REF 52920 EN Rx Only IVD CE

Stat Profile PRIME® CCS Analyzer

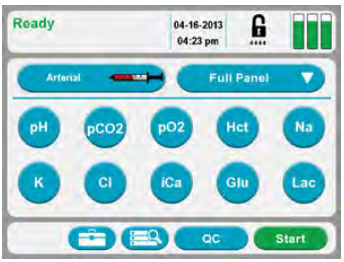
Instructions for Use Manual

nova® biomedical

Nova Prime CCS Analyzer 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
	Device for near-patient testing
	Caution
	Consult Instructions for Use
	Biological risk
REF	Catalog number
	Manufactured by
CONTROL	Control
LEVEL	Level
LOT	Batch code
SN	Serial number
	Temperature limitation
 YYYY - MM - DD	Use by date
	Electronic Waste
EC REP	Authorized representative in the European Commission
	Laser radiation: Do not stare into beam
	Prescription use only

Revision History

PN52920 Prime CCS Instructions for Use Manual		
Rev	**Release**	**Description**
H	05 – 2022	Update to meet IVDR requirements
J	01 – 2023	Hazardous Waste Disposal Advisory

Ordering Information

The *Stat Profile PRIME CCS Analyzer Instructions for Use Manual* can be ordered from Nova Biomedical Order Services. Call, fax, or write to:

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

EC REP Authorized Representative

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Nova Biomedical recommends users report any serious incidents/ adverse events to Nova Biomedical or Nova Biomedical's Authorized Representative, as well as to local Competent Authorities as required.

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1 Introduction

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

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

WARNING: Blood samples and blood products are potential sources of infectious agents. Handle all blood products, flow path components, and accessories (waste-line, capillary adaptor, probe, MicroSensor Card, clot catchers, flush tools/fixtures, safety sample port, etc.) with care. Gloves and protective clothing are recommended. When performing maintenance and troubleshooting procedures, also use protective eyewear.

1.1 About This Manual

This manual is for the Stat Profile Prime CCS Analyzer.

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

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 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 adaptor.
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.

Barcode Scanner Safety

A Class 2 laser is incorporated into the bar code scanner.

WARNING: Do not stare into the laser beam.

Laser Specifications:

- Wavelength: 650 nm
- Max Output: 1.9 mW

EN 60825-1: 2014

The laser complies with 21 CFR 1040.10 and 1040.11, except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

Disposal of Electronic Waste

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

Devices/Accessories: To ensure the product is disposed properly, decontaminate the product according to the instructions provided in section 1.5 of this manual and hand over the product to the applicable collection point for the recycling of electrical and electronic equipment.

1.3 Installation and Use

This section covers the installation requirements and assembly procedures for the Stat Profile Prime CCS 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.

Table 1-1 Prime CCS Requirements

Electrical Requirements	
Operating Voltage Range	100 – 240 VAC
Operating Frequency	50 – 60 Hz
Power Consumption	Less than 100 W
Ambient Operating Temperature	15 °C – 32 °C (59°F – 89.6°F)
Operate at Humidity	20 to 85% without condensation
Operate at Altitude	≤ 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 Cleaning the Analyzer

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

1.6 Intended Use, Tests Performed, and Clinical Utility

Intended Use

The Stat Profile Prime CCS Analyzer System is intended for *in vitro* diagnostic use by health care professionals in clinical laboratory settings and in Point-of-Care/Near-Patient Testing settings for the quantitative determination of pH, PCO_2, PO_2, Hct, Na+, K+, Cl^-, iCa, Glu (Glucose), and Lac (Lactate) in heparinized whole blood.

Measured Parameters

Stat Profile Prime CCS Analyzer: pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, Glu (Glucose), and Lac (Lactate).

Calculated Parameters

From the directly measured results, the calculated results are shown in Table 1-2.

Table 1-2 Calculated Parameters	
pH, PCO_2, PO_2 (corrected to patient temperature)	Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)
Bicarbonate level (HCO_3^-)	Arterial Alveolar Oxygen Tension Ratio (a/A)
Total Carbon Dioxide (TCO_2)	Respiratory Index (RI)
Base Excess of the blood (BE-b)	P50
Base Excess of extracellular fluid (BE-ecf)	PO_2/FIO_2 ratio
Standard Bicarbonate Concentration (SBC)	Oxygen Saturation (SO_2%)
Oxygen Content (O_2Ct)	Hemoglobin (Hb)
Oxygen Capacity (O_2Cap)	Anion Gap
Alveolar Oxygen (A)	Normalized Calcium (nCa)

Clinical Utility[1]

Table 1-3 provides the clinical utility information for each of the analytes measured on the Stat Profile Prime CCS Analyzer.

Table 1-3 Prime CCS Analyzer Clinical Utility	
pH ***PCO_2*** ***PO_2***	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.
Hct	Whole blood measurements of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
Na^+	Sodium measurement is used in the diagnosis and treatment of electrolyte imbalance.

Table 1-3 Prime CCS Analyzer Clinical Utility	
K^+	Potassium measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
Cl^-	Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders.
iCa	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Glu	Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus and hypoglycemia.
Lac	Lactate (lactic acid) measurement is used to evaluate the acid-base status of animals suspected of having lactic acidosis.

1.7 The Sample

Lithium heparin whole blood samples from syringes, open tubes, small cups, and capillary tubes can be used on the Stat Profile Prime CCS Analyzer. The minimum sample size for analysis is 100 µL.

1.7.1 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.[2]

Potassium

Correct sample handling is critical to ensure whole blood potassium values obtained accurately reflect the *in vivo* state. For example, a hemolyzed specimen of 50 mg/dL hemoglobin will increase the potassium blood concentration by 3%.[3]

1.7.2 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.
- 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.

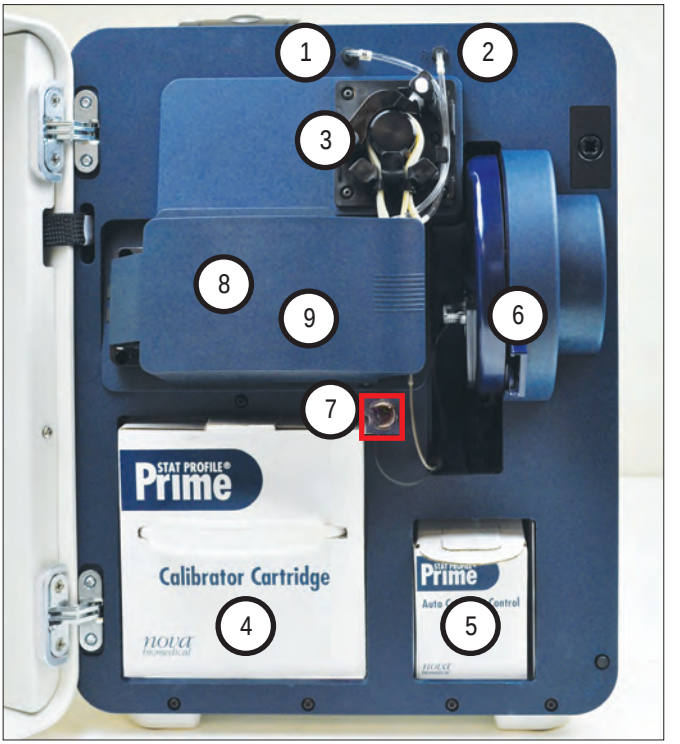
CAUTION: Stat Profile Prime CCS Analyzer users should take careful note of these considerations when establishing reference intervals and interpreting results.

2 Getting Started

The Stat Profile Prime CCS Analyzer is pictured below.

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

Figure 2.1 Nova Stat Profile Prime CCS



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. *MicroSensor Card (under cover)*
9. *Reference Cartridge (under cover)*

Figure 2.2 Analytical Compartment

2.1 Power Up Procedure

When the analyzer is powered on, it displays the Stat Profile Prime CCS 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 MicroSensor Card use life; the calibrator cartridge fluid level; and the internal auto QC cartridge fluid level are checked.

*Figure 2.3 **Initializing** Screen*

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

*Figure 2.4 **Not Ready** Screen*

2.2 The Home Screen: Ready

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

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 MicroSensor Card, Calibrator Cartridge, and Control Cartridge status are displayed.

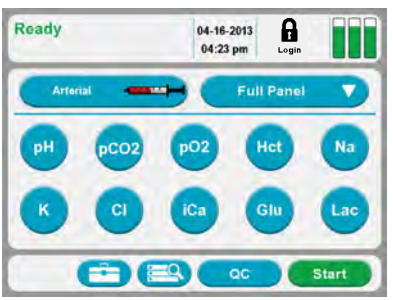


*Figure 2.5 Home Screen: **Ready***

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 using the Lock icon 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 MicroSensor 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 information about sensor availability are found here.

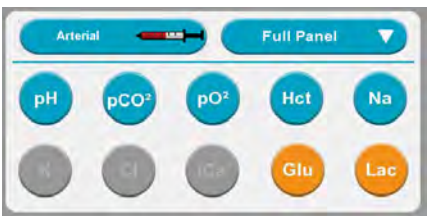
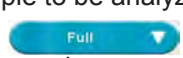


Figure 2.6 Selection Area

- Analytes displayed in **Orange** are unavailable for analysis. If you press the icon of the Orange Analyte, the Sensor Status Screen with additional information will display.
- Analytes 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 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.

Use the Container button 

to select thetype of conatiner and sample to be analyzed.

Use the Panel button 

to select from a predefined list of test panels.

2.2.3 Sensor Status Screen

Analytes displayed in **Orange** are unavailable for analysis. Press an orange analyte button to see the Sensor Status Screen, which displays the status of that analyte. Detected sensor errors or QC Lockout conditions display 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 unavailable.
- Touching the Left Arrow button displays the status of the prior sensor that is unavailable.

Figure 2.7 Sensor Status Screen

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 button 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 the 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 the Enter button.
3. If required, enter or scan your **Password,** then press the Enter button.

2.4 Automatic Calibrations

The Stat Profile Prime CCS analyzer performs a 2-point calibration 30 minutes after being powered on and regularly thereafter to maintain optimal MicroSensor Card and air detector performance.

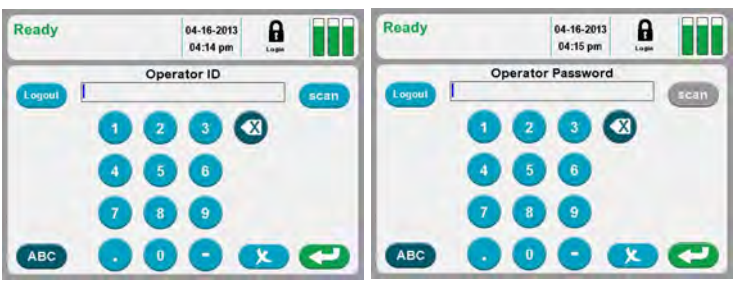


Figure 2.8 Operator ID Screen and Operator Password Screen

A 1-point calibration is performed at regular intervals to monitor MicroSensor Card 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 unavailable for testing.

Scheduled 2-point calibrations can be delayed once for 10 minutes by pressing the Cancel button. After 10 minutes the rescheduled calibration begins 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 button 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 select the Toolbox icon and then select the Calibrate button .

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

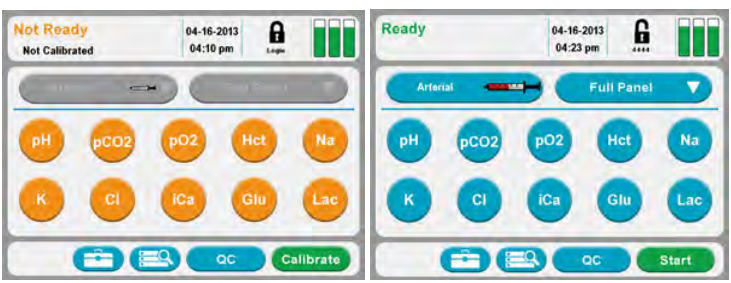


*Figure 2.9 **Not Ready** Screen and **Ready** Screen*

2.4.2 Air Detector Calibration

The Air Detectors are automatically calibrated once a day. An Air Detector calibration can be initiated manually, if needed, as follows:

> > 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 auto 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.

INTERFERENCE WARNING: Do not perform glucose and lactate testing on patients taking the drug hydroxyurea. Refer to section A.3 for additional interference information.

3.1.1 Analyzing Syringe Samples

From the Home screen, log in if necessary.

1. Select the syringe button 

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

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

3. Press the Start button Start to begin the analysis.
4. If prompted, enter all Required Information and press Start again 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 the **Aspirate** Aspirate button.

The sample probe retracts automatically once sufficient sample has been aspirated into the analyzer.

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

NOTE: *The Sample Information remains disabled 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 3.3 Syringe Sample

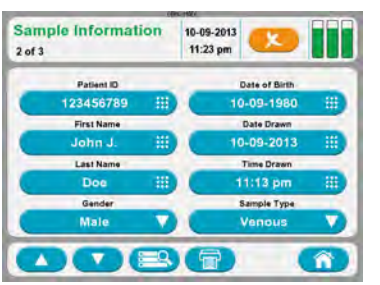


Figure 3.4
Sample Information Screen

3.1.2 Using 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 using 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 flow path. 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 appropriate syringe button 

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 the Start button Start to begin the analysis.
5. If prompted, enter all Required Information and press the Start button once more to begin the analysis.
6. Press the Aspirate button Aspirate to aspirate sample into the analyzer. The sample probe retracts 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: *The 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.*

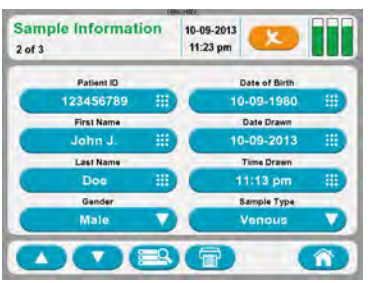


Figure 3.7
Sample Information Screen

Figure 3.8 Position Sample Screen: Safety Sample Port

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 the Start button to begin the analysis.
4. If prompted, enter all Required Information and press Start Start once more to begin the analysis.
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.
6. Enter any Required or Optional information while the analysis is running.

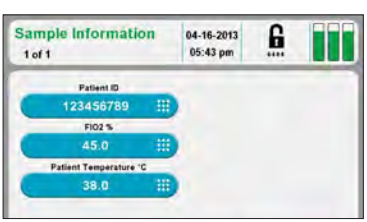


Figure 3.10 Sample Information Screen

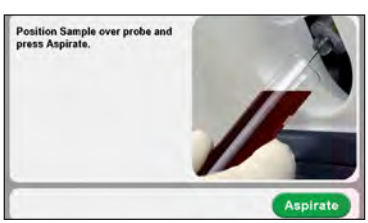


Figure 3.11 Position Sample Screen:

NOTE: *The 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.*

3.1.4 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.
3. Press Start Start to begin the analysis.
4. If prompted, enter all Required Information and press the Start button again to begin the analysis.
5. Prepare the sample for analysis (mix well). Then position the capillary tube into the capillary adaptor and press Aspirate Aspirate.
6. When prompted, remove the capillary tube and press ↵.
7. 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 canceled by pressing the X icon* ✕ *but results will not be printed or transmitted.*

Figure 3.12 Ready Screen: Container and Panel Drop-down Lists

Figure 3.13 Sample Information Screen

Figure 3.14 Position Sample Screen:

3.2 The Sample Results Display

Once the sample analysis is complete, results for the selected and calculated analytes display (Figure 3.16).

Each analyte is shown with its measured value, the unit of measure, and a 3-segment bar that provides a visual indication of the sample concentration: **Green** for normal results, **Orange** exceeds normal limits, and **Red** exceeds panic limits. Sample results displayed as **--** were determined to be outside the analyzer's analytical measurement range.

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

The color bar consists of 3 segments:

1. The first (left hand) segment 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.
2. The middle segment 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.

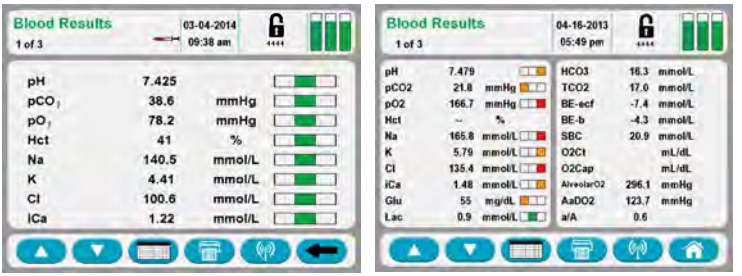


Figure 3.15
Blood Results Screens: Displayed in 1 Column (left) or 2 Columns

3. The last (right hand) segment indicates the sample result is higher than the entered normal range.
   - The segment is **Orange** when a sample result is between the high Normal and high Alert range.
   - The segment is **Red** 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 Home screen.

