REF 53097 Rx Only IVD CE

Stat Profile® PRIME™ ABG Analyzer

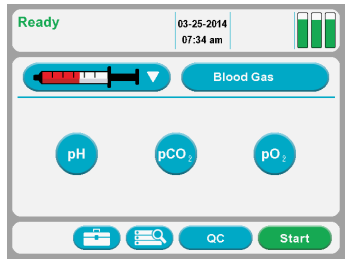


Instructions for Use Manual

nova® biomedical

Nova Prime Quick Start Guide

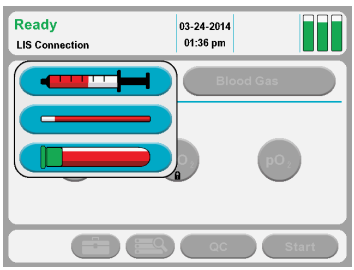
1. Confirm the analyzer is **Ready** for analysis.
   Displays **Ready**, desired test menu shows no **Orange** Icons.

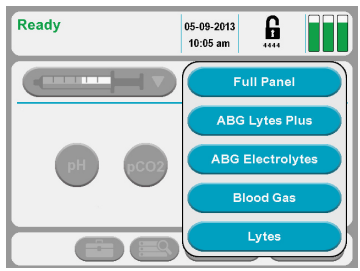


2. Login if necessary. Press the Login 

icon then enter or scan your User ID and Password.

3. Select the Sample Container and the Panel.





4. Prepare the sample for analysis then press **Start** to extend the sample probe.

5. Position the sample over the sample probe then press **Aspirate** to aspirate the sample.



6. Enter any additional patient or sample information needed while the analysis is completed.

7. Review results.

NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD — *In vitro* diagnostic medical device

CE — Product fulfills the requirements of Directive 98/79 EC (IVDD)

Caution, consult accompanying documents

Consult instructions for use

Biological risk

REF — Catalog number

Manufactured by

CONTROL — Control

LEVEL — Level

LOT — Batch code

SN — Serial Number

Temperature limitation

Upper Limit of Temperature

Use by (last day of the month)
YYYY - MM

Electronic Waste

EC REP — Authorized Representative in the European Community



Laser Radiation - Do Not Stare Into Beam
Class II/IEC 825 Laser Product
Wavelength: 655 nm

℞ — Prescription Use Only

Stat Profile PRIME ABG Instructions for Use Manual

Ordering Information

The *Stat Profile PRIME ABG Instructions for Use Manual* can be ordered from Nova Biomedical Order Services. Write or call:

Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454-9141
U.S.A.

Telephone:1-800-458-5813
FAX: 1-781-893-6998
(in the U.S.A.)
+1-781-899-0417
(outside the U.S.A.)
Web: www.novabiomedical.com

The Stat Profile Prime ABG is manufactured in the USA by Nova Biomedical Corporation.

EC REP Authorized Representative

Nova Biomedical UK
Innovation House
Aston Lane South, Runcorn
Cheshire, WA7 3FY, UK

Telephone:+ 44 1928 704040
Fax:+ 44 1928 796792

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Nova Biomedical Canada Ltd.
17 - 2900 Argentia Road
Mississauga, Ontario L5N 7X9
Canada
Tel: 1-800-263-5999
1 905 567 7700

Nova Biomedical France
Parc Technopolis - Bât. Sigma
3 avenue du Canada 1er étage
Les Ulis courtaboeuf
91940
France
Tel: + 33 1 64 86 11 74

Nova Biomedical UK
Innovation House
Aston Lane South, Runcorn
Cheshire, WA7 3FY
UK
Tel: + 44 1928 704040

Nova Biomedical GmbH
Messenhauser Str. 42
Roedermark
Urberach 63322
Germany
Tel: + 49 6074 8448 0

Nova Biomedical KK
Mita43MT Bldg-7F,
Mita 3-chome,
Minato-ku, Tokyo 108-0073
JAPAN
Tel: +81 3-5418-4141
Fax: +81 3-5418-4676

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1 Introduction

This manual provides all necessary instructions for the routine operation and upkeep of the Stat Profile Prime ABG Analyzer. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Analyzer.

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



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

1.1 About This Manual

This manual is for the Stat Profile Prime ABG 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.

1.2 Safety

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

General Safety

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

Electrical Safety

1. To reduce the risk of electric shock, do not remove the cover.
2. There are no user serviceable parts inside the analyzer.
3. Servicing must be done by qualified service personnel.
4. To reduce the risk of fire or electric shock, do not expose the analyzer to water.
5. Use Nova Part Number 52413 external power supply to power up the analyzer.
6. Ensure that the wall outlet receptacle is properly wired and earth grounded.
7. DO NOT use a 3-to-2 wire plug adapter.
8. DO NOT use a 2-wire extension cord or a 2-wire multiple-outlet power strip.

Chemical and Biological Safety

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

1.3 Installation and Use

This section covers the installation requirements and assembly procedures for the Stat Profile Prime ABG Analyzer. Prior to use of the analyzer, operators should be familiar with Chapter 2 Operation and Chapter 3 Operating Procedures.

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

1.4 Requirements

Working Area Requirements (Environmental):
Keep the working area around the system free of dirt, corrosive fumes, vibration, and excessive temperature changes.

Electrical Requirements:

- Operating Voltage Range: 100 - 240 VAC
- Operating Frequency: 50 - 60 Hz
- Power Consumption: Less than 100 Watts

Ambient Operating Temperature:

- 15°C to 32°C (59°F to 89.6°F)

Operate at Humidity:

- 20 to 85% without condensation

Operate at Altitude:

- up to 12,000 feet/3650 meters

Dimensions:

Height:	15.4 in (39.1 cm)
Width:	12.0 in (30.5 cm)
Depth:	14.4 in (36.2 cm)

Weight:

17.5 lb (8.164 kg) without reagent pack
23 lb (10.45 kg) with full reagent pack

Lifting the Analyzer:

1. One person is needed to lift the analyzer.

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

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

1.5 Intended Use, Tests Performed, and Clinical Utility

Intended Use

The **Stat Profile Prime ABG Analyzer System** is intended for *in vitro* diagnostic use by health care professionals in clinical laboratory settings and for point-of-care usage for the quantitative determination of pH, PCO_2, and PO_2 in heparinized whole blood.

Measured Parameters

Stat Profile Prime ABG Analyzer: pH, PCO_2, and PO_2

Calculated Parameters

From the directly measured results, the calculated results are shown in Table 1-1.

Table 1-1. Calculated Parameters

Calculated Parameters
pH, PCO_2, PO_2 (corrected to patient temperature)
Bicarbonate level (HCO_3^-)
Total Carbon Dioxide (TCO_2)
Base Excess of the blood (BE-b)
Base Excess of extracellular fluid (BE-ecf)
Standard Bicarbonate Concentration (SBC)
Oxygen Content (O_2Ct)
Oxygen Capacity (O_2Cap)
Alveolar Oxygen (A)
Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)
Arterial Alveolar Oxygen Tension Ratio (a/A)
Respiratory Index (RI)
PO_2/FIO_2 ratio
Oxygen Saturation (SO_2%)

Clinical Utility[1] The following list includes the clinical utility information for each of the analytes measured on the Stat Profile Prime ABG Analyzer.

PCO_2, PO_2, pH Whole blood measurement of certain gases in whole blood, or pH of whole blood, is used in the diagnosis and treatment of life-threatening acid-base disturbances.

Ref. 1. Burtis, Carl A. Ashwood, Edward R., Burns, David R., 2011. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 5th ed,* Philadelphia, PA: W. B. Saunders Co.

1.6 The Sample

Lithium heparin whole blood samples from syringes, open tubes, small cups, and capillary tubes can be used on the Stat Profile Prime ABG Analyzer. The minimum sample size for analysis is 50 µL.

1.6.1 Handling Requirements

pH, PCO_2, PO_2

Correct sample handling is critical to ensure that the blood gas values obtained accurately reflect the *in vivo* state. Ensure that all samples have been obtained and stored following consistent, clinically 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 within 15 minutes for blood gases. Storing samples on ice is not recommended. Using iced samples may elevate the PO_2 result.[1]

1. Clinical and Laboratory Standards Institute (CLSI), (March 4) 2009, *Blood Gas and pH Analysis and Related Measurements*; Approved Guideline—Second Edition (C46-A2).

1.6.2 Acceptable Anticoagulants

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

CAUTION: Stat Profile Prime ABG Analyzer users should take careful note of these considerations when establishing reference intervals and interpreting results.

2 Getting Started

The Stat Profile Prime ABG Analyzer is pictured below.



Figure 2.1 Nova Stat Profile Prime ABG

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



Figure 2.2 Analytical Compartment

1. Waste Line
2. Reference Line
3. Pump and Pump Tubing Cartridge
4. Calibrator Cartridge Opening
5. Control Cartridge Opening
6. Sampler
7. Air Detector
8. Micro Sensor Card (under cover)
9. Reference Sensor (under cover)

2.1 Power Up Procedure

When the analyzer is powered on, it displays the Stat Profile Prime ABG logo. During this time, an internal Power On Self Test (POST) is run. Any errors encountered during the POST will display on the analyzer's screen.

After successfully completing the POST, the Home screen displays with **Initializing**. During initialization, an internal diagnostic sequence is run: the Micro Sensor Card use life; the calibrator cartridge fluid level; and the internal QC cartridge fluid level are checked.

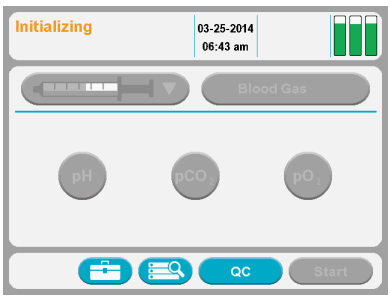


*Figure 2.3 **Initializing** Screen*

The Prime ABG performs a prime cycle. After completion, the screen displays **Not Ready**.



*Figure 2.4 **Not Ready** Screen*

2.2 The Home Screen: Ready

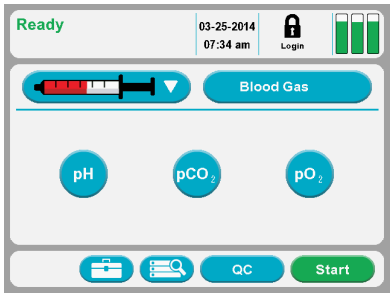


*Figure 2.5 Home Screen: **Ready***

The screen of the Prime ABG Analyzer is a Touch-screen. The touch-screen display provides prompts, menus, status information, sensor status, panel selection, date and time, etc.

2.2.1 Header Bar

The Header Bar is the top section of the display. This is where **Ready** or **Not Ready**, Date and Time, Login, and Micro Sensor Card, Calibrator Cartridge, and Control Cartridge status are displayed.



The current Date and Time is displayed.



When a timed operation is in process, the Date and Time is replaced by a countdown timer.



Login with a Lock icon is displayed in the Header Bar. Press the Lock and proceed to login with your Operator ID and password.



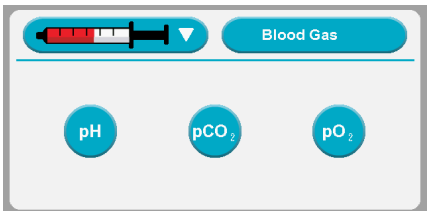
Only one person can be logged into the analyzer at a time. When logged onto the analyzer, an open lock is shown with the logged in operator ID displayed under it.

The analyzer can also be run with the login featured turned off.

The upper right corner of the Home screen (Header Bar) has the Status Graph which when touched will display the status of the Micro Sensor Card, calibrator cartridge, and QC cartridge.

2.2.2 Selection Area

The Selection Area is the middle of the display. Panel selection, Sample container selection, and sensor availability are selected here.



- Analytes that are displayed in **Orange** are not available for analysis. If you press the icon of the **Orange Analyte**, the Sensor Status Screen with additional information will display.

- Analytes that are displayed in **Blue** are available and selected for analysis. If you press the icon of a **Blue Analyte**, it turns **Grey** indicating it is not selected for analysis.

- Analytes that are displayed in Grey are available but not selected for analysis. If you press the icon of a **Grey Analyte**, it turns **Blue** indicating it is selected for analysis.

The Container icon  allows you to select the type of container and sample to be analyzed.

The Panel icon 

allows you to select from a predefined list of test panels.

2.2.3 Sensor Status Screen

Analytes that are displayed in **Orange** are not available for analysis. If you press the icon of the **Orange Analyte**, a Sensor Status Screen with additional information will display.

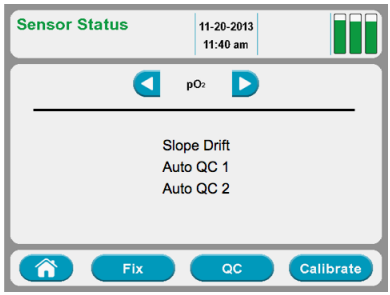


Figure 2.6 Sensor Status Screen

The Sensor Status Screen displays the status of the orange analyte that you pressed. Detected sensor errors or QC Lockout conditions are displayed on the screen.

- Touching the Calibrate button starts a Calibration sequence then returns to the Home Screen.
- Touching the QC button displays the Analyze QC Screen if more than one Internal QC is locked out or an External QC is locked out for all the sensors.
- Touching the QC button starts the QC Level sequence for the QC Lockout then returns to the Home Screen if there is only 1 Internal QC Locked out for all the sensors.
- Touching the Fix button starts a Calibration sequence then returns to the Home Screen.
- If all sensors pass Calibration from a Fix, all Internal QCs that failed QC Lockout will be executed.
- Touching the Right Arrow button displays the status of the next sensor that is not available.
- Touching the Left Arrow button displays the status of the prior sensor that is not available.

2.2.4 Menu Bar



The Menu Bar is the bottom section of the screen. The Tool Box icon (System Menu screens), Find Results icon, QC icon (to run QC and QC Menu Screens), and the Start (Run Test) or Calibrate icon.



The Home icon returns the analyzer to the Home screen by touching this icon. This icon does not display on the Home screen.



The Tool Box icon is located at the Menu Bar. Press this icon to display Screen one of the System Menus. The up/down arrow key is pressed to display screen two. From the System Menu, you can also navigate to the Setup Menu.



The recall results icon of the Menu Bar will display all the patient results stored on the analyzer.



The QC icon will display the QC Menu screen: Run QC, Setup QC Levels, View QC Data, and Setup QC Operations.



The Calibrate icon is displayed when all analytes are not calibrated. Press **Calibrate** to initiate a system calibration.



