.1 BioProfile pHOx 2-Point Calibration Sequence

Fluid	Function
	Sequence Start
Std A	Standard A readings for AD1, AD2, AD3, AD4, pH, PCO_2, PO_2
Std B	Standard B readings for pH and PCO_2
Air	Air reading for PO_2
Std D	Standard D reading for AD1, AD2, AD3, AD4, pH
Std C	Standard C reading for pH
	Sensor Slopes are calculated
	ADT thresholds are calculated
	Initialization
	End Calibration

When you troubleshoot flow problems, it is important to view the system as a whole. This means that you must consider all of the various components that interact in order to transport fluids throughout the system. These components include the pump, sampler probe, fluid fountain, rotary valve, pinch valves, and tubing.
The information in this section, along with an understanding of the flow path components and their functions, will give you the knowledge and tools you will need to resolve most of the problems you will encounter.

Rapid Reference Guide for Resolving Quality Control Problems

pH	
Results High	• External Control Material not at 25°C. • Check for low sensor slope (<9.5) • Condition pH sensor with pH Conditioning Solution • Check for low fluid pack
Results Low	• Condition sensor module with cell-free media • Check for low fluid pack
PO_2	
Results High	• External Control Material below 25°C. • Check for air leak in system
Results Low	• External Control Material above 25°C. • Clean probe/preheater • Run deproteinizing solution • Check waste line for restrictions • Change membrane
PCO_2	
Results High	• External Control Material below 25°C. • Check for low slope • Change membrane • Change sensor
Results Low	• External Control Material above 25°C. • Debubble sensor • Condition sensor module with cell-free media
Combination Problems	
Gases low/pH high on ext. controls	• Confirm External Controls temp is not > 25°C
Gases high/pH low on ext. controls	• Confirm External Controls temp is not < 25°C
Gases consistently out	• Check barometer

5.3 Status Codes

Table 5.3 lists the analyzer's status codes and the corrective action.

Table 5.3 BioProfile pHOx Status Codes

Status Code	Corrective Action
01 pH Slope 02 pH Instability 03 pH Overload 04 pH Drift	1. Recalibrate. 2. Condition pH sensor. (See Section 5.4.) 3. Replace pH sensor.
11 PCO_2 Slope 12 PCO_2 Instability 13 PCO_2 Overload 14 PCO_2 Drift	1. Recalibrate. 2. Replace PCO_2 membrane cap 3. Replace PCO_2 sensor.
15 PCO_2 Dependency	1. Recalibrate pH sensor. 2. Condition pH sensor. 3. Replace pH sensor.
21 PO_2 Slope 22 PO_2 Instability 23 PO_2 Overload 24 PO_2 Drift	1. Recalibrate. 2. Replace PO_2 membrane cap 3. Replace PO_2 sensor.
For air detector problem, check the Error Log to see which air detector has the problem.	
Air detector 1	1. Run Flowpath Cleaning cycle. 2. Recalibrate. 3. Replace air detector
Air detector 2 or 3	1. Clean sensor module. 2. Replace sensor module.
Air detector 4	1. Run Flowpath Cleaning cycle. 2. Recalibrate. 3. Replace reference electrode.

71 Std A Flow 72 Std B Flow 73 Std C Flow 74 Std D Flow	1. Flush flow path and prime standard. 2. Replace reagent cartridge.
75 Flowtime 76 Sample Flow 77 Air Flow	1. Check flowpath for proper operation.
78 Back Flow	1. Check waste line flowpath for proper operation. 2. Refer to Operator Flow Test. (See Section 5.5.1.)
81 Ctrl 1 Flow 82 Ctrl 2 Flow 83 Ctrl 3 Flow	1. Check control Cartridge.
91 Barometer 92. Printer 93. Temperature 94 Communication 95 Hardware 96 Hardware 97 Software 98 Schedule QC	1. Call Nova Technical Service.

5.4 pH Conditioning

1. From the Operation Menu screen, select Flowpath/Probe Maintenance.
2. Open the door and locate the pH sensor.
3. Remove the sensor from the sensor module by pinching the front and rear of the sensor clip.
4 Fill bottom chamber of sensor conditioning holder (PN 09458) with pH conditioning solution (PN 23397).
5. Immerse sensor tip in conditioning solution to soak. The pH sensor is conditioned for 15 minutes.
6. Remove sensor and rinse tip with deionized water.
7. Dry tip with lint-free tissue.
8. Dry flow cell with lint-free tissue.
9. Insert the pH sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.
10. Press Prime.
11. Please wait until the time bar completes.
12. Recalibrate.

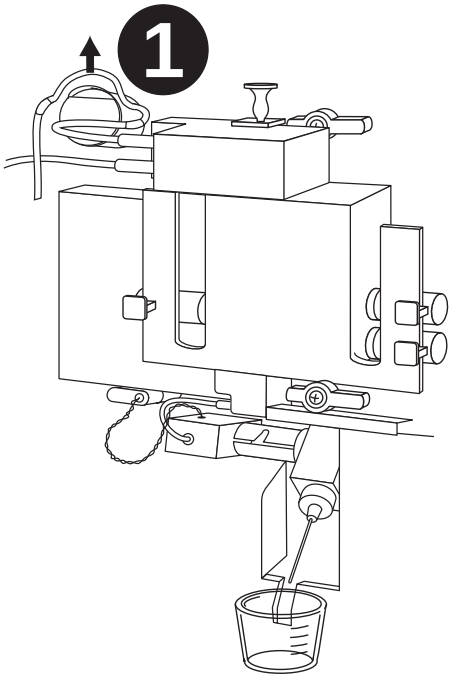
5.5 Troubleshooting Flow Problems

5.5.1 Operator Flow Test

The flow test verifies that fluid can be pulled through the system from the probe. If fluid cannot be pulled through the system, a clog or leak exists. The procedure for the flow test and sensor module back flush is diagramed on the next 2 pages.
This procedure is also used as a corrective action for Status Code 78 Back Flow.