3.2.1 Sample Results Printout

The Sample Results printout contains a customizable header followed by the measured and calculated test results. Each test result contains the **test name**, the **measured value** and the **unit of measure**. A **result flag** consisting of one or more up (↑) or down (↓) arrows may also be displayed. Some event codes prevent a test

result from being printed. Should this occur the event code is printed in place of the test result. Results printed as **- -** were determined to be outside the analyzer's measurement range.

Flags

- A single up arrow ↑ is printed if the measured value is above the upper end of the normal range.
- A double up arrow ↑↑ is printed if the measured value is above than the upper end of the critical range.
- A triple up arrow ↑↑↑ is printed if the measured value is above than the upper end of the measurement range.
- A single down arrow ↓ is printed if the measured value is below the lower end of the normal range.
- A double down arrow ↓↓ is printed if the measured value is below the lower end of the critical range.
- A triple down arrow ↓↓↓ is printed if the measured value is below the lower end of the measurement range.

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 QC Samples

From the Home screen:

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

Figure 3.16 Quality Control Screens

4. From the drop-down list, select the Internal Control Level to be analyzed.
5. Enter a QC comment if desired.
6. Press **Start** to begin the analysis.
7. Wait until probe is fully extended.
8. Position the well-mixed sample over the probe. Select the Aspirate button. The sample probe retracts automatically when sufficient sample has been aspirated. Tests are performed and the QC results are displayed on the screen.
9. Once the analysis is complete press the Save button to keep the QC results or press Delete to discard the QC results.

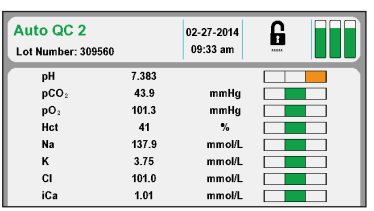


Figure 3.17 Quality Control Results Screen

3.3.2 Analyzing External QC Samples

From the Home screen:

1. From the Home Screen, press the QC button 

2. Press the Analyze QC button 
.

Figure 3.18 Quality Control Screens

3. From the drop-down list, select the External Control Level to be analyzed.
4. Select the lot number to be analyzed.
5. Enter a QC Comment if desired.
6. Press **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 the **Aspirate** button. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.
9. Once the analysis is complete, press **Save** to keep the QC results or press Delete to discard the QC results.

Figure 3.19 Position External QC Screen

3.3.3 Analyzing Proficiency Samples

1. From the Home Screen, press the QC button QC
2. Press the Analyze QC button Analyze QC.
3. From the drop-down list, press Select QC Level to Analyze.
4. From the drop-down list select Proficiency.
5. Press **Start** Start to begin the analysis.
6. Wait for the Sample Probe to fully extend.

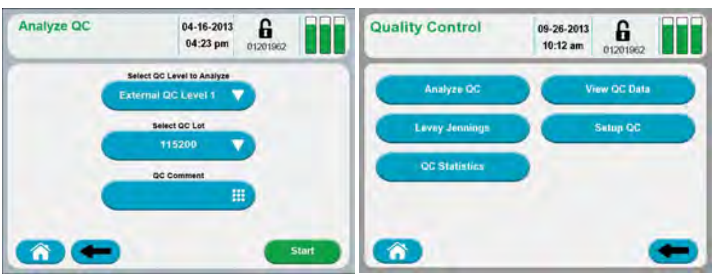


Figure 3.20 Quality Control Screens

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

Figure 3.21 Proficiency Sample Positioned on Probe

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)
3. Then press to display the selected sample results (Figure 4.2).

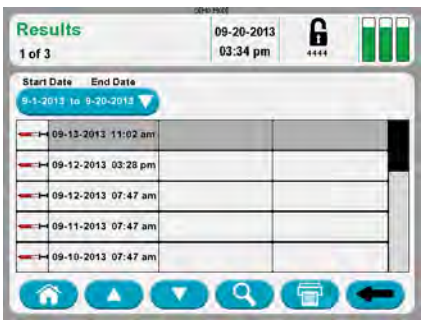


Figure 4.1 Results Screen

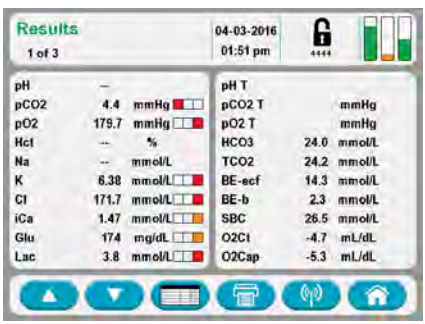


Figure 4.2 Patient Result Selected Data

4. If there is 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.
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 desired patient result, then press  to display results.
9. To print the data, press the print icon on the footer of the screen.

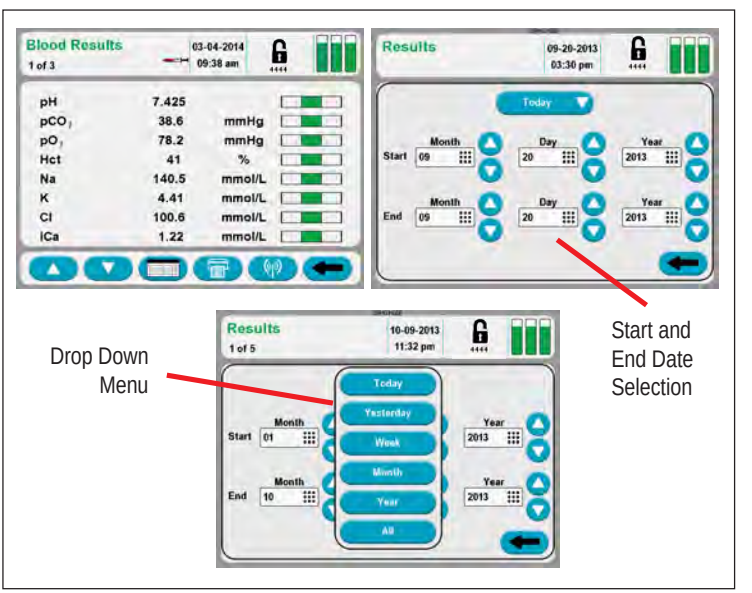


Figure 4.3 Results Screens

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.
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 list.
7. A Lot button is available for choosing a QC lot.
8. Select a QC data date and press the  to display the data screen.
9. To print the data, press the print icon on the footer of the screen.

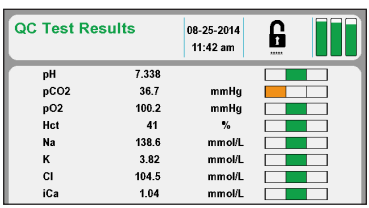


Figure 4.5 QC Results Screen

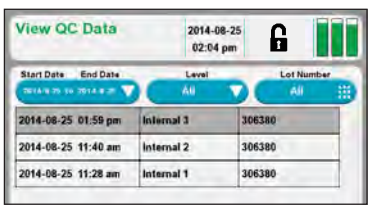


Figure 4.4 View QC Data Screen

4.3 QC Statistics

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

1. Press the QC button on the Home screen.

The Quality Control Screen displays.

2. Press the QC Statistics button to display the QC Statistics screen.

Figure 4.6 Quality Control Screen

3. On this screen, press the Start Date End Date button.
4. 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.
5. Press the back button to display all the QC Statistics for these selected dates.
6. 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.

The Quality Control Screen displays.

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

Figure 4.7 Quality Control 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 dispays showing a Y-axis for the test result and an X-axis for each day of a selected level,lot, test, and month.
8. 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 Levey Jennings Graph, press the print icon on the footer of the screen.

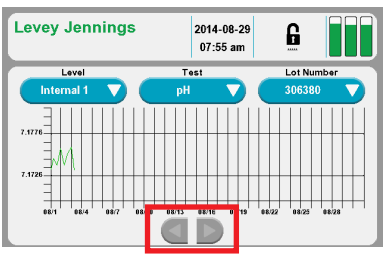


Figure 4.8 Levey Jennings Graph

5 Consumables Replacement

The following sections provide directions to operate and maintain the Stat Profile Prime CCS Analyzer at peak efficiency. From the Home screen, press the Tool box icon to display the System Menu screens (Figure 5.1). From these screens, press the appropriate button to replace the following consumables:

- MicroSensor Card
- Calibrator Cartridge
- Auto QC Cartridge

WARNING: Blood samples and blood products are potential sources of infectious agents. Handle all blood products, flow path components, and accessories (waste-line, probe, MicroSensor Card, clot catchers, flush tools/fixtures, safety sample port, 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 (Figure 5.2) displays when a new MicroSensor Card, Calibrator Cartridge, Auto QC Cartridge, or Reference Cartridge has been removed or requires replacement.

- The Sensor Card button displays if the MicroSensor Card is not present, has zero remaining life, or has not completed hydration.

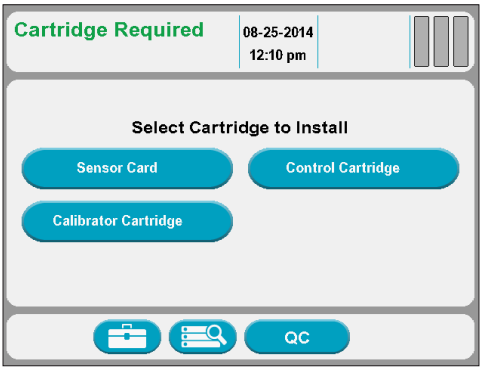


Figure 5.2 Cartridge Required Screen

- The Calibrator Cartridge and/or Auto QC Cartridge buttons display if the cartridge is not present or has zero remaining life.
- The Reference Sensor button displays if the Reference Sensor is not present.

Touching the button will bring you to the screen for replacing this item.

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, as needed.

Mix the cartridge thoroughly by gentle inversions. Then follow the directions on the screen to replace the cartridge and the Capillary Adaptor.

WARNING: When the Calibrator Cartridge or Auto QC Cartridge is removed, keep your fingers and hands away from the back of the cartridge compartment. Sharp needles can cause injury, and the waste needle is a biohazard.

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

NOTE: *The Calibrator Cartridge and 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 of 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 of these screens, go to the appropriate screen and press Prime.*

NOTE: *The Capillary Adaptor comes in the Calibrator Cartridge box. It is very important for the proper operation of the analyzer that the Capillary Adaptor be changed with every Calibrator Cartridge change.*

5.1.1 Replace the 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 button.

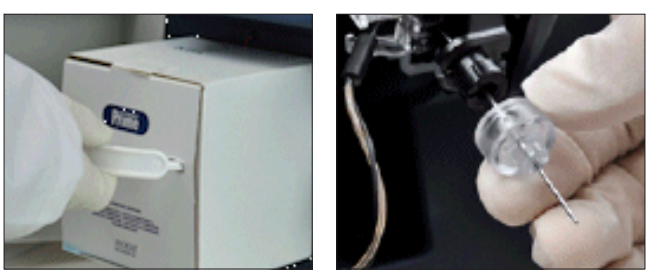


Figure 5.3 Remove Calibrator Cartridge and Capillary Adaptor

3. Open the door and remove the cartridge.
4. Slide in a new cartridge past the front retaining lip.

CAUTION: Probe will move when Enter is pressed.

5. To replace the Capillary Adaptor, press the Enter button. Slide off the used capillary adaptor. Slide on the adaptor provided with Calibrator Cartridge.
6. Close the analyzer door. Press the Prime button.

Calibrator Cartridge status can be viewed at any time by pressing the Cartridge Status indicator icon at upper right of the header bar.

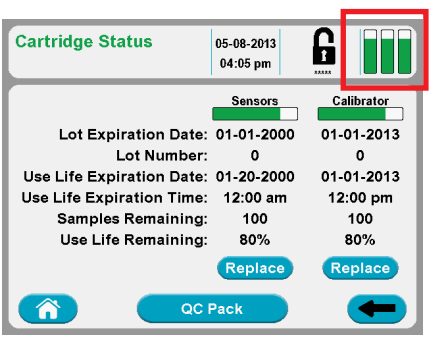


Figure 5.4 MicroSensor Card Status

- The Calibrator status bar is empty (white) when no Calibrator Cartridge is installed.
- The status bar is green and indicates the with the remaining use life of the Calibrator Cartridge when the use life remaining percentage is > 5%.
- The Calibrator status bar is orange when the remaining use life is ≤ 5%.
- The screen displays the lot expiration date, lot number, use life expiration date and time, number of samples remaining, and percentage use life remaining.

- When no cartridge is installed, all of the above are blank.
- Press as appropriate the Install button or Replace button.

5.1.2 Replace the Auto QC Cartridge

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 button.
3. Open the analyzer door. Remove the Auto QC Cartridge, if present.
4 Slide in a new cartridge, past the front retaining lip.
5. Close the door. Press the Prime button.

Figure 5.5 Remove Auto QC Cartridge

Auto QC Cartridge status can be viewed at any time by pressing the Status icon at upper right of the screen.

- The Auto QC status bar is empty (white) when the Auto QC Cartridge is not installed.
- The Auto QC status bar is green when the percentage remaining use life is > 5%.

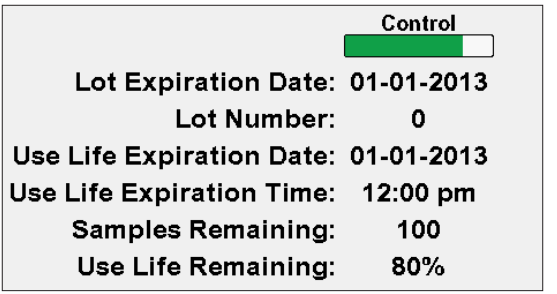


Figure 5.6 Auto QC Cartridge Status

- The Auto QC bar is orange with the percentage remaining use life of the Auto QC Cartridge if the use life remaining percentage is ≤ 5%.
- The screen displays the lot expiration date, lot number, use life expiration date, use life expiration time, number of samples remaining, and percentage use life remaining.
- If no pack is installed, all above is blank.
- There is either an install button to Install an Auto QC Cartridge or a Replace button to replace an Auto QC Cartridge.

5.2 Replace the MicroSensor Card

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

1. Press the Tool Box icon.
2. From the System Menu, press the Replace Sensor Card button. Wait for the pump to stop.
3. Open the analyzer door. Then open the MicroSensor Card door. Remove the card.

NOTE: *Hold the MicroSensor Card as indicated in Figure 5.7.*

Figure 5.7 MicroSensor Card

4 Insert the new card. Close the MicroSensor Card door.

5. Close the analyzer door. Press the Prime button.

MicroSensor Card status can be viewed at any time by pressing the Status icon on the upper right corner of the screen.

- The sensor status bar is empty (white) when no MicroSensor Card is installed.
- The bar is green and indicates the remaining use life of the MicroSensor Card if the remaining use life is greater than 5%.
- The status bar is orange and indicates the remaining use life of the MicroSensor Card if the use life remaining is less than or equal to 5%.

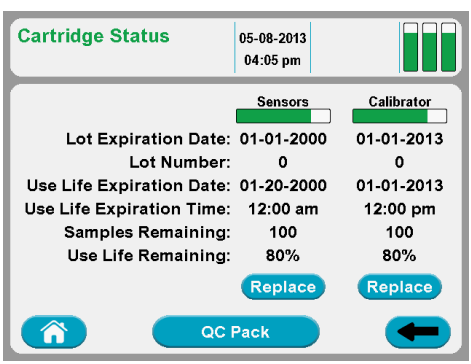


Figure 5.8 MicroSensor Card Status

- 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 MicroSensor Card is installed, all above is blank.
- There is either an Install button to install a MicroSensor Card or a Replace button to replace the Card.

5.3 Prime MicroSensor Card Warranty Process

If one or more analytes are unable to calibrate within the MicroSensor Card warrantied use life, the analyzer will generate a 16-digit warranty code that can be submitted for credit towards a new MicroSensor card.

The scenarios described in Table 5-1 generate a warranty code.

Warranty code generation depends upon the answers to a series of questions the user is prompted to answer. Following is a description of the screens and choices presented to the user.