If one or more analytes are calibrated, the Start icon displays. Press **Start** to begin an analysis.



The Prime icon is displayed in the footer after an Auto QC Cartridge, a Control Cartridge, or tubing is replaced. Press **Prime** to initiate a system prime.



Pressing the Enter icon moves the analyzer to the next screen in the procedure.

Screens may contain other navigational icons including:

Press the Back icon to return to the previous screen.

The Page Up and Page Down icons scroll through the menus that have multiple pages.

2.3 Login to Analyzer

From the Home screen, login if you are prompted to login.

1. Press the **Login** icon to log into the analyzer.
2. Enter or scan your **Operator ID** then press .
3. If required, enter or scan your **Password** then press .

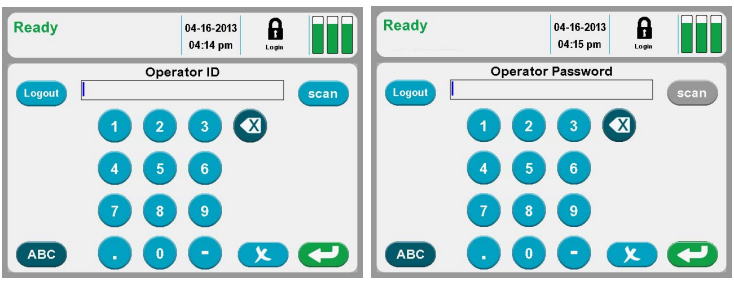


Figure 2.6 Operator ID Screen and Operator Password Screen

2.4 Automatic Calibrations

The Stat Profile Prime ABG analyzer performs a 2-point calibration 30 minutes after being powered on and regularly thereafter to maintain optimal Micro Sensor Card and air detector performance. A 1-point calibration is performed at regular intervals to monitor the Micro Sensor Card's performance between each 2-point calibration. If a calibration error occurs, an alert is shown to notify the operator and the test button of the affected analyte is displayed with an **orange** background to indicate it is not available for testing. Scheduled 2-point calibrations can be delayed once for 10 minutes by pressing the Cancel button. After 10 minutes the rescheduled calibration will begin and cannot be cancelled.

2.4.1 Manual Calibrations

A manually initiated 2-point calibration can be performed whenever the analyzer displays Ready or Not Ready on the header bar.

A Not Ready (Not Calibrated) status is displayed after powering the analyzer on, after replacing some consumable items or as a result of a system error. When the analyzer displays Not Ready, samples cannot be run until a 2-point calibration is performed that successfully calibrates the air detectors and at least one analyte. To initiate a calibration from the Not Ready state, press the **Calibrate** icon Calibrate on the Menu Bar.

A Ready status indicates the air detectors and one or more analytes are calibrated and ready for analysis. To manually calibrate the analyzer from the Ready state press Toolbox icon then press **Calibrate** Calibrate.

Analytes that display an **orange** background may be uncalibrated. Press the icon and select **Calibrate** Calibrate if displayed to initiate a 2-point calibration.

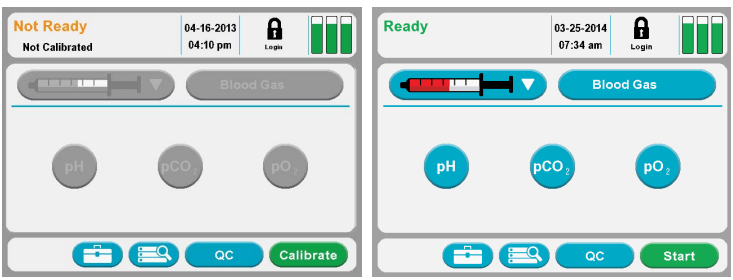


*Figure 2.6 **Not Ready** Screen and **Ready** Screen*

2.4.2 Air Detector Calibration

The Analyzer's Air Detectors are automatically calibrated once a day. An Air Detector calibration can be initiated manually if needed by selecting , , Service, Calibrate Air Detector.

3 Sample Analysis

WARNING: While the probe is extended, do not open or close the door.

When **Ready** is displayed on the Home screen the analyzer is ready to analyze samples for any analyte not displaying an **Orange** test button. The analyzer can measure whole blood samples from capillary tubes, syringes, test tubes, and open containers as well as external Quality Control material from ampules and internal Quality Control material from an internal QC cartridge

3.1 Analyzing Patient Samples

Before running a patient sample verify the analyzer is Ready to perform the analysis and that all the desired analytes are available for selection. If necessary, refer to Chapter 2 for additional information.

3.1.1 Analyzing Syringe Samples

From the Home screen, login if necessary.

1. Select the syringe  icon from the container drop-down list.
2. Select the desired Test Panel from the drop-down list or select one or more analytes to create a Custom Panel.

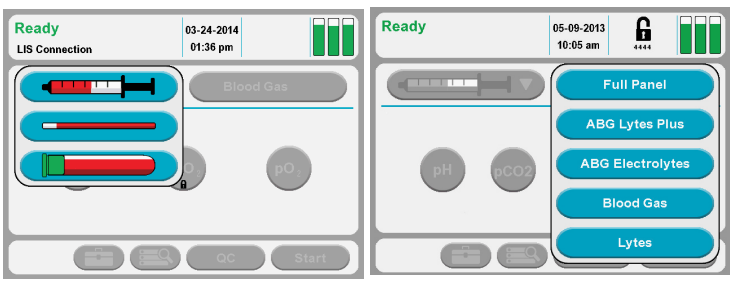


Figure 3.1 Ready Screen: Container and Panel Drop-down List

3. Press Start  icon to begin the analysis.

4. If prompted, enter all **Required Information** and press **Start** Start once more to begin the analysis.

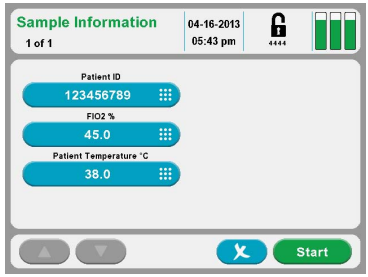


Figure 3.2 Sample Information Screen

5. Prepare the sample for analysis (mix well) then position the sample over the probe and press **Aspirate** Aspirate. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.



Figure 3.3 Syringe Sample

6. Enter any Required or Optional information while the analysis is running.

NOTE: *The Sample Information screen will remain until all Required fields have been entered. The analysis can be cancelled by pressing the X icon* X *but results will not be printed or transmitted.*

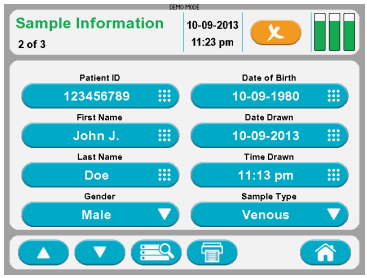


Figure 3.4 Sample Information Screen

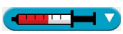
3.1.2 Utilizing the Safety Sample Port

The Safety Sample Port provides a means of attaching a syringe to the analyzer instead of manually positioning the sample probe in the sample. When utilizing the Safety Sample Port Nova recommends using the Nova Syringe Clot Catcher to ensure that the sample is positioned correctly for aspiration and to prevent clots from entering the flowpath. If a clot catcher is not used, syringes must be filled with sufficient sample for the probe to travel approximately 1-inch (26 mm) into the syringe.



Figure 3.5 Safety Sample Port

From the Home screen:

1. Select the syringe  icon from the container drop-down list.
2. Select the desired Test Panel from the drop-down list or select one or more analytes to create a Custom Panel.

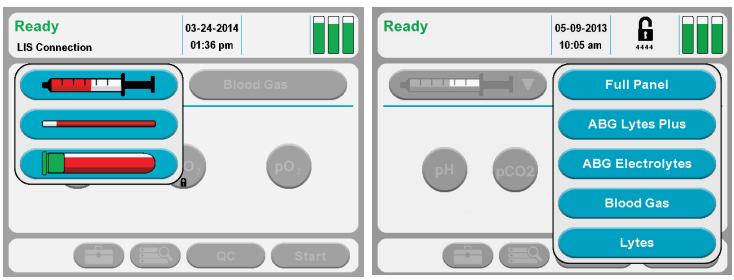


Figure 3.6 Ready Screen: Container and Panel Drop-down List

3. Prepare the sample for analysis (mix well) then attach the syringe to the Safety Sample Port.

4. Press Start 

icon to begin the analysis.



Figure 3.7 Position Sample Screen: Safety Sample Port

5. If prompted, enter all **Required Information** and press Start 

once more to begin the analysis.

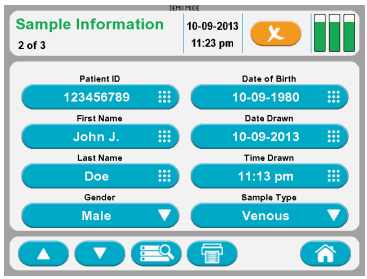


Figure 3.8 Sample Information Screen

6. Press the Aspirate icon 

to aspirate sample into the analyzer. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.
7. Remove the syringe from the Safety Sample Port.
8. Enter any Required or Optional information while the analysis is running.

NOTE: *Sample Information screen will remain until all Required fields have been entered. The analysis can be cancelled by pressing the X icon*  *but results will not be printed or transmitted.*

3.1.3 Analyzing Sample from a Blood Collection Tube

From the Home screen:

1. Select the blood collection tube  icon from the container drop-down list.
2. Select the desired Test Panel from the drop-down list or select one or more analytes to create a Custom Panel.

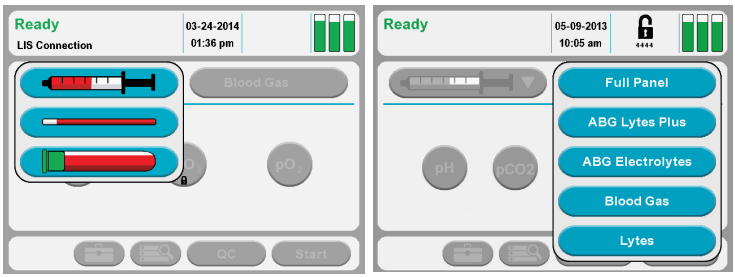


Figure 3.9 Ready Screen: Container and Panel Drop-down List

3. Press **Start**  icon to begin the analysis.
4. If prompted, enter all **Required Information** and press Start  once more to begin the analysis.

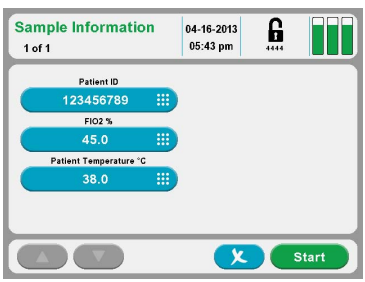


Figure 3.10 Sample Information Screen

5. Prepare the sample for analysis (mix well) then position the sample over the probe and press Aspirate (Aspirate). The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.



Figure 3.11 Position Sample Screen: Blood Tube Sample

6. Enter any Required or Optional information while the analysis is running.

NOTE: *The Sample Information screen will remain until all Required fields have been entered. The analysis can be cancelled by pressing the X icon (X) but results will not be printed or transmitted.*

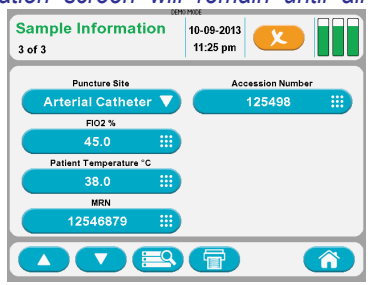


Figure 3.12 Sample Information Screen

3.1.4 Analyzing Sample from a Capillary Tube

From the Home screen:

1. Select the capillary  icon from the container drop-down list.
2. Select the desired Test Panel from the drop-down list or select one or more analytes to create a Custom Panel.

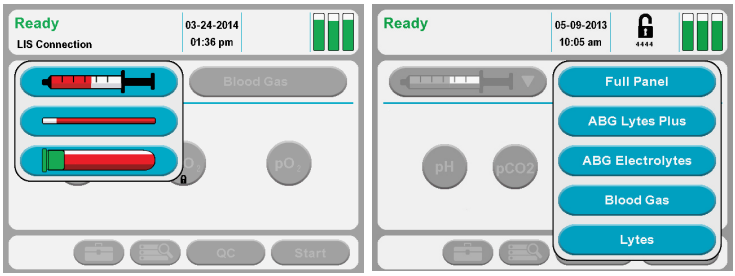


Figure 3.13 Ready Screen: Container and Panel Drop-down List

3. Press Start  to begin the analysis.
4. If prompted, enter all Required Information and press Start  once more to begin the analysis.

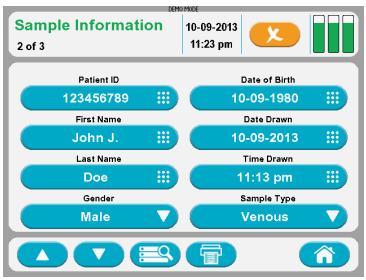


Figure 3.14 Sample Information Screen

5. Prepare the sample for analysis (mix well). Then position the capillary tube into the capillary adapter and press **Aspirate** Aspirate.

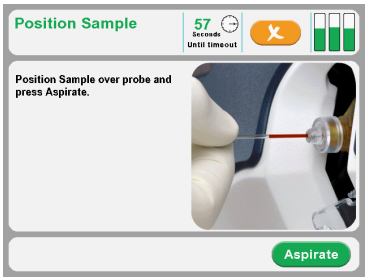


Figure 3.15 Position Sample Screen: Capillary Sample

6. When prompted, remove the capillary tube and press ↵.

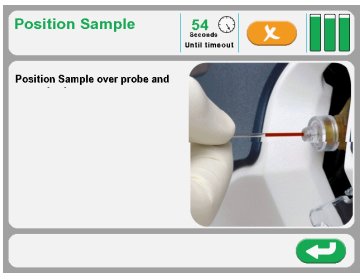


Figure 3.16 Position Sample Screen 2

7. Enter any Required or Optional information while the analysis is running.

NOTE: *Sample Information screen will remain until all Required fields have been entered. The analysis can be cancelled by pressing the X icon* ✕ *but results will not be printed or transmitted.*

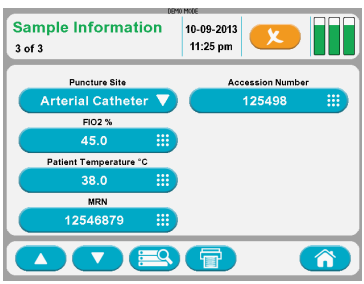


Figure 3.17 Sample Information Screen

3.2 The Sample Results Display

Once the sample analysis is complete, results for the selected and calculated analytes are shown on the following screen for Blood Results. Each analyte is shown with its measured value, the unit of measure, and a bar graph that provides a visual indication of the sample concentration: **Green** for normal results, **Orange** exceeds normal limits, and **Red** exceeds panic limits.