Operator Flow Test

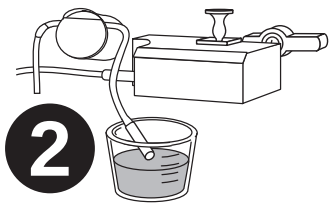
From Ready Menu - Service - System Test - Operator Flow Test



1 - Lift the tubing out of the Waste solenoid.
- If tubing remains pinched, roll it between fingers to loosen.
- Place the sample probe in a cup of water.

Is fluid flow noticed in the waste line tubing?

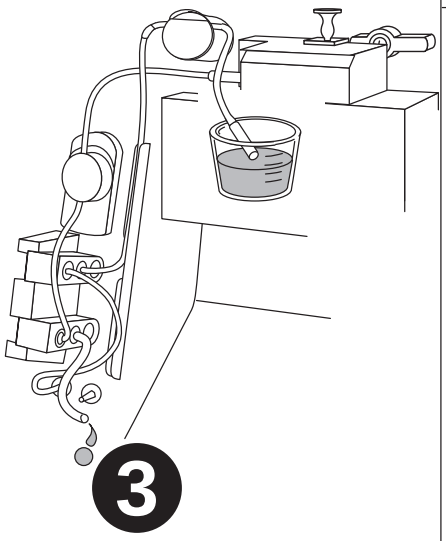
A. IF YES, call your Nova Service Representative.
B. IF NO, go to Step 2.



2 - Disconnect the Waste (W) from the Reference Electrode.
- Place this end of the W tubing into a cup of water.

Is fluid flow seen in the Waste line tubing?

A. IF YES, press "PUMP" to turn off the pump motor. Go to the other side of this page, "Sensor Module Back Flush" procedure.
B. IF NO, go to Step 3.



3 - Disconnect the Waste line tubing from the front panel port.
- Place this end of the tubing over a gauze to prevent spilling.
- Aspirate water from the same location as in Step 2 above.

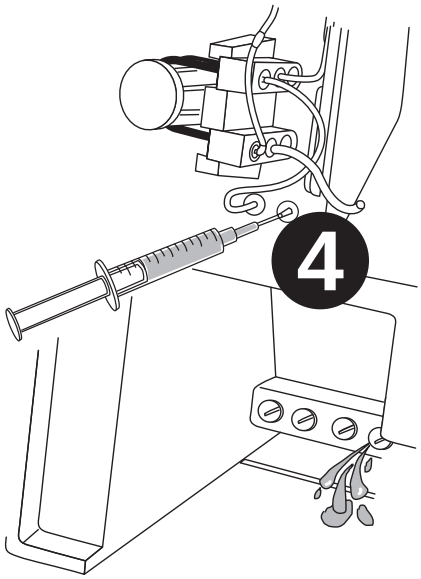
Is fluid seen exiting the Waste tubing end you just disconnected?

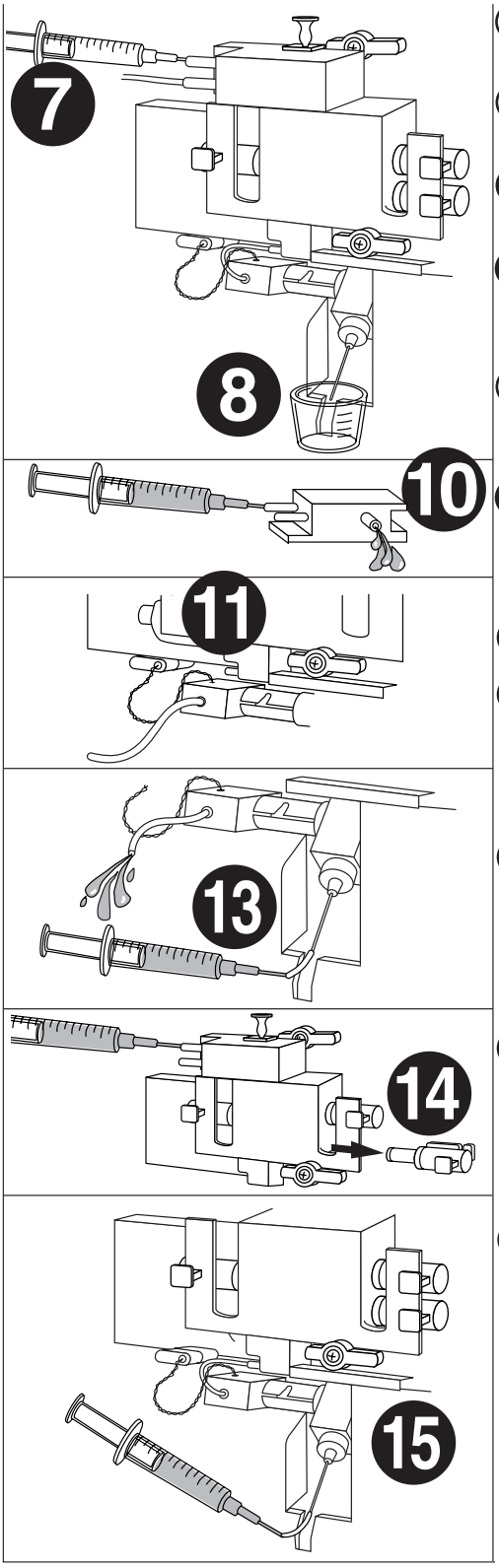
A. IF YES, go to Step 4.
B. IF NO, Replace the W/R Tubing Harness (P/N 23023)

4 - Press the "PUMP" key to stop the Pump Motor
- Remove the Calibrator Cartridge from the unit.
- Install the flush adapter.
- Place the flush adapter tubes into an empty beaker.
- Inject water to the front panel Waste port.
- Water should flow through the adapter waste tube. (Adapter waste line is last to the right)

* Loss of Reference flow will change the flow rate. Reference solution will flow at a rate of 1 -2 drops/second during a pumping cycle.

** If this tubing cannot be flushed call your Nova Service Representative. If tubing flushes easily, change the Calibrator Cartridge. In a small number of cases the original problem may have been poor alignment of the Calibrator Cartridge.





