REF 52920

IVD CE

Stat Profile® PRIME™ CCS Analyzer

Instructions for Use Manual

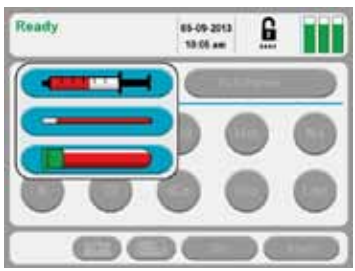
nova® biomedical

Nova Prime Quick Start Guide

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

2. Login if necessary. Press the Login icon then enter or scan your User ID and Password.

3. Select the Sample Container and the Panel.



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

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

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

7. Review results.

NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD — *In vitro* diagnostic medical device

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

 Caution, consult accompanying documents

 Consult instructions for use

 Biological risk

REF — Catalog number

 Manufactured by

CONTROL — Control

LEVEL — Level

LOT — Batch code

SN — Serial Number

 Temperature limitation

 Upper Limit of Temperature

 Use by (last day of the month)

YYYY - MM

 Electronic Waste

EC REP — Authorized Representative in the European Community

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

Stat Profile® PRIME™ CCS Instructions for Use Manual

Ordering Information

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

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1 Introduction

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

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

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

1.1 About This Manual

This manual is for the Stat Profile Prime CCS Analyzer.

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

1.2 Safety

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

General Safety

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

Electrical Safety

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

Federal Communications Commission (FCC) Notice

This device complies with Part 15 of the FCC Rules:
Operation is subject to the following conditions:

1. This device many not cause harmful interference, and
2. This device must accept any interference received, Including interference that may cause undesired operation

Changes and Modifications not expressly approved by Nova Biomedical Corporation can void your authority to operate this equipment under Federal Communications Commissions rules.

Radio Standards Specifications (RSS) Notice

This device complies with Industry Canada licence-exempt RSS standard(s).
Operation is subject to the following 2 conditions:

1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.
L'exploitation est autorisée aux deux conditions suivantes :

1. l'appareil ne doit pas produire de brouillage, et
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Chemical and Biological Safety

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

1.3 Installation and Use

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

Electrical Requirements:

- Operating Voltage Range: 90 - 270 VAC
- Operating Frequency: 47 - 63 Hz
- Power Consumption: Less than 100 Watts

Ambient Operating Temperature:

- 15°C to 30°C (59°F to 86°F)

Operate at Humidity:

- 20 to 85% without condensation

Operate at Altitude:

- up to 12,000 feet/3650 meters

Dimensions:

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

Weight:

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

Lifting the Analyzer:

1. One person is needed to lift the analyzer.

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

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

1.5 Intended Use, Tests Performed, and Clinical Utility

Intended Use

The **Stat Profile Prime CCS Analyzer System** is intended for *in vitro* diagnostic use by health care professionals in clinical laboratory 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. It is not intended for Point of Care use.

Measured Parameters

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

Glucose and Lactate are optional.

Calculated Parameters

From the directly measured results, the calculated results are shown in Table 1-1 for each analyzer in the Stat Profile Prime CCS.

Table 1-1. Calculated Parameters

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

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

***P*CO_2, *P*O_2, pH**	Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases.
Na^+	Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
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 such as cystic fibrosis and diabetic acidosis.
iCa	Ionized Calcium measurement is used in the diagnosis and treatment of hypertension, renal disease, and vitamin D related disorders. Also useful in the diagnosis and treatment of patients with increased total protein and/or albumin levels, as in dehydration.
Glu	Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Lac	Lactate (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis.

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

1.6 The Sample

Sodium or 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.

1.6.1 Handling Requirements

Correct sample handling is critical to ensure that the blood gas values obtained accurately reflect the *in vivo* state. Ensure that all samples have been obtained and stored following consistent, clinically accepted protocols. It is particularly important to ensure that samples are well mixed before introduction into the analyzer. Nova Biomedical recommends that you analyze the sample within 15 minutes for blood gases. Storing samples on ice is not recommended. Using iced samples may elevate the PO_2 result.[1]

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

1.6.2 Acceptable Anticoagulants

- **Sodium** and **lithium heparins** are the **acceptable anticoagulants** for use with the analyzer.
- EDTA, citrate, oxalate, 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.
- **Excess** sodium heparin may **elevate** sodium results.
- Liquid or dry heparin when present in **excess** may **cause errors.** Ensure blood collection devices are filled per manufacturer instructions.
- Our experience suggests that lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable.

CAUTION: Stat Profile Prime 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.

Figure 2.1 Nova Stat Profile Prime CCS

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

Figure 2.2 Analytical Compartment

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

2.1 Power Up Procedure

When the analyzer is powered on, it displays the Nova 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 Sensor Card life; the calibrator cartridge fluid level; and the internal 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

Header Bar

Selection Area

Menu Bar

*Figure 2.5 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, panel selection, date and time, etc.

2.2.1 Header Bar

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

The current Date and Time is displayed.

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

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

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

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

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

2.2.2 Selection Area

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

- Analytes that are displayed in **Orange** are not available for analysis. If you press the icon of the **Orange Analyte**, a pop-up window with additional information will display.

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

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

The Container icon allows you to select the type of container and sample to be analyzed.
The Panel icon allows you to select from a predefined list of test panels.

2.2.3 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 find 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.

These screens may have other navigational icons.

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 Automatic Calibrations

The Stat Profile Prime CCS analyzer performs a 2-point calibration on all analytes and air detectors 30 minutes after being powered on and regularly thereafter to maintain optimal sensor card and air detector performance. A 1-point calibration is performed at regular intervals to monitor the sensor card's performance between each 2-point calibration. If a calibration error occurs, an alert is shown to notify the operator and the test button of the affected analyte is displayed with an orange background to indicate it is not available for testing.

Scheduled 2-point calibrations can be delayed once for 10 minutes by pressing the Cancel button. After 10 minutes the rescheduled calibration will begin and cannot be cancelled.

2.3.1 Manual Calibrations

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

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

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

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

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

3 Sample Analysis

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

3.1 Analyzing Patient Samples

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

3.1.1 Analyzing Syringe Samples

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

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

Figure 3.1 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

1. Select the syringe icon from the container drop-down list.

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

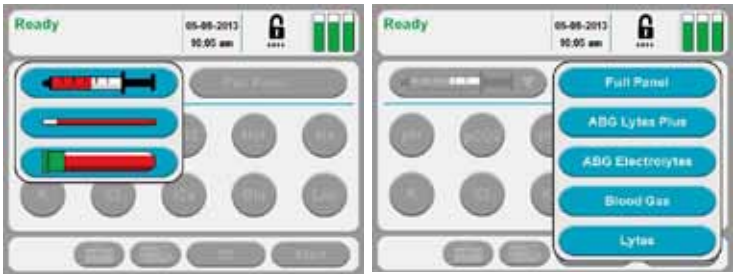


Figure 3.2 Ready Screen: Container and Panel Drop-down List

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

Figure 3.3 Sample Information Screen

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

Figure 3.4 Syringe Sample without Luer

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

NOTE: *The sample will remain on screen 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 3.5 Sample Information Screen

3.1.2 Utilizing the Luer Station

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

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

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

Figure 3.6 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

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

Figure 3.7 Ready Screen: Container and Panel Drop-down List

3. Prepare the sample for analysis (mix well) then attach the syringe to the luer station.

4. Press Start  icon to begin the analysis.

Figure 3.8 Syringe Sample with Luer

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

Figure 3.9 Sample Information Screen

6. Press the Aspirate icon  to aspirate sample into the analyzer. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.
7. Remove the syringe from the luer station.
8. Enter any Required or Optional information while the analysis is running.