NOTE: Results can be displayed 2 different ways (Setup configurable).

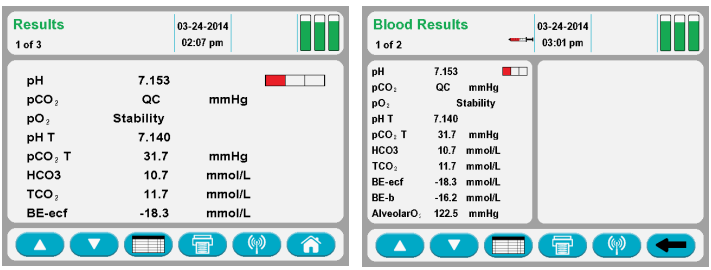


Figure 3.18 Blood Results Screens: Displayed 1 or 2 columns

The bar graph consists of 3 sections.
The first (left hand) section indicates the sample result is lower than the entered normal range.

- The segment is displayed with a **Orange** background if a sample result is between the low Normal and low Alert range.
- The segment is displayed with a **Red** background when a sample exceeds the low Alert range.

The middle section indicates the sample result is within the entered normal range.

- The segment is displayed with a **Green** background when the sample result is within the entered normal range

The last (right hand) section indicates the sample result is higher than the entered normal range.

- The segment is displayed with a Orange background if a sample result is between the high Normal and high Alert range.
- The segment is displayed with a Red background when a sample exceeds the high Alert range.

Use the Page Up ▲ and Page Down ▼ buttons to scroll through additional pages of result screens. The number of pages is shown in the upper left corner of the display, e.g., 1 of 3.

Press the Print button to print the results on the analyzer's thermal printer.

Press the Transmit button to transmit the results to the LIS/HIS system.

Press the Home Button to return to the Home screen.

3.3 Analyzing QC and Proficiency Samples

Before running a QC sample verify the analyzer is Ready to perform the analysis and that all the desired analytes are available for selection. If necessary, refer to Chapter 2 for additional information.

3.3.1 Analyzing Internal Quality Control Samples

From the Home screen:

1. From the Home Screen, press the QC button QC.
2. Press the Analyze QC button Analyze QC.

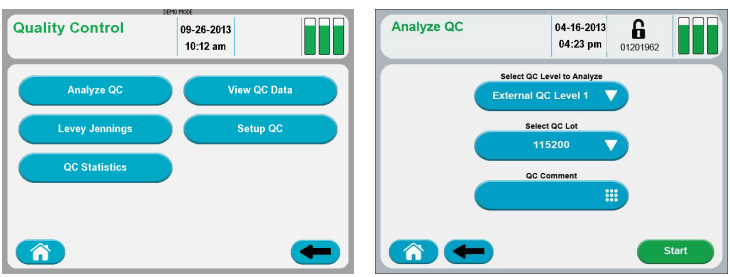


Figure 3.19 Quality Control Screens

3. From the drop-down list select the Internal Control Level to be analyzed.
4. Enter a QC comment if desired.
5. Press **Start** to begin the analysis.
6. Once the analysis is complete press Save to keep the QC results or press Delete to discard the QC results.

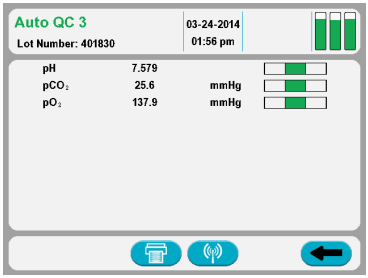


Figure 3.20 Quality Control Results Screen

3.3.2 Analyzing External Quality Control Samples

From the Home screen:

1. From the Home Screen, press the QC button QC.
2. Press the Analyze QC button Analyze QC.

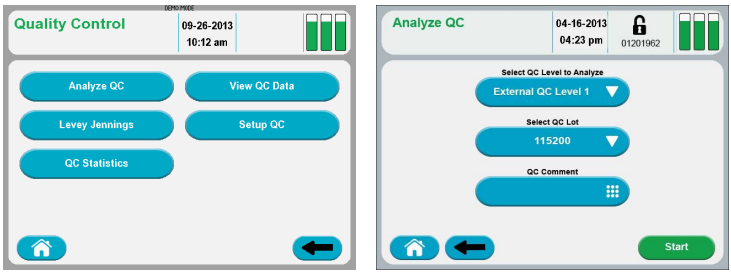


Figure 3.21 Quality Control Screens

3. From the drop-down list select the External Control Level to be analyzed.
4. Select the lot number of the External Control to be analyzed.
5. Enter a QC Comment if desired.
6. Press **Start** Start to begin the analysis.
7. Wait for the Sample Probe to fully extend.
8. Prepare the sample for analysis (mix well) then position the sample over the probe and press **Aspirate** Aspirate. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.



Figure 3.22 Position (External) QC Screen

9. Once the analysis is complete press Save to keep the QC results or press Delete to discard the QC results.

3.3.3 Analyzing Proficiency Samples

1. From the Home Screen, press the QC button QC.
2. Press the Analyze QC button Analyze QC.

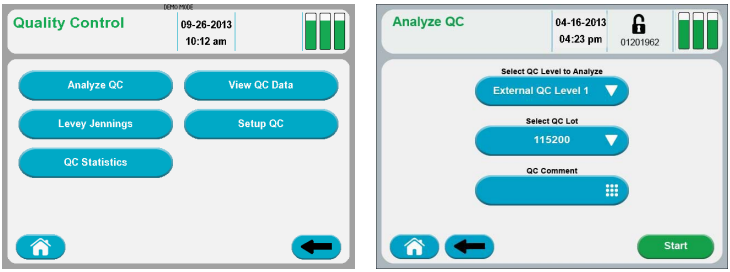


Figure 3.23 Quality Control Screens

3. From the drop-down list select Proficiency.
4. Press **Start** Start to begin the analysis.
5. Wait for the Sample Probe to fully extend.
6. Prepare the sample for analysis (mix well) then position the sample over the probe and press **Aspirate** Aspirate. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.



Figure 3.24 Proficiency Sample to Probe

7. Once the analysis is complete press Save to keep the QC results or press Delete to discard the QC results.

4 Reviewing Patient and QC Data

Patient and QC Data are stored on the analyzer and can be reviewed at any time. The following section will demonstrate how to find your data.

4.1 Reviewing Patient Data

To recall patient data, proceed as follows:

1. Press the Recall Results icon on the Menu Bar to display the current date's patient results
2. Select the patient result to review.

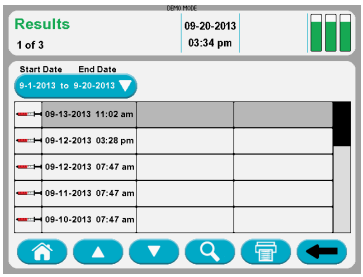


Figure 4.1 Results Screen

3. Then press to display the selected sample results.

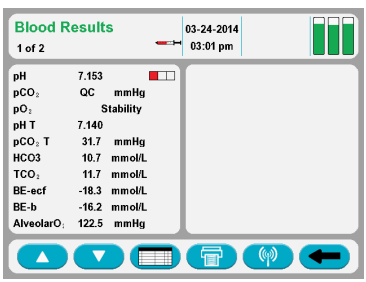


Figure 4.2 Patient Result Selected Data (Date)

4. If there are more than one page of data, up and down arrow buttons will appear on the footer to display all screens.
5. To view additional sample results, press the "Start Date End Date" button.

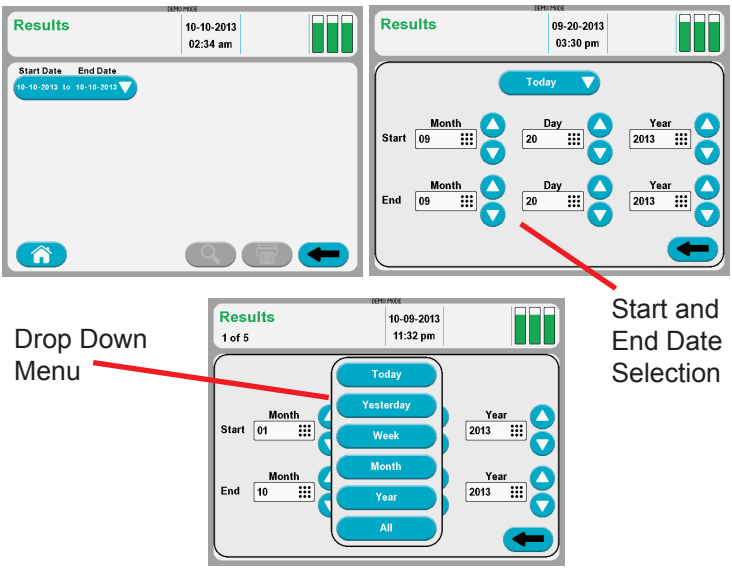


Figure 4.3 Results Screens

6. Press the drop down menu for "Today, Yesterday, Week, Month, Year, or All" for patient data; or select the start and end dates on the screen.
7. Press the back button to display patient results for the selected date range.
8. Select the patient result then press the  to display the selected sample results.

4.2 Reviewing QC Data

To recall any QC data on the analyzer, proceed as follows:

1. Press the QC button on the Home screen located in the footer of the screen.
2. The Quality Control screen displays: press the "View QC Data" button.
3. The View QC Data screen displays. From this screen, press the Start Date End Date button.

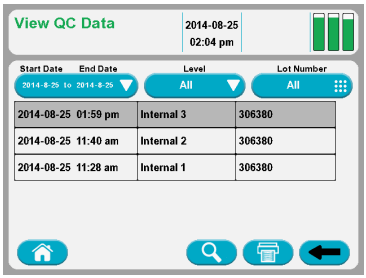


Figure 4.4 View QC Data Screen

4. Press the drop down menu for "Today, Yesterday, Week, Month, Year, or All" for QC data; or select the start and end dates on the screen.
5. Press the back button to display QC results.
6. A level button is also available to select a QC level from a drop down.
7. A lot button is also available to select from a drop down a QC lot number.

8. Select a QC data date and press the to display the data screen.

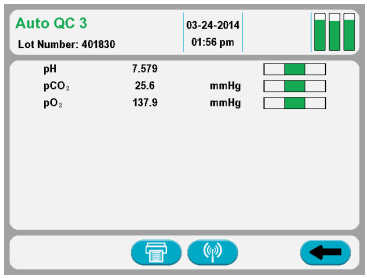


Figure 4.4 QC Test Result Screen

9. To print the data, press the print icon on the footer of the screen.

4.3 QC Statistics

To view QC Statistics on the analyzer, proceed as follows:

1. Press the QC button on the Home screen.
2. The Quality Control Screen will display.

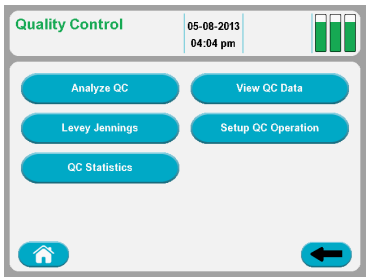


Figure 4.5 Quality Control Screen

3. Press the QC Statistics button to display the QC Statistics screen.
4. On this screen, press the Start Date End Date button.

5. Press the drop down menu for "Today, Yesterday, Week, Month, Year, or All" for patient data; or select the start and end dates on the screen.
6. Press the back button to display all the QC Statistics for these selected dates.
7. To print the QC Statistics, press the print icon on the footer of the screen.

4.4 Levey Jennings Graphs

To generate a Levey Jennings graph on the analyzer, proceed as follows:

1. Press the QC button on the Home screen.
2. The Quality Control Screen will display.

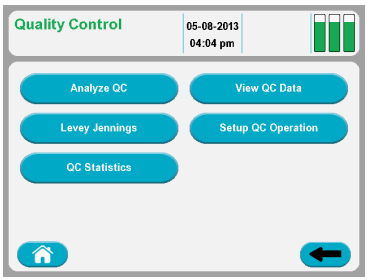


Figure 4.6 Quality Control Screen

3. Press the Levey Jennings button to display the Levey Jennings Graph screen.

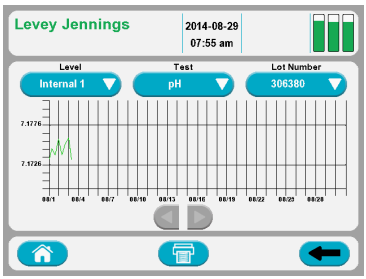


Figure 4.7 Levey Jennings Graph Screen

4. Select the QC Level with the Level button for the QC data. This displays a list of the levels that have QC data.
5. Select the Test with the Test button. This displays a list of the tests configured for the analyzer.
6. Select the Lot Number with the Lot Number button. This displays a list of the available lots for the QC Level.
7. A graph with a Y-axis for the test result and an X-axis for each day of a selected level,lot, test, and month is displayed.
8. There is a Left Arrow button and Right Arrow button at the base of the graph.
   Touch the Right Arrow button to graph the QC data of the next month that is available. Touch the Left Arrow button to graph the QC data of the prior month that is available.
9. To print the LJ Graph, press the print icon on the footer of the screen.

5 Consumable Replacements

The following sections provide detailed information and directions to operate and to maintain the Stat Profile Prime ABG Analyzer at peak efficiency. From the Home screen, press the Tool box icon to display the System Menu screens. From these screens, the following consumable replacements can be performed:

- Replace Micro Sensor Card
- Replace Calibrator Cartridge
- Replace Auto QC Cartridge

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

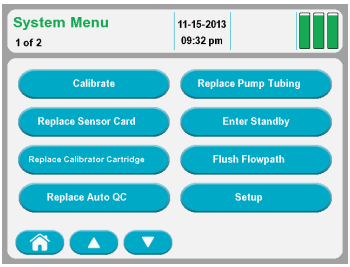


Figure 5.1 System Menu Screens

The Cartridge Required screen displays when a new Micro Sensor Card, Calibrator Cartridge, Auto QC Cartridge, or Reference Sensor Cartridge has been removed or requires replacement.