5. If you are starting from the Operator Flow Test, turn the Pump OFF by pressing the "PUMP" key.

6. If you are starting from the Ready Screen, press Service, System Test and select the Operator Flow Test. Turn the pump OFF as in Step 5.

7. Connect a syringe filled with water to the Reference electrode waste port.

8. Back flush the flow path by injecting the water.
CAUTION: *Place a gauze or towel at the sample probe tip to receive the obstruction or water.*

9. If the water easily flushes through the sensor module, you may have an air leak into the flowpath. This will be from an interconnect tubing, failed membrane, or poorly seated electrode. Go to Step 15.

10. If water does NOT exit the sample probe, lift the Reference electrode off the sensor module. Flush the Reference electrode. If it flows freely, confirm that the interconnect tubing is properly positioned and reinstall the Reference Electrode.

11. Disconnect the Air Detector from the bottom of Sensor Module.

12. Inject water into the W port of the Reference Electrode.
Does water flow through the sensor module?

    IF YES, go to Step 13.

    IF NO, go to Step 14.

13. Connect the syringe to the Sample Probe tip. Inject water through the Probe. Water should exit the Air Detector (ADT) tubing.

    IF NO flow is noted, flush the ADT and probe separately.
    IF the water flows easily, the seal between the ADT and probe may be leaking. Replace the Air Detector.

14. (NO from Step 12) The obstruction lies in the flowcell. While continuing to inject, remove one electrode at a time. Starting with the bottom electrode. When water starts to flow either the obstruction flushed into the flowcell or the electrode just removed was the cause. Re-membrane if needed. Dry the flowcell before reinserting the electrode.

15. (From Step 9) Connect the syringe with water to the sample probe tip. Reconnect the Reference electrode Waste line. Apply a slight pressure to the syringe. Look for water entering a flowcell, electrode cap, or leaking from the interconnect tubing. Replace the membrane, or tubing as required.

If the above does not identify the problem,
please contact your Nova Service Representative.

5.5.2 Flushing the Reference Electrode

1. Select the Flowpath/Probe Maintenance button to purge the flowpath.
2. Remove the W-line and R-line from the reference electrode.
3. Lift the reference electrode off the sensor module by pulling up on the locking pin that is on the top of the reference electrode.
4. Connect a syringe (Probe Cleaning Syringe PN 02702) filled with water, that has a length of tubing attached to it, to the W-port of the reference electrode. While covering the R-port with your finger, push water through the electrode so that the water flows out of the flow cell port. Repeat by attaching the syringe to the R-port and covering the W-port while pushing water through the electrode.

6 Service Menu

The analyzer's service menu provides a means of:

- Exercising the analyzer's mechanical assemblies
- Viewing biosensor calibration data
- Printing system information
- Viewing system errors
- Installing software
- Calibrate the touch screen
- Adjust the screen brightness
- Clear the analyzer's non-volatile memory
- View calibrator and QC cartridge information

6.1 System Test

The System Test screen displays real-time biosensor data and the system temperature. On the display below the biosensor data are selections for the analyzer's mechanical assemblies. To use one of these assemblies, press the selection button for that assembly then make a selection from the drop-down list.
Press Exit to return to the Service Menu, or press Home to return to the Ready screen.

> ***NOTE:*** *The assemblies are reset when you exit the System Test screen.*

- Rotary Valve – Home, CAL A, AIR CAL A, CAL B, AIR CAL B, CAL C, AIR CAL C, CAL D, AIR CAL D, Ctrl 1, Air Ctrl 1, Ctrl 2, Air Ctrl 2, Ctrl 3, Air Ctrl 3, Dummy 1
- PUMP – STOP, Fast, Medium Fast, Medium Slow, Slow
- Waste Valve – Open, Closed
- X level – Service Use
- Sampler – Home, Air, Syringe, Pipette
- Air Oscillator – Service Use
- Reference Valve – Open, Closed

6.1.1 Operator Flow Test

The Operator Flow Test button found at the bottom of the System Test screen provides a quick means of verifying that the analyzer's flow path is not blocked or has an air leak. Pressing the Operator Flow Test button will cause the analyzer to extend the sample probe to the syringe position, open the waste valve, and turn the pump on high speed. Follow the on screen directions for using the operator flow test.

6.1.2 Service Flow Test

The Service Flow Test checks the flow of the calibrators and internal controls through the analyzer. Running the test will display the time it takes to move each calibrator and internal control through the analyzer's flow path, first with the Reference Valve closed then with the Reference Valve open.
Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.2 Sensor Subsystem

The Sensor Subsystem displays 2-point calibration data and sample analysis data for each biosensor on the analyzer. To view, select the desired biosensor from the drop down list. Calibration data is displayed on the screen and can be printed by pressing the Print button.
Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.3 Printer Menu

The printer menu provides a means of printing out the system error log, a system report, and operator passwords.

- Print System Error Log – prints the analyzers current error log.
- Print System Report – prints the analyzer's setup configuration including analyzer ID number, reference and alert limits, biosensor offsets, units of measure, results display resolution, operation, calibration and system configuration settings, screen settings, lab computer settings, and QC setup information.
- Print Operator Passwords – prints a list of operator passwords entered in the analyzer.

Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.4 Error Log

The error log displays the last 96 system errors/messages beginning with the most recent event. Use the Next Page and Previous Page buttons to scroll through the error log.
Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.5 Install Software

To install new software, first insert a USB drive containing the new software into one of the analyzer's 2 USB ports. Press Install and follow the on-screen instructions to load the new software.

6.6 Calibrate Touch Screen

If the touch screen alignment is out of adjustment, the screen can be recalibrated using Calibrate Touch Screen. Follow the on screen directions to calibrate the screen.
Press Service to return to the System Test Screen or Home to return to Ready screen.