1. If a MicroSensor Card fails prior to its stated warranty, the user is presented with the following screen.

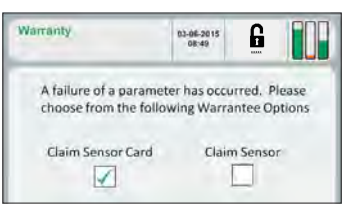


Figure 5.9 Warranty Screen

2. The user must select one of three options:

   - **Option 1:** “Claim Sensor Card”. This option provides the user with a warranty code which will reimburse them for all of the available parameters remaining on the MicroSensor Card to the end of

Table 5-1 Failures that Generate Warranty Codes

Failure Mode	Action
Hydration Failure – PCO_2 channel	The entire card is disabled. A single warranty code is generated. The customer must install a new card.
Hydration Failure – All other parameters	The sensor is automatically disabled and a warranty code is generated and printed automatically. The customer can continue using the card or disable the remaining channels. To disable the remaining channels and generate a code for the rest of the card, the user must select the disabled sensor – and follow the prompts.
PCO_2 channel failure during normal use	The PCO_2 is automatically disabled and a warranty code is generated and printed automatically. The customer can continue using the card or disable the remaining channels. To disable the remaining channels and generate a code for the rest of the card, the user must select the white PCO_2 icon and follow the prompts.
Any other channel in normal use	The customer is presented with a popup that allows disabling of the sensor or card.

the warranty period. If this option is selected, the software will permanently deactivate the card.

- **Option 2:** "Claim Sensor". This option provides the user with a credit for only the failed parameter but does not disable the remaining parameters. The user is allowed to continue using the remaining parameters on the card for patient testing.
- **Option 3:** Choose to defer the choice by selecting the cancel button . This only defers the choice until the next time the failure is detected.

3. Once the user has made a selection, the appropriate confirmation dialogues are presented.

Figure 5.10 Confirmation Dialogs

4. After confirmation, the Stat Profile Prime analyzer will automatically print and save the 16-digit code. The code is stored in the analyzer for future retrieval and is not lost.
5. The warranty codes can be retrieved at a later time by pressing Menu > Service > Credits. The codes are searchable by date range or printed status. Note that the “Printed” status (right hand column) refers to a reprint initiated from this screen. It does not refer to the automatic printing that occurs. This allows for easy identification of any unclaimed codes.
6. Once the code is generated, the user must provide it to customer support for a warranty credit. Customers in the USA should contact Nova Technical Support at 800-545–6682, In Canada contact Nova Technical Support at 1-800-263-5999. Outside the USA or Canada contact your local distributor.

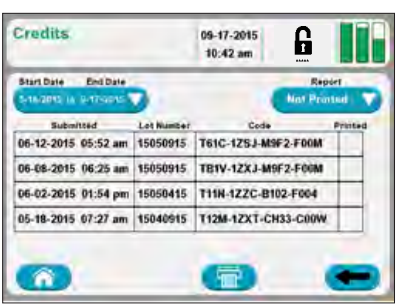


Figure 5.11 Warranty Credits Screen

6 Periodic Replacements

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

6.1 Pump Tubing Harness Replacement

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

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

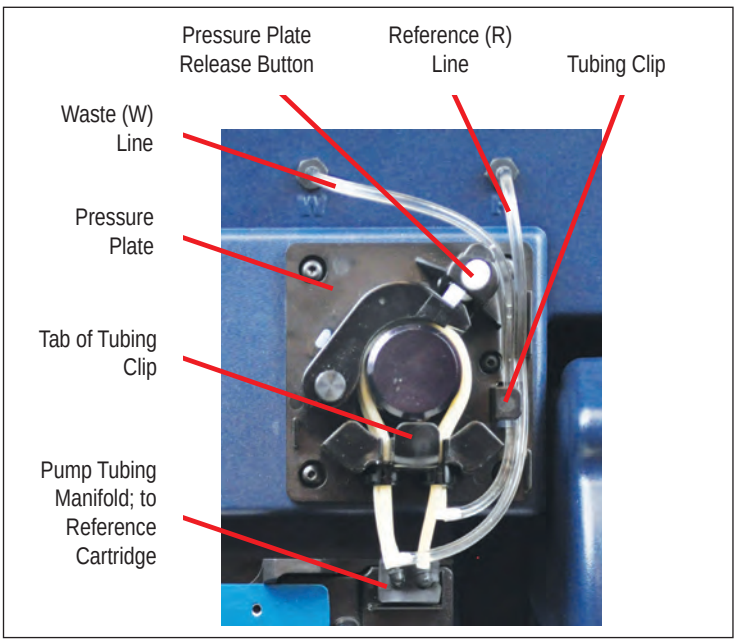


Figure 6.1 Pump Tubing

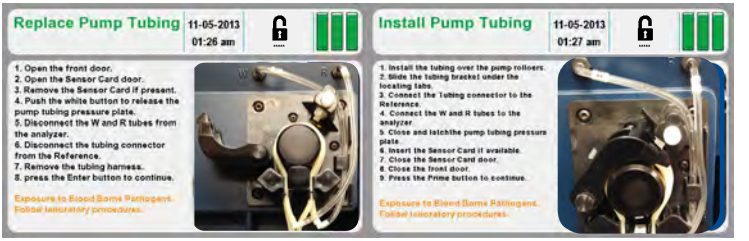


Figure 6.2 Replace and Install Pump Tubing Screens

1. From the Home screen, press the Tool Box icon.
2. From the System Menu, select Replace Pump Tubing. Wait for the pump to stop.
3. Open the analyzer door. Then open the MicroSensor Card door. Remove the MicroSensor Card, if present.
4. Push the white button to release the Pump Tubing Pressure Plate.

Figure 6.3 Release Pump Tubing Pressure Plate

5. Disconnect the W and R tubes from the analyzer.
6. Disconnect the tubing connector from the Reference Cartridge.
7. Remove the tubing harness and discard.
8. Press the Enter button to continue.

Figure 6.4
Disconnect Pump Manifold

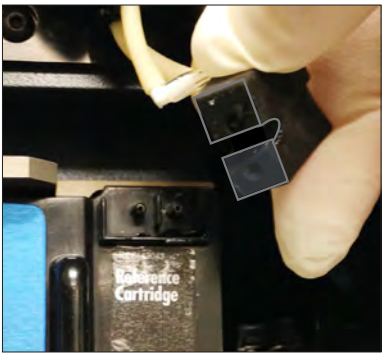


Figure 6.5 Disonnect Tubing Connector from Reference Cartridge

6.1.1 Install the Pump Tubing

1. Install the tubing over the pump rollers.
2. Slide the tubing bracket under the locating tabs.
3. Connect the tubing connector to the Reference Cartridge.
4. Connect the W and R tubes to the analyzer.
5. Close and latch the Pump Tubing Pressure Plate.
6. Insert the MicroSensor Card.
7. Close the MicroSensor Card door.
8. Close the analyzer door.
9. Press the Prime button to continue.

6.2 Probe Replacement

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

If the Probe or Sample/Air Detector line become damaged, replace the assembly. Use the following procedure:

1. From the Home screen, press the Tool Box icon. From the System Menu select Replace S-Line Probe and wait for the pump to stop.
2. Remove the capillary adaptor from the front of the probe by gently pulling (Figure 6.6).
3. Disconnect the Air Detector Tube (Figure 6.7).
4. Disconnect the Air Detector Sample Line from the Reference Cartridge module using the removal

Figure 6.6
Remove Capillary Adaptor

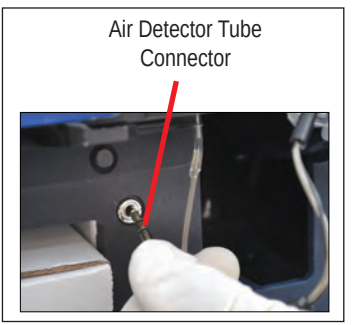


Figure 6.7 Disconnect Air Detector Tube

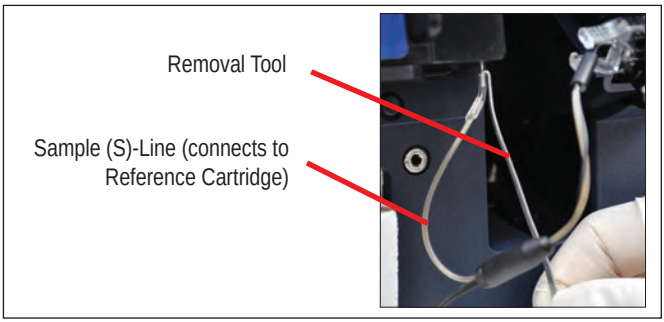


Figure 6.8 Remove the S-line from the Reference Cartridge

tool (Figure 6.8).

5. Squeeze the white pinch clamp (Figure 6.9). Remove the Probe, S-line, and Air Detector tube

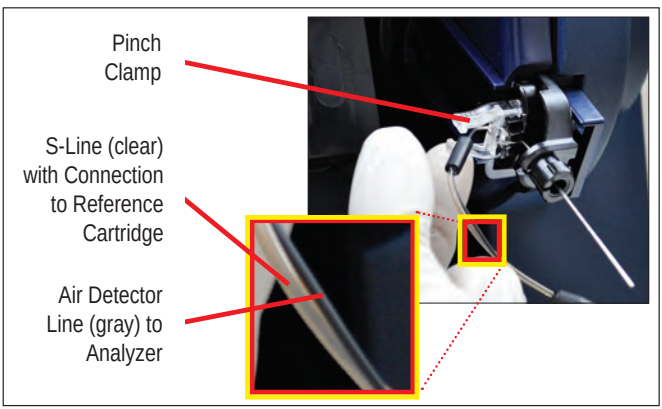


Figure 6.9 Remove Probe, S-line, and Air Detector Line

and discard.

6. Insert the new Probe assembly until it clicks into place.
7. Install the Capillary Adaptor onto the probe.
8. Reconnect the S-line to the Reference Cartridge
9. Reconnect the Air Detector line into the analyzer.
10. Close the door.
11. Press the Calibrate Calibrate button.

6.3 Reference Cartridge Replacement

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 the Replace Reference button.
3. Open the door. Open the MicroSensor Card door.
4 Remove the MicroSensor Card, if present.
5. Disconnect the Sample (S)-line from the bottom of the Reference Cartridge (Figure 6.10).

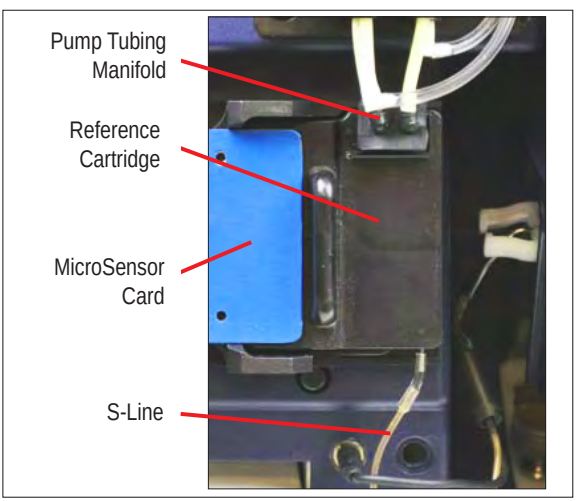


Figure 6.10 Reference Cartridge

6. Disconnect the Pump Tubing from the top of the Reference Cartridge.
7. Slide the Reference Cartridge right to remove (Figure 6.11)..
8. Press the Enter button to continue.

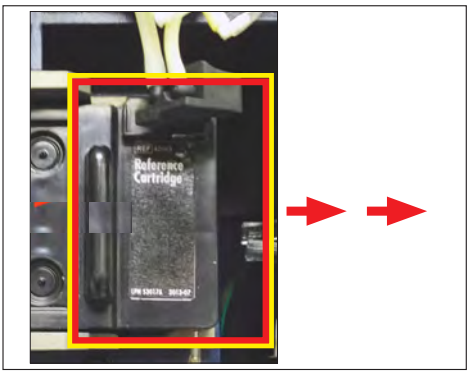


Figure 6.11 Slide the Reference Cartridge Right to Remove

6.3.1 Install the Reference Cartridge

1. Position the new Reference Cartridge to the right of its installed position.
2. Slide the Reference Cartridge left and into place.
3. Attach the S-Line to the bottom and Pump Tubing to the top.
4. Insert the MicroSensor Card.
5. Close the MicroSensor Card door.
6. Close the analyzer 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.

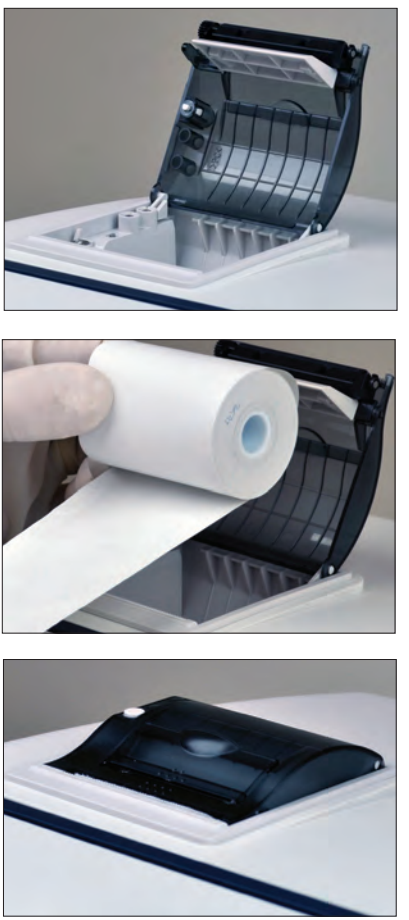


Figure 6.12 Replace the Printer Paper

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.

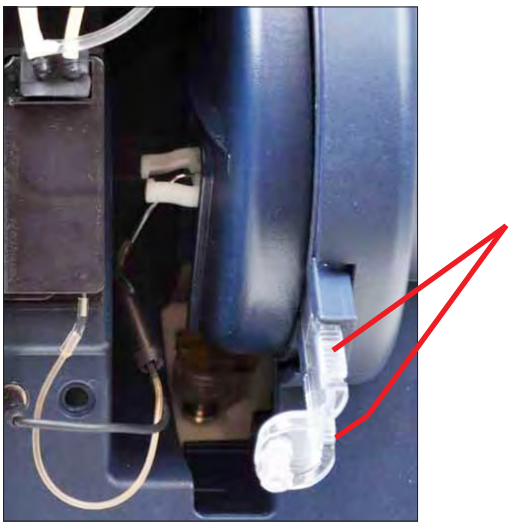


Figure 6.13 Replace the Safety Sample Port

7 Troubleshooting

This section describes the recommended troubleshooting procedures for use with the Stat Profile Prime CCS 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, accessories, and flow path components (waste-line, capillary adaptor, 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:

> > Logs and Reports > Event Log

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 .

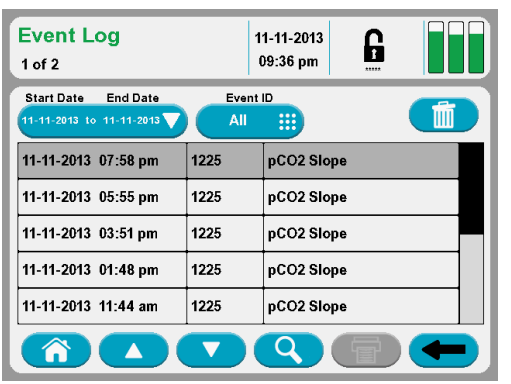


Figure 7.1 Event Screen

7.2 Resolving Event Codes

Event Codes are grouped into one of 5 categories, Cartridge errors, Flow errors, Printer errors, MicroSensor 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 MicroSensor Card Event Codes

Event Code	Description and Corrective Action
1201 **1209** **1217** **1225** **1233** **1241** **1249** **1257** **1265** **1289** **1297**	**Slope** **pH Slope** ***P*O$_2$ Slope** ***P*CO$_2$ Slope** **K Slope** **Na Slope** **Cl Slope** **Ca Slope** **Hct Slope** **Glucose Slope** **Lactate 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 flow path and recalibrate the analyzer. Refer to Section 7.3.2, Flushing the Flow Path. 3. Replace the MicroSensor Card. 4. Replace the Calibrator Cartridge. 5. Replace the Reference Cartridge. 6. Call Nova Biomedical Technical Support.