- Micro Sensor Card button displays if the Micro Sensor Card is not present, has zero remaining life, or has not completed hydration.
- Calibrator Cartridge and/or Auto QC Cartridge buttons display if the cartridge is not present or has zero remaining life.
- Reference Sensor button displays if the Reference Sensor is not present.
- Touching the button will bring you to the replacing of this item screen.

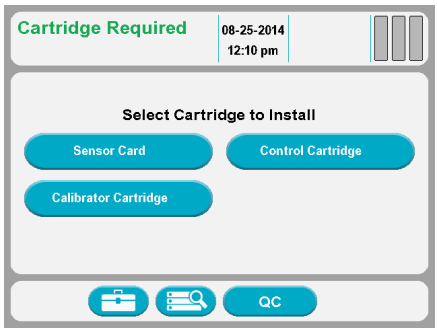


Figure 5.2 Cartridge Required Screen

5.1 Calibrator Cartridge and Auto QC Cartridge Replacement

The Calibrator Cartridge and/or Auto QC Cartridge should be changed when the system indicates the cartridge is empty. From the Home screen, press the Tool Box icon. Then press Replace Calibrator Cartridge or Replace Auto QC Cartridge. **Mix the cartridge thoroughly by gentle inversions.** Then follow the directions on the screen to replace the cartridges and the capillary adapter.

WARNING: When the calibrator cartridge or Auto QC 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.

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

NOTE: *The calibrator or the Auto QC cartridge must be replaced through the Tool Box screens. If you remove and replace a cartridge (even if it is the same one) outside these screens, you will not be able to prime the analyzer, and you will not be able to calibrate or to analyze samples (Calibrator Cartridge) or to analyze internal controls (Auto QC Cartridge). If you have removed and replaced a cartridge outside these screens, go to the appropriate screen and press Prime.*

NOTE: *The capillary adapter comes in the calibrator cartridge box. It is very important for the proper operation of the analyzer that the capillary adapter be changed with every calibrator cartridge change.*

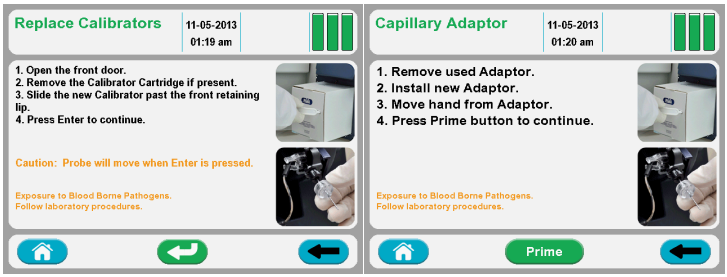


Figure 5.3 Replace Calibrator Cartridge and Adapter Screens

5.1.1 Replace Calibrator Cartridge

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

1. Press the Tool Box icon.
2. From the System Menu, press the Replace Calibrator Cartridge.
3. Open the door, remove old cartridge.
4. Slide new cartridge in past the front retaining lip.
5. To replace the capillary adaptor, press the Enter icon: slide off used capillary adapter and replace with new one that is provided with Calibrator Cartridge.

CAUTION: Probe will move when Enter is pressed.

6. Close door, press the Prime button.

The Calibrator Cartridge status can be viewed at any time by pressing the Status Graph on the upper right corner of the header bar.

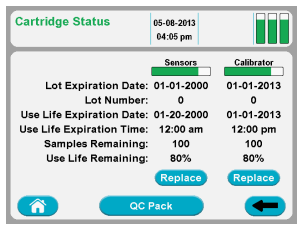


Figure 5.4 Calibrator Cartridge Status

- Calibrator progress bar is empty if the Calibrator Cartridge is not installed.
- Calibrator progress bar is in green with the percentage remaining use life of the Calibrator Cartridge if the use life remaining percentage is greater than 5%.
- Calibrator progress bar is in orange with the percentage remaining use life of the Calibrator Cartridge if the use life remaining percentage is less than or equal to 5%.
- The screen displays the lot expiration date, the lot number, the use life expiration date, the use life expiration time, the number of samples remaining, the percentage use life remaining.
- If no pack is installed, all above is blank.
- There is either an install button to Install a Calibrator Cartridge or a Replace button to replace a Calibrator Cartridge.

5.1.2 Replace Auto QC Cartridge



Figure 5.5 Replace Controls Screen

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

1. Press the Tool Box  icon.
2. From the System Menu, press the Replace Auto QC.
3. Open the door, remove the used Auto QC Cartridge if present.
4 Slide new cartridge in past the front retaining lip.

5. Close door, press the Prime  icon.

The Auto QC Cartridge status can be viewed at any time by pressing the Status Graph  on the upper right corner of the header bar.

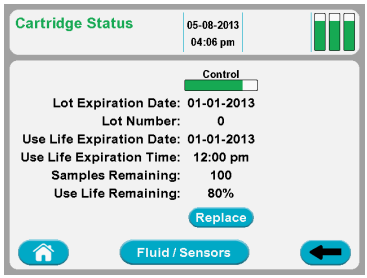


Figure 5.6 Auto QC Cartridge Status

- Auto QC progress bar is empty if the Auto QC Cartridge is not installed.
- Auto QC progress bar is in green with the percentage remaining use life of the Auto QC Cartridge if the use life remaining percentage is greater than 5%.
- Auto QC progress bar is in orange with the percentage remaining use life of the Auto QC Cartridge if the use life remaining percentage is less than or equal to 5%.
- The screen displays the lot expiration date, the lot number, the use life expiration date, the use life expiration time, the number of samples remaining, the percentage use life remaining.
- If no pack is installed, all above is blank.
- There is either an install button to Install a Auto QC Cartridge or a Replace button to replace a Auto QC Cartridge.

5.2 Replace Micro Sensor Card



Figure 5.7 Replace Sensors Screen

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

1. Press the Tool Box icon.
2. From the System Menu, press the Replace Micro Sensor Card and wait for pump to stop.
3. Open the door then open the Micro Sensor Card door, remove old card.
4 Insert new card. Close Micro Sensor Card door.
5. Close door, press the Prime button.

NOTE: *Hold Micro Sensor Card by the edges and replace it as pictured.*



Figure 5.8 Micro Sensor Card

The Micro Sensor Card status can be viewed at any time by pressing the Status Graph on the upper right corner of the header bar.

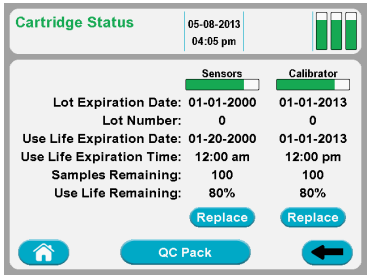


Figure 5.9 Micro Sensor Card Status

- Sensor progress bar is empty if the Micro Sensor Card is not installed.
- Sensor progress bar is in green with the percentage remaining use life of the Micro Sensor Card if the use life remaining percentage is greater than 5%.
- Sensor progress bar is in orange with the percentage remaining use life of the Micro Sensor Card if the use life remaining percentage is less than or equal to 5%.
- The screen displays the lot expiration date, the lot number, the use life expiration date, the use life expiration time, the number of samples remaining, the percentage use life remaining.
- If no Micro Sensor Card is installed, all above is blank.
- There is either an install button to Install a Micro Sensor Card or a Replace button to replace a Micro Sensor Card.

6 Periodic Replacements

Periodically the Pump Tubing Cartridge, Reference Sensor, Sample Probe, or printer paper may need to be replaced. This chapter gives detailed procedures on replacements of these consumable Items.

6.1 Pump Tubing Cartridge Replacement

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

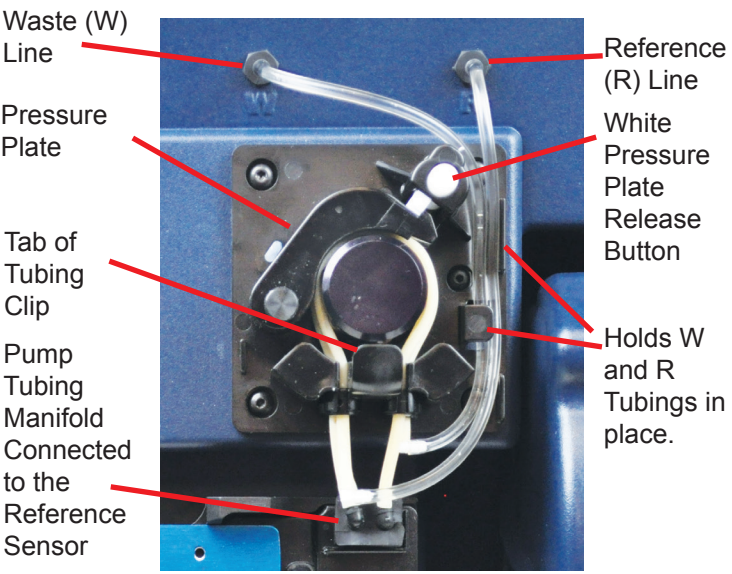


Figure 6.1 Pump Tubing

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

1. From the Home screen, press the Tool Box icon.
2. From the System Menu, select Replace Pump Tubing and wait for pump to stop.

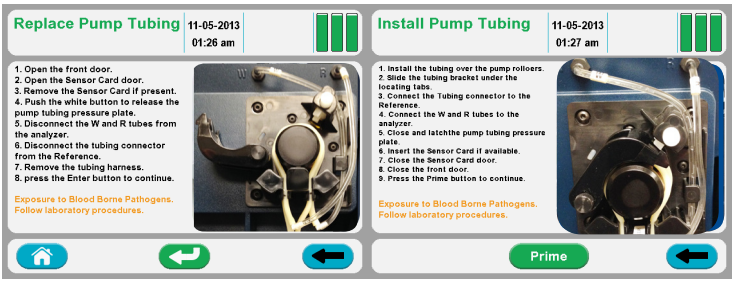


Figure 6.2 Replace and Install Pump Tubing Screens



Figure 6.3 Release Pump Tubing Pressure Plate

3. Open the analyzer door. Then Open the Micro Sensor Card door and remove the Micro Sensor Card if present.
4. Push the white button to release the pump tubing Pressure Plate release icon to release the Pump Tubing Pressure Plate.
5. Disconnect the W and R tubes from the analyzer.
6. Disconnect the tubing connector from the Reference Sensor.



Figure 6.4 Disconnect Pump Manifold

7. Remove the tubing harness and discard.
8. Press the Enter button to continue.

Install the Pump Tubing

9. Install the tubing over the pump rollers..
10. Slide the tubing bracket under the locating tabs.
11. Connect the tubing connector to the Reference Sensor.

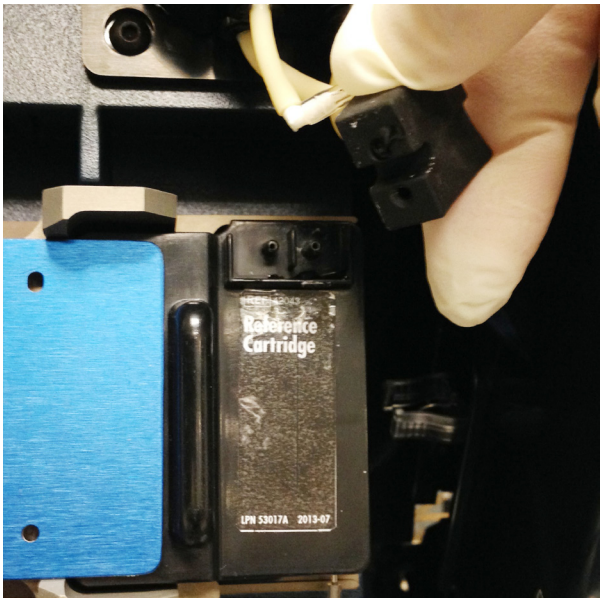


Figure 6.5 Connect Tubing Connector to Reference Sensor

12. Connect the W and R tubes to the analyzer.
13. Close and latch the pump tubing pressure plate.
14. Insert the Micro Sensor Card.
15. Close the Micro Sensor Card door.
16. Close the front door.
17. Press the Prime button to continue.

6.2 Probe Replacement

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

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

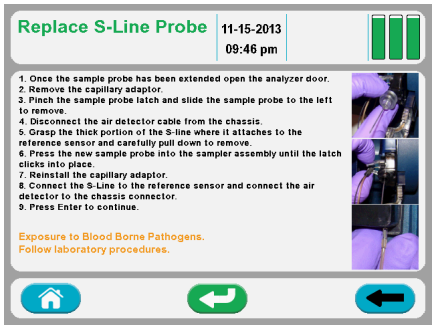


Figure 6.6 Replace S-Line Probe Screen

1. From the Home screen, press the Tool Box icon. From the System Menu select Replace S-Line Probe and wait for pump to stop.
2. Remove the capillary adapter from the front of the probe by gently pulling.



Figure 6.7 Removing Capillary Adapter

3. Disconnect the cable of the air detector from the analyzer.

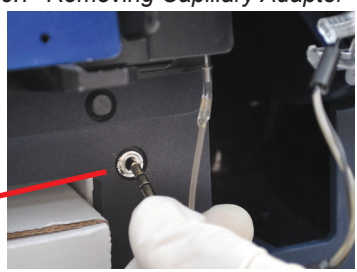


Figure 6.8 Disconnect the Cable of the Air Detector

4. Disconnect the air detector's sample line from the Reference Sensor module using the removal tool

.

S-Line with Connection to Reference Sensor

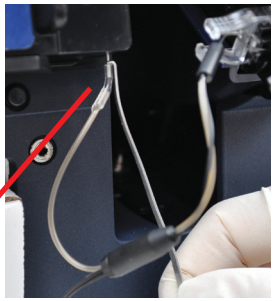


Figure 6.8 Removing Sample Line from Reference Sensor

5. Pinch together the white probe holder and remove the probe together with the S-line and air detector cable and discard.

Pinch Clamp

S-Line with Connection to Reference Sensor

Cable of Air Detector to Analyzer

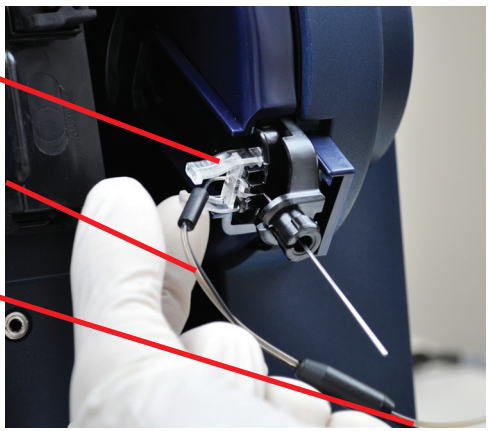


Figure 6.89 Removing Probe, S-line, and Cable of Air Detector

6. Place new Probe assembly until it clicks into place.
7. Replace the capillary adaptor back onto the probe
8. Reconnect the S-line to the Reference Sensor
9. Reconnect the Air Detector Cable into the analyzer.
10. Close the door.
11. Press the Calibrate Calibrate icon.