6.7 Screen Brightness

Select Screen Brightness to increase or to decrease the screen brightness, to enable auto dimming and to select the dimming delay time.
To adjust the screen brightness, press Decrease or Increase until the screen brightness is at an acceptable level.
To enable the auto dimming feature, select ON from the drop down list. Select OFF to disable auto dimming.
If auto dimming is enabled select the dimming delay time from the drop down list.
Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.8 Clear NVRAM

Clear NVRAM is a service function and is normally not used.

6.9 RMS Data

RMS refers to the Reagent Management System pod located on the front of the reagent cartridge. The RMS pod contains the lot number, lot expiration date, the cartridge use-life, expiration date, and time of the installed reagent cartridge. Additionally an estimated number of Samples Remaining in the cartridge and estimated volumes of individual calibration standards in the cartridge are displayed.
Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.10 CMS Data

CMS refers to the Control Management System pod located on the front of the Auto-QC cartridge. The CMS pod contains the lot number, lot expiration date, the cartridge use-life, expiration date, and time of the installed control cartridge. Additionally an estimated number of Samples Remaining in the cartridge and estimated volumes of individual QC levels in the cartridge are displayed.
Press Exit to return to the System Test Screen or Home to return to Ready screen.

6.11 External Devices

The BioProfile pHOx Analyzer contains 2 USB connectors and a PS2 connector for use with devices such as a keyboard or bar code scanner. The analyzer does not support USB printers or USB mouse/trackball.
The analyzer also contains one serial port (COM1). Detailed information on the communication protocol is contained in Section 7 of this manual.
The analyzer contains 2 Ethernet connections, however they are not used.

7 Communications

This document describes how the Nova BioProfile pHOx transmits data to an external computer. Data transmission involves a low-level protocol and a high-level protocol. The low-level protocol is concerned with establishing communication, detecting errors, and sending and receiving messages. It is not concerned with message content. The high-level protocol is concerned with message content.
The protocols used are designed to conform to specifications published by the American Society for Testing and Materials (ASTM). Copies of the specifications can be obtained by contacting ASTM:

ASTM
100 Barr Harbor Drive
West Conshohocken, PA 19428-2959
USA
phone: 610-832-9585
FAX: 610-832-9555

The low-level protocol used by the Nova BioProfile pHOx is designed to conform to **ASTM E1381-91**. This document is concerned with the high level protocol only.
The following information pertains to pHOx only samples, pHOx only calibration, pHOx Only QC, and Combined results.

7.1 High-Level Protocol

The high-level protocol used by the Nova BioProfile pHOx is designed to conform to **ASTM E1394-91**.
The tables that follow describe the data records that are sent by pHOx. The column “ASTM REF” lists the section of the ASTM E1394-91 specification that defines the field. The column “ASTM NAME” lists the field name that appears in the ASTM specification.
Unless otherwise noted, any field that involves date and time conforms to section 6.6.2 of ASTM 1394-91. Each record ends with a carriage return.

7.1.1 Header Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
7.1.1	Record Type ID	Single character: “H”
7.1.2	Delimiter Definition	Standard delimiters: |\^&
7.1.3	Message Control ID	*Not Used*
7.1.4	Access Password	*Not used*
7.1.5	Sender Name or ID	NOVA^pHOx^vv..vv^dd Where ‘vv..vv’ is the version of pHOx software, and ‘dd’ is Analyzer Identification # set by the pHOx operator.
7.1.13	Version No.	Version of ASTM Spec., single char.: “1”
7.1.14	Date and Time of Message	Date and time at which message was transmitted. (This is not the time of the analysis or calibration.)

7.1.2 Test Order Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
9.4.1	Record Type ID	Single character: “O”
9.4.2	Sequence Number	Single character: “1”. (This will always be “1” because Ultra will send only one order per message.) **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
9.4.3	Sample ID	For patient samples, accession # if available; otherwise, blank. For QC analyses, the ID is one of the following: “QC0 Proficiency” “QC1 Level 1 Internal” “QC2 Level 2 Internal” “QC3 Level 3 Internal” “QC4 Level 1 External” “QC5 Level 2 External” “QC6 Level 3 External” “QC7 Level 4 External” “QC8 Level 5 External” For calibrations, this field is blank.
9.4.4	Instrument Sample ID	Sample Number from pHOx’s Sample Number Counter.
9.4.16	Sample Descriptor	For samples, this is the sample type (“Pipette”). For QC samples, this is “Control”. For calibrations, this is “Cal”.

7.1.3 Result Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION__
10.1.1	Record Type	Single character: “R”
10.1.2	Sequence Number	Counts the parameters sent for this order; ‘1’ for the first parameter, ‘2’ for the second, etc. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
10.1.3	Universal Test ID	Four or five components; the first three are not used (see sections 6.6.1.1-6.6.1.3 of ASTM E1394-91). The fourth is a parameter name assigned by NOVA. The fifth, if present, will be the parameter type; it will be one of the following: C - Calculated D - Default E - Entered M - Measured T - Temperature Corrected **NOTE:** Parameter names are listed elsewhere in this document.
10.1.4	Data or Measurement Value	Value of the parameter as an ASCII string.
10.1.5	Units	Abbreviation of units.
10.1.7	Result Abnormal Flags	HH - Above High Panic value H - Above High Reference value L -Below Low Reference value LL- Below Low Panic value > - Above the range of the analyzer < - Below the range of the analyzer When calibration data is sent, this field will be one of the following: A - (abnormal) channel is not calibrated N - (normal) channel is calibrated **NOTE:** When this field is blank, at least one of the following is true: a. A reference range has been set, and the measurement is within the reference range. b. A reference range has not been set, but a panic range has been set, and the measurement is within the panic range. c. Neither a reference range nor a panic range has been set. d. The sample is a Q.C. sample.

10.1.9	Result Status	'F' - final results (Results do not require remote review.) There is no remote review mode on the pHOx.
10.1.11	Operator Identification	Operator ID#
10.1.12	Date/Time Test Started	Date&time at which the analysis or cal. started.
10.1.14	Instrument Identification	pHOx Analyzer ID.

7.1.4 Comment Record

Comment Record(s) will immediately follow a Test Order if and only if there were any errors during sample analysis. There will be one Comment Record for each error.