1202 1210 1218 1226 1234 1242 1250 1258 1266 1290 1298	**Overload** **pH Overload** ***P*O$_2$ Overload** ***P*CO$_2$ Overload** **K Overload** **Na Overload** **Cl Overload** **Ca Overload** **Hct Overload** **Glu Overload** **Lac 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 flow path and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flow Path. 3. Replace the MicroSensor Card. 4. Call Nova Biomedical Technical Support.	

1205 **1213** **1221** **1229** **1237** **1245** **1253** **1261** **1269** **1293** **1301**	**Stability** **pH Stability** ***P*O$_2$ Stability** ***P*CO$_2$ Stability** **K Stability** **Na Stability** **Cl Stability** **Ca Stability** **Hct Stability** **Glu Stability** **Lac 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 flow path and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flow Path. 3. Replace the MicroSensor Card. 4. Replace the Reference Cartridge. 5. Call Nova Biomedical Technical Support.	

1206 1214 1222 1230 1238 1246 1254 1262 1270 1294 1302	**E-Zero Drift** **pH E-Zero Drift** ***P*O$_2$ E-Zero Drift** ***P*CO$_2$ E-Zero Drift** **K E-Zero Drift** **Na E-Zero Drift** **Cl E-Zero Drift** **Ca E-Zero Drift** **Hct E-Zero Drift** **Glu E-Zero Drift** **Lac 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 flow path and recalibrate the analyzer. Refer to Section 7.3.2, Flushing the Flow Path. 3. Replace the MicroSensor Card. 4. Call Nova Biomedical Technical Support.	

1207 **1215** **1223** **1231** **1239** **1247** **1255** **1263** **1271** **1295** **1303**	**A to A Drift** **pH A to A Drift** ***P*O$_2$ A to A Drift** ***P*CO$_2$ A to A Drift** **K A to A Drift** **Na A to A Drift** **Cl A to A Drift** **Ca A to A Drift** **Hct A to A Drift** **Glu A to A Drift** **Lac 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 flow path and recalibrate the analyzer. Refer to Section 7.3.2 Flushing the Flow Path. 3. Replace the MicroSensor Card. 4. Call Nova Biomedical Technical Support.	

1208 **1216** **1224** **1232** **1240** **1248** **1256** **1264** **1272** **1296** **1304**	**Slope Drift** **pH Slope Drift** ***P*O$_2$ Slope Drift** ***P*CO$_2$ Slope Drift** **K Slope Drift** **Na Slope Drift** **Cl Slope Drift** **Ca Slope Drift** **Hct Slope Drift** **Glu Slope Drift** **Lac 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 flow path and recalibrate the analyzer. 3. Replace the MicroSensor 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 flow path 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 flow path.*

7.3.1 The Flow Path Flush Tool

The Flow Path Flush Tool (Figure 7.2) consists of a 30 mL syringe and a special adaptor to safely clear the flow path in the event it becomes obstructed.

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 Cartridge in only one direction (Figure 7.3). The tubing connected to the adaptor should point up to ensure it is not pinched shut when the MicroSensor Card door is closed.

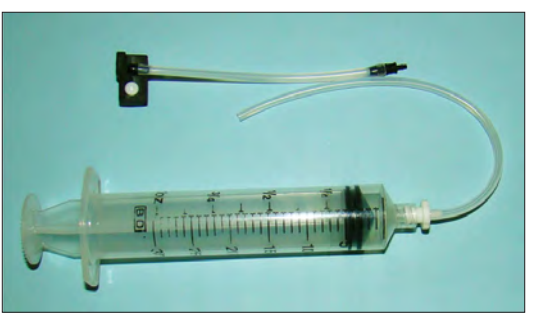


Figure 7.2 Flow Path Flush Tool

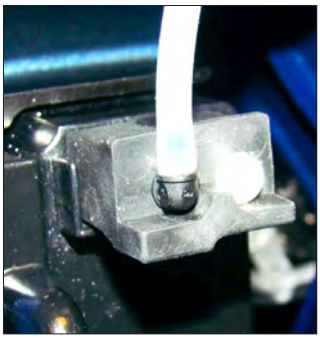


Figure 7.3 Tubing Connected to the Adaptor Points Up

7.3.2 Flushing the Flow Path

The analyzer's flow path 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 MicroSensor Card and is not recommended.

Following is the recommended procedure for clearing the flow path when needed.

1. From the Home screen, press  >
2. When the pump stops turning, open the analyzer door then open the MicroSensor 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 Cartridge.

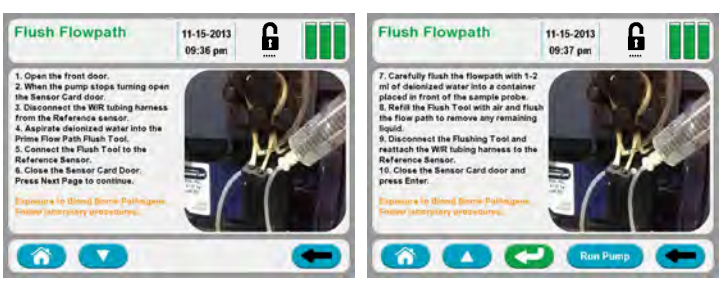


Figure 7.4 Flush Flow Path Screens

5. Connect the Flush Tool to the Reference Cartridge and close the MicroSensor Card door.
6. Using moderate pressure, carefully flush the flow path 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 Cartridge.
9. Close the MicroSensor Card door; press Done.
10. Recalibrate the analyzer 3 times.

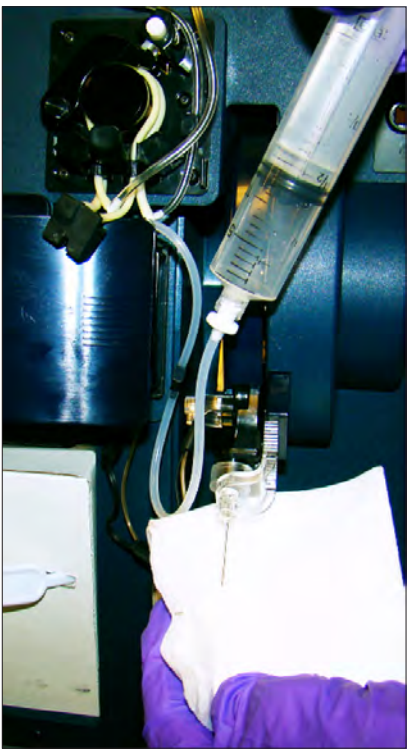


Figure 7.5
Flushing the Flow Path into Gauze

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 flow path if possible. As a result, the sample probe may become obstructed and require manual flushing to remove an obstruction. Following is the recommended procedure for clearing obstructions from the sample probe and S-line.

1. From the Home screen, press  > Flush Flowpath
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 Cartridge 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.

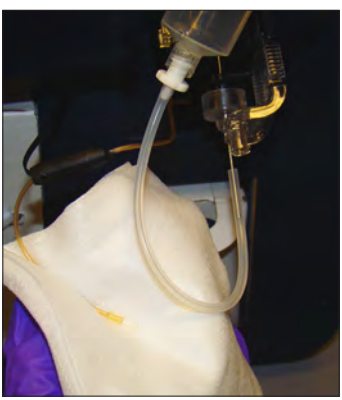


Figure 7.6 Flushing the S-Line

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  > Flush Flowpath
2. Once the pump stops and the sample probe has been extended, press  to scroll to page 2.
3. Fill a small container with de-ionized 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.

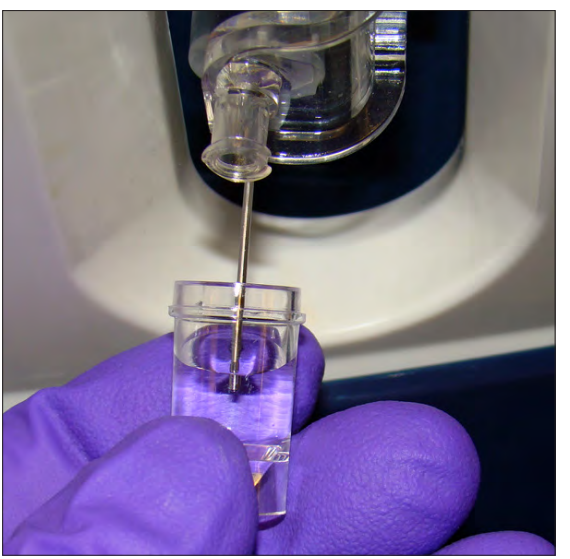


Figure 7.7 Flow Test

7.4 Long Term Shutdown

The Prime ABG analyzer can be safely shut down for several hours without taking any special precautions. However, if the analyzer is to be shut down for a longer period, the following shutdown procedure is strongly recommended.

1. Remove the Calibrator Cartridge and Internal QC Cartridge from the analyzer.
2. Insert the Calibrator Flush Fixture into the Calibrator Cartridge bay. Insert the Control Flush Fixture into the Internal QC Cartridge bay.
3. Place the Waste (W) line into an empty container. Place the remaining tubing lines into a container of deionized water.
4. From the Home screen, press Toolbox > Service > Diagnostics.
5. Press the Pump Speed button. Select Very Fast.
6. Press the Rotary Valve and select Flush.
7. Press Run Pump. Allow the pump to run long enough to ensure that water has passed through the entire flowpath and into the waste container.
8. Repeat Steps 6 and 7, selecting Standard A, Standard B, and OBC (On Board Control) 1, 2 and 3.
9. Remove the tubing lines from the container of deionized water. Repeat Steps 6, 7, and 8 until all water has been flushed from the system.
10. Remove the Flush Fixtures. Remove the pump tubing harness from the pump. Power off the analyzer.

A Appendix

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

A.1 Specifications

Analyte Measurement Ranges		
Analyte	Units of Measure	
	Default	Alternate
pH	6.500 - 8.000 (pH units)	316.2 - 10.0 nmol/L (H+ units)
PCO2	3.0 - 200.0 mmHg	0.40 - 26.70 kPa
PO2	5.0 - 765.0 mmHg	0.66 - 102.00 kPa
Hct	12% - 70%	
Na+	80.0 - 200.0 mmol/L	
K+	1.0 - 20.0 mmol/L	
Cl-	50.0 - 200.0 mmol/L	
iCa	0.20 - 2.70 mmol/L	0.8 - 10.8 mg/dL
Glu	15 - 500 mg/dL	0.8 - 28.0 mmol/L
Lac	0.4 - 20.0 mmol/L	4 - 178 mg/dL

Calculated Result Resolution			
Parameter	Units of Measure		
	Default	Alternate	
HCO_3^-	0.1 mmol/L		
TCO_2	0.1 mmol/L		
nCa	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
P50	0.1 mmHg	0.1 kPa	
O_2Cap	0.1 mL/dL	1 mL/L	0.1 mmol/L
$SO_2\%$	0.1		
Hb	0.1 g/dL	0.1 mmol/L	1 g/L
Anion Gap	0.1 mmol/L		
With Entered FiO_2			
A	0.1 mmHg	0.01 kPa	
$AaDO_2$	0.1 mmHg	0.01 kPa	
a/A	0.1		
$PO2/FiO_2$	0.1 mmHg	0.01 kPa	
RI	0.1		

Sample	
Acceptable Sample	Whole Blood (heparinized)
Sample Volume, Capillary or Syringe	100 µL
Barometer	400 – 800 ±1 mmHg, accurate to 1.5%

A.2 Quality Control and Calibration

A.2.1 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.2.2 Quality Control

Healthcare facilities should follow federal, state, and local guidelines for testing quality control materials. At a minimum, Nova Biomedical recommends that each laboratory performs the following minimum QC procedures (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.2.3 Calibrator Cartridge

In addition to the calibrators and solutions, the Calibrator Cartridge has a self-contained waste bag for safe disposal of waste. For information on Automatic and Manual Calibrations, see Section 2.4

A.3 Analytical Specificity, Human Whole Blood

An interference study was performed according to CLSI guideline EP7-A2. The study used spiked and diluted human specimens containing potential interfering substances for pH, PO_2, PCO_2, Na, K, iCa, Cl, glucose and lactate 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	Analytes Tested
Acetaminophen	20.0 mg/dL	Glu, Lac
Acetoacetate	2.0 mmol/L	pH, Na, K, iCa, Cl, Glu, Lac
Acetylsalicylic acid	3.62 mmol/L	Na, K, Cl, Glu, Lac
Albumin	15 g/dL	Hct
Ammonium Chloride	107.0 µmol/L	Na, K, Cl, iCa, Glu, Lac
Ascorbic Acid	50 mg/dL	Cl, Glu, Lac
Benzylkonium Chloride	10.0 mg/L	pH, Na, K, Cl, iCa, Glu, Lac
BetaHydroxybutyrate	2.0 mmol.L	Glu, Lac
Bilirubin	20.0 mg/dL	Hct, pH, PCO_2, PO_2, Na,K,Cl,iCa,Glu,Lac
Calcium Chloride	2.0 mmol/L	pH,PCO_2,PO_2,Na,K
D-Galactose	1.0 mmol/L	Glu, Lac
Dobutamine	2.0 mg/dL	pH,Na,K,iCa,Glu, Lac
Dopamine Hydrochloride	5.87 µmol/L	Glu, Lac
EDTA	3.4 umol/L	Glu, Lac
Ethanol	86.8 mmol/L	Glu,Lac,pH,PCO_2, PO_2
Fluorescein	1.0 mmol/L	PCO_2, PO_2
Fluoride	105 µmol/L	Glu, Lac
Glucose	1,000 mg/dL	Lac
Glycolic Acid	1 mmol/L	Glu, Lac
Glucosamine	30.0 µmol/L	Glu, Lac
Hemoglobin	2.0 g/L	Hct, pH, PCO_2, PO_2, Na,K,Cl iCa, Glu, Lac
Heparin	100 IU/mL	Glu, Lac, Hct
Ibuprofen	2.4 mmol/L	Na, K, iCa, Cl, Glu, Lac

Continued on next page

Continued from previous page

Interfering Substance	Highest Concentration Tested	Analytes Tested
Intralipid	10.0 mg/mL	Hct, pH, PCO_2, PO_2, Na,K,Cl iCa, Glu, Lac
Lithium Lactate	6.6 mmol/L	Na, K, iCa, Glu
Magnesium Chloride	15.0 mmol/L	Na, Cl
Maltose	13.0 mmol/L	Glu, Lac
Mannose	1.0 mmol/L	Glu, Lac
Perchlorate	1.0 mmol/L	iCa
Potassium Chloride	5.0 mmol/L	pH, PCO_2, PO_2, iCa
Pyruvate	309 µmol/L	Glu, Lac
Salicylic Acid	4.34 mmol/L	Na, K, Cl, Glu, Lac
Sodium Bromide	37.5 mmol/L	pH, K, iCa, Lac
Sodium Chloride	10.0 mmol/L	pH, PCO_2, PO_2, iCa
Sodium Citrate	12.0 mmol/L	Cl, Glu, Lac
Sodium Oxalate	500 mg/dL	Cl, Glu, Lac
Thiocyanate	6.8 mmol/L	Cl, Glu, Lac
Urea	40.0 mg/dL	Lac
Uric Acid	1.4 mmol/L	Lac
Xylose	25.0 mg/dL	Glu, Lac
Zinc Chloride	1.3 mg/dL	Na, K, iCa

The following table represents substances that were tested that demonstrated a clinically significant effect on test results.

Analyte	Interfering Substance	Concentration	Interference
Chloride	Bromide	2.5 mmol/L	No interference observed
		5.0 mmol/L	Bias of 12.7%
	Thiocyanate	3.4 mmol/L	No interference observed
		5.1 mmol/L	Bias of 15.2%
Ionized Calcium	$MgCl_2$	3.75 mmol/L	No interference observed
		7.50 mmol/L	Bias of 13.5%
Glucose	Hydroxyurea	0.2 mg/dL	No interference observed
		0.4 mg/dL	Bias of 19.2%
	Oxalate	125 mg/dL	No interference observed
		250 mg/dL	Bias of -10.9%
	Thiocyanate	1.7 mmol/L	No interference observed
		3.4 mmol/L	Bias of 10.0%
Lactate	Glycolic acid	0.0 mmol/L	No interference observed
		0.25 mmol/L	Bias of 11.7%
	Hydroxyurea	0.0 mg/dL	No interference observed
		0.2 mg/dL	Bias of 20.1%
Hct	Albumin	2.8 g/dL	No interference observed
		5.7 g/dL	Bias of 12.7%
	Hemolysis	5%	No interference observed
		10%	Bias of -10.7%
	Triglycerides	986.4 mg/dL	No interference observed
		1233 mg/dL	Bias of 12.9%
	White Blood Count (WBC)	>50,000 WBC/µL	May increase the Hct Value

***NOTE**: Elevated White Blood Count (WBC) >50,000 WBC/µL may increase the Hct Value.*[18]

A.4 Healthcare Professional Analytical Performance Studies

Three Stat Profile Prime CCS analyzers were compared to 2 Stat Profile pHOx Ultra Analyzers in a laboratory setting by healthcare professionals. 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 CCS Analyzers to the Stat Profile pHOx Ultra Analyzers.