6.3 Reference Sensor Replacement

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

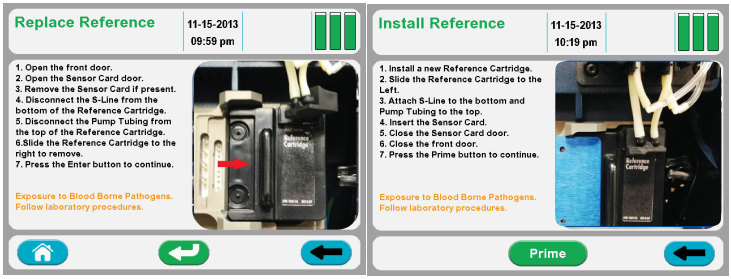


Figure 6.10 Replace and Install Reference Sensor Screens

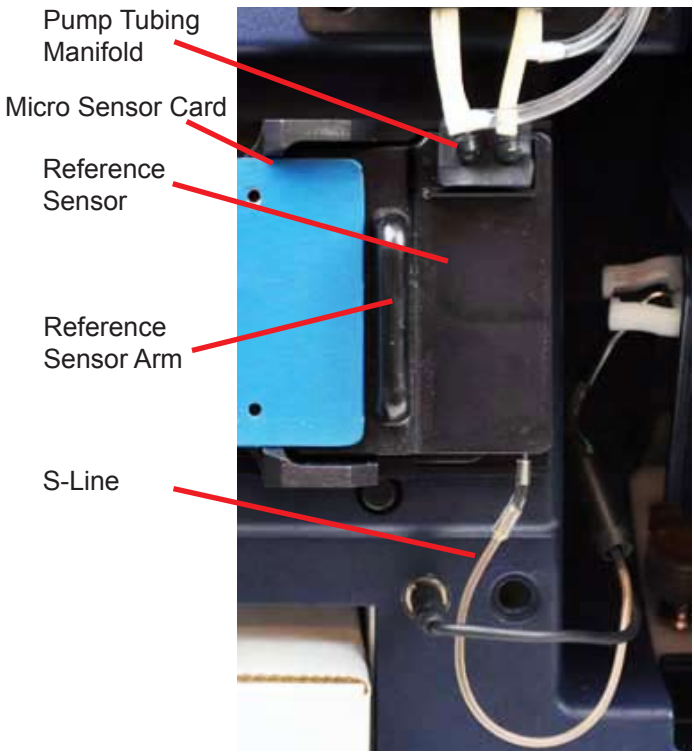


Figure 6.11 Reference Sensor

1. From the Home screen, press the Tool Box icon.
2. From the System Menu select the Replace Reference Sensor.
3. Open the door; open the Micro Sensor Card door.
4 Remove the Micro Sensor Card if present.
5. Disconnect the S-line from the bottom of the Reference Sensor.
6. Disconnect the Pump Tubing from the top of the Reference Sensor.
7. Slide the Reference Sensor to the right to remove.
8. Press the Enter button to continue.

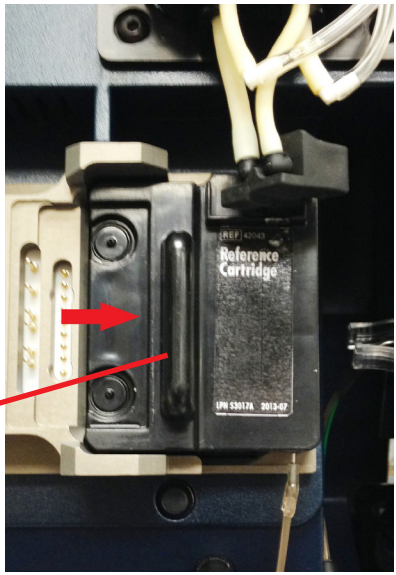


Figure 6.12 Slide the Reference Sensor Off to the Right

Install the Reference Sensor

1. Install a new Reference Sensor.
2. Slide the Reference Sensor to the left.
3. Attach S-Line to the bottom and Pump Tubing to the top.
4. Insert the Micro Sensor Card.
5. Close the Micro Sensor Card door.
6. Close the front door.
7. Press the Prime button to continue.

6.4 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.

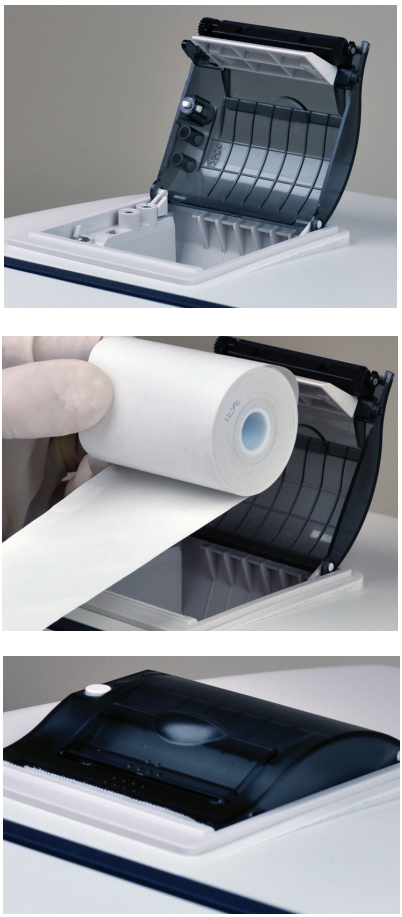


Figure 6.13 Replacing the Printer Paper

6.5 Safety Sample Port Replacement

WARNING: Exposure to Blood Borne Pathogens. Follow laboratory procedures.

1. Open the door.
2. Slide out the old Safety Sample Port.
3. Slide in a new Safety Sample Port.
4. Close the door.



Figure 6.14 Replacing the Safety Sample Port

7 Troubleshooting

This section describes the recommended troubleshooting procedures for use with the Stat Profile Prime ABG analyzer. The procedures use the most logical and direct steps to resolve each problem and are written to minimize the replacement of any unnecessary parts. If the recommended solutions do not resolve the problem please contact Nova Biomedical Technical Support for troubleshooting assistance.

FOR TECHNICAL ASSISTANCE, CALL TOLL FREE:

USA	1-800-545-NOVA
Canada	1-800-263-5999
Other Countries	Contact the local Nova Biomedical Sales Office or Authorized Nova Biomedical Distributor



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

7.1 Event Log

The Event Log displays a list of events that have occurred during a selected time frame. To access the Event Log; from the Home Screen, press , , , .

The Event Log initially displays events that occurred on the current date but may be changed to show events that occurred during a specified time frame or that contain a specific Event ID. Events are displayed chronologically with the most recent event at the top of the page. Each event is shown with the date and time the event occurred, the event

ID and a description of the event. To view additional details of a specific event, select (highlight) the event of interest then press the Details button . To print the Event Log press .

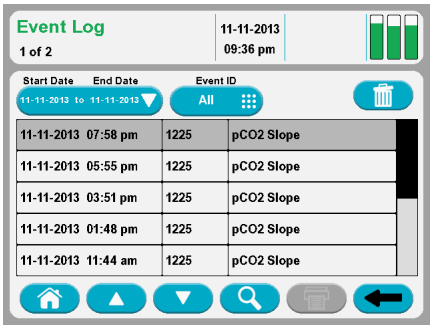


Figure 7.1 Event Screen

7.2 Resolving Event Codes

Event Codes are grouped into one of 5 categories, Cartridge errors, Flow errors, Printer errors, Micro Sensor Card errors, and Hardware/Software errors. Use the following troubleshooting steps to resolve the listed codes. If a displayed code is not listed please contact Nova Biomedical Technical Support for assistance.

7.2.1 Flow Event Codes

Event Code	Description and Corrective Action
602	**Insufficient Sample –** During the last sample analysis, the leading edge of the sample was not detected at the reference air detector when expected. Recommended Solution 1. Rerun the sample and insure the sample probe is not being obstructed by the sample container. 2. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 3. Replace the W/R Pump Harness. 4. Contact Nova Biomedical Technical Support.
604	**No Flush When Required –** During the last calibration or sample analysis, Flush solution was not detected when expected. **Recommended Solution** 1. Verify the % remaining in the Calibrator Cartridge. If the pack indicates less than 10% remaining, replace the Calibrator Cartridge. 2. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 3. Calibrate the Air Detector. 4. Contact Nova Biomedical Technical Support.

605	**No Air When Required -** During the last calibration or sample analysis, Air was not detected when expected. **Recommended Solution** 1. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Prime Flow Path. 2. Calibrate the Air Detector. 3. Contact Nova Biomedical Technical Support.
606	**No Standard A When Required -** During the last calibration or sample analysis, calibrator standard A solution was not detected when expected. **Recommended Solution** 1. Verify the % remaining in the Calibrator Cartridge. If the pack indicates less than 10% remaining, replace the Calibrator Cartridge. 2. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 3. Calibrate the Air Detector. 4. Contact Nova Biomedical Technical Support.
607	**No Standard B When Required -** During the last calibration, calibrator standard B solution was not detected when expected. **Recommended Solution** 1. Verify the % remaining in the Calibrator Cartridge. If the pack indicates less than 10% remaining, replace the Calibrator Cartridge. 2. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 3. Calibrate the Air Detector. 4. Contact Nova Biomedical Technical Support.

608	**No Internal QC When Required –** During the last Internal QC analysis, QC solution was not detected when expected. **Recommended Solution** 1. Verify the % remaining in the Internal QC Cartridge. If the pack indicates less than 10% remaining, replace the QC Cartridge. 2. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 3. Calibrate the Air Detector. 4. Contact Nova Biomedical Technical Support.
609	**No Sample When Required –** During the last sample analysis, no sample was detected by the analyzer. **Recommended Solutions** 1. If analyzing a whole blood sample, verify that the sample is not clotted. If the sample is clotted, Nova Biomedical recommends that the sample be redrawn or that a clot catcher be utilized prior to repeating the analysis. 2. If analyzing an external QC sample, repeat the analysis. If the problem recurs, proceed to step 3. 3. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 4. Calibrate the Air Detector. 5. Contact Nova Biomedical Technical Support.

611	**Sample Position Not Confirmed –** During the last analysis, the sample was not detected at one of the air detectors. **Recommended Solutions** 1. If analyzing a whole blood sample, verify that the sample is not clotted. If the sample is clotted, Nova Biomedical recommends that the sample be redrawn or that a clot catcher be utilized prior to repeating the analysis. 2. If analyzing an external QC sample, repeat the analysis. If the problem recurs, proceed to step 3. 3. Flush the flow path with deionized water and recalibrate the analyzer. Refer to Section 7.3, Flushing the Flow Path. 4. Contact Nova Biomedical Technical Support.

7.2.2 Printer Event Codes

Event Code	Description and Corrective Action
904	**Printer Paper Out –** No paper was detected in the thermal printer. **Recommended Solution** 1. Check and or replace printer paper supply. 2. Contact Nova Biomedical Technical Support if printer paper is not recognized.
905	**Printer Cover Open –** The printer cover is not completely closed. **Recommended Solution** 1. Insure the printer cover is fully closed. 2. Contact Nova Biomedical Technical Support if unable to resolve.
906	**Printer –** A printer error has occurred. **Recommended Solution** 1. Check the printer paper supply. Clear any paper jam that may have occurred. 2. Contact Nova Biomedical Technical Support if unable to resolve.

7.2.3 Micro Sensor Card Event Codes

Event Code	Description and Corrective Action
1201 **1209** **1217** **1225**	**Slope** **pH Slope** **pO_2 Slope** **pCO_2 Slope** The measured difference between the indicated analytes' calibration standards did not meet the minimum specifications for a properly performing sensor during the last 2-point calibration. **Recommended Solution** 1. Recalibrate the analyzer. 2. Flush the flowpath and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flowpath. 3. Replace the Micro Sensor Card. 4. Replace the Calibrator Cartridge. 5. Replace the Reference Sensor. 6. Call Nova Biomedical Technical Support.

1202 **1210** **1218** **1226**	**Overload** **pH Overload** **pO_2 Overload** **pCO_2 Overload**	During the last calibration or analysis sequence, the indicated analytes' sensor reading exceeded the software limits.
	Recommended Solution 1. Recalibrate the analyzer. 2. Flush the flowpath and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flowpath. 3. Replace the Micro Sensor Card. 4. Call Nova Biomedical Technical Support.	
1205 **1213** **1221** **1229**	**Stability** **pH Stability** **pO_2 Stability** **pCO_2 Stability**	During the last calibration or analysis sequence, the indicated analytes' sensor did not reach a stable endpoint.
	Recommended Solution 1. Recalibrate the analyzer. 2. Flush the flowpath and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flowpath. 3. Replace the Micro Sensor Card. 4. Replace the Reference Sensor. 5. Call Nova Biomedical Technical Support.	
1206 **1214** **1222** **1230**	**E-Zero Drift** **pH E-Zero Drift** **pO_2 E-Zero Drift** **pCO_2 E-Zero Drift**	During the last analysis sequence, the indicated analytes' performance changed significantly since the last successful 2-point calibration.
	Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, flush the flowpath and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flowpath. 3. Replace the Micro Sensor Card. 4. Call Nova Biomedical Technical Support.	

1207 **1215** **1223** **1231**	**A to A Drift** **pH A to A Drift** **pO_2 A to A Drift** **pCO_2 A to A Drift**	During the last analysis sequence, the indicated analytes' performance changed significantly from the previous analysis.
	Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, flush the flowpath and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flowpath. 3. Replace the Micro Sensor Card. 4. Call Nova Biomedical Technical Support.	
1208 **1216** **1224** **1232**	**Slope Drift** **pH Slope Drift** **pO_2 Slope Drift** **pCO_2 Slope Drift**	During the last calibration, the indicated analytes' performance changed significantly from the previous calibration.
	Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, flush the flowpath and recalibrate the analyzer. 3. Replace the Micro Sensor Card. 4. Call Nova Biomedical Technical Support.	

7.3 Troubleshooting Flow Problems

The analyzer may experience flow problems as a result of aspirating clots from poorly heparinized whole blood samples. If this should occur operators can use the following procedures to clear the analyzer flowpath and verify the analyzer is capable of aspirating from the sample probe.