Figure 3.10 Sample Information Screen

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

3.1.3 Analyzing Sample from a Blood Collection Tube

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

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

Figure 3.11 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

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 3.12 Ready Screen: Container and Panel Drop-down List

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

Figure 3.13 Sample Information Screen

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

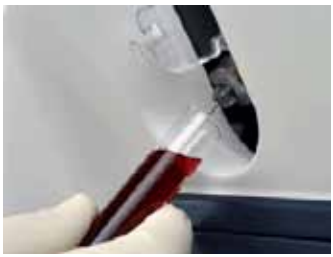


Figure 3.14 Blood Tube Sample

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

NOTE: *The sample will remain on screen 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 3.15 Sample Information Screen

3.1.4 Analyzing Sample from a Capillary Tube

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

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

Figure 3.16 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

1. Select the capillary icon from the container drop-down list.

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

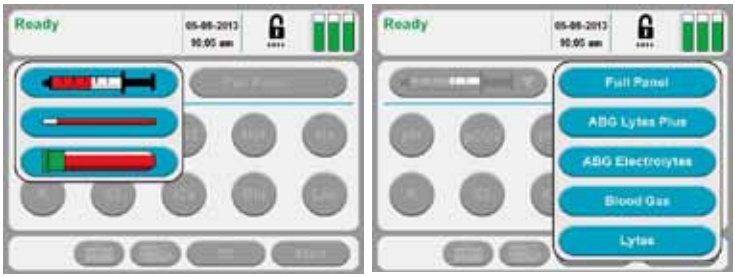


Figure 3.17 Ready Screen: Container and Panel Drop-down List

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

Figure 3.18 Sample Information Screen

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

Figure 3.19 Capillary Sample

6. When prompted, remove the capillary tube and press Continue.
7. Enter any Required or Optional information while the analysis is running.

NOTE: *The sample will remain on screen 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 3.20 Sample Information Screen

3.2 The Sample Results Display

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

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

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

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

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

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

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

Figure 3.21 Blood Results Screen

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

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

Press <Home Button> to return to the Home screen.

3.3 Analyzing QC and Proficiency Samples

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

3.2.1 Analyzing Internal Quality Control Samples

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

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

Figure 3.22 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

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

Figure 3.23 Quality Control Screens

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

Option 1
QC Setup

Option 2
QC Setup

Figure 3.24 Quality Control Results Screens

3.2.2 Analyzing External Quality Control Samples

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

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

Figure 3.22 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

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

Figure 3.23 Quality Control Screens

3. From the drop-down list select the External Control Level to be analyzed.
4. Select the lot number of the External Control to be analyzed.
5. Enter a QC Comment if desired.

6. Press Start Start to begin the analysis.
7. Wait for the Sample Probe to fully extend.
8. Prepare the sample for analysis (mix well) then position the sample over the probe and press Aspirate Aspirate. The sample probe will retract automatically once sufficient sample has been aspirated into the analyzer.

Figure 3.24 External Control to Probe

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

3.2.3 Analyzing Proficiency Samples

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

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

Figure 3.25 Operator ID Screen and Operator Password Screen

If login is not required or after logging into the analyzer:

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

Figure 3.26 Quality Control Screens

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

Figure 3.27 Proficiency Sample to Probe

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

4 Consumable Replacements

The following sections provide detailed information and directions to operate and to maintain the Stat Profile Prime CCS Analyzer at peak efficiency. From the Home screen, press the Tool box icon. From these 2 screens, the following consumable replacements can be performed:

- Change Sensor Card
- Change Calibrate Cartridge
- Change Control Cartridge
- Replace Pump Tubing

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

4.1 Scheduled Replacements

It is important to perform preventive care as scheduled. The **Analyzer Log** gives suggested schedules based on number of test. Space is provided for slopes and control results in the **Analyzer Log**. Replacement procedures are accessed in the System Menu.

Figure 4.1 Screen 1 System Menu

Figure 4.2 Screen 2 System Menu

4.2 Calibrator Cartridge and Control Cartridge Changing

The reagent calibrator and/or control cartridge should be changed when the system indicates the cartridge is empty. From the Home screen, press the Tool Box icon. Then press Change Calibrator Cartridge or Change Control Cartridge. **Mix the cartridge thoroughly by gentile inversions.** Then follow the directions on the screen to replace the cartridges and the capillary adapter.

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

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

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

Figure 4.3 Replacing Calibrator Cartridge and Control Cartridge

4.2.1 Change Calibrator Cartridge

1. Press the Tool Box icon.
2. From the System Menu, press the Change Calibrator Cartridge and wait for pump to stop.
3. Open the door, remove old cartridge.
4. Slide new cartridge in past the front retaining lip.
5. Change the capillary adaptor: slide off used capillary adapter and replace with new one that is provided with Calibrator Cartridge.
6. Close door, press the Calibrate icon.

4.2.2 Change Control Cartridge

1. Press the Tool Box icon.
2. From the System Menu, press the Change Control Cartridge and wait for pump to stop.
3. Open the door, remove old cartridge.
4 Slide new cartridge in past the front retaining lip.
5. Close door, press the Calibrate icon.

4.3 Change Sensor Card

1. Press the Tool Box icon.
2. From the System Menu, press the Change Sensor Card and wait for pump to stop.
3. Open the door, remove old cartridge.
4 Open Cartridge door. Insert new cartridge. Close Cartridge door.
5. Close door, press the Calibrate icon.

NOTE: *Touch Sensor Card by the edges and replace it the same way back as pictured.*

Figure 4.4 Sensor Card

5 Periodic Replacements

Periodically the pump tubing or probe may may need to be replaced; the Reference Sensor has run out of use-life; and the printer needs a new roll of paper. This chapter gives detailed procedures on replacements of these consumable Items.