A.4.1 Method Comparison Study

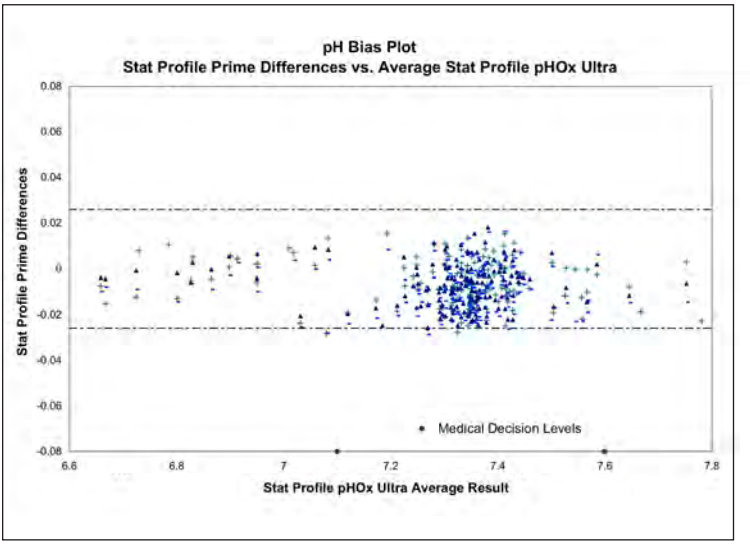
Lithium Heparin arterial whole blood discarded specimens from hospital patients were analyzed in duplicate on the 3 Stat Profile Prime CCS Analyzers and 2 Stat Profile pHOx Ultra reference analyzers. The number of samples per run and the total number of runs each day depended upon the availability of 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.

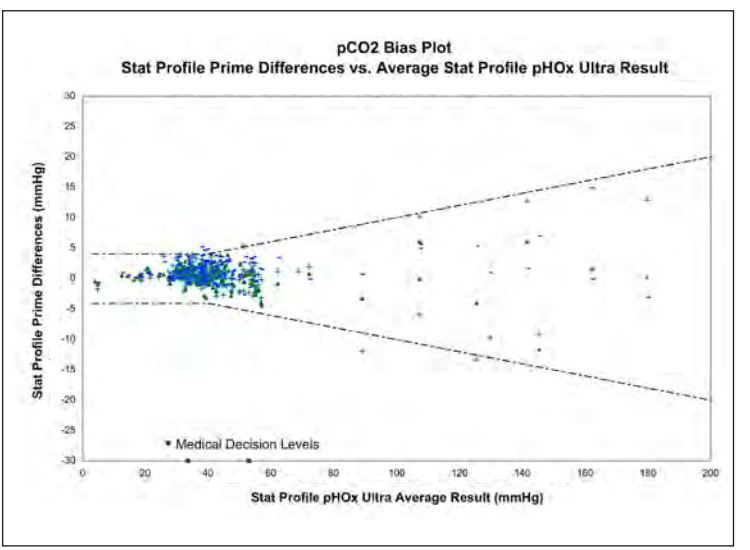
A minimum of 150 whole blood specimens were analyzed for each parameter in syringe collection devices. The samples were analyzed on each of the Stat Profile Prime CCS analyzers and on each of the pHOx Ultra analyzers. The Stat Profile Prime CCS results for each analyzer were compared to the average of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

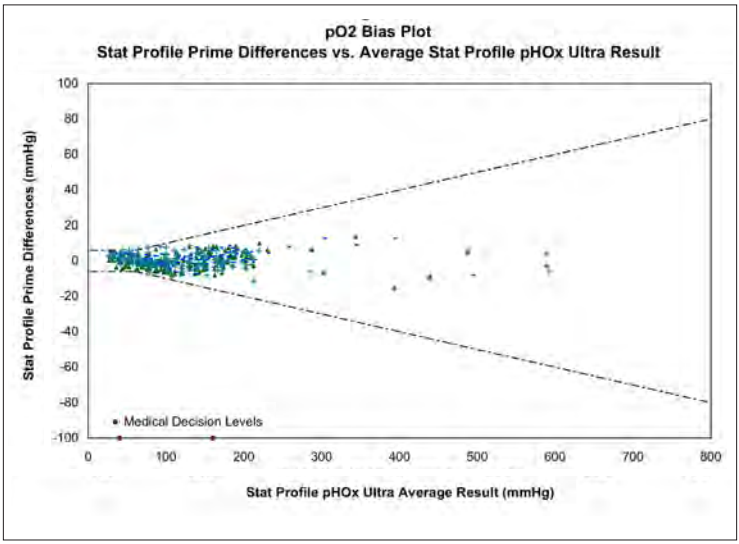
A minimum of 100 whole blood specimens were analyzed for each parameter in capillary collection tubes. Each specimen was analyzed one time from a capillary container on each Stat Profile Prime CCS analyzer and then immediately run as a syringe specimen on the same Stat Profile Prime CCS analyzer. The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

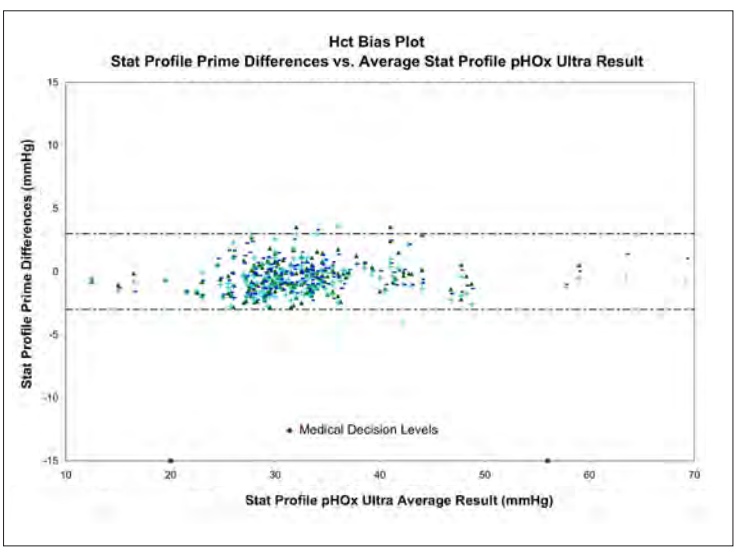
Bias Chart Results

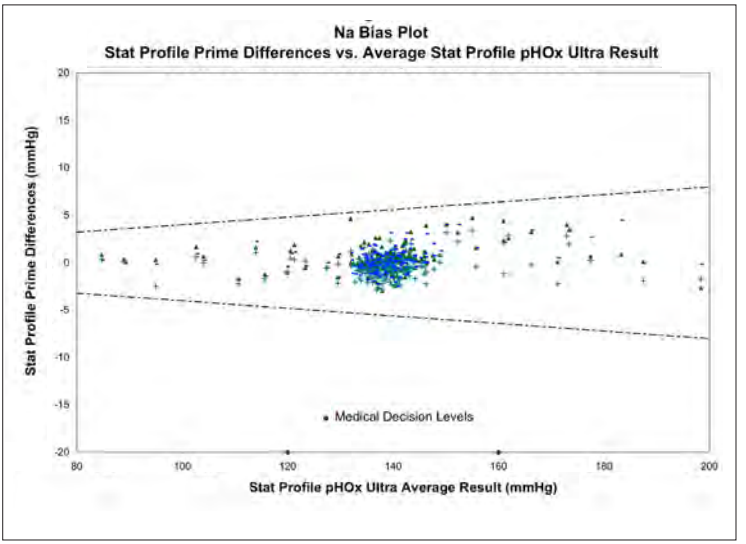
The method comparison bias estimate was analyzed using CLSI Standard EP09-A2 as a reference document. The bias plots for each parameter are summarized and include boundary lines that represent the 95% confidence interval across the measurement range based upon each parameter's between analyzer day-to-day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

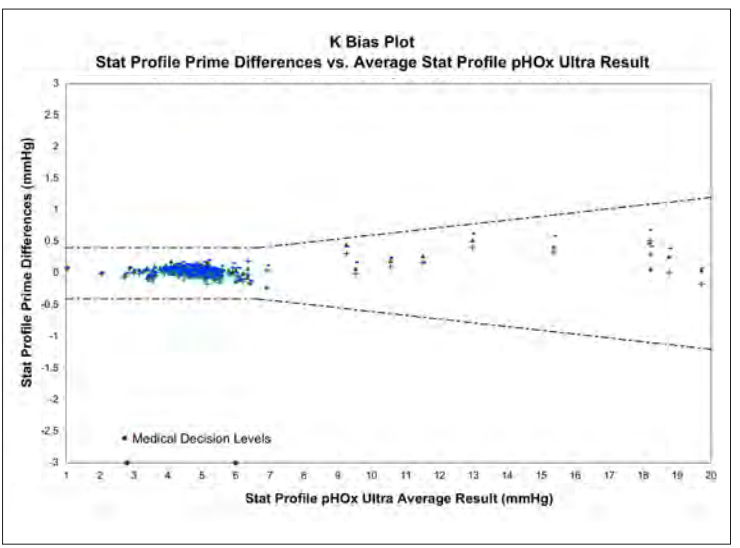

pH Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra
Stat Profile Prime Differences
0.08
0.06
0.04
0.02
0
-0.02
-0.04
-0.06
-0.08
6.6
6.8
7
7.2
7.4
7.6
7.8
Medical Decision Levels
Stat Profile pHOx Ultra Average Result

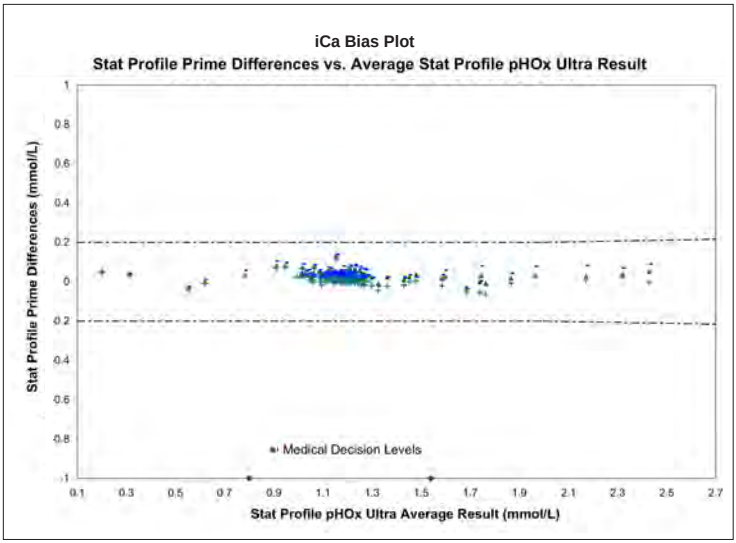

pCO2 Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmHg)
30
25
20
15
10
5
0
-5
-10
-15
-20
-25
-30
0
20
40
60
80
100
120
140
160
180
200
Medical Decision Levels
Stat Profile pHOx Ultra Average Result (mmHg)

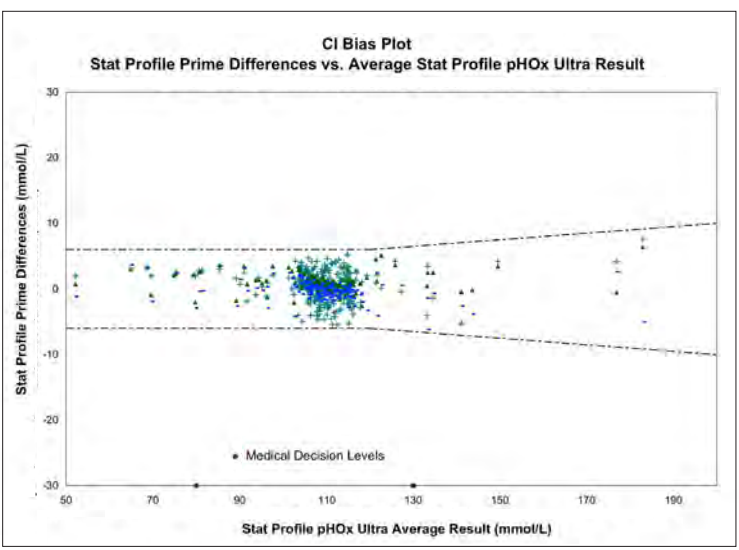

pO2 Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmHg)
100
80
60
40
20
0
-20
-40
-60
-80
-100
Medical Decision Levels
0
100
200
300
400
500
600
700
800
Stat Profile pHOx Ultra Average Result (mmHg)


Hct Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmHg)
15
10
5
0
-5
-10
-15
Medical Decision Levels
10
20
30
40
50
60
70
Stat Profile pHOx Ultra Average Result (mmHg)


Na Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmHg)
20
15
10
5
0
-5
-10
-15
-20
Medical Decision Levels
80
100
120
140
160
180
200
Stat Profile pHOx Ultra Average Result (mmHg)


K Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmHg)
3
2.5
2
1.5
1
0.5
0
-0.5
-1
-1.5
-2
-2.5
-3
Medical Decision Levels
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Stat Profile pHOx Ultra Average Result (mmHg)


iCa Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmol/L)
1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
-0.8
-1
Medical Decision Levels
0.1
0.3
0.5
0.7
0.9
1.1
1.3
1.5
1.7
1.9
2.1
2.3
2.5
2.7
Stat Profile pHOx Ultra Average Result (mmol/L)


Cl Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result
Stat Profile Prime Differences (mmol/L)
30
20
10
0
-10
-20
-30
Medical Decision Levels
50
70
90
110
130
150
170
190
Stat Profile pHOx Ultra Average Result (mmol/L)

Syringe Method Comparison Study Results vs. Stat Profile pHOx Ultra

Test Parameter	Analyzer	Total specimens	Altered specimens	Specimen range	Slope	Intercept	r
pH	#1	172	40	6.523 - 7.862	0.9976	0.0099	0.9985
	#2	170	38	6.519 - 7.875	0.9977	0.0106	0.9990
	#3	168	41	6.520 - 7.953	1.0018	-0.0225	0.9989
***P*CO$_2$**	#1	179	34	3.4 - 200.0	0.9854	0.9344	0.9977
	#2	181	29	3.1 - 192.6	1.0091	0.1547	0.9920
	#3	176	32	3.3 - 199.10	1.0019	1.1679	0.9980
***P*O$_2$**	#1	177	43	26.9 - 586.3	1.0046	-1.2710	0.9986
	#2	167	43	29.5 - 593.2	0.9897	1.4508	0.9988
	#3	180	42	31.3 - 587.6	1.0035	0.5961	0.9990
Hct	#1	174	22	12 - 70	1.0445	-1.9271	0.9889
	#2	170	24	12 - 68	1.0007	-0.6236	0.9871
	#3	164	19	13 - 70	1.0207	-0.9936	0.9895
Na	#1	180	30	85.5 - 195.7	1.0189	-2.2841	0.9955
	#2	186	29	85.1 - 196.7	1.0109	-2.0438	0.9960
	#3	181	31	85.0 - 198.2	1.0278	-3.5873	0.9961
K	#1	179	26	1.11 - 19.75	1.0163	-0.0371	0.9996
	#2	182	25	1.11 - 19.54	1.0138	-0.0619	0.9995
	#3	183	25	1.12 - 19.79	1.0272	-0.0769	0.9995
iCa	#1	181	25	0.25 - 2.48	0.9880	0.0457	0.9974
	#2	180	25	0.25 - 2.42	0.9752	0.0432	0.9958
	#3	179	25	0.25 - 2.52	1.0059	0.0345	0.9962
Cl	#1	186	39	52.8 - 189.3	1.0003	1.0158	0.9955
	#2	183	40	54.1 - 190.6	0.9952	0.6980	0.9787
	#3	180	37	51.0 - 179.5	0.9569	4.4537	0.9944
Glu	#1	181	22	35 - 432	0.9987	1.1978	0.9960
	#2	184	22	39 - 466	1.0005	0.6501	0.9940
	#3	185	24	39 - 474	1.0007	-2.6844	0.9892
Lac	#1	182	25	0.4 - 17.8	0.9841	0.0937	0.9974
	#2	182	26	0.5 - 20.0	1.0463	-0.0577	0.9959
	#3	182	26	0.4 - 18.7	1.0101	-0.0342	0.9946