NOTE: *Nova Biomedical recommends but does not require the use of clot catchers as an effective means of preventing the aspiration of clots into the analyzer's flowpath.*

7.3.1 The Flow Path Flush Tool

The Flow Path Flush Tool consists of a 30 mL syringe and a special adaptor to safely clear the flowpath in the event it becomes obstructed.

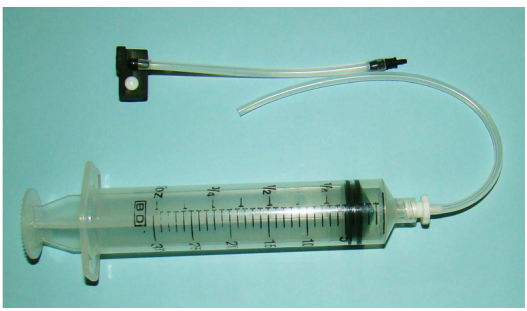


Figure 7.2 Flowpath Flush Tool

The tool can be used with or without the adaptor to flush individual flow path components. The adaptor is keyed to connect to the Reference Sensor in only one direction as shown. The tubing connected to the adaptor should point up to ensure it is not pinched shut when the Micro Sensor Card door is closed.

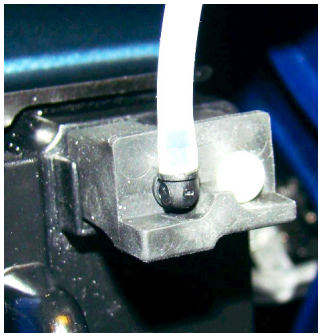


Figure 7.3 Tubing Connected to the Adapter Points Up

7.3.2 Flushing the Flowpath

The analyzer's flowpath can be flushed to remove clots or other debris that may have been aspirated into the system. Use of a device other than the Flush Tool may damage the Micro Sensor Card and is not recommended.

The following is the recommended procedure for clearing the flowpath when needed.

1. From the Home screen, press  then Flush Flowpath.
2. When the pump stops turning, open the analyzer door then open the Micro Sensor Card door.
3. Aspirate a small amount of deionized water into the Flow Path Flush Tool.
4. Disconnect the W/R Pump Harness from the Reference Sensor.

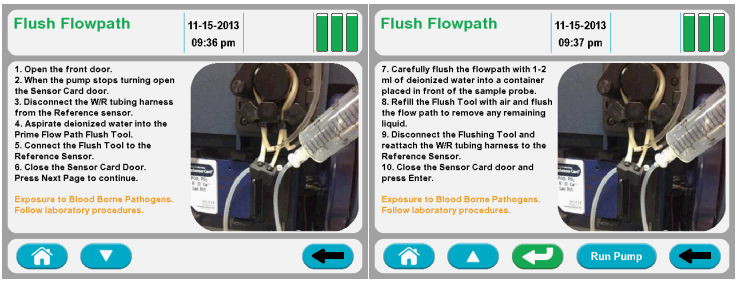


Figure 7.4 Flush Flowpath Screens

5. Connect the Flush Tool to the Reference Sensor and close the Micro Sensor Card door.
6. Using moderate pressure, carefully flush the flowpath with 1-2 ml of deionized water into a container placed in front of the sample probe.
7. Refill the Flush Tool with air and flush the flow path to remove any remaining liquid.
8. Disconnect the Flushing Tool and reattach the W/R tubing harness to the Reference Sensor.
9. Close the Micro Sensor Card door and press Done.
10. Recalibrate the analyzer 3 times.

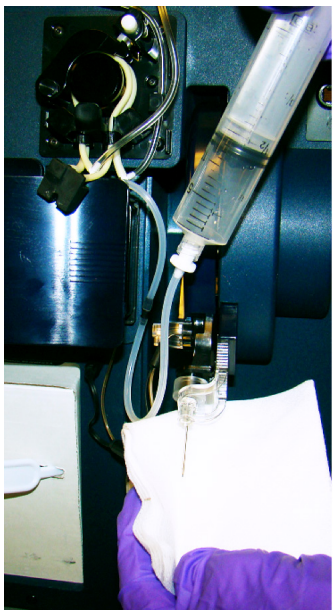


Figure 7.4 Flushing Flowpath into Gauze

7.3.3 Flushing the Sample Probe/S-Line

The Sample Probe is designed to prevent large clots and other debris from advancing into the analyzer's flowpath if possible. As a result, the sample probe may become obstructed and require manual flushing to remove an obstruction.
The following is the recommended procedure for clearing obstructions from the sample probe and S-line.

1. From the Home screen, press  then 

.
2. When the pump stops turning, open the analyzer door.
3. Draw a small amount of deionized water into the Flow Path Flush Tool.
4. Carefully disconnect the Sample probe/S-line tubing from the bottom of the Reference Sensor using the removal tool.
5. Slide the flush tool tubing over the extended sample probe.
6. Using moderate pressure, flush water through the sample probe and S-line into a container or gauze placed in front of the s-line.
7. Refill the Flush Tool with air and flush the sample probe to remove any remaining liquid.
8. Press Done when finished.
9. Recalibrate the analyzer as needed.



Figure 7.5 Flushing the S-Line

7.3.4 Flow Test

The following procedure can be used to verify the analyzer is able to aspirate from the sample probe. Use this procedure in tandem with the flushing procedures to clear obstructions and verify flow.

1. From the Home screen, press  then Flush Flowpath.
2. Once the pump stops and the sample probe has been extended press  to scroll down to page 2.
3. Fill a small container with deionized water and immerse the sample probe into the water.
4. Press Run Pump on the display to start the peristaltic pump. The water level in the container should drop quickly if the analyzer is aspirating correctly.
5. Press Done when finished.
6. Recalibrate the analyzer as needed.

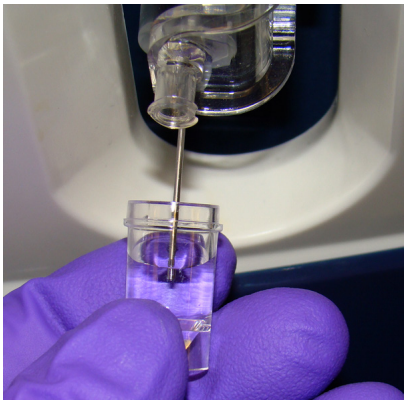


Figure 7.6 Flow Test

A Appendix

Appendix A includes analyzer specifications, performance data, solutions and reagents, consumable lists, reference information, and warranty for the Stat Profile Prime ABG Analyzer.

A.1 Specifications

Measurement Range:

pH	6.500 - 8.000	
PCO_2	3.0 - 200 mmHg	0.4 - 26.7 kPa
PO_2	5.0 - 765 mmHg	0.66 - 102.0 kPa

Resolution

Calculated Result:

HCO_3^-	0.1 mmol/L		
TCO_2	0.1 mmol/L		
BE-ecf	0.1 mmol/L		
BE-b	0.1 mmol/L		
SBC	0.1 mmol/L		
O_2Ct	0.1 mL/dL	1 mL/L	0.1 mmol/L
O_2 Cap	0.1 mL/dL	1 mL/L	0.1 mmol/L
SO_2%	0.1		

With entered FiO_2:

A	0.1 mmHg	0.1 kPa
$AaDO_2$	0.1 mmHg	0.1 kPa
a/A	0.1	
PO_2/FiO_2	0.1 mmHg	0.1 kPa
RI	0.1	

Acceptable Samples: Whole Blood (heparinized)

Blood Gas Sample Volume Capillary or Syringe: 50 µL

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

A.1.1 Quality Control

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

- During each 8 hours of testing, analyze one level of Control.
- Analyze all 3 levels during each day of operation.
- After performing system maintenance, follow good laboratory practice guidelines for performing quality control analysis.

CAUTION: Sensor performance may be affected by use of controls other than Stat Profile PRIME Controls. Contact Nova Biomedical for additional information.

When a new lot number of Auto-Cartridge QC is installed, the previous lot number becomes inactive. Thus, you are unable to run lots in parallel to validate the new lot to the old by alternating packs on the same unit.

Nova Recommendation: All Nova controls ship with a product insert sheet. This product insert sheet contains the target value ranges for each level of QC contained in the pack. Nova's recommendation for conversion to a new lot number is to use the product insert sheet range levels for the first 30 days or until sufficient data is collected to establish the new target values. After sufficient data is collected, the established values and ranges can be entered into the analyzer.

Alternate Method: If this method is inadequate, Nova recommends the use of the external controls run in parallel and overlapping with the on-board product change over. This method offers continuity in monitoring performance during the change over period. The external QC monitoring can be done using the QC program on the analyzer.

A.1.2 Analytical Specificity

An interference study was performed according to CLSI guideline EP7-A2. The study used spiked and diluted specimens containing potential interfering substances for pH, PO_2, and PCO_2 at normal physiological levels. Each sample containing the interfering substance was evaluated against a reference specimen without the interfering substance. Potential interfering substances were selected for test based upon a known potential to interfere with the test methodology. The following table represents substances that were tested without demonstrating a clinically significant effect on test results:

Interfering Substance	Highest Concentration Tested	Analyte(s) Tested
Acetoacetate	2.0 mmol/L	pH
Benzylkonium Chloride	10.0 mg/L	pH
Bilirubin	20.0 mg/dL	pH, PCO_2, PO_2
Calcium Chloride	2.0 mmol/L	pH, PCO_2, PO_2
Dobutamine	2.0 mg/dL	pH
Ethanol	86.8 mmol/L	pH, PCO_2, PO_2
Fluorescein	1.0 mmol/L	PCO_2, PO_2
Hemoglobin	2.0 g/L	pH, PCO_2, PO_2
Intralipid	10.0 mg/mL	pH, PCO_2, PO_2
Potassium Chloride	5.0 mmol/L	pH, PCO_2, PO_2
Sodium Chloride	10.0 mmol/L	pH, PCO_2, PO_2
Sodium Bromide	37.5 mmol/L	pH

A.2 Analytical Performance Studies

Three Stat Profile Prime ABG Analyzers were compared to 2 Stat Profile Prime CCS Comp Analyzers in a laboratory setting. The protocol consisted of within run precision runs, day-to-day precision runs, linearity validation, and method comparison studies comparing the performance of the Stat Profile Prime ABG Analyzers to the Stat Profile Prime CCS Comp Analyzers.

Method Comparison Study

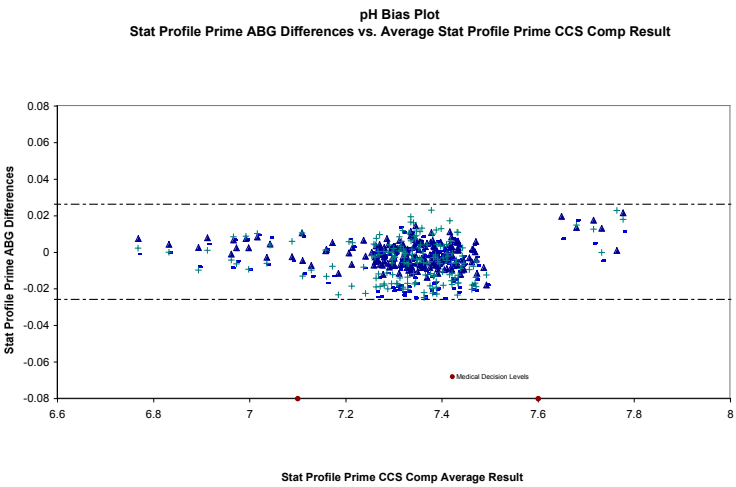
Lithium Heparin arterial whole blood discarded specimens from hospital patients were analyzed in duplicate on the 3 Stat Profile Prime ABG Analyzers and 2 Stat Profile Prime CCS Comp reference analyzers. The number of samples per run and the total number of runs each day depended upon the availability of blood specimens on any given test day. Some additional whole blood specimens from consenting donors were tonometered, spiked, or diluted with saline to cover the analytical measurement range for all analytes. The number of data points (N) varies for each parameter due to error, instrument calibration status, or insufficient sample volume to complete analysis.

A minimum of 150 whole blood specimens were analyzed for each parameter in syringe collection devices. The samples were analyzed on each of the Stat Profile Prime ABG analyzers and on each of the CCS Comp analyzers. The Stat Profile Prime ABG results for each analyzer were compared to the average of the 2 results from the CCS Comp comparative method.

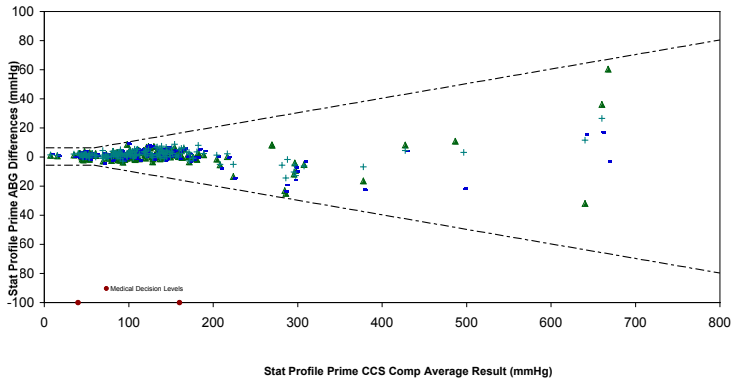
A minimum of 100 whole blood specimens were analyzed for each parameter in capillary collection tubes. Each specimen was analyzed one time from a capillary container on each Stat Profile Prime ABG analyzer and then immediately run as a syringe specimen on the same Stat Profile Prime ABG analyzer. The capillary test result was compared to the syringe test result from each test system.