5.1 Pump Tubing Replacement

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

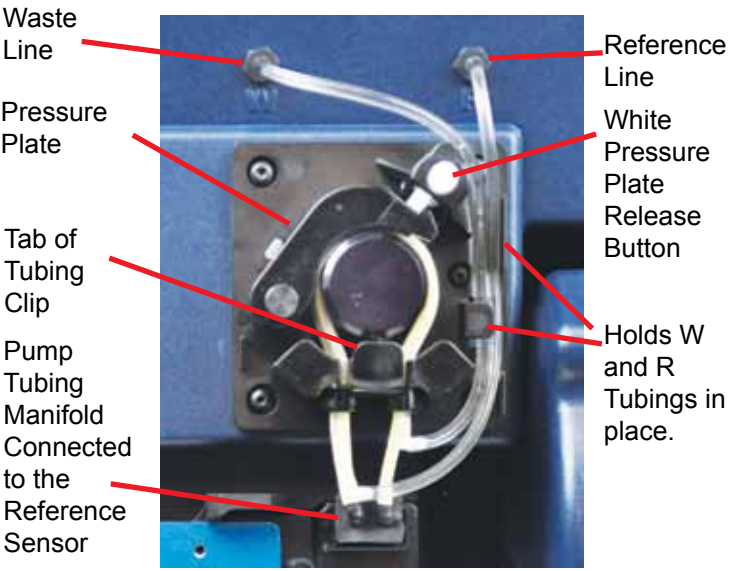


Figure 5.1 Pump Tubing

1. From the Home screen, press the Tool Box icon.
2. From the System Menu, select Change Pump Tubing and wait for pump to stop.
3. Open the door and push the White Pressure Plate release icon to release the Pump Tubing Pressure Plate.

Figure 5.2 Release Pump Tubing Pressure Plate

3. Disconnect the Waste-line and Reference-line above the pump.
4. Disconnect the pump tubing manifold from the Reference Sensor.

Figure 5.3 Disconnect Pump Manifold

5. Slide the pump tubing out by holding the tab of the tubing clip.
6. Discard the used tubing assembly.
7. Stretch the 2 pump tubings around the pump and slide the tubing clip into the slot under the pump.
8. Connect the W-line to the W-labelled outlet above the pump.
9. Connect the R-line to the R-labelled outlet above the pump.
10. Reconnect the W-pump and R-pump manifold to the top of the Reference Sensor.
11. Close the pressure plate until you hear it click into place.
12. Place the W and R lines into the hold positions on the right side of the pump as shown in Figure 4.5.
13. Close the door and press the Calibrate 

icon.

5.2 Probe Replacement

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

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

Figure 5.4 Removing Capillary Adapter

NOTE: *Capillary Adapter is usually changed with the Calibrator Cartridge since a new capillary adapter comes with the cartridge.*

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

Figure 5.5 Disconnect the Cable of the Air Detector

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

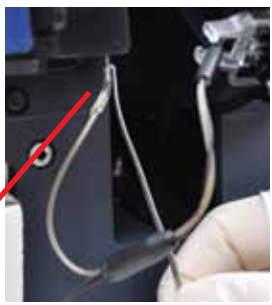


Figure 5.6 Removing Sample Line from Reference Sensor

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

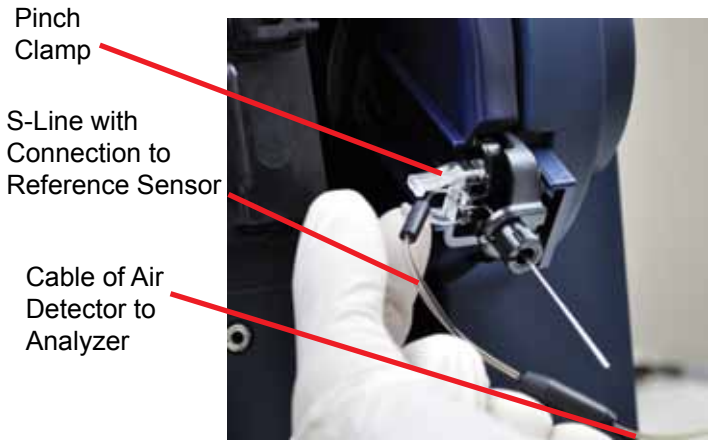


Figure 5.7 Removing Probe, S-line, and Cable of Air Detector

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

5.2 Reference Sensor Replacement

1. From the Home screen, press the Tool Box icon.
2. From the System Menu select the Change Reference Sensor and wait for the pump to stop.
3. Open the door; open Cartridge door.
4 Remove Sensor Card.

NOTE: *To change the Reference Sensor the Sensor Card must be removed first. Only touch Sensor Card by the edges.*

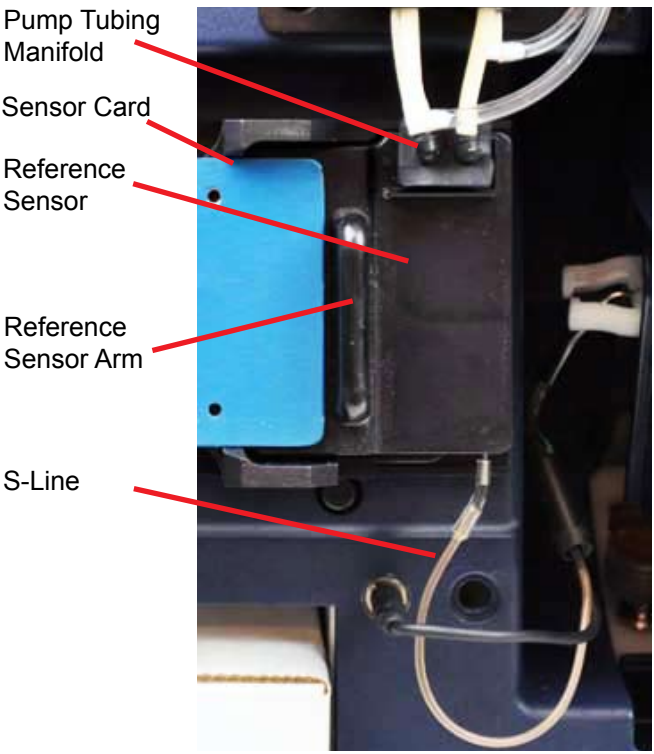


Figure 5.8 Reference Sensor

5. Unplug pump tubing manifold from top of sensor.
6. Disconnect the S-line from the bottom of the sensor using the removal tool attached to the door.
7. Use the Sensor Arm on the left of the sensor to push the sensor to the right and off.

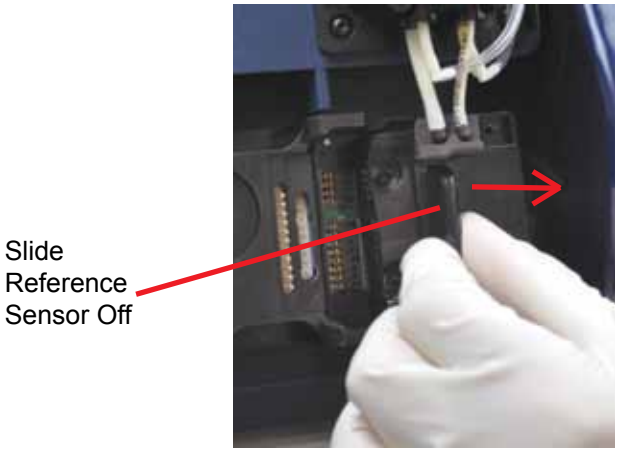


Figure 5.9 Slide the Reference Sensor Off to the Right

8. Take a new sensor by the arm and slide it back onto the analyzer from right to left.
9. Plug the pump tubing manifold to the top of the sensor.
10. Reconnect the S-line to the bottom of the sensor.
11. Replace the Sensor Card. (See Figure 4.4.)
12. Close door, press the Calibrate Calibrate icon.