ASTM REF	ASTM NAMEpHOx IMPLEMENTATION	
11.1.1	Record Type	Single character: "C"
11.1.2	Sequence Number	Counts the comments sent for this order; '1' for the first comment, '2' for the second, etc. **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
11.1.3	Comment Source	Single character: "I"
11.1.4	Comment Text	An error code followed by descriptive text. (e.g., "22 PO_2 Instability").
11.1.5	Comment Type	Single character: "I"

7.1.5 Message Terminator Record

ASTM REF	ASTM NAME	pHOx IMPLEMENTATION
13.1.1	Record Type	Single character: "L"
13.1.2	Sequence Number	For this record type this is always "1". **NOTE:** This is NOT the Frame Number (FN) referred to in ASTM E1381-91.
13.1.3	Termination Code	One of the following: N - normal termination T - sender aborted

7.1.6 Parameter Names

The parameter names listed here are used as *Manufacturer's or Local Code* (see ASTM E1394-91 sec. 6.6.1.4). They are used to create the Universal Test ID field of the result record (see Result Record above and see ASTM E1394-91 sec. 10.1.3). In most cases only a subset of these parameters will be transmitted. For example, during setup of the pHOx, the operator can disable transmission of any or all of the following:

- Analysis diagnostic data
- Calibration diagnostic data
- Calibration drift data

Parameter Name	Units	Description
pH	*None*	pH Concentration
pH_SM	mV	pH Sample Millivolts
pHTC	*None*	pH Conc. Corrected to Temperature
pH_M1	mV	pH Millivolts #1
pH_M2	mV	pH Millivolts #2
pH_M3	mV	pH Millivolts #3
pH_M4	mV	pH Millivolts #4
pH_SL	*None*	pH Slope
pH_D1	*None*	pH Drift #1
pH_D2	*None*	pH Drift #2
pH_V1	*None*	pH Calibration Std. Value #1
pH_V2	*None*	pH Calibration Std. Value #2
PO2	mmHg, kPa	PO_2 Concentration
PO2TC	mmHg, kPa	PO_2 Conc. Corrected to Temperature
PO2_SM	mV	PO_2 Sample Millivolts
PO2_M1	mV	PO_2 Millivolts #1
PO2_M2	mV	PO_2 Millivolts #2
PO2_M3	mV	PO_2 Millivolts #3
PO2_SL	*None*	PO_2 Slope
PO2_D1	*None*	PO_2 Drift #1
PO2_V1	*None*	PO_2 Calibration. Gas Value #1

PCO2	mmHg, kPa	*P*CO_2 Concentration
PCO2_SM	mV	*P*CO_2 Sample Millivolts
PCO2TC	mmHg, kPa	Corrected *P*CO_2 Concentration
PCO2_M1	mV	*P*CO_2 Millivolts #1
PCO2_M2	mV	*P*CO_2 Millivolts #2
PCO2_SL	*None*	*P*CO_2 Slope
PCO2_D1	*None*	*P*CO_2 Drift #1
PCO2_D2	*None*	*P*CO_2 Drift #2
PCO2_V1	*None*	*P*CO_2 Calibration. Gas Value #1
PCO2_V2	*None*	*P*CO_2 Calibration. Gas Value #2
BP	mmHg	Barometric Pressure
TempM	deg C, deg F	Measurement Temperature
HCO3-	mmol/L	Bicarbonate Ion Concentration
TCO2	mmol/L	Total CO_2

7.2 Examples

The following examples do not include any special characters such as ENQ and STX. Also, each line ends before the checksum.

7.2.1 pHOx Sample

```
<STX>1H|\^&|||NOVA^Bio-pHOx^V00.00^007|||||||1|20001205161800<CR><ETX>8F<CR><LF>
<STX>2P|1||008033<CR><ETX>65<CR><LF>
<STX>3O|1|22602|80||||||||||||Arterial||||||||||F<CR><ETX>BD<CR><LF>
<STX>4R|1|^^^pH^M|7.309|||||F|||20001205134500||007<CR><ETX>25<CR><LF>
<STX>5R|2|^^^PCO2^M|16.5|mmHg||||F|||20001205134500||007<CR><ETX>D5<CR><LF>
<STX>6R|3|^^^PO2^M|131.8|mmHg||||F|||20001205134500||007<CR><ETX>C5<CR><LF>
<STX>7R|4|^^^HCO3-^C|8.4|mmol/L||||F|||20001205134500||007<CR><ETX>6C<CR><LF>
<STX>0R|5|^^^TCO2^C|8.9|mmol/L||||F|||20001205134500||007<CR><ETX>49<CR><LF>
<STX>1R|6|^^^AirSat^C|88.7|%||||F|||20001205134500||007<CR><ETX>A2<CR><LF>
<STX>2R|7|^^^CO2Sat^C|2.3|%||||F|||20001205134500||007<CR><ETX>0A<CR><LF>
<STX>3R|8|^^^TempP^D|37.0|deg C||||F|||20001205134500||007<CR><ETX>AA<CR><LF>
<STX>4R|9|^^^BP^M|757.9|mmHg||||F|||20001205134500||007<CR><ETX>99<CR><LF>
<STX>5R|10|^^^TempM^M|36.9|deg C||||F|||20001205134500||007<CR><ETX>E3<CR><LF>
<STX>6R|11|^^^pH_SM^M|246.88|||||F|||20001205134500||007<CR><ETX>90<CR><LF>
<STX>7R|12|^^^PCO2_SM^M|101.46|||||F|||20001205134500||007<CR><ETX>DE<CR><LF>
<STX>0R|13|^^^PO2_SM^M|-112.35|||||F|||20001205134500||007<CR><ETX>C2<CR><LF>
<STX>1R|14|^^^pH_M1^M|240.57|||||F|||20001205134500||007<CR><ETX>62<CR><LF>
<STX>2R|15|^^^PCO2_M1^M|112.45|||||F|||20001205134500||007<CR><ETX>BB<CR><LF>
<STX>3R|16|^^^PO2_M1^M|-137.34|||||F|||20001205134500||007<CR><ETX>AC<CR><LF>
<STX>4R|17|^^^pH_SL^M|10.80|||||F|||20001205134500||007<CR><ETX>50<CR><LF>
<STX>5R|18|^^^PCO2_SL^M|10.55|||||F|||20001205134500||007<CR><ETX>B0<CR><LF>
<STX>6R|19|^^^PO2_SL^M|-8.65|||||F|||20001205134500||007<CR><ETX>74<CR><LF>
<STX>7L|1|N<CR><ETX>0A<CR><LF>
```