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 pH units	#1	100	6.787 - 7.683	1.0094	-0.0721	0.9988
	#2	100	6.820 - 7.669	1.0157	-0.1176	0.9986
	#3	100	6.806 - 7.668	1.0097	-0.0714	0.9989
PCO_2 mmHg	#1	100	17.7 - 111.0	1.0026	-0.4347	0.9989
	#2	100	19.6 - 103.7	0.9939	-0.1404	0.9981
	#3	100	18.0 - 123.2	0.9897	-0.1897	0.9991
PO_2 mmHg	#1	100	25.5 - 435.2	0.9942	2.1791	0.9996
	#2	100	25.1 - 399.1	1.0082	0.3311	0.9994
	#3	100	25.6 - 442.7	0.9944	2.2551	0.9994
Hct %	#1	100	14 - 69	1.0013	0.0485	0.9963
	#2	100	14 - 66	0.9863	0.6676	0.9960
	#3	100	13 - 67	1.0161	-0.4917	0.9950
Na mmol/L	#1	100	85.0 - 198.1	0.9995	-0.1711	0.9978
	#2	100	85.0 - 192.0	1.0016	-0.4681	0.9988
	#3	100	85.0 - 194.7	0.9926	0.9061	0.9987
K mmol/L	#1	100	2.70 - 19.37	0.9966	0.0934	0.9996
	#2	100	2.63 - 19.36	0.9933	0.0872	0.9996
	#3	100	2.64 - 19.48	1.0042	0.0375	0.9995
iCa mmol/L	#1	98	0.33 - 2.76	1.0228	-0.0603	0.9855
	#2	98	0.32 - 2.70	0.9995	-0.0140	0.9826
	#3	99	0.34 - 2.52	1.0308	-0.0542	0.9803
Cl mmol/L	#1	100	55.8 - 197.1	0.9897	0.1776	0.9997
	#2	100	51.0 - 184.1	0.9921	-0.0870	0.9988
	#3	100	54.1 - 199.3	0.9905	0.9342	0.9978
Glu mg/dL	#1	100	17 - 488	0.9855	-0.4734	0.9998
	#2	100	19 - 491	0.9919	-0.5176	0.9998
	#3	100	21 - 489	0.9813	0.2346	0.9999
Lac mmol/L	#1	100	1.1 - 18.1	1.0034	0.0120	0.9994
	#2	100	1.2 - 19.9	1.0030	-0.0057	0.9995
	#3	100	1.2 - 19.5	0.9911	-0.0010	0.9994

A.4.2 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 CCS 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 **pH units**	Mean	7.165	7.161	7.167	7.165
	SD	0.001	0.001	0.001	0.003
***P*CO$_2$** **mmHg**	Mean	56.7	56.0	56.3	56.3
	SD	0.2	0.2	0.1	0.3
	CV%	0.4	0.4	0.3	0.6
***P*O$_2$** **mmHg**	Mean	70.1	70.4	70.5	70.3
	SD	0.3	0.5	0.4	0.4
	CV%	0.5	0.8	0.6	0.6
Hct **%**	Mean	38	38	38	38
	SD	0.5	0.4	0.3	0.5
	CV%	1.32	1.05	0.79	1.32
Na **mmol/L**	Mean	158.1	157.5	158.7	158.1
	SD	0.1	0.4	1.4	0.9
	CV%	0.1	0.2	0.9	0.6

Within Run Precision Summary (Level 1 Continued)					
Parameter	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
K mmol/L	Mean	5.80	5.84	5.81	5.82
	SD	0.00	0.02	0.03	0.03
	CV%	0.08	0.31	0.54	0.45
iCa mmol/L	Mean	1.51	1.52	1.52	1.52
	SD	0.01	0.01	0.00	0.01
	CV%	0.33	0.36	0.30	0.37
Cl mmol/L	Mean	131.0	133.3	130.8	131.7
	SD	0.1	0.4	0.1	1.2
	CV%	0.1	0.3	0.1	0.9
Glu mg/dL	Mean	74	71	74	73
	SD	0.0	0.3	0.0	1.5
	CV%	0.0	0.4	0.0	2.0
Lac mmol/L	Mean	0.9	0.8	0.8	0.8
	SD	0.0	0.0	0.0	0.1
	CV%	2.5	1.1	1.3	7.4

Stat Profile Prime Quality Control Level 2

Within Run Precision Summary					
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
pH pH units	Mean	7.361	7.360	7.362	7.361
	SD	0.002	0.002	0.002	0.002
***P*CO$_2$ mmHg**	Mean	41.6	41.3	41.6	41.5
	SD	0.3	0.3	0.3	0.3
	CV%	0.7	0.8	0.7	0.8
***P*O$_2$ mmHg**	Mean	108.8	109.6	109.6	109.4
	SD	0.6	1.4	0.3	0.9
	CV%	0.5	1.3	0.3	0.9

Within Run Precision Summary (Level 2 Continued)					
Parameter	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
Hct %	Mean	55	55	55	55
	SD	0.5	0.3	0.3	0.4
	CV%	0.91	0.55	0.55	0.72
Na mmol/L	Mean	140.2	140.1	140.0	140.1
	SD	0.1	0.2	0.6	0.4
	CV%	0.1	0.1	0.5	0.3
K mmol/L	Mean	3.84	3.81	3.80	3.82
	SD	0.02	0.01	0.02	0.02
	CV%	0.43	0.33	0.41	0.53
iCa mmol/L	Mean	0.97	0.97	0.98	0.97
	SD	0.01	0.00	0.01	0.01
	CV%	0.92	0.50	0.52	0.68
Cl mmol/L	Mean	102.3	102.2	101.8	102.1
	SD	0.5	0.2	0.1	0.4
	CV%	0.4	0.2	0.1	0.4
Glu mg/dL	Mean	200	202	198	200
	SD	1.1	1.1	0.8	1.9
	CV%	0.5	0.5	0.4	0.9
Lac mmol/L	Mean	2.6	2.6	2.6	2.6
	SD	0.0	0.0	0.0	0.0
	CV%	0.3	0.3	0.2	0.7

Stat Profile Prime Quality Control Level 3

Within Run Precision Summary					
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
pH pH units	Mean	7.596	7.597	7.594	7.596
	SD	0.002	0.002	0.002	0.002
***P*CO$_2$ mmHg**	Mean	23.6	23.7	23.8	23.7
	SD	0.3	0.3	0.4	0.3
	CV%	1.2	1.2	1.5	1.3

Within Run Precision Summary (Level 3 Continued)					
Parameter	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
PO_2 mmHg	Mean	142.2	138.7	142.3	141.1
	SD	0.7	0.6	0.3	1.8
	CV%	0.5	0.4	0.2	1.3
Hct %	Mean	69	68	69	69
	SD	0.5	0.5	0.5	0.5
	CV%	0.72	0.74	0.72	0.72
Na mmol/L	Mean	120.4	120.5	120.2	120.4
	SD	0.1	0.3	0.3	0.3
	CV%	0.1	0.2	0.3	0.2
K mmol/L	Mean	1.88	1.86	1.86	1.86
	SD	0.01	0.01	0.00	0.01
	CV%	0.64	0.46	0.24	0.64
iCa mmol/L	Mean	0.52	0.52	0.53	0.52
	SD	0.00	0.00	0.00	0.00
	CV%	0.90	0.43	0.42	0.95
Cl mmol/L	Mean	84.7	84.6	84.9	84.8
	SD	0.5	0.4	0.1	0.4
	CV%	0.6	0.4	0.1	0.4
Glu mg/dL	Mean	320	322	321	321
	SD	1.0	0.9	1.0	1.4
	CV%	0.3	0.3	0.3	0.4
Lac mmol/L	Mean	6.4	6.4	6.5	6.4
	SD	0.0	0.0	0.0	0.0
	CV%	0.3	0.3	0.2	0.4

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

Within Run Precision Summary				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**
pH **pH units**	Mean	7.388	7.426	7.403
	SD	0.004	0.003	0.004
***P*CO$_2$** **mmHg**	Mean	34.5	35.6	36.8
	SD	0.5	0.7	0.6
	CV%	1.6	1.9	1.7
***P*O$_2$** **mmHg**	Mean	119.0	123.2	123.3
	SD	0.9	0.8	0.8
	CV%	0.8	0.7	0.7
Hct **%**	Mean	47	46	47
	SD	0.6	0.9	1.0
	CV%	1.28	1.96	2.13
Na **mmol/L**	Mean	146.7	144.3	146.0
	SD	0.9	0.7	0.9
	CV%	0.6	0.5	0.6
K **mmol/L**	Mean	3.84	3.79	3.74
	SD	0.07	0.06	0.05
	CV%	1.73	1.59	1.45
iCa **mmol/L**	Mean	1.06	1.02	1.02
	SD	0.02	0.04	0.03
	CV%	2.05	4.12	2.59
Cl **mmol/L**	Mean	109.8	108.1	110.4
	SD	0.3	0.6	0.3
	CV%	0.3	0.6	0.3
Glu **mg/dL**	Mean	81	108	91
	SD	1.4	1.9	1.6
	CV%	1.7	1.8	1.8
Lac **mmol/L**	Mean	5.6	3.1	4.4
	SD	0.1	0.1	0.1
	CV%	1.9	4.6	2.3

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

Within Run Precision Summary				
Parameter	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**
pH **pH units**	Mean	7.285	7.294	7.290
	SD	0.003	0.003	0.003
***P*CO$_2$** **mmHg**	Mean	48.1	47.3	46.2
	SD	0.8	0.7	0.5
	CV%	1.6	1.4	1.2
***P*O$_2$** **mmHg**	Mean	68.9	68.2	67.8
	SD	0.3	0.3	0.3
	CV%	0.5	0.4	0.5
Hct %	Mean	42	42	41
	SD	0.8	0.2	0.4
	CV%	1.9	0.48	0.98
Na **mmol/L**	Mean	140.5	140.4	139.8
	SD	0.3	0.3	0.2
	CV%	0.2	0.2	0.1
K **mmol/L**	Mean	3.75	3.72	3.70
	SD	0.02	0.01	0.01
	CV%	0.59	0.33	0.26
iCa **mmol/L**	Mean	1.21	1.20	1.18
	SD	0.00	0.00	0.00
	CV%	0.38	0.40	0.37
Cl **mmol/L**	Mean	104.3	103.8	104.3
	SD	0.6	0.4	0.8
	CV%	0.6	0.4	0.7
Glu **mg/dL**	Mean	63	65	63
	SD	0.9	0.8	1.0
	CV%	1.4	1.2	1.6
Lac **mmol/L**	Mean	4.9	4.7	4.8
	SD	0.1	0.1	0.1
	CV%	1.4	1.2	1.8

A.4.3 Run-to-Run or Total Imprecision

QC and Linearity Total Imprecision

Estimates of the total imprecision were determined for the Stat Profile Prime CCS 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.
- Linearity Standards – 5 levels for each parameter in QC mode.

Whole Blood Run-to-Run Precision Performance

Estimates of the whole blood run-to-run precision were determined in Syringe Mode and Capillary Mode. For each run, tonometered whole blood was analyzed in triplicate on 3 Stat Profile Prime analyzers over 10 separate runs for a total of 30 results per analyzer. Statistical analysis for each analyzer for both Syringe Mode and Capillary Mode was calculated.

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	7.164	240	0.002	---	0.002	---
QC Level 2	7.362	240	0.000	---	0.001	---
QC Level 3	7.596	240	0.000	---	0.002	---
Linearity Std 1	6.899	240	0.003	---	0.005	---
Linearity Std 2	7.186	240	0.001	---	0.003	---
Linearity Std 3	7.444	240	0.001	---	0.002	---
Linearity Std 4	7.615	240	0.001	---	0.002	---
Linearity Std 5	7.817	240	0.002	---	0.004	---

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	58.4	240	0.58	1.00	1.37	2.35
QC Level 2	41.9	240	0.06	0.13	0.56	1.33
QC Level 3	23.0	240	0.07	0.29	0.45	1.94
Linearity Std 1	76.6	240	0.46	0.60	2.22	2.90
Linearity Std 2	61.4	240	0.19	0.31	1.32	2.16
Linearity Std 3	41.0	240	0.36	0.88	0.59	1.44
Linearity Std 4	25.3	240	0.06	0.23	0.51	2.02
Linearity Std 5	17.3	240	0.10	0.56	0.83	4.82

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	70.2	240	0.84	1.19	2.04	2.91
QC Level 2	110.1	240	0.55	0.50	1.18	1.07
QC Level 3	143.8	240	0.39	0.27	1.24	0.86
Linearity Std 1	21.6	240	1.45	6.70	2.68	12.43
Linearity Std 2	60.6	240	1.07	1.77	2.96	4.88
Linearity Std 3	107.2	240	0.98	0.91	2.23	2.08
Linearity Std 4	158.9	240	0.69	0.44	2.41	1.52
Linearity Std 5	453.9	240	3.92	0.86	14.33	3.16

Hct Precision Data						
Sample	Pooled Mean (%)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	37.9	240	0.44	1.15	0.82	2.17
QC Level 2	55.0	240	0.20	0.37	0.34	0.63
QC Level 3	68.6	240	0.18	0.26	0.44	0.65
Linearity Std 1	73.4	240	0.30	0.41	0.43	0.59
Linearity Std 2	58.5	240	0.38	0.65	0.44	0.74
Linearity Std 3	55.3	240	0.29	0.52	0.40	0.73
Linearity Std 4	36.4	240	0.34	0.93	0.45	1.24
Linearity Std 5	27.7	240	0.38	1.37	0.48	1.73

Na Precision Data

Sample	Pooled Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	158.3	240	0.56	0.35	0.71	0.45
QC Level 2	140.1	240	0.12	0.09	0.26	0.19
QC Level 3	120.2	240	0.08	0.07	0.22	0.18
Linearity Std 1	89.7	240	0.55	0.62	0.64	0.71
Linearity Std 2	116.1	240	0.25	0.21	0.52	0.45
Linearity Std 3	132.0	240	0.53	0.40	0.71	0.54
Linearity Std 4	154.5	240	0.40	0.26	0.63	0.41
Linearity Std 5	163.7	240	0.43	0.26	0.80	0.49

K Precision Data

Sample	Pooled Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	5.81	240	0.020	0.34	0.03	0.59
QC Level 2	3.81	240	0.005	0.14	0.01	0.37
QC Level 3	1.87	240	0.002	0.13	0.02	1.12
Linearity Std 1	11.70	240	0.041	0.35	0.07	0.59
Linearity Std 2	1.91	240	0.006	0.32	0.02	0.92
Linearity Std 3	4.36	240	0.014	0.32	0.02	0.55
Linearity Std 4	6.38	240	0.024	0.38	0.04	0.63
Linearity Std 5	1.60	240	0.006	0.40	0.02	1.23

iCa Precision Data

Sample	Pooled Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	1.51	240	0.007	0.45	0.02	1.48
QC Level 2	0.97	240	0.002	0.22	0.01	0.53
QC Level 3	0.53	240	0.001	0.23	0.01	2.37
Linearity Std 1	2.81	240	0.031	1.09	0.05	1.78
Linearity Std 2	1.44	240	0.004	0.26	0.01	0.53
Linearity Std 3	1.06	240	0.002	0.21	0.01	0.63
Linearity Std 4	0.51	240	0.001	0.14	0.01	1.31
Linearity Std 5	0.17	240	0.001	0.58	0.01	6.38

Cl Precision Data						
Sample	Pooled Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	131.6	240	0.63	0.48	1.51	1.15
QC Level 2	103.0	240	0.72	0.70	1.55	1.51
QC Level 3	86.1	240	0.27	0.32	1.43	1.67
Linearity Std 1	73.5	240	0.15	0.21	1.26	1.71
Linearity Std 2	82.6	240	0.10	0.12	0.67	0.82
Linearity Std 3	100.5	240	0.11	0.11	0.67	0.66
Linearity Std 4	124.5	240	0.11	0.09	1.45	1.17
Linearity Std 5	133.5	240	0.13	0.10	2.04	1.53