5.3 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 5.10 Replacing the Printer Paper

5.4 Safety Sample Port Replacement

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 5.11 Replacing the Safety Sample Port

6 Troubleshooting

This section describes the status screens and error codes, and explains the troubleshooting procedures for the Stat Profile Prime CCS Analyzer.

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

6.1 Troubleshooting Procedures

The recommended troubleshooting procedures use the most logical and direct steps to resolve the error code. The solutions are set up in a block format that lists groups of steps to perform in order to restore operation. The steps are also organized to prevent unnecessary parts replacement until the more common causes for an error have been checked. In the case of multiple error codes, those errors that apply to flow are at the top of the hierarchy. In most cases, when you resolve the flow error codes, the other errors will be resolved as well.

If the recommendations given here do not resolve the problem, contact Nova Technical Services for troubleshooting assistance

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

6.2 Error Log

From the Service Menu, select Error Log. The Error Log screen is displayed with errors displayed in chronological order. To go to the next or previous error log pages, press Next Page or Previous Page. To print the error log, select Printer Menu from the Service Menu.

Table 6.1 lists the analyzer's error logs and the corrective action.

Table 6.1 Stat Profile Prime Error Logs

Error	Corrective Action
To Be Determined	

6.3 Operator Flow Test

The flow test verifies that fluid can be pulled through the system from the probe. If water cannot be pulled through the system, a clog or leak exists. The procedure for the flow test and sensor cartridge, reference sensor, and sample probe back flush are as follows.

6.3.1 Flushing the Reference Sensor

1. From the Home screen, press the Tool Box  icon.
2. From the System Menu select the Change Reference Sensor and wait for the pump to stop.
3. Open the door; open Cartridge door.
4 Remove Sensor Card.

NOTE: *To change the Reference Sensor the Sensor Card must be removed first. Only touch Sensor Card by the edges.*

5. Unplug pump tubing manifold from top of sensor.
6. Disconnect the S-line from the bottom of the sensor using the removal tool attached to the door.

7. Use the sensor arm on the left of the sensor to push the sensor to the right and off.
8. Use a syringe filled with distilled water and a tube to attach to the S-line port.
9. Push the distilled water through the bottom of the Reference Sensor.
10. Next attach the tubing of the syringe to the top right pump tubing port. Push the distilled water through the top of the Reference Sensor.
11. With the Reference Sensor cleared, take the sensor by the arm and slide it back onto the analyzer from right to left.
12. Plug the pump tubing manifold to the top of the sensor.
13. Reconnect the S-line to the bottom of the sensor.
14. Replace the Sensor Card.
15. Close door, press the Calibrate  icon.

6.3.2 Flushing the Sensor Cartridge

1. Press the Tool Box  icon.
2. From the System Menu, press the Change Sensor Card and wait for pump to stop.
3. Open the door, remove the Sensor Cartridge.
4. Use the Sensor Cartridge Flushing tool with syringe to flush the cartridge.
5. Attach the Flushing Tool to the topnport of the Sensor Cartridge and push distilled water through the cartridge.
6 With the Sensor Cartridge now cleared, open cartridge door, insert the cartridge, and close the cartridge door.
5. Close the Prime door and press the Calibrate  icon.

NOTE: *Touch Sensor Card by the edges and replace it the same way back.*

6.3.3 Flushing the Sample Probe

1. From the Home screen, press the Tool Box  icon. From the System Menu select Replace Probe and wait for pump to stop.
2. Disconnect the air detector's sample line from the Reference Sensor module using the removal tool attached to the door.
3. Use the syringe with attached tubing to flush distilled water through the S-line and out the Sample Probe. A small sample cup can be held in front of the Sample Probe to catch the water.
4. With the Sample Probe now cleared, reconnect the S-line to the Reference Sensor
5. Close the door.
6. Press the Calibrate 

icon.

A Appendix

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

A.1 Specifications

Measurement Range:

pH	6.500 - 8.000	
PCO_2	3.0 - 200 mmHg	0.4 - 26.7 kPa
PO_2	0 - 800 mmHg	0.0 - 106.7 kPa
Hct	12% - 70%	
Na^+	80 - 200 mmol/L	
K^+	1.0 - 20.0 mmol/L	
Cl^-	50 - 200 mmol/L	
iCa	0.10 - 2.70 mmol/L	0.40 - 10.8 mg/dL
Glu	15 - 500 mg/dL	0.8 - 28 mmol/L
Lac	0.3 - 20.0 mmol/L	2.7 - 178.0 mg/dL

Resolution

Calculated Result:

HCO_3^-	0.1 mmol/L	
TCO_2	0.1 mmol/L	
nCa^{++}	0.10 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	
P50	0.1 mmHg	0.1 kPa

With entered FiO_2:

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

Acceptable Samples: Whole Blood (heparinized)

Sample Volume:

Blood Gas and Electrolyte	100 µL
Blood Gas, Electrolyte, Metabolite	100 µL
Capillary	100 µL

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

A.1.1 Analytical Specificity

An interference study was performed according to CLSI guideline EP7-A2. The study used spiked and diluted specimens containing potential interfering substances for pH, PO_2, 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	Analyte(s) Tested
Acetaminophen	20.0 mg/dL	Glu, Lac
Acetylsalicylic acid	3.62 mmol/L	Cl, Glu, Lac
Ammonium Chloride	107.0 µmol/L	Na, K, Cl
Ascorbic Acid	50 mg/dL	Cl, Glu, Lac
Benzylkonium Chloride	1.0 mg/dL	Na, K, Cl, iCa,
Calcium Chloride	2.0 mmol/L addition	pH, PCO_2, PO_2, Na, K
D-Galactose	10.0 mmol/L	Lac
Dopamine Hydrochloride	5.87 µmol/L	Glu, Lac
EDTA	3.4 umol/L	Glu
Ethanol	0.5%	Glu, Lac
Fluorescein	1.0 mmol/L	PCO_2, PO_2
Fluoride	105 µmol/L	Glu Lac
Glucose	1,000 mg/dL	Lac
Glycolic Acid	160.0 mg/dL 80.0 mg/dL	Glu Lac

Interfering Substance	Highest Concentration Tested	Analyte(s) Tested
Glucosamine	30.0 µmol/L	Lac
Heparin	100 IU/mL	Glu, Lac
Hydroxyurea	0.8 mg/dL	Lac
Ibuprofen	2,425 µmol/L	Glu, Lac
Intralipid	0.1%	pH, PCO_2, PO_2, Na, K, Cl, iCa, Glu, Lac
Lithium Lactate	25.0 mmol/L	Na, K, iCa, Glu
Magnesium Chloride	15.0 mmol/L	Na, Cl, iCa
Maltose	13.0 mmol/L	Glu, Lac
Mannose	10.0 mmol/L	Glu, Lac
Perchlorate	1.0 mmol/L	iCa,
Potassium Chloride	5.0 mmol/L addition	pH, PCO_2, PO_2, iCa
Potassium Thiocyanate	2,064 µmol/L	Cl, Glu, Lac
Pyruvate	309 µmol/L	Lac
Sodium Bromide	2.0 mmol/L	Cl
Sodium Chloride	10.0 mmol/L addition	pH, PCO_2, PO_2, iCa
Sodium Citrate	12.0 mmol/L	Glu, Lac
Sodium Oxalate	500 mg/dL	Glu, Lac
Sodium Salicylate	50.0 mg/dL	Glu, Lac
Urea	40.0 mg/dL	Lac
Uric Acid	1.4 mmol/L	Lac
Xylose	25.0 mg/dL	Glu, Lac
Zinc Chloride	1,300 µg/dL	Na, K, iCa,