7.2.2 pHOx Only QC Sample

```
1H|\^&|||NOVA^pHOx^I00.53^123||||||||1|19980827180000
2P|1||123456
3O|1|QC4 Level 1 External|0|||||||||||Control|||||||||F
4R|1|^^^pH^M|7.309|||||F|||20001205134500||00725
5R|2|^^^PCO2^M|16.5|mmHg||||F|||20001205134500||007D5
6R|3|^^^PO2^M|131.8|mmHg||||F|||20001205134500||007C5
7R|4|^^^HCO3-^C|8.4|mmol/L||||F|||20001205134500||0076C
0R|5|^^^TCO2^C|8.9|mmol/L||||F|||20001205134500||00749
1R|6|^^^AirSat^C|88.7|%||||F|||20001205134500||007A2
2R|7|^^^CO2Sat^C|2.3|%||||F|||20001205134500||0070A
3R|8|^^^TempP^D|37.0|deg C||||F|||20001205134500||007AA
4R|9|^^^BP^M|757.9|mmHg||||F|||20001205134500||00799
5R|10|^^^TempM^M|36.9|deg C||||F|||20001205134500||007E3
6R|11|^^^pH_SM^M|246.88|||||F|||20001205134500||00790
7R|12|^^^PCO2_SM^M|101.46|||||F|||20001205134500||007DE
0R|13|^^^PO2_SM^M|-112.35|||||F|||20001205134500||007C2
1R|14|^^^pH_M1^M|240.57|||||F|||20001205134500||00762
2R|15|^^^PCO2_M1^M|112.45|||||F|||20001205134500||007BB
3R|16|^^^PO2_M1^M|-137.34|||||F|||20001205134500||007AC
4R|17|^^^pH_SL^M|10.80|||||F|||20001205134500||00750
5R|18|^^^PCO2_SL^M|10.55|||||F|||20001205134500||007B0
6R|19|^^^PO2_SL^M|-8.65|||||F|||20001205134500||00774
7L|1|N0A
5R|24|^^^S1_SM^M|201.127|||||F||1|19980827175800||123
6R|25|^^^S2_SM^M|170.187|||||F||1|19980827175800||123
7R|26|^^^S1_M1^M|200.144|||||F||1|19980827175800||123
0R|27|^^^S2_M1^M|169.418|||||F||1|19980827175800||123
1R|28|^^^S1_SL^M|0.770|||||F||1|19980827175800||123
2R|29|^^^S2_SL^M|1.104|||||F||1|19980827175800||123
3L|1|N
```

A Appendix

Appendix A includes analyzer specifications, solutions and reagents, consumable lists, reference information, and warranty for the BioProfile pHOx Analyzer.

A.1 BioProfile pHOx Specifications*

Measurement Range:	pH	5.00 - 8.00	
	PCO_2	3.0 - 400 mmHg	0.4 - 53.3 kPa
	PO_2	0 - 800 mmHg	0.0 - 106.7 kPa
	BarP	400.0 - 800.0 mmHg	53.3 - 106.7
	kPa	15.7 - 31.5 inHg	

Calculated Result Resolution:	HCO_3	0.1 mmol/L
	TCO_2	0.1 mmol/L
	Air Sat	0.1 %
	CO_2 Sat	0.1 %

Acceptable Samples: Aqueous Cell Culture/Fermentation

Measuring Technology: Ion Selective Electrodes (pH, PCO_2)
Amperometry (PO_2)

Analysis Rate:

Stat Analysis Time	Throughput Time
45 seconds	60 seconds

Sample Volume: 300 microliters sample size for full panel

Barometer: 400 - 800 ±1 mmHg, accurate to 1.5 mmHg

Slope Limits:	pH	9.1 - 11.6
	PO_2	-15.0 - (-1.6)
	PCO_2	7.9 - 12.6

Slope and Offset Limits:	Slope	Offset
pH	0.700 - 1.300	-2.000 - 2.00
PCO_2	0.70 - 1.30	-20.0 - 20.0
PO_2	0.70 - 1.30	-30.0 - 30.0

*Specifications are subject to change.

Analytical Specifications for Imprecision

Analyte	Within-run Precision n=10		Day-to-Day Precision n=10	
	Whichever is Greater		Whichever is Greater	
	CV%	SD	CV%	SD
pH		0.005		0.013
PCO_2	3.0	1.0 (mmHg)	5.0	2.0 (mmHg)
PO_2	3.0	1.5 (mmHg)	5.0	3.0 (mmHg)

Electrical Compliance: Meets IEC 1010, UL, and CSA standards

Temperature Thermostatting: 37 °C ± 0.1 °C

Dimensions: Height: 15.0 in (38.1 cm)
Width: 12.0 in (30.5 cm)
Depth: 15.0 in (38.1 cm)

Weight: 18 lb (8.19 kg) without reagent pack
23 lb (10.45 kg) with full reagent pack

Power: 100-120; 220-240 VAC, 50/60 Hz, 130W

Environmental: Indoor use at temperature of 15°C - 30°C (59°F - 86°C);
Altitude up to 2000 meters;
Relative Humidity of 0-85% (noncondensing)

Lifting the Analyzer:

1. One person is needed to lift the analyzer.

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

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

*Specifications are subject to change.

A.2 Reagents and Solutions

This section covers the reagents and solutions required for proper operation and maintenance of the BioProfile pHOx Analyzer.