Glucose Precision Data						
Sample	Pooled Mean (mg/dL)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	71.3	240	1.28	1.79	1.71	2.40
QC Level 2	196.9	240	0.81	0.41	1.40	0.71
QC Level 3	318.6	240	2.32	0.73	3.69	1.16
Linearity Std 1	378.0	240	5.31	1.41	14.89	3.94
Linearity Std 2	67.4	240	0.60	0.88	2.46	3.64
Linearity Std 3	179.7	240	1.64	0.91	3.79	2.11
Linearity Std 4	260.0	240	1.92	0.74	5.50	2.11
Linearity Std 5	n/a					

Lactate Precision Data						
Sample	Pooled Mean (mmol/L)	N	Within run SD (Sr)	Within run % CV	Total imprecision SD (St)	Total Imprecision %CV
QC Level 1	0.79	240	0.022	2.77	0.03	3.67
QC Level 2	2.60	240	0.012	0.47	0.01	0.55
QC Level 3	6.38	240	0.023	0.35	0.06	0.90
Linearity Std 1	12.99	240	0.169	1.30	1.12	8.60
Linearity Std 2	0.67	240	0.013	1.97	0.08	12.71
Linearity Std 3	2.53	240	0.022	0.87	0.07	2.88
Linearity Std 4	6.59	240	0.056	0.85	0.26	3.92
Linearity Std 5	10.51	240	0.086	0.82	0.45	4.26

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	7.406	7.407	7.409
pH units	SD	0.006	0.005	0.008
***PCO*$_2$**	Mean	43.7	43.2	42.1
mmHg	SD	1.4	1.2	2.1
	CV%	3.1	2.8	4.9
***PO*$_2$**	Mean	27.6	28.4	30.0
mmHg	SD	0.5	1.5	0.3
	CV%	1.9	5.2	1.0
Hct	Mean	48	47	48
%	SD	0.7	0.7	0.9
	CV%	1.46	1.49	1.88
Na	Mean	140.2	141.6	140.4
mmol/L	SD	0.4	0.6	0.6
	CV%	0.3	0.4	0.4
K	Mean	4.15	4.15	4.18
mmol/L	SD	0.03	0.04	0.05
	CV%	0.80	0.90	1.30

Run-to-Run Precision Whole Blood - Syringe (Continued)				
Parameter	n = 30	Analyzer # 1	Analyzer # 2	Analyzer # 3
iCa **mmol/L**	Mean SD CV%	1.22 0.01 0.60	1.24 0.01 0.60	1.22 0.01 1.20
Cl **mmol/L**	Mean SD CV%	107.5 0.3 0.3	106.4 0.5 0.4	107.4 0.4 0.4
Glu **mg/dL**	Mean SD CV%	106 3.1 2.9	104 2.7 2.6	108 2.9 2.7
Lac **mmol/L**	Mean SD CV%	1.2 0.1 6.8	1.3 0.0 3.6	1.3 0.1 5.9

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 **pH units**	Mean SD	7.385 0.010	7.423 0.009	7.377 0.007
***P*CO$_2$** **mmHg**	Mean SD CV%	32.5 0.8 2.5	33.4 1.1 3.4	33.7 0.9 2.6
***P*O$_2$** **mmHg**	Mean SD CV%	97.8 1.3 1.4	95.4 1.2 1.3	95.2 0.9 1.0
Hct %	Mean SD CV%	49 1.3 2.65	47 0.4 0.85	44 0.8 1.82

Run-to-Run Precision Whole Blood - Capillary (Continued)				
Parameter	n = 30	Analyzer # 1	Analyzer # 2	Analyzer # 3
Na mmol/L	Mean	144.0	141.3	140.8
	SD	0.8	0.6	0.4
	CV%	0.6	0.4	0.3
K mmol/L	Mean	4.15	3.81	3.65
	SD	0.02	0.10	0.04
	CV%	0.58	2.69	0.98
iCa mmol/L	Mean	1.12	1.10	1.10
	SD	0.01	0.02	0.02
	CV%	1.11	1.91	1.68
Cl mmol/L	Mean	110.5	106.7	108.8
	SD	0.3	0.3	0.3
	CV%	0.3	0.3	0.3
Glu mg/dL	Mean	82	84	82
	SD	2.5	2.4	2.1
	CV%	3.0	3.0	2.0
Lac mmol/L	Mean	1.8	1.9	1.8
	SD	0.1	0.1	0.1
	CV%	5.0	5.5	5.7

A.5 Point-of-Care/Near-Patient Testing Performance Studies

The Stat Profile Prime CCS analyzer may be used in point-of-care settings. The Stat Profile Prime CCS Analyzer was evaluated by point-of-care (POC)/near-patient testing (NPT) personnel in 3 POC/NPT sites, including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU), and a trauma/neuro intensive care unit. A total of 43 respiratory therapy and 10 nursing POC/NPT personnel participated in the testing within the 3 POC/NPT setting sites on 3 Stat Profile Prime CCS analyzers. The personnel represent trained, qualified staff found in typical POC/NPT sites where blood gas analyzers are utilized.

A.5.1 Within-Run Precision or Reproducibility

The within run precision test data included in the following tables was obtained from different POC/NPT personnel running 20 replicates of 3 levels of Stat Profile Prime External Quality Control material (Levels 1-3) on a Stat Profile Prime CCS 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/NPT personnel using the Stat Profile Prime CCS analyzer utilizing external quality control materials and heparinized whole blood specimens.

Within Run Precision/Reproducibility Results
Point-of-Care/Near-Patient Testing Study
Trauma/Neuro

Stat Profile Prime External Quality Control Materials (N=20)

Within Run Precision - Level 1				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.152	0.004	0.05	7.145-7.160
***P*CO$_2$**	63.9	0.9	1.3	62.2-65.6
***P*O$_2$**	56.4	1.3	2.3	53.8-59.0
Hct	33	0.51	1.6	32-34
Within Run Precision - Level 1				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
Na	163.2	0.3	0.2	162.6-163.8
K	5.67	0.03	0.6	5.61-5.74
Cl	130.0	0.2	0.1	129.6-130.4
iCa	1.54	0.02	1.3	1.50-1.58
Glu	82	1.0	2.0	79-84
Lac	1.0	0.0	0.0	1.0-1.0

Within Run Precision - Level 2				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.371	0.003	0.04	7.365-7.377
***P*CO$_2$**	41.4	0.3	0.8	40.8-42.1
***P*O$_2$**	99.2	1.9	1.9	95.4-102.9
Hct	51	0.89	1.8	49-52
Na	139.8	0.2	0.2	139.4-140.3
K	3.70	0.03	0.7	3.7-3.8
Cl	101.9	0.1	0.1	101.7-102.1
iCa	1.01	0.003	0.3	1.00-1.02
Glu	201	3.0	1.0	196-207
Lac	2.8	0.1	1.7	2.7-2.9
Within Run Precision - Level 3				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.562	0.003	0.05	7.555-7.569
***P*CO$_2$**	23.6	0.4	1.9	22.7-24.5
***P*O$_2$**	141.5	1.5	1.0	138.5-144.4
Hct	65	0.47	0.7	64-66
Na	117.7	0.2	0.2	117.3-118.1
K	1.87	0.003	0.2	1.86-1.88
Cl	87.4	0.1	0.2	87.1-87.7
iCa	0.56	0.00	0.0	0.56-0.56
Glu	301	3.0	1.0	294-308
Lac	7.0	0.1	1.0	6.8-7.1
Within Run Precision - Low Hematocrit				
Hct	20	0.49	2.5	19-21

Within Run Precision/Reproducibility Results
Point-of-Care/Near-Patient Testing Study: CVICU

Stat Profile Prime External Quality Control Materials (N=20)

Within Run Precision - Level 1				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.150	0.003	0.04	7.144-7.156
***P*CO$_2$**	63.4	0.7	1.0	62.1-64.7
***P*O$_2$**	50.4	1.1	2.2	48.1-52.6
Hct	33	0.55	1.7	32-34
Na	163.5	0.4	0.2	162.7-164.3
K	5.70	0.02	0.3	5.67-5.74
Cl	129.8	0.5	0.4	128.9-130.8
iCa	1.55	0.01	0.5	1.53-1.56
Glu	83	1.0	1.0	81-84
Lac	1.0	0.0	0.0	1.0-1.0
Within Run Precision - Level 2				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.367	0.003	0.04	7.361-7.373
***P*CO$_2$**	42.6	0.6	1.4	41.4-43.8
***P*O$_2$**	98.2	1.6	1.7	94.9-101.4
Hct	51	0.68	1.3	49-52
Na	139.9	0.4	0.3	139.1-140.6
K	3.70	0.01	0.3	3.7-3.8
Cl	102.3	0.2	0.2	102.0-102.6
iCa	1.00	0.01	0.7	0.99-1.02
Glu	210	3.0	1.0	205-215
Lac	2.8	0.0	0.0	2.8-2.8

Within Run Precision - Level 3				
Parameter	**Mean**	**SD**	**CV%**	**95% CI**
pH	7.559	0.003	0.04	7.553-7.565
***PCO*$_2$**	25.5	0.7	2.6	24.2-26.8
***PO*$_2$**	145.3	1.7	1.2	141.9-148.8
Hct	64	0.73	1.1	63-66
Na	117.6	0.3	0.2	117.0-118.2
K	1.88	0.003	0.2	1.87-1.89
Cl	87.1	0.1	0.1	86.9-87.3
iCa	0.56	0.01	1.7	0.54-0.58
Glu	329	5.0	1.0	319-338
Lac	7.0	0.1	0.7	6.9-7.1
Within Run Precision - Low Hematocrit				
Hct	19	0.37	1.9	18-20

Within Run Precision/Reproducibility Results Point-of-Care/Near-Patient Testing Study MICU

Stat Profile Prime External Quality Control Materials (N=20)

Within Run Precision - Level 1				
Parameter	Mean	SD	CV%	95% CI
pH	7.142	0.005	0.07	7.132-7.151
***PCO*$_2$**	61.7	2.1	3.3	57.6-65.8
***PO*$_2$**	55.9	1.8	3.2	52.3-59.5
Hct	33	0.47	1.4	32-34
Na	164.4	0.3	0.2	163.8-165.0
K	5.74	0.02	0.4	5.70-5.79
Cl	128.9	0.1	0.1	128.6-129.1
iCa	1.59	0.01	0.4	1.57-1.60
Glu	82	1.0	1.0	80-83
Lac	1.0	0.0	0.0	1.0-1.0

Within Run Precision - Level 2				
Parameter	Mean	SD	CV%	95% CI
pH	7.365	0.003	0.04	7.359-7.372
***P*CO$_2$**	42.7	0.4	1.0	41.8-43.5
***P*O$_2$**	97.2	1.5	1.5	94.3-100.2
Hct	51	0.59	1.2	49-52
Na	140.5	0.2	0.1	140.1-140.9
K	3.70	0.01	0.2	3.7-3.8
Cl	101.8	0.1	0.1	101.6-101.9
iCa	1.00	0.01	0.5	0.99-1.01
Glu	203	2.0	1.0	199-207
Lac	2.8	0.1	1.8	2.7-2.9
Within Run Precision - Level 3				
pH	7.555	0.008	0.11	7.538-7.572
***P*CO$_2$**	25.9	1.0	3.8	23.9-27.9
***P*O$_2$**	139.5	1.4	1.0	136.7-142.4
Hct	65	0.55	0.8	64-66
Na	117.9	0.2	0.1	117.6-118.2
K	1.87	0.01	0.3	1.85-1.88
Cl	87.6	0.2	0.3	87.1-88.0
iCa	0.55	0.00	0.0	0.55-0.55
Glu	309	5.0	2.0	298-320
Lac	7.0	0.1	1.0	6.9-7.2
Within Run Precision - Low Hematocrit				
Hct	20	0.50	2.6	19-21

A.5.2 Quality Control Total Imprecision

The estimates of total imprecision test data included in the following table was obtained from different POC/NPT 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 CCS 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/NPT personnel using the Stat Profile Prime CCS analyzer using external quality control materials.

Total Imprecision Results Point-of-Care/ Near-Patient Testing Study

Stat Profile Prime External Quality Control Materials (N=120 runs, 3 sites combined)

Total Imprecision Data - Level 1						
Parameter	Pooled Mean	N	Within Run SD (Sr)	Within Run %CV	Total Imprecision SD(St)	Total Imprecision %CV
pH	7.144	120	0.004	0.06	0.007	0.10
PCO_2	64.6	120	0.8	1.3	1.5	2.3
PO_2	56.2	120	1.8	3.2	2.6	4.7
Hct	33	120	0.5	1.6	0.6	1.9
Na	163.6	120	0.6	0.4	1.1	0.7
K	5.69	120	0.05	0.9	0.08	1.4
Cl	128.2	120	0.3	0.2	1.3	1.0
iCa	1.56	120	0.007	0.5	0.023	1.5
Glu	81.0	120	1.1	1.4	1.4	1.8
Lac	1.0	120	0.02	2.0	0.02	2.0

Total Imprecision Data - Level 2						
Parameter	Pooled Mean	N	Within Run SD (Sr)	Within Run %CV	Total Imprecision SD(St)	Total Imprecision %CV
pH	7.368	120	0.002	0.03	0.005	0.07
PCO_2	42.5	120	0.4	1.0	0.8	2.0
PO_2	98.0	120	0.9	1.0	2.2	2.3
Hct	51	120	0.5	0.9	0.6	1.2
Na	139.7	120	0.5	0.3	1.0	0.7
K	3.73	120	0.02	0.5	0.05	1.3
Cl	102.1	120	0.2	0.2	0.4	0.4
iCa	1.00	120	0.005	0.5	0.009	0.9
Glu	203.0	120	2.2	1.1	4.9	2.4
Lac	2.8	120	0.05	1.8	0.06	2.1
Total Imprecision Data - Level 3						
pH	7.562	120	0.008	0.11	0.009	0.12
PCO_2	25.1	120	0.7	2.7	1.3	5.2
PO_2	140.8	120	1.2	0.9	3.2	2.3
Hct	65	120	0.5	0.8	0.7	1.0
Na	117.6	120	0.3	0.2	0.5	0.4
K	1.87	120	0.01	0.5	0.02	1.1
Cl	87.0	120	0.4	0.5	0.9	1.1
iCa	0.55	120	0.004	0.7	0.07	1.3
Glu	318.0	120	4.2	1.3	9.0	2.8
Lac	7.1	120	0.1	0.7	0.12	1.7
Total Imprecision Data - Low Hematocrit						
Hct	19	120	0.4	2.2	0.5	2.6

A.5.3 Syringe Mode Method Comparison

Syringe Mode method comparison studies were performed by POC/NPT participants from 3 POC/NPT settings, including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU), and a trauma/neuro intensive care unit on 3 Stat Profile Prime CCS analyzers. The studies included a minimum of 20 testing days.[19] Heparinized blood gas specimens were used to compare the whole blood results obtained by POC/NPT 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/NPT 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/NPT personnel when compared to trained laboratory personnel using a Prime CCS analyzer on heparinized syringe whole blood specimens on the same analyzer.

Syringe Mode Method Comparison Study Results
Point-of-Care/Near-Patient Testing Study
POC/NPT Personnel vs. Health Care Professional

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	234	6.874 - 7.665	0.983	0.116	0.997
***P*CO$_2$ mmHg**	230	4.1 - 195.5	1.007	0.750	0.998
***P*O$_2$ mmHg**	234	15.2 - 714.5	1.005	-0.094	0.999
Hct %	222	12 - 70	0.997	0.395	0.985
Na mmol/L	229	83.2 - 192.3	1.020	-2.540	0.998
K mmol/L	231	1.10 - 18.80	0.974	0.110	0.999
iCa mmol/L	234	0.26 - 2.55	1.001	0.004	0.999
Cl mmol/L	234	53.0 - 188.7	1.000	-0.020	0.999
Glu mg/dL	233	17 - 478	0.989	1.517	0.998
Lac mmol/L	233	0.6 - 19.5	1.018	-0.093	0.998

A.5.4 Capillary Mode Method Comparison

Capillary Mode method comparison studies were performed by POC/NPT participants from 3 POC/NPT settings including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU) and a trauma/neuro intensive care unit on 3 Stat Profile Prime

CCS 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/NPT 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 POC/NPT respiratory therapy 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/NPT personnel when compared to trained laboratory personnel using a Stat Profile Prime CCS analyzer on heparinized capillary whole blood specimens.

