REF 60278 Rx Only IVD

Stat Profile PRIME Plus®
Analyzer

Instructions for Use
Manual

nova® biomedical

NOVA BIOMEDICAL SYMBOL DIRECTORY

IVD	*In vitro* diagnostic medical device
	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
 YYYY - MM	Use by date (last day of month)
	Electronic waste
	Laser radiation: Do not stare into beam
	Prescription use only

Ordering Information

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

Nova Biomedical Corporation	Telephone:	1-800-458-5813
200 Prospect Street	FAX:	1-800-316-1178 (In the USA)
Waltham, MA 02454		1-978-439-3763 (USA and International)
USA		1-781-891-9718 (International Only)
	Web:	www.novabiomedical