A.2.1 Reagents and Solutions

Reagents and solutions are as follows:

1. Reagent Cartridge: PN 41874
2. pH Electrode Conditioning Solution: PN 23397
3. Preheater Cleaning Agent: PN 11802
4. Nova BioProfile pHOx Controls external:
    - Level 1 - with pH, high PCO_2, low PO_2 PN 22600
    - Level 2 - with pH, PCO_2, and PO_2 PN 22601
    - Level 3 - with pH, low PCO_2, high PO_2 PN 22602
5. Nova BioProfile pHOx Auto-cartridge QC: PN 42751
6. Nova Deproteinizing Solution: PN 12704

Nova will not be responsible for any of its warranties on sensors, electrodes, tubing, probes, 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. Some reagent formulations not manufactured by Nova contain acids, concentrated salt solutions, and artificial preservatives which have been shown to cause problems such as shortened sensor/electrode life, sensor/electrode membrane damage, sensor/electrode drift, erratic analytical results, and unacceptable instrument performance.

> ***NOTE:*** *Refer to the Nova BioProfile Control insert for storage requirements for these controls. Store all other Nova Stat Profile reagents, standards, and solutions at 15 to 30° C.*

A.2.2 Reagent Cartridge

The concentrations of the internal standards are printed on the reagent cartridge. In addition to the reagents and solutions, the reagent cartridge has a self-contained waste bag for safe disposal of waste.

A.2.3 Verifying the Analyzer's Performance

Nova Biomedical recommends that each laboratory performs the following minimum QC procedures on each analyzer:

- BioProfile pHOx Controls Levels 1, 2, 3
  - Analyze all 3 levels of controls once every day.
  - After performing electrode maintenance, analyze all 3 levels of controls.

CAUTION: *The sensor performance of the analyzer may be affected by use of controls other than Nova BioProfile pHOx Controls. Contact Nova Biomedical for additional information.*

A.2.3.1 Nova BioProfile pHOx External Controls Levels 1, 2, 3: Quality Control

The Nova BioProfile pHOx Controls are formulated as Levels 1, 2, and 3:

Level 1 - with pH, PCO_2, PO_2

Level 2 - with pH, PCO_2, and PO_2

Level 3 - with pH, PCO_2, PO_2

The ampules must be at 25° C for at least 24 hours before opening.

> ***CAUTION:*** *The sensor performance of the analyzer may be affected by use of controls other than Nova BioProfile pHOx Controls.*

Analyze the Nova BioProfile pHOx Control Levels 1, 2, 3, as follows:

1. Before opening, shake the ampule for about 10 seconds.
2. Protect the fingers with tissue or gloves. Snap open the ampule.

   > ***CAUTION:*** *Analyze the liquid within 30 SECONDS of opening to prevent contamination with room air and alteration of stated values.*

3. Press QC, select level, present the control, press Continue (soft key) to initiate aspiration, and press Analyze (soft key) to present sample to sensors.
4. Compare the results with those listed in the assay data sheet included with the controls.

A.3 Reference Values

Each laboratory should establish and maintain its own reference values.

A.4 Ordering Information

Supplies and parts for the BioProfile pHOx Analyzer are available from Nova Biomedical.

DESCRIPTION	Part #
Maintenance Log	33578
Reference Manual	52942
Air Detector (Sample)	21513
Bar Code Scanner (optional)	23591
BioProfile pHOx Reagent Cartridge	41874
Blank Sensor (Electrode)	22507
Clot Removal Tool	18431
Deproteinizing Solution	12704
Electrode Conditioning Holder	09458
Flowcell Interconnect Tubing	23105
Flush Fixture (QC Cartridge)	24819
Flush Fixture (Reagent Cartridge)	24327
Line Power Cord	01498
PCO_2 Conditioning Solution	06857
PCO_2 Sensor and Washer	21524
PCO_2 Membrane Kit	25048
pH Sensor Conditioning Solution	23397
Pipette Adapter Packaged	45648
pH Sensor	21522
PO_2 Sensor	21521
PO_2 Membrane Kit	21795
Preheater Cleaning Agent	11802
Printer Paper (5 Rolls)	23298
Probe Cleaning Kit	02702
Reference Electrode	21520
Reference Line	21497
Sample Probe Assembly	21519
Sensor Module	34653
BioProfile External Control Level 1	22600
BioProfile External Control Level 2	22601
BioProfile External Control Level 3	22602
BioProfile pHOx Auto-Cartridge QC	42751
Waste Line	21926
W/R Pump Tube assembly (W/R Tubing only)	49846
W/R Pump Tube assembly (with Waste & Reference Segments)	49847

A.5 Shutdown Procedure

If the analyzer is to be turned off for more than 24 hours, flush the tubing harness first with distilled water then with air. Use the Flush Fixture (PN 24327 & PN 24819) to perform this procedure.

> ***NOTE:*** *If the analyzer is to be shutdown for more than 1 week, remove the sensors and rinse and dry the flow cell.*

1. Remove the Reagent Cartridge from the analyzer.
2. Install the Flush Fixture (PN 24327) into the analyzer in the same way as the Reagent Cartridge.
3. Install the QC Cartridge Flush Fixture (PN 24819) into the analyzer the same way as the QC Cartridge.
4. Place the W-line of the fixtures into an empty container.
5. Place the other tubing ends into a beaker of distilled water.
6. From the Ready/Not Ready screen, press Menu (soft key).
7. Select Flowpath Maintenance and press Enter.
8. Press Purge (soft key).
9. When the cycle ends, take all the tubings out of the distilled water. Leave the W-line in its container.
10. Repeat the purge with air.
11. When this cycle is completed, remove the flush fixtures.
12. Relax the pump tubing by removing one of the mounting blocks from its bracket.
13. Remove the sections of the W & R lines from the pinch valves.
14. Release the spring pressure from each of the sensors by pressing the release tab.
15. The pHOx Analyzer is now ready to be powered off for extended time.