Bias Chart Results

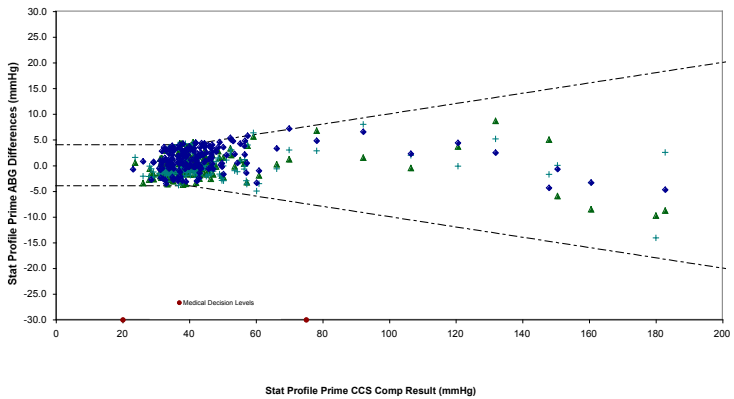
The method comparison bias estimate was analyzed using CLSI Standard EP09-A2 as a reference document. The bias plots for each parameter are summarized and include boundary lines that represent the 95% confidence interval across the measurement range based upon each parameter's between analyzer day-to-day (+/-2SD) performance specification or CV% (whichever is greater). Each bias plot represents 3 Stat Profile Prime ABG analyzers compared to the average result from 2 Stat Profile Prime CCS Comp analyzers. Medically relevant low and high concentrations are annotated.



pO2 Bias Plot
Stat Profile Prime ABG Differences vs. Average Stat Profile Prime CCS Comp Result



pCO2 Bias Plot
Stat Profile Prime ABG Differences vs. Average Stat Profile Prime CCS Comp Result



Syringe Method Comparison Study Results *vs.* Stat Profile Prime CCS Comp

Test Parameter	Analyzer	Total # specimens	# Altered specimens	Specimen Range	Slope	Intercept	r
pH	#1	170	17	6.771 - 7.796	0.9987	0.0042	0.9971
	#2	175	14	6.768 - 7.789	0.9933	0.0431	0.9978
	#3	187	18	6.776 - 7.799	0.9937	0.0433	0.9986
PCO_2	#1	161	16	22.7 - 174.1	0.9899	0.7042	0.9972
	#2	163	12	24.0 - 185.4	0.9834	0.5996	0.9975
	#3	168	10	22.4 - 178.1	0.9923	1.8045	0.9940
PO_2	#1	153	10	8.8 - 728.3	1.0141	-0.6862	0.9975
	#2	165	11	10.2 - 677.6	1.0074	0.8237	0.9985
	#3	165	9	9.3 - 687.1	1.0080	0.7950	0.9991

Syringe Method Comparison Study Results *vs.* Capillary Results

	Individual Analyzer Performance Data Capillary vs. Syringe Comparison					
Parameter	Analyzer	Total # specimens	Specimen range	Slope	Intercept	r
pH	#1	103	6.938 - 7.938	0.9985	0.0176	0.9940
pH units	#2	102	6.930 - 7.863	0.9960	0.0310	0.9949
	#3	102	6.930 - 7.945	0.9764	0.1720	0.9963
PCO_2	#1	101	29.3 - 118.6	0.9946	-0.8320	0.9857
mmHg	#2	100	30.6 - 118.8	0.9701	1.1084	0.9931
	#3	100	28.2 - 117.2	0.9932	0.0413	0.9912
PO_2	#1	103	38.8 - 632.5	1.0080	1.5136	0.9986
mmHg	#2	100	39.5 - 671.0	1.0312	-0.9238	0.9986
	#3	101	38.2 - 626.4	1.0151	0.5726	0.9985

Analytical Precision or Repeatability

Quality Control Within Run Precision Performance

The protocol consisted of 20 replicates per run for each of 3 different quality control materials on each of 3 Stat Profile Prime ABG Analyzers. The average, SD, CV%, and N for each analyzer for each QC level and parameter was calculated. The pooled average, SD, CV%, and N from all 3 analyzers for each QC level and parameter was calculated.

Whole Blood Within Run Precision Performance

Estimates of the whole blood within run precision were determined in syringe mode and capillary mode. For each run, tonometered whole blood was analyzed 20 times on 3 Stat Profile Prime Analyzers for a total of 20 results per analyzer. Statistical analysis for each analyzer for both Syringe Mode and Capillary Mode was calculated.

Stat Profile Prime Quality Control Level 1

Within Run Precision Summary					
Parameter	**n = 20**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**	**Pooled**
pH	Mean	7.149	7.146	7.150	7.148
pH units	SD	0.001	0.001	0.001	0.002
***P*CO$_2$**	Mean	58.0	58.1	57.6	57.9
mmHg	SD	0.4	0.4	0.3	0.5
	CV%	0.8	0.7	0.6	0.8
***P*O$_2$**	Mean	58.3	62.1	62.1	60.8
mmHg	SD	0.6	0.3	0.3	1.8
	CV%	1.1	0.5	0.5	3.0

Stat Profile Prime Quality Control Level 2

Within Run Precision Summary					
Parameter	**n = 20**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**	**Pooled**
pH	Mean	7.355	7.350	7.355	7.353
pH units	SD	0.001	0.001	0.001	0.002
***P*CO$_2$**	Mean	40.5	40.7	40.7	40.6
mmHg	SD	0.5	0.4	0.3	0.4
	CV%	1.2	1.0	0.9	1.0
***P*O$_2$**	Mean	97.2	101.5	97.8	98.8
mmHg	SD	0.5	0.3	0.3	2.0
	CV%	0.5	0.3	0.3	2.0

Stat Profile Prime Quality Control Level 3

Within Run Precision Summary					
Parameter	**n = 20**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**	**Pooled**
pH	Mean	7.563	7.554	7.563	7.560
pH units	SD	0.001	0.002	0.002	0.005
***P*CO$_2$**	Mean	24.8	25.2	25.0	25.0
mmHg	SD	0.4	0.4	0.5	0.5
	CV%	1.7	1.7	2.1	1.9
***P*O$_2$**	Mean	133.0	134.9	135.4	134.4
mmHg	SD	0.5	0.6	0.4	1.1
	CV%	0.4	0.4	0.3	0.9

Stat Profile Prime Within-Run Precision Summary - Whole Blood - Syringe

Within Run Precision Summary				
Parameter	**n = 20**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**
pH	Mean	7.367	7.356	7.370
pH units	SD	0.005	0.004	0.004
***P*CO$_2$**	Mean	40.7	41.9	41.0
mmHg	SD	0.4	0.4	0.5
	CV%	1.1	0.9	1.1
***P*O$_2$**	Mean	86.2	88.6	86.5
mmHg	SD	1.2	1.2	1.2
	CV%	1.4	1.3	1.3

Stat Profile Prime Within-Run Precision Summary - Whole Blood - Capillary

Within Run Precision Summary				
Parameter	**n = 20**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**
pH	Mean	7.349	7.335	7.348
pH units	SD	0.005	0.005	0.004
***P*CO$_2$**	Mean	39.3	40.9	39.8
mmHg	SD	0.6	0.7	0.6
	CV%	1.5	1.7	1.5
***P*O$_2$**	Mean	92.4	94.0	92.9
mmHg	SD	1.8	1.8	1.9
	CV%	2.0	1.9	2.0

Linearity Performance

For each parameter, samples were prepared by tonometering, spiking, or diluting whole blood to span the analytical measurement range for each parameter. Each blood level was analyzed in duplicate on each of the 3 test analyzers and on the Stat Profile Prime CCS Comp analyzers. The Prime CCS Comp analyzers were used to establish the target value of each blood level for each parameter. The observed values from each test analyzer were compared to the results from the comparative method.

Stat Profile Prime ABG Whole Blood Linearity

	Individual Analyzer Performance Data					
Parameter	**Analyzer**	**Total # levels**	**Specimen range**	**Slope**	**Intercept**	**r**
pH	#1	13	6.555 - 8.221	0.9915	0.0632	0.9998
pH units	#2	13	6.558 - 8.250	0.9948	0.0432	0.9997
	#3	13	6.531 - 8.230	0.9997	0.0006	0.9998
PCO_2	#1	14	0.9 - 230.8	1.0017	-0.5304	0.9982
mmHg	#2	14	0.3 - 228.1	0.9939	0.8671	0.9975
	#3	15	1.0 - 229.3	0.9934	2.2697	0.9990
PO_2	#1	13	8.3 - 719.7	0.9936	-1.7134	0.9994
mmHg	#2	13	9.7 - 721.2	1.0204	-1.9551	0.9996
	#3	12	9.3 - 728.8	1.0035	0.1656	0.9995

QC Total Imprecision Performance

Estimates of the total imprecision were determined for the Stat Profile Prime ABG analyzers by analyzing the following solutions in duplicate over a period of 20 days.

- 2 runs per day for a total of 40 runs
- Quality Control Material – 3 levels for each parameter in QC mode

Total Imprecision Results

pH Precision Data						
Sample	Pooled Mean	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	7.151	240	0.001	---	0.004	---
QC Level 2	7.358	240	0.000	---	0.006	---
QC Level 3	7.569	240	0.000	---	0.008	---

PCO_2 Precision Data						
Sample	Pooled Mean (mmHg)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	57.0	240	0.33	0.58	0.92	1.61
QC Level 2	39.7	240	0.27	0.68	0.63	1.59
QC Level 3	24.0	240	0.19	0.79	0.80	3.33

PO_2 Precision Data						
Sample	Pooled Mean (mmHg)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	57.4	240	0.43	0.75	2.22	3.87
QC Level 2	101.5	240	0.29	0.29	2.57	2.53
QC Level 3	137.2	240	0.34	0.25	3.51	2.56

Stat Profile Prime Run-to-Run Precision Summary - Whole Blood - Syringe

Run-to-Run Precision				
Parameter	**n = 30**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**
pH	Mean	7.339	7.337	7.336
pH units	SD	0.010	0.007	0.009
***P*CO$_2$**	Mean	49.3	49.6	50.0
mmHg	SD	1.2	1.2	1.2
	CV%	2.4	2.5	2.3
***P*O$_2$**	Mean	34.2	35.1	36.6
mmHg	SD	0.5	0.5	0.5
	CV%	1.4	1.3	1.3

Stat Profile Prime Run-to-Run Precision Summary - Whole Blood - Capillary

Run-to-Run Precision				
Parameter	**n = 30**	**Analyzer # 1**	**Analyzer # 2**	**Analyzer # 3**
pH	Mean	7.205	7.204	7.176
pH units	SD	0.006	0.007	0.005
***P*CO$_2$**	Mean	73.0	74.1	69.7
mmHg	SD	2.2	2.6	2.4
	CV%	3.0	3.5	3.5
***P*O$_2$**	Mean	61.7	64.2	61.6
mmHg	SD	0.7	1.2	0.7
	CV%	1.2	1.8	1.1

A.3 Point-of-Care Usage Performance Studies

The Stat Profile Prime ABG analyzer may be used in point-of-care settings. The Stat Profile Prime ABG Analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU), and a Pulmonary Care Unit (PCU). A total of 35 respiratory therapy and 17 nursing POC personnel participated in the testing within the 3 POC setting sites on 3 Stat Profile Prime ABG analyzers. The personnel represent trained, qualified staff found in typical POC sites where blood gas analyzers are utilized.

Within Run Precision/Reproducibility Study Design

The within run precision test data included in the following tables was obtained from different POC personnel running 20 replicates of 3 levels of Stat Profile Prime External Quality Control material (Levels 1-3) on a Stat Profile Prime ABG analyzer. The protocol was based upon methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second edition," CLSI EP5-A2. The test data is representative of the expected within run precision performance obtainable by respiratory therapy and nursing POC personnel using the Stat Profile Prime ABG analyzer utilizing external quality control materials and heparinized whole blood specimens.

Within Run Precision/Reproducibility Results
Point-of-Care Study - PCU
Stat Profile Prime External Quality Control Materials (N=20)

Within Run Precision - Level 1				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.156	0.004	0.06	7.148 - 7.164
***P*CO$_2$**	59.8	1.0	1.7	57.8 - 61.8
***P*O$_2$**	62.8	1.6	2.5	59.7 - 65.9
Within Run Precision - Level 2				
pH	7.368	0.002	0.03	7.363 - 7.372
***P*CO$_2$**	41.4	0.5	1.3	40.3 - 42.5
***P*O$_2$**	98.9	2.3	2.3	94.3 - 103.4
Within Run Precision - Level 3				
pH	7.551	0.011	0.15	7.530 - 7.573
***P*CO$_2$**	26.9	0.9	3.3	25.1 - 28.7
***P*O$_2$**	137.9	2.0	1.4	134.0 - 141.9

Within Run Precision/Reproducibility Results
Point-of-Care Study - CVICU
Stat Profile Prime External Quality Control Materials (N=20)

Within Run Precision - Sample 1				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.151	0.002	0.03	7.147 - 7.156
PCO_2	61.9	0.7	1.2	60.4 - 63.4
PO_2	63.0	1.3	2.1	60.4 - 65.6
Within Run Precision - Sample 2				
pH	7.371	0.001	0.01	7.368 - 7.374
PCO_2	40.1	0.4	1.1	39.2 - 40.9
PO_2	101.5	2.5	2.5	96.4 - 106.5
Within Run Precision - Sample 3				
pH	7.556	0.009	0.12	7.539 - 7.574
PCO_2	25.1	0.9	3.6	23.3 - 26.9
PO_2	144.9	1.8	1.2	141.3 - 148.6

Within Run Precision/Reproducibility Results
Point-of-Care Study - MICU
Stat Profile Prime External Quality Control Materials (N=20)

Within Run Precision - Sample 1				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.154	0.003	0.04	7.148 - 7.160
PCO_2	59.5	0.5	0.8	58.5 - 60.5
PO_2	62.3	1.8	2.9	58.6 - 66.0
Within Run Precision - Sample 2				
pH	7.368	0.002	0.03	7.364 - 7.372
PCO_2	41.6	0.5	1.2	40.7 - 42.6
PO_2	97.6	1.9	2.0	93.7 - 101.4
Within Run Precision - Sample 3				
pH	7.568	0.003	0.04	7.562 - 7.573
PCO_2	24.3	0.4	1.6	23.5 - 25.1
PO_2	136.6	3.1	2.3	130.4 - 142.9

Quality Control Total Imprecision Performance

The estimates of total imprecision test data included in the following table was obtained from different POC personnel running 3 levels of Stat Profile Prime External Quality Control material (Levels 1-3) in duplicate each day for a total of 20 runs on 3 Stat Profile Prime ABG analyzers. The protocol was based upon methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second edition," CLSI EP5-A2. The test data is representative of the expected total imprecision between analyzer performance obtainable by POC personnel using the Stat Profile Prime ABG analyzer using external quality control materials.