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

Glucose

Interfering Substance	Concentration of interfering substance	Analyte (Glu) concentration	Bias mg/dL
D-Galactose	10.0 mmol/L	94 mg/dL	- 10.7 mg/dL
Glucosamine	30 µmol/L	99 mg/dL	- 16.6 mg/dL
Hydroxyurea	0.8 mg/dL	112 mg/dL	- 18.8 mg/dL

Lactate

Interfering Substance	Concentration of interfering substance	Analyte (Lac) concentration	Bias mmol/L
Glycolic acid	80 mg/dL	2.7 mmol/L	(+) 3.6 mmol/L

A.2 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.

Method Comparison Study
Heparinized 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 to complete analysis.

A minimum of 150 whole blood specimens were analyzed for each parameter in syringe collection devices. The samples were analyzed on each of the Stat Profile Prime 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 test result from each test system.

Bias Chart Results

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

Figure 1
pH Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra

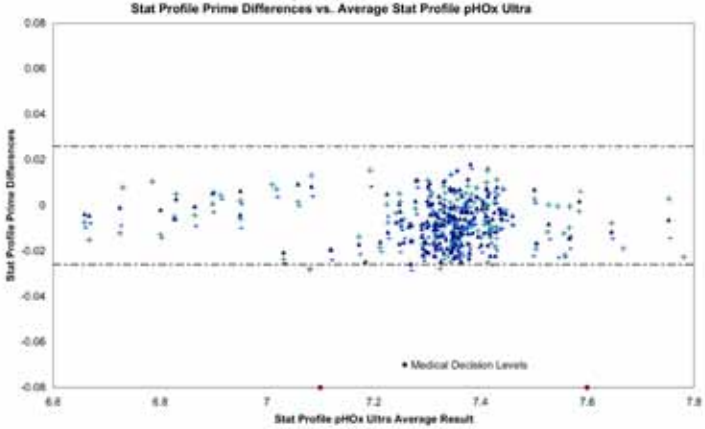


Figure 2
pCO2 Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

Figure 3
pO2 Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

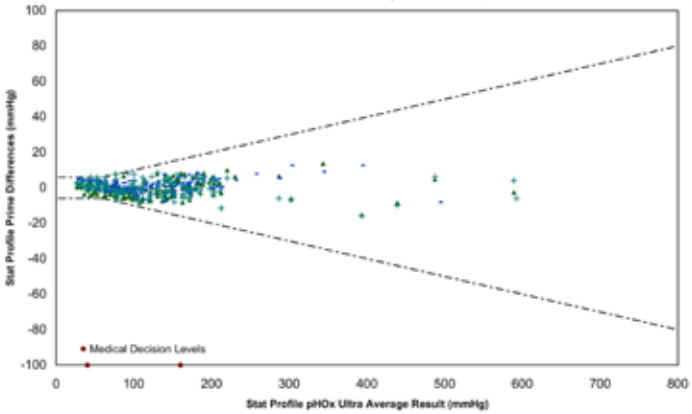


Figure 4
Hct Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

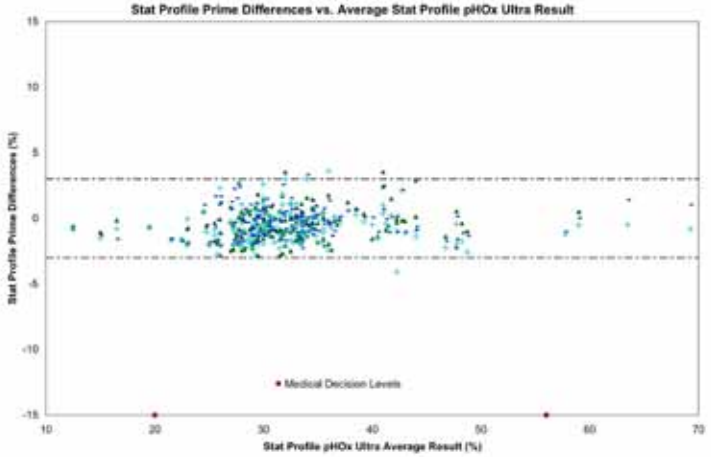


Figure 5
Na Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

Figure 6
K Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

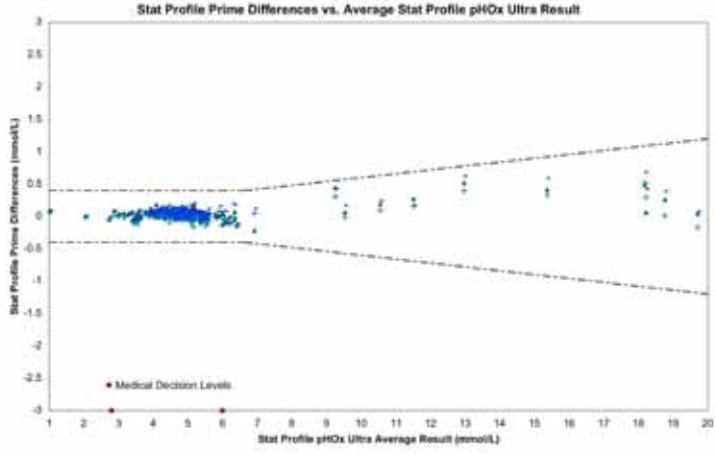


Figure 7
Ca Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

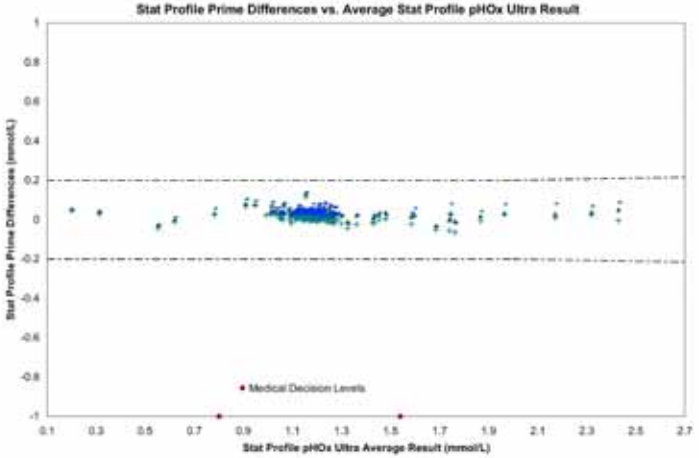


Figure 8
Cl Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

Figure 9
Glucose Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result

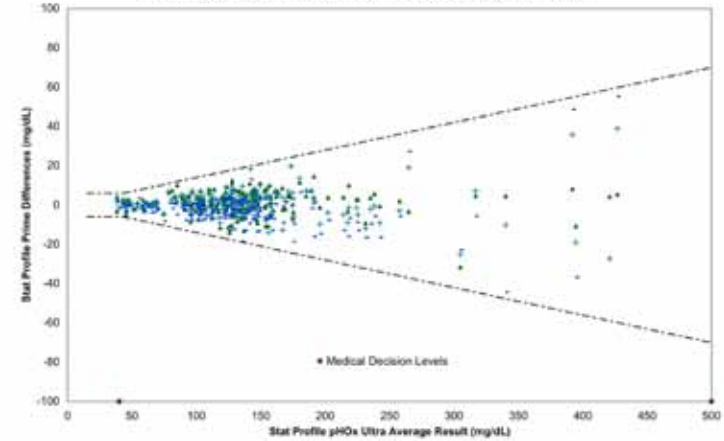
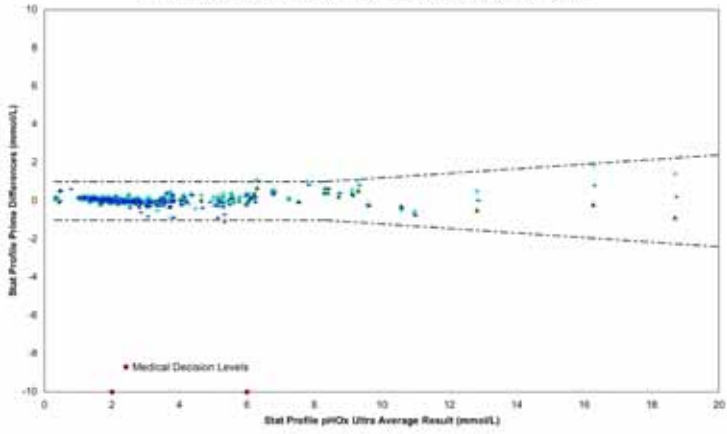


Figure 10
Lactate Bias Plot
Stat Profile Prime Differences vs. Average Stat Profile pHOx Ultra Result



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

	Individual Analyzer Performance Data Capillary vs. Syringe Comparison					
Parameter	**Analyzer**	**Total # specimens**	**specimen range**	**Slope**	**Intercept**	**r**
pH	#1	100	6.787 - 7.683	1.0094	-0.0721	0.9988
pH units	#2	100	6.820 - 7.669	1.0157	-0.1176	0.9986
	#3	100	6.806 - 7.668	1.0097	-0.0714	0.9989
***P*CO_2**	#1	100	17.7 - 111.0	1.0026	-0.4347	0.9989
mmHg	#2	100	19.6 - 103.7	0.9939	-0.1404	0.9981
	#3	100	18.0 - 123.2	0.9897	-0.1897	0.9991
***P*O_2**	#1	100	25.5 - 435.2	0.9942	2.1791	0.9996
mmHg	#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	#1	100	85.0 - 198.1	0.9995	-0.1711	0.9978
mmol/L	#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	#1	100	2.70 - 19.37	0.9966	0.0934	0.9996
mmol/L	#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	#1	100	0.13 - 2.76	1.0083	-0.0422	0.9873