A.6 Warranty

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

The following exceptions apply:

1. The pH, PCO_2, PO_2, and reference electrodes 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/electrode does not meet that use life, then Nova Biomedical will replace that sensor/electrode at no charge under this warranty. This warranty is invalid under the conditions specified after item 3.
2. Consumable items, including the reagent pack, calibration gases, replaceable membranes, tubing and tubing harnesses, electrolyte solutions, external standards, and septum assemblies 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 3.
3. Freight is paid by the customer.

The above warranties are invalid if:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows:

   Nova Biomedical will not be responsible for any warranties on sensors/electrodes, tubing, probes, septa, 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/electrode and septa life, sensor/electrode membrane damage, sensor/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.

B Theory

This section explains instrument theory of the BioProfile pHOx Analyzer.

B.1 Sensor Calibration

B.1.1 Two-Point Calibration

The analyzer uses a 2-point calibration to set sensor slope and verify sensor performance. The Reagent Cartridge contains the standards which are used for this purpose. Calibration can be initiated manually by pressing CALIBRATE and is also initiated automatically by the system at intervals of 2, 4, or 6 hours depending on user setup.

B.1.2 One-Point Calibration

Sensor drift is the slow variation in sensor response over time. The determination of the activity for an unknown sample is dependent on both the sensor potential generated by the unknown and that generated by the standard. The analyzer uses a 1-point calibration to monitor and minimize the effect of the sensor drift on the analytical results. A 1-point calibration occurs at 30 or 45 minute intervals and is independent of the sample cycle.
A drift error code is displayed when sensor drift is beyond the drift limits.

B.2 Parameter Definitions

Definition of pH

The pH of an unknown sample is calculated using the following equation:

$$pH_x = pH_{Std\ C} + \frac{E_{Std\ C} - E_x}{Slope} \qquad \text{Equation 1}$$

$$\text{where Slope} = \frac{E_{Std\ C} - E_x}{pH_{Std\ C} - pH_{std\ D}} \qquad \text{Equation 2}$$

Principle of pH Measurement

pH is measured using a hydrogen ion selective glass membrane. One side of the glass 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, then, of the pH of the unknown solution.

B.2.1 Partial Pressure of Carbon Dioxide (PCO_2)

Definition of 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.

Principle of PCO_2 Measurement

PCO_2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a gas permeable membrane mounted on a combination measuring/reference electrode. CO_2 diffuses across the membrane into a thin layer of electrolyte solution in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure. CO_2 in the solution becomes hydrated producing carbonic acid which results in a change in hydrogen ion activity.

$$CO_2 + H_2O <=> H_2CO_3 <=> H^+ + [HCO_3^-] \qquad \text{Equation 3}$$

The electrolyte solution behind the membrane is in contact with a glass hydrogen ion selective sensor. The change in hydrogen ion activity in the electrolyte solution produces a potential which is measured against the internal filling solution. This change in potential is measured against the constant potential of the reference electrode half cell and is logarithmically related to the PCO_2 of the unknown sample.

B.2.2 Partial Pressure of Oxygen (PO_2)

Definition of 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.

Principle of PO_2 Measurement

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.3 Calculated Values

The analyzer's microcomputer uses the measured results to calculate other valuable parameters. This section outlines the equations used to calculate these values.

B.3.1 Temperature Correction for Measured Values*

The BioProfile pHOx 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:

$$pH_{(corrected)} = pH + [- 0.0147 + 0.0065 (7.400 - pH)](T - 37) \quad \text{Equation 4}$$

$$PCO_{2\ (corrected)} + PCO_2 \times e\ (0.04375\ (T - 37)) \quad \text{Equation 5}$$

$$PO_{2\ (corrected)} = PO_2 \times 10^{U} \quad \text{Equation 6}$$

where $U = ([\ \frac{(5.49 \times 10^{-11})\ Y + 0.071}{(9.72 \times 10^{-9})\ Y + 2.30}\ ] \times (T - 37))$ and $Y = e\ [3.88 \times \ln (PO_2)]$

*The equations are from NCCLS standards[2].

B.3.2 Calculated Parameters

Calculated Bicarbonate Concentration [HCO_3^-]*

Bicarbonate Concentration (mmol/L) is calculated using the Henderson-Hasselbalch equation:

$$pH = pK + \log \frac{[HCO_3^-]}{\alpha(PCO_2)} \quad \text{Equation 7}$$

where pH and PCO_2 are measured.

pK = 6.091

α = 0.0307 = solubility coefficient of CO_2 in solution at 37 °C

Rearranging Equation 7 gives:

$$\log_{10} [HCO_3^-] = pH + \log_{10} PCO_2 - 7.604 \quad \text{Equation 8}$$

*The equations are from NCCLS standards[2].

Total Carbon Dioxide Content (TCO_2)*

TCO_2 (mmol/L) includes both dissolved carbon dioxide and $[HCO_3^-]$ and is calculated as follows:

$$TCO_2 = [HCO_3^-] + \alpha(PCO_2) \qquad \text{Equation 9}$$

where PCO_2 is measured and $[HCO_3^-]$ is calculated from Equation 8.

*The equations are from NCCLS standards[2].

Air Saturation %

$$\text{Air Saturation \%} = \frac{PO_2 \text{ mmHg}}{(\text{BP mmHg} - 47) \times 0.209} \times 100\% \qquad \text{Equation 10}$$

CO_2 Saturation %

$$CO_2 \text{ Saturation \%} = \frac{PCO_2 \text{ mmHg}}{(\text{BP mmHg} - 47)} \times 100\% \qquad \text{Equation 11}$$

References:

1. Mohan, M.S. and Bates, R.G. 1977. *Blood pH, Gases and Electrolytes.* NBS Special Publication, 450. U.S. Government Printing Office.
2. National Committee for Clinical Laboratory Standards. 1982. *Tentative Standard for Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis.* NCCLS 2:10.
3. Williams, W.J., Beutler, E., Ersley, A.J., and Rundles, R.W. 1977. *Hematology.* 2nd ed. McGraw-Hill Co.
4. Tietz, Norbert W., ed. 1986. *Textbook of Clinical Chemistry.* W.B. Saunders Co. Philadelphia, Penn.