Capillary Mode Method Comparison Study Results
Point-of-Care/Near-Patient Testing Study
POC/NPT Personnel vs. Health Care Professional

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	173	6.881 - 7.780	0.962	0.275	0.997
PCO_2 mmHg	170	3.2 - 181.4	0.989	0.899	0.998
PO_2 mmHg	173	22.8 - 597.3	0.979	3.141	0.999
Hct %	157	13 - 68	0.978	0.399	0.984
Na mmol/L	169	83.2 - 197.0	1.010	-1.258	0.997
K mmol/L	168	1.15 - 19.47	1.006	-0.025	0.998
iCa mmol/L	173	0.32 - 2.45	0.977	0.029	0.996
Cl mmol/L	173	55.9 - 188.1	1.007	-0.710	0.997
Glu mg/dL	173	15 - 484	1.004	0.036	0.999
Lac mmol/L	173	0.6 - 18.4	1.019	-0.127	0.998

A.6 Reference Values

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

Prime CCS Reference Values [5,6,10]	
Test	Value
pH	7.35 – 7.45
PO_2	83 – 108 mmHg
PCO_2	35 – 45 mmHg
Hematocrit (Hct)	
Male	39 - 49%
Female	35 - 45%
Sodium[6]	136 - 146 mmol/L
Potassium[6]	3.5 - 5.1 mmol/L
Chloride[6]	98 - 106 mmol/L
Glucose[6]	65 - 95 mg/dL
Lactate[8,9]	0.7 - 2.5 mmol/L
Ionized Calcium (iCa)[10]	1.09 - 1.30 mmol/L

A.7 Cybersecurity

A.7.1 Cybersecurity Protection Overview

The Stat Profile Prime Analyzer System includes extensive safeguards to protect the system from outside cybersecurity attacks. A summary of the safeguards is found below. For professional laboratory and Information Technology users that require extensive information and details, contact your authorized Stat Profile Prime distributor.

A.7.2 Software Updates

Stat Profile Prime software updates are performed exclusively by factory trained Field Support Specialists through the analyzer's integrated USB port. The software update image is not made public or left at healthcare facility sites. All valid software updates contain an embedded Cyclical Redundancy Check (CRC). The Stat Profile Prime analyzer will not execute a software update if the image is questionable or the image does not pass the embedded CRC.

A.7.3 Operating System Patches

The Stat Profile Prime analyzer uses an embedded real time operating system (RTOS). The operating system is built into the application software. All necessary operating system security patches will be applied at the factory and distributed through software application updates.

A.7.4 Malware Control

The Stat Profile Prime software update image is created following a strict factory procedure that defines the process steps required to ensure that software is free of viruses, malware, and other non-intended consequences.

A.7.5 Creation of Software for Release

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

A.7.6 Security Related to the USB Port

The Stat Profile Prime analyzer contains a single USB port. In addition to software application updates, the USB port is used to import/export operators and configuration data from one analyzer to another. The files on the USB stick are in binary format and protected by a CRC. The import/export operations on the analyzer are password protected.

A.8 Ordering Information

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

Description	Part No.
Ampuled Control ABG/CCS, Prime	52714
Auto QC Cartridge CCS 300 Sample, Prime	52864
Auto QC Cartridge CCS 200 Sample, Prime	45150
Auto QC Cartridge CCS 100 Sample, Prime	53455
Backup Power Supply, 120V Prime	53727
Backup Power Supply, 230V Prime	53726
Calibrator Cartridge CCS Comp 100 Sample, Prime	52861
Calibrator Cartridge CCS Comp 200 Sample, Prime	53365
Calibrator Cartridge CCS Comp 300 Sample, Prime	52427
Calibrator Cartridge CCS Comp 400 Sample, Prime	53105
Calibrator Cartridge CCS Comp 500 Sample, Prime	53469
Calibrator Flush Fixture, Prime	52865
Control Flush Fixture, Prime	24819
Flow Path Flush Tool	53443
Kit; Sample Probe Sensor Flush	16829
Kit; Clot Catcher Capillary 250	38846
Kit; Clot Catcher Syringe 200	38883
Kit; Clot Catcher Syringe 200	40089
Kit; Clot Catcher Syringe 200	48590
Linearity Standard Set A Levels 1,2,3,4 Multipack	25217
Nova Linearity Levels 1,2,3,4	55229
Prime Cart	53367
Probe S Line 100 µL, Prime CCS	52582
Pump Harness, Prime	52484
Reference Cartridge, Prime	42043
Safety Sample Port 5 Pk, Prime	52669
Sensor Card CCS Comp (High Volume), Prime	55264
Sensor Card CCS Comp 100, Prime	64251
Sensor Card CCS Comp, Prime	42033
Thermal Paper	49200

A.9 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 CCS Analyzer.

B.1 Measured Values

Measuring Technology: Ten Planar Sensors (Na, K, Cl, iCa, pH, PCO_2, PO_2, Glucose, Lactate, Hematocrit) in a MicroSensor Card.

B.1.1 Sodium, Potassium, Chloride, and Ionized Calcium

Principle of Measurement

The parameters are measured by the Ion-Selective Electrode (ISE) selectively measures the activity of ionic species. When the ISE is contacted with a sample, potential is developed. The potential is proportional to the logarithm of the ionic activity (ai) and is measured versus a reference electrode. This relationship can be described by the Nernst equation as in Equation 1 where S is the Nernstian slope, and Er and Ej are the reference and junction potential, respectively.

Calculating Sample Concentration

Equation 1 links the voltage of the cell (E_m) to the activity of the ion. Activity is related to concentration (C) through the activity coefficient in the relation a = f * C. The activity coefficient is a function of ionic strength. Thus, Equation 1 can be rewritten in terms of concentration as follows:

$$E_{cell} = E_o + S \log a_o - E_r - E_j \qquad \text{Equation 1}$$

$$E_{cell} = E_o + S (\log(f * C)_o) - E_r - E_j \qquad \text{Equation 2}$$

Similarly, Equation 2 is rewritten:

$$E = E_x - E_{std} = S \log \frac{(fC)_x}{(fC)_{std}} \qquad \text{Equation 3}$$

The total ionic strength of whole blood is relatively constant over the physiological range.[8] As a result, the activity coefficients of sodium, potassium, calcium, and chloride can be assumed to be constant. The internal standards are formulated to reflect the same ionic strength as that of whole blood. Therefore, a given ion's activity coefficient can be assumed to be equal in the standard and sample. The activity coefficient terms in Equation 3 cancel out with these results:

$$E = E_x - E_{std} = S \log \frac{C_x}{C_{std}} \qquad \text{Equation 4}$$

By holding C_{std} in Equation 4 constant, E is dependent on only 1 variable, C_x, the concentration of the ion of interest in the sample. Equation 5 can be rearranged to isolate this variable:

$$C_x = (C_{std})\ 10^{(E/S)} \qquad \text{Equation 5}$$

The analyzer's microcomputer uses Equation 5 to calculate the concentration of sodium, potassium, calcium, and chloride ions in the sample.

B.1.2 pH Sensor

Definition of pH

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

$$pH\ E_{std\ C} - E_x = pH_{std\ C} + \frac{E_{std\ C} - E_x}{Slope} \qquad \text{Equation 6}$$

where

$$Slope = \frac{E_{std\ C} - E_x}{pH\ E_{std\ C} - pH_{std\ D}} \qquad \text{Equation 7}$$

Principle of pH Measurement

pH is measured using a hydrogen ion selective glass 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.1.3 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.

$$CO_2 + H_2O <=> H_2CO_3 <=> H^+ + [HCO^-_3] \qquad \text{Equation 8}$$

The pH of this internal solution varies with the *P*CO_2 according to the Henderson-Hasselbalch equation.

$$pH = pKa + \log \{HCO^-_3 / PCO_2 * a\} \qquad \text{Equation 9}$$

The measured potential is related to the logarithm of *P*CO_2 content of the sample after compensation of the measured potential of the pH sensor.

B.1.4 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.1.5 Hematocrit

Hematocrit is defined as the percentage of red blood cells to the total blood volume and can be obtained by measuring electrical resistance of the blood sample. Two standard solutions are used to calibrate the hematocrit sensor and to obtain the slope. The analyzer then measures the electrical resistance of the blood sample to obtain the hematocrit value. The hematocrit value obtained is corrected for the concentration of the sodium ion [10].

B.1.6 Glucose

Glucose measurement is based on the level of H_2O_2 produced during the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme. The reaction is described by the following equation:

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

Equation 10

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

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^- \qquad \text{Equation 11}$$

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

B.1.7 Lactate

Lactate measurement is based on the level of H_2O_2 produced during the enzymatic reaction between lactate and oxygen molecules in the presence of the lactate oxidase enzyme. The reaction is described by the following equation:

$$\text{Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate acid} + H_2O_2$$

Equation 12

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

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^- \qquad \text{Equation 13}$$

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

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 CCS 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:

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

Equation 14

$$PCO_{2\ (corrected)} = PCO_2 \times e^{(0.04375(T - 37))}$$

Equation 15

$$PO_{2\ (corrected)} = PO_2 \times 10^{U}$$

Equation 16

where

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

Equation 17

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

Equation 18

B.2.2 Bicarbonate Concentration (HCO_3^-) [9]

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

$$pH = pK + \log \frac{[HCO_3^-]}{\alpha(PCO_2)} \qquad \text{Equation 19}$$

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 16 gives:

$$\text{Log}_{10}\,[HCO_3^-] = pH + \log_{10} PCO_2 - 7.604 \qquad \text{Equation 20}$$

B.2.3 Total Carbon Dioxide Content (TCO_2)[9]

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

$$TCO_2 = [HCO_3^-] + \alpha(PCO_2) \qquad \text{Equation 21}$$

where PCO_2 is measured and $[HCO_3^-]$ is calculated from Equation 17.

B.2.4 Hemoglobin

Hemoglobin is calculated as follows:

Hemoglobin g/dL = Measured Hematocrit ÷ 3.0

Equation 22

CAUTION: The Stat Profile Prime CCS Analyzer provides an estimation of hemoglobin only from normal hematocrit values citing the specific normal adult male/female range. In

cases of abnormal blood composition, e.g., red cell dyscrasia or hemoglobinopathies or in cases of disease states, e.g., anemia, repeat testing by conventional laboratory methods is indicated.

NOTE: *The hemoglobin calculation is an estimation based on a normal mean corpuscular hemoglobin concentration of 33.3% and a nominal male Hct of 39% to 49% or female Hct of 35% to 45% [4]. Hemoglobin estimations made from samples with Red cell dyscrasia or hemoglobinopathies may vary significantly from hemoglobin measured by cyanmethemoglobin method. The estimated hemoglobin may vary significantly in cases of abnormal blood composition or disease states such as anemia in which abnormal values may be unreported. These conditions should warrant repeat testing by conventional lab methods.*

B.2.5 Base Excess of Blood (BE-B)[9]

Base excess of blood is the concentration of titratable base needed to titrate blood to pH 7.40 at 37 °C while 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 23

B.2.6 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 24

where Z = [BE-B] - 0.19 [Hb] ((100 - SO_2)/100)

Equation 25

[Hb] = Hemoglobin value measured and manually entered, or the default value of 14.3 g/dL

B.2.7 Base Excess Extracellular Fluid (BE-ECF)[9]

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:

$BE\text{-}ECF = [HCO_3^-] - 25 + 16.2\ (pH - 7.40)$ Equation 26

B.2.8 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

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

Equation 27

Therefore, $O_2Ct = (1.39\ [Hb])\ (SO_2/100) + (0.0031[PO_2])$

where 0.0031 is the solubility coefficient of O_2. Equation 28

On the analyzer, hemoglobin can be manually entered, calculated from measured hematocrit, or occur as a default value.

B.2.9 Oxygen Saturation (SO_2)

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:

$$SO_2\% = \frac{[PO_2']^3 + 150\,[PO_2']}{[PO_2']^3 + 150\,[PO_2'] + 23400} \times 100$$

Equation 29

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

Equation 30

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

B.2.10 Alveolar Oxygen (A)

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

Equation 31

$$A = \frac{\%FIO_2}{100}\,(B.P. - 0.045T2 + 0.84T - 16.5) - {}^{**}PCO_2 \left[\frac{\%FIO_2}{100} + \left(\frac{1 - (\%FIO_2/100)}{0.8}\right)\right]$$

Equation 32

where

T = patient temperature

B.P. = barometric pressure

$\%FIO_2$ = fraction inspired oxygen (%)

** Temperature corrected gas value

B.2.11 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:

$$Aa\ DO_2 = A - {}^{**}PO_2 \qquad \text{Equation 33}$$

** Temperature corrected gas value

NOTE: *For capillary samples, $AaDO_2$ results have an asterisk (*). $AaDO_2$ results are dependent on how the samples are drawn and handled, thus care must be taken when interpreting these calculated results.*

B.2.12 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.

$$a/A = {}^{**}PO_2/A \qquad \text{Equation 34}$$

** Temperature corrected gas value

B.2.13 P50 or PO_2 (0.5)[3]

*P*50 is defined as the PO_2 of a sample at which the hemoglobin is 50% saturated with oxygen at pH 7.4, 37°C, and 40 mm Hg PCO_2 for SO_2% values between 40% and 80%.

$$P50_{(uncorrected)} = PO_2/(SO_2\%/(100 - SO_2\%))^{0.37}$$

Equation 35

For measured SO_2% between 80 and 96.9%, the equation is as follows:

$$P50_{(uncorrected)} =$$

$$26.902 * \exp(1.121 * (y - x - 3.5z)/(1.87 * z^2 + z - 2.87))$$

Equation 36

where

$$z = \tanh(0.5343 * x)$$ Equation 37

$$x = \ln(0.133 * PO_2/7)$$ Equation 38

$$y = \ln(SO_2\%/(100-SO_2\%))-1.875$$ Equation 39

The corrected equation is as follows:

$$\log P50_{(corrected)} =$$

$$\log P50_{(uncorrected)} + 0.43\,(pH - 7.4) - 0.05\,(\log PCO_2/40) - 0.0131(T - 37)$$

Equation 40

B.2.14 Ionized Calcium Normalized to pH 7.4

The activity and concentration of ionized calcium in whole blood is pH dependent. *In vitro*, a pH increase of 0.1 unit decreases the ionized calcium level by 4 to 5% (conversely, a pH decrease has an equal but opposite effect). The sample of choice for ionized calcium determination is anaerobically collected whole blood.

If an anaerobic sample is not available, by measuring the actual pH of the sample at which the ionized calcium concentration was measured normalized ionized calcium can be calculated. The normalized ionized calcium represents what the ionized calcium concentration would have been if the initial pH was 7.40 (the midpoint of the pH reference range). The equation used for this calculation is as follows:

$$\log [iCa]_{7.4} = \log [Ca^{++}]_X - 0.24\ (7.4 - x)$$

Equation 41

where x = measured pH of the sample

$[iCa]_X$ = ionized calcium concentration in the sample at the measured pH

$[iCa]_{7.4}$ = normalized concentration of ionized calcium at pH 7.40

The equation assumes a normal concentration of total protein and may be used for measured values between pH 7.2 and 7.6. Between pH 6.9 and 7.2 and between pH 7.6 and 8.0, modified forms of the equation are used. Normalized ionized calcium values for samples with pH outside the range pH 6.9 to pH 8.0 are not displayed.

B.2.15 Anion Gap

Anion gap is the difference between the sum of the sodium and potassium concentrations (the cations) and the sum of the chloride and bicarbonate concentrations (the anions), as follows:

$$\text{Anion Gap} = (Na + K) - (Cl + [HCO_3^-]) \qquad \text{Equation 42}$$

No anion gap is reported if any of the 4 concentrations are not reported. Any calculated anion gap less than 0.0 mmol/L is not reported.

B.2.16 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:

$$O_2Cap = 1.39 \times [tHb] \qquad \text{Equation 43}$$

B.2.17 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.

$$PO_2/FIO_2 = PO_2/(\%FIO_2/100\%) \qquad \text{Equation 44}$$

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. 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 critically ill patients with clinically adequate perfusion states [10, 11, 12, 13].

The Estimated Shunt has been demonstrated to be far superior to oxygen tension based indices in reliably reflecting changes in the Q_{sp}/QT[14]. Monitoring of the $tcPO_2$ Index and the $P_{(a-et)}CO_2$ 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.

B.2.18 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 [10].

$$RI = (P_AO_2 - PaO_2)/PaO_2 \qquad \text{Equation 45}$$

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