Total Imprecision Results Point-of-Care Study
Stat Profile Prime External Quality Control Materials
(N=20 runs, 3 sites combined)

Parameter	Pooled Mean	N	Within Run SD (Sr)	Within Run %CV	Total Imprecision SD(St)	Total Imprecision %CV
Total Imprecision Data - Level 1						
pH	7.152	120	0.004	0.056	0.005	0.070
PCO_2	61.3	120	0.8	1.3	1.7	2.7
PO_2	64.0	120	1.6	2.5	3.2	5.0
Total Imprecision Data - Level 2						
pH	7.367	120	0.002	0.027	0.003	0.041
PCO_2	41.4	120	0.4	1.0	0.6	1.5
PO_2	101.7	120	1.4	1.4	3.0	2.9
Total Imprecision Data - Level 3						
pH	7.560	120	0.006	0.079	0.007	0.093
PCO_2	25.5	120	0.8	3.1	1.2	4.7
PO_2	139.8	120	1.7	1.2	4.0	2.8

Syringe Mode Method Comparison Study Design

Syringe Mode method comparison studies were performed by POC participants from 3 POC settings including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU), and a Pulmonary care unit (PCU) on 3 Stat Profile Prime ABG analyzers. The studies included a minimum of 20 testing days, using methods described in CLSI "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition," CLSI EP9-A2. Heparinized blood gas specimens were used to compare the whole blood results obtained by POC personnel in these settings to the whole blood results obtained by trained laboratory personnel on the same specimens on the same analyzer. The pooled method comparison test data included in the following table was obtained by respiratory therapy and nursing POC personnel compared to results obtained by trained laboratory personnel on the same specimens. Spiked and tonometered specimens were needed to support the full reportable range. The syringe mode method comparison test data is representative of the expected results obtained by POC personnel when compared to trained laboratory personnel using a Stat Profile Prime ABG analyzer on heparinized syringe whole blood specimens on the same analyzer.

Syringe Mode Method Comparison Study Results
Point-of-Care Study
POC Personnel vs. Health Care Professional

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	188	6.785 - 7.758	0.997	0.018	0.999
PCO_2 mmHg	188	4.3 - 188.5	1.001	1.063	0.998
PO_2 mmHg	188	11.8 - 755.3	1.015	-0.94	1.0

Capillary Mode Method Comparison Study Design

Capillary Mode method comparison studies were performed by POC participants from 3 POC settings including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU) and a Pulmonary care unit (PCU) on 3 Stat Profile Prime ABG analyzers. The studies included a minimum of twenty testing days. using methods described in CLSI "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition," CLSI EP9-A2. Heparinized blood gas capillary tubes were used to compare the whole blood results obtained by POC personnel in these settings to the capillary whole blood result obtained by trained laboratory personnel on the same specimen on the same analyzer. The pooled method comparison test data included in the following table was obtained by respiratory therapy POC and nursing personnel compared to results obtained by trained laboratory personnel on the same specimens on the same analyzer. Spiked and tonometered specimens were needed to support the full reportable range. The capillary mode method comparison test data is representative of the expected results obtained by POC personnel when compared to trained laboratory personnel using a Stat Profile Prime ABG analyzer on heparinized capillary whole blood specimens.

Capillary Mode Method Comparison Study Results
Point-of-Care Study
POC Personnel vs. Health Care Professional

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	127	6.791 - 7.724	0.993	0.047	0.998
PCO_2 mmHg	127	4.3 - 187.8	0.984	1.347	0.997
PO_2 mmHg	127	14.5 - 672.9	1.041	-2.761	0.999

A.4 Calibrator Cartridge

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

A.4.1 Traceability of Calibrators, Controls, and Standards

Chemistry analytes are traceable to the Standard Reference Materials of the National Institute of Standards and Technology (NIST). SO_2 is traceable to tonometry.

A.5 Reference Values

Each laboratory should establish and maintain its own reference values. The values given here should be used **only as a guide.**

Table A.1 Reference Values[1,2,3]

Test	Value
pH	7.35 - 7.45
PCO_2	35 - 45 mmHg
PO_2	83 - 108 mmHg

References:

1. Statland, Bernard. 1987. *Clinical Decisions Levels for Lab Tests*, Medical Economics Books.
2. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.
3. Burtis, Carl A. Ashwood, Edward R., Burns, David R., 2011. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 5th ed,* Philadelphia, PA: W. B. Saunders Co.

A.6 Ordering Information

Stat Profile Prime ABG Analyzer supplies and parts are available from Nova Biomedical.

DESCRIPTION	Part #
Ampuled Control ABG/CCS, Prime	52714
Auto QC Cartridge ABG, Prime 300 Sample	53108
Auto QC Cartridge ABG, Prime 200 Sample	53107
Auto QC Cartridge ABG, Prime 100 Sample	53456
Backup Power Supply, 120V Prime	53727
Backup Power Supply, 230V Prime	53726
Calibrator Cartridge ABG 100 Sample, Prime	53104
Calibrator Cartridge ABG 200 Sample, Prime	53360
Calibrator Cartridge ABG 300 Sample, Prime	53359
Calibrator Cartridge ABG 400 Sample, Prime	53463
Calibrator Cartridge ABG 500 Sample, Prime	53464
Calibrator Cartridge ABG 600 Sample, Prime	53465
Calibrator Flush Fixture, Stat Profile Prime	52865
Control Flush Fixture, CCX, pHOx/Basic/Plus/L/C/M	24819
Flowpath Flush Tool	53443
Kit Clot Catcher Capillary 250	38846
Kit Clot Catcher Syringe CCX 200	38883
Linearity Standard Set A Levels 1,2,3,4 Multipack	25217
Prime Cart	53367
Probe S Line 50 µL Prime ABG	53111
Pump Harness, Prime	52484
Reference Cartridge, Prime	42043
Safety Sample Port 5 Pk, Prime	52669
Sensor Card ABG, Prime	42031
Thermal Paper, pHOx Ultra and Prime only	49200

A.7 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 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 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 life, 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 Principles of Measurement

This section explains the Principles of Measurement for the Stat Profile Prime ABG Analyzer.

B.1 Measured Values

Measuring Technology: Ten Planar Sensors (pH, PCO_2, and PO_2) in a Micro Sensor Card

B.1.1 pH Sensor

Definition of pH

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

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

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

Principle of pH Measurement

pH is measured using a hydrogen ion selective membrane. One side of the membrane is in contact with a solution of constant pH. The other side is in contact with a solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions.
This change in potential is measured against a reference electrode of constant potential. The magnitude of the potential difference is a measure, then of the pH of the unknown solution.

B.1.2 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 blood.

Principle of PCO_2 Measurement

PCO_2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a hydrogen ion selective membrane CO_2 diffuses across the membrane into a thin layer of bicarbonate buffer in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure of the fluid in contact with the outer surface of the membrane. CO_2 in the solution becomes hydrated producing carbonic acid which results in a change in hydrogen ion activity.

$CO_2 + H_20 <=> H_2CO_3 <=> H^+ + [HCO^-_3]$ Equation 3

The pH of this internal solution varies with the PCO_2 according to the Henderson-Hasselbalch equation.

pH = pKa + log {HCO3- / PCO_2 * a}

The measured potential is related to the logarithm of PCO_2 content of the sample after compensation of the measured potential of the pH sensor.

B.1.3 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 blood. PO_2 provides an indication of the availability of oxygen in inspired air.

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.2 Calculated Values

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

B.2.1 Temperature Correction for Measured Values

The Stat Profile Prime ABG Analyzer allows you to enter the patient temperature when this differs from 37 °C, as for example in patients having surgery under hypothermia. The pH, PCO_2, and PO_2 sample values, at the patient's actual temperature, are then calculated as follows:

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

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

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

$$U = \left(\left[\frac{(5.49 \times 10^{11})\ Y + 0.071}{(9.72 \times 10^{-9})Y + 2.30} \right] \times (T - 37) \right)$$

and $Y = e[3.88 \times \ln(PO_2)]$

B.2.2 Calculated Parameters

Calculated Bicarbonate Concentration [HCO_3^-][2]

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

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

where pH and PCO_2 are measured.

pK = 6.091

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

Rearranging Equation 7 gives:

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

*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 Reference 2.

Base Excess of Blood (BE-B)*

Base excess of blood is defined as the concentration of titratable base needed to titrate blood to pH 7.40 at 37 °C while the PCO_2 is held constant at 40 mm Hg. Base excess of blood is calculated as follows:

$$BE\text{-}B = (1 - 0.014[Hb])([HCO_3^-] - 24 + (1.43[Hb] + 7.7)(pH - 7.4))$$

Equation 10

* The equations are from Reference 2.

Standard Bicarbonate Concentration (SBC)

The Standard Bicarbonate is defined as the bicarbonate concentration of the plasma of whole blood equilibrated to a PCO_2 of 40 mmHg at a temperature of 37 °C with the hemoglobin fully saturated with oxygen. Standard bicarbonate is calculated as follows:

$$SBC = 24.5 + 0.9Z + Z(Z - 8)(0.004 + 0.00025[Hb])$$

Equation 11

where $Z = [BE\text{-}B] - 0.19[Hb]((100 - SO_2)/100)$

[Hb] = The hemoglobin value which is measured, manually entered, or is the 14.3 g/dL default value

Base Excess Extracellular Fluid (BE-ECF)*

The Base Excess Extracellular fluid is a corrected form of the Base Excess Blood in which allowance has been made for the fact that blood is only approximately 37% of the extracellular fluid volume. Base excess is calculated as follows:

$$BE\text{-}ECF = [HCO_3^-] - 25 + 16.2\ (pH - 7.40) \qquad \text{Equation 12}$$

* The equations are from Reference 2.

Oxygen Content (O_2Ct)

Oxygen content is defined as the total amount of oxygen contained in a given volume of whole blood, including dissolved oxygen and oxygen bound to hemoglobin. It is expressed in milliliters of oxygen per 100 milliliters of blood (volume %) as calculated from the oxygen saturation and the hemoglobin concentration. Four moles of oxygen (22,393 mL/mol at standard temperature and pressure) can combine with 1 mole of hemoglobin (64,458 g/mol) so that oxygen capacity is equal to

$$\frac{4\ (22393)}{64458} = 1.39 \text{ mL of } O_2 \text{ per gram of Hb} \qquad \text{Equation 13}$$

therefore

$$O_2Ct = (1.39\ [Hb])\ (SO_2/100) + (0.0031\ [PO_2]) \qquad \text{Equation 14}$$

where 0.0031 is the solubility coefficient of O_2.
On the analyzer, hemoglobin can be manually entered, calculated from the measured hematocrit, or occur as a default value.

Oxygen Saturation (O_2Sat)

Oxygen saturation is defined as the amount of oxyhemoglobin in blood expressed as a fraction of the total amount of hemoglobin able to bind oxygen. It is calculated as follows:

$$O_2Sat = \frac{[PO_2']^3 + 150\,[PO_2']}{[PO_2']^3 + 150\,[PO_2'] + 23400} \times 100 \quad \text{Equation 15}$$

where $[PO_2'] = [PO_2] \times e\,[2.3026 \times (0.48\,(pH - 7.4) - 0.0013([HCO_3^-] - 25))]$

NOTE: *The equation for calculating oxygen saturation assumes a normal shape and position of the patient's oxygen dissociation curve.*

Alveolar Oxygen (A)

Alveolar Oxygen refers to the partial pressure of oxygen in alveolar gas. It is calculated as follows:

$$A = \frac{\%FIO_2}{100}\,(B.P. - 0.045T2 + 0.84T - 16.5) - **PCO2\left[\frac{\%FIO_2}{100} + \left(\frac{1-(\%FIO2/100)}{0.8}\right)\right]$$

Equation 16

where T = patient temperature
B.P. = barometric pressure
$\%FIO_2$ = fraction inspired oxygen, as a percent

** Temperature corrected gas value

Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)

The arterial alveolar oxygen tension gradient is a useful index of gas exchange within the lungs and is defined as:

$$Aa\ DO_2 = A - {}^{**}PO_2 \qquad \text{Equation 17}$$

** Temperature corrected gas value

NOTE: *For capillary samples, AaDO2 results have an asterisk (*). AaDO2 results are dependent on how the samples are drawn and handled, thus care must be taken when interpreting these calculated results.*

Arterial Alveolar Oxygen Tension Ratio (a/A)

The arterial alveolar oxygen tension ratio is useful to predict oxygen tension in alveolar gas and to provide an index of oxygenation which remains relatively stable when FIO_2 changes.

$$a/A = {}^{**}PO_2/A \qquad \text{Equation 18}$$

** Temperature corrected gas value

Oxygen Capacity of Hemoglobin (O_2Cap)

Oxygen capacity is the total amount of oxygen that a given volume of hemoglobin can carry. Oxygen capacity of hemoglobin is determined using the following equation:

$$O_2Cap = 1.39 \times [tHb] \qquad \text{Equation 19}$$

PO_2/FIO_2 Oxygenation Index (PO_2/FI)

Inspired oxygen fraction ratio is the ratio of partial pressure oxygen to the fraction inspired oxygen.

$$PO_2/FIO_2 = PO_2/(\%FIO_2/100\%) \qquad \text{Equation 20}$$

Where % FIO_2 = fraction inspired oxygen as a percent.

The Oxygen tension based index of PO_2/FIO_2 is used in the estimation of the intrapulmonary shunt fraction when pulmonary artery blood samples are not available. The Estimated Shunt,an oxygen content based index, is derived by mathematical manipulation of the Classic Shunt Equation 5. In assessing the lung as an Oxygenator, the calculation of the intrapulmonary shunt fraction at maintained inspired oxygen concentrations (Q_{sp}/QT or $Q_{\bar{v}a}/QT$) is generally recognized as the most reliable way to quantitate disruption of pulmonary oxygen transfer and therefore the extent to which pulmonary disease is contributing to arterial hypoxemia.

The most significant factor limiting the widespread clinical use of shunt fractions is that the calculation requires oxygen analysis of pulmonary artery blood. The Estimated Shunt calculation is based on use of an assumed $Q_{(a-\bar{v})}O_2$ of 3.5 mL/dL which has been shown to be a representative mean for large samples of critical ill patients with clinically adequate perfusion states [5,6,7,8].

The Estimated Shunt has been demonstrated to be far superior to oxygen tension based indices in reliably reflecting

changes in the Q_{sp}/QT[9]. Monitoring of the tcPO_2 Index and the $P_{(a\text{-}et)}CO_2$ should allow for verification of the adequacy of cardiac output and peripheral perfusion, thereby confirming the reliability of the Estimated Shunt to quantitate changes in Q_{sp}/QT.

Respiratory Index (RI)

RI is the ratio of the alveolar-arterial oxygen tension gradient to the arterial oxygen tension. It is used to assess the extent of the pulmonary shunting [5].

$$RI = (P_AO_2 - PaO_2)/PaO_2 \qquad \text{Equation 21}$$

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