mmol/L	#2	100	0.12 - 2.70	0.9936	-0.0069	0.9855
	#3	100	0.13 - 2.52	1.0231	-0.0445	0.9818
Cl	#1	100	55.8 - 197.1	0.9897	0.1776	0.9997
mmol/L	#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	#1	100	17 - 488	0.9855	-0.4734	0.9998
mg/dL	#2	100	19 - 491	0.9919	-0.5176	0.9998
	#3	100	21 - 489	0.9813	0.2346	0.9999
Lac	#1	100	1.1 - 18.1	1.0034	0.0120	0.9994
mmol/L	#2	100	1.2 - 19.9	1.0030	-0.0057	0.9995
	#3	100	1.2 - 19.5	0.9911	-0.0010	0.9994

Precision Study Results

Analytical Precision or Repeatability

Three Stat Profile Prime CCS Analyzers were assessed for within run precision or repeatability within a laboratory setting. The protocol consisted of within run precision, and run–to-run precision studies using 3 different quality control materials.

- **Stat Profile Prime Quality Control Level 1**
- **Stat Profile Prime Quality Control Level 2**
- **Stat Profile Prime Quality Control Level 3**

Within Run Precision Performance

The protocol consisted of 20 replicates per run for each QC level 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.

Stat Profile Prime Quality Control Level 1

Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Pooled
pH	Mean	7.165	7.161	7.167	7.165
pH units	SD	0.001	0.001	0.001	0.003
***P*CO$_2$**	Mean	56.7	56.0	56.3	56.3
mmHg	SD	0.2	0.2	0.1	0.3
	CV%	0.4	0.4	0.3	0.6
***P*O$_2$**	Mean	70.1	70.4	70.5	70.3
mmHg	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
Na	Mean	158.1	157.5	158.7	158.1
mmol/L	SD	0.1	0.4	1.4	0.9
	CV%	0.1	0.2	0.9	0.6
K	Mean	5.80	5.84	5.81	5.82
mmol/L	SD	0.00	0.02	0.03	0.03
	CV%	0.08	0.31	0.54	0.45
iCa	Mean	1.51	1.52	1.52	1.52
mmol/L	SD	0.01	0.01	0.00	0.01
	CV%	0.33	0.36	0.30	0.37
Cl	Mean	131.0	133.3	130.8	131.7
mmol/L	SD	0.1	0.4	0.1	1.2
	CV%	0.1	0.3	0.1	0.9
Glu	Mean	74	71	74	73
mg/dL	SD	0.0	0.3	0.0	1.5
	CV%	0.0	0.4	0.0	2.0
Lac	Mean	0.9	0.8	0.8	0.8
mmol/L	SD	0.0	0.0	0.0	0.1
	CV%	2.5	1.1	1.3	

Stat Profile Prime Quality Control Level 2

Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Pooled
pH	Mean	7.361	7.360	7.362	7.361
pH units	SD	0.002	0.002	0.002	0.002
***P*CO$_2$**	Mean	41.6	41.3	41.6	41.5
mmHg	SD	0.3	0.3	0.3	0.3
	CV%	0.7	0.8	0.7	0.8
***P*O$_2$**	Mean	108.8	109.6	109.6	109.4
mmHg	SD	0.6	1.4	0.3	0.9
	CV%	0.5	1.3	0.3	0.9
Hct	Mean	55	55	55	55
%	SD	0.5	0.3	0.3	0.4
Na	Mean	140.2	140.1	140.0	140.1
mmol/L	SD	0.1	0.2	0.6	0.4
	CV%	0.1	0.1	0.5	0.3
K	Mean	3.84	3.81	3.80	3.82
mmol/L	SD	0.02	0.01	0.02	0.02
	CV%	0.43	0.33	0.41	0.53
iCa	Mean	0.97	0.97	0.98	0.97
mmol/L	SD	0.01	0.00	0.01	0.01
	CV%	0.92	0.50	0.52	0.68
Cl	Mean	102.3	102.2	101.8	102.1
mmol/L	SD	0.5	0.2	0.1	0.4
	CV%	0.4	0.2	0.1	0.4
Glu	Mean	200	202	198	200
mg/dL	SD	1.1	1.1	0.8	1.9
	CV%	0.5	0.5	0.4	0.9
Lac	Mean	2.6	2.6	2.6	2.6
mmol/L	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

Parameter	n = 20	Analyzer # 1	Analyzer # 2	Analyzer # 3	Pooled
pH	Mean	7.596	7.597	7.594	7.596
pH units	SD	0.002	0.002	0.002	0.002
***PCO*$_2$**	Mean	23.6	23.7	23.8	23.7
mmHg	SD	0.3	0.3	0.4	0.3
	CV%	1.2	1.2	1.5	1.3
***PO*$_2$**	Mean	142.2	138.7	142.3	141.1
mmHg	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
Na	Mean	120.4	120.5	120.2	120.4
mmol/L	SD	0.1	0.3	0.3	0.3
	CV%	0.1	0.2	0.3	0.2
K	Mean	1.88	1.86	1.86	1.86
mmol/L	SD	0.01	0.01	0.00	0.01
	CV%	0.64	0.46	0.24	0.64
iCa	Mean	0.52	0.52	0.53	0.52
mmol/L	SD	0.00	0.00	0.00	0.00
	CV%	0.90	0.43	0.42	0.95
Cl	Mean	84.7	84.6	84.9	84.8
mmol/L	SD	0.5	0.4	0.1	0.4
	CV%	0.6	0.4	0.1	0.4
Glu	Mean	320	322	321	321
mg/dL	SD	1.0	0.9	1.0	1.4
	CV%	0.3	0.3	0.3	0.4
Lac	Mean	6.4	6.4	6.5	6.4
mmol/L	SD	0.0	0.0	0.0	0.0
	CV%	0.3	0.3	0.2	0.371

Run-to-Run Precision Performance

Estimates of the run to run precision were determined for each of 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 – 2 tonometered levels for PCO_2 and PO_2 were prepared on each test day and analyzed in syringe mode.
- Whole Blood – 2 levels for Hematocrit were prepared on each test day and were analyzed in syringe mode.

Estimates of the run to run precision were determined for each level of Quality Control, Linearity Standard, tonometered blood, and Hematocrit. Statistical analysis for each parameter include the pooled mean, Sr, ST, CV% (pH excluded), and N for all analyzers was calculated.

Run-to-Run Precision 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	1.33	2.28
QC Level 2	41.9	240	0.06	0.13	0.53	1.26
QC Level 3	23.0	240	0.07	0.29	0.42	1.83
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
Blood Gas (A)	26.5	240	0.34	1.29	0.93	3.52
Blood Gas (B)	53.4	240	0.44	0.82	2.03	3.80

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	2.02	2.88
QC Level 2	110.1	240	0.55	0.50	1.16	1.05
QC Level 3	143.8	240	0.39	0.27	1.21	0.84
Linearity Std 1	21.6	240	1.45	6.73	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
Blood Gas (A)	111.5	240	1.29	1.16	3.05	2.74
Blood Gas (B)	61.4	240	0.50	0.81	2.09	3.40

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	0.81	2.15
QC Level 2	55.0	240	0.20	0.37	0.32	0.58
QC Level 3	68.6	240	0.18	0.26	0.43	0.63
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	0.41	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
Hct (A)	43.4	240	0.20	0.46	1.12	2.57
Hcy (B)	60.7	240	0.28	0.47	1.22	2.01

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	0.68	0.43
QC Level 2	140.1	240	0.12	0.09	0.25	0.18
QC Level 3	120.2	240	0.08	0.07	0.18	0.15
Linearity Std 1	89.7	240	0.45	0.50	0.56	0.62
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	0.48
QC Level 2	3.81	240	0.005	0.14	0.01	0.36
QC Level 3	1.87	240	0.002	0.13	0.02	0.97
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	1.13
QC Level 2	0.97	240	0.002	0.22	0.00	0.43
QC Level 3	0.53	240	0.001	0.23	0.01	1.85
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	131.5	240	0.57	0.43	2.30	1.75
QC Level 2	103.0	240	0.72	0.70	1.52	1.48
QC Level 3	86.1	240	0.27	0.32	1.38	1.60
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	1.69	2.37
QC Level 2	196.9	240	0.81	0.41	1.33	0.67
QC Level 3	318.6	240	2.32	0.73	3.31	1.04
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	3.58
QC Level 2	2.60	240	0.012	0.47	0.01	0.54
QC Level 3	6.38	240	0.023	0.35	0.06	0.87
Linearity Std 1	13.36	240	0.229	1.71	0.79	5.91
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

A.3 Calibrator Cartridge

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

A.3.1 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.4 Reference Values

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

Table A.1 Reference Values[1,2,6]

Test	Value
pH	7.35 - 7.45
PCO_2	35 - 45 mmHg
HCO_3^-	21 - 28 mmol/L
Base Excess (Blood)	(-2)-(+3) mmol/L
PO_2	83 - 108 mmHg
SO_2 (arterial whole blood)	95 - 98%
Hematocrit (Hct)	
(Male)	39 - 49%
(Female)	35 - 45%
Hemoglobin (Hb)	
(Male)	13.2 - 17.3 g/dL
(Female)	11.7 - 15.5 g/dL

Table A.2 Reference Values for Adult Whole Blood

Test	Value
Sodium[2]	136 - 146 mmol/L
Potassium[2]	3.5 - 5.1 mmol/L
Chloride[2]	98 - 106 mmol/L
Glucose[2]	65 - 95 mg/dL
Lactate[4,5]	0.7 - 2.5 mmol/L
Calcium[3]	1.09 - 1.30 mmol/L

References:

1. Statland, Bernard. 1987. *Clinical Decisions Levels for Lab Tests*, Medical Economics Books.
2. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.
3. Kost, G.T. 1993. The Significance of Ionized Calcium in Cardiac and Critical Care. *Arch. Pathol.* Lab Med. Vol. 117: pp 890-896.
4. Toffaletti, J., Hammes, M. E., Gray, R., Lineberry, B., and Abrams, B. 1992. Lactate Measured in Diluted and Undiluted Whole Blood and Plasma: Comparison of Methods and Effect of Hematocrit. *Clinical Chemistry*, Vol. 38, No. 12.
5. Bernstein, W.K., Aduen, J., Bhatiani, A., Kerzner, R., Davison, L., Miller, C., and Chernow, B. 1994. Simultaneous Arterial and Venous Lactate Determinations in Critically Ill Patients. *Critical Care Medicine*, Vol. 22.
6. Burtis, Carl A. Ashwood, Edward R., Burns, David R., 2011. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 5th ed,* Philadelphia, PA: W. B. Saunders Co.

A.5 Ordering Information

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

DESCRIPTION	Part #
Assembly Probe S Line 100 µL Prime CCS	52582
Auto Cartridge Control Prime CCS	45150
Calibrator Cartridge Prime CCS	52427
Luer Station Packaged (5x) Prime CCS	52669
Prime Calibrator Cartridge CCS 100 Sample	52862
Prime Calibrator Cartridge CCS 200 Sample	53364
Prime Calibrator Cartridge CCS 300 Sample	52863
Prime Calibrator Cartridge CCS 400 Sample	53466
Prime Calibrator Cartridge CCS 500 Sample	53467
Prime Calibrator Cartridge CCS 600 Sample	53468
Prime Calibrator Cartridge CCS Comp 100 Sample	52861
Prime Calibrator Cartridge CCS Comp 200 Sample	53365
Prime Calibrator Cartridge CCS Comp 300 Sample	52427
Prime Calibrator Cartridge CCS Comp 400 Sample	53105
Prime Calibrator Cartridge CCS Comp 500 Sample	53469
Prime Calibrator Cartridge CCS Comp 600 Sample	53470
Prime Pump Harness	52484
Prime Sensor Card CCS (without Glu/Lac)	42032
Prime Sensor Card CCS Comp	42033
Reference Sensor, Prime CCS	42043

A.6 Warranty

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

The 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.

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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 Sensor Technology (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

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.[1] 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 = $\dfrac{E_{std\ C} - E_x}{pH_{std\ C} - pH_{std\ D}}$ Equation 7

Principle of pH Measurement

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

B.1.3 Partial Pressure of Carbon Dioxide (PCO_2)

Definition of PCO2

The partial pressure (tension) of carbon dioxide in solution is defined as the partial pressure of carbon dioxide in the gas phase in equilibrium with the blood.

Principle of PCO_2 Measurement

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

$$CO_2 + H_20 <=> H_2CO_3 <=> H^+ + [HCO^-_3] \qquad \text{Equation 8}$$

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

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

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

B.1.4 Partial Pressure of Oxygen (PO_2)

Definition of PO2

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.

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:

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose Oxidase}} \text{Gluconic acid} + H_2O_2 \qquad \text{Equation 9}$$

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

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^- \qquad \text{Equation 10}$$

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:

$$\text{Lactate} + O_2 \xrightarrow[H_2O_2]{\text{Lactate Oxidase}} \text{Pyruvate acid} + \qquad \text{Equation 11}$$

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

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^- \qquad \text{Equation 12}$$

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:

$$pH_{(corrected)} = pH + [- 0.0147 + 0.0065\ (7.400 - pH)](T - 37) \qquad \text{Equation 13}$$

$$PCO_{2\ (corrected)} = PCO_2 \times e\ (0.04375(T - 37)) \qquad \text{Equation 14}$$

$$PO_{2\ (corrected)} = PO_2 \times 10^{U} \qquad \text{Equation 15}$$

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

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

B.2.2 Calculated Parameters

Calculated Bicarbonate Concentration [HCO_3^-][2]

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

$$pH = pK + \log \frac{[HCO_3^-]}{\alpha(PCO_2)} \qquad \text{Equation 16}$$

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:

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

Equation 17

*The equations are from NCCLS standards[2].

Total Carbon Dioxide Content (TCO_2)*

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

$$TCO_2 = [HCO_3^-] + \alpha(PCO_2) \qquad \text{Equation 18}$$

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

* The equations are from Reference 2.

Hemoglobin (Calculated)

The hemoglobin is calculated based on the following calculation:

Hemoglobin g/dL = Measured Hematocrit ÷ 3.0 Equation 19

NOTE: *The hemoglobin calculation is an estimation based on a normal mean corpuscular hemoglobin concentration of 33.3%. The Stat Profile Prime CCS Analyzer hemoglobin estimation from samples with Red cell dyscrasia or hemoglobinopathies may vary significantly from hemoglobin measured by cyanmethemoglobin method.*

Base Excess of Blood (BE-B)*

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

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

Equation 20

* The equations are from Reference 2.

Standard Bicarbonate Concentration (SBC)

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

$$SBC = 24.5 + 0.9Z + Z\,(\,Z - 8\,)(0.004 + 0.00025\,[Hb])$$ Equation 21

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

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

Base Excess Extracellular Fluid (BE-ECF)*

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

$$BE\text{-}ECF = [HCO_3^-] - 25 + 16.2\,(pH - 7.40)$$ Equation 22

* The equations are from Reference 2.

Oxygen Content (O_2Ct)

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

$$\frac{4\ (22393)}{64458} = 1.39 \text{ mL of } O_2 \text{ per gram of Hb} \quad \text{Equation 23}$$

$$\text{therefore } O_2Ct = (1.39\ [Hb])\ (SO_2/100) + (0.0031\ [PO_2]) \quad \text{Equation 24}$$

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

Oxygen Saturation (O_2Sat)

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

$$O_2Sat = \frac{[PO_2']^3 + 150\ [PO_2']}{[PO_2']^3 + 150\ [PO_2'] + 23400} \times 100 \quad \text{Equation 25}$$

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

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

Alveolar Oxygen (A)

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

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

Equation 26

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

** Temperature corrected gas value

Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)

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

$$Aa\ DO_2 = A - {}^{**}PO_2 \qquad \text{Equation 27}$$

** Temperature corrected gas value

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

Arterial Alveolar Oxygen Tension Ratio (a/A)

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

$$a/A = {}^{**}PO_2/A \qquad \text{Equation 28}$$

** Temperature corrected gas value

Arterial-Mixed Venous O_2 Content Difference ($a - \bar{v}\ DO_2$)

When the oxygenated blood from the lungs comes into contact with tissues, it releases oxygen and takes up carbon dioxide. The quantity of oxygen donated depends on 2 factors:

- The speed of blood flow
- The consumption by tissues

The first factor can be detected from the cardiac output, and the second depends on the metabolic rate of the patient. The $a - \bar{v}\ DO_2$ is the measurement of the difference in oxygen content between the arterial blood and the mixed venous blood (the amount of oxygen donated to the tissues). This parameter is not an indication of the basic metabolism or of the cardiac output. It is an nonspecific indication; even if, in some cases completely relaxed patients with a constant metabolic rate, it can be related to the cardiac output.

$$a - \bar{v}\ DO_2 = CaO2 - C\bar{v}\ O_2 \qquad \text{Equation 29}$$

P50 or PO_2 (0.5)*

The *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 30

For measured SO_2% between 80 and 96.9%, the equation is as follows:
Where z = tanh(0.5343 * x); x = ln(0.133 * PO_2/7); y = ln(SO_2%/(100-SO_2%))-1.875

$P50_{(uncorrected)} = 26.902 * \exp(1.121 * (y-x-3.5z)/(1.87 * z^2 + z - 2.87))$ Equation 31

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 32

* The equations are from Reference 4.

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 33

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.

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:

$$\text{Anion Gap} = (Na + K) - (Cl + [HCO_3^-\}) \quad \text{Equation 34}$$

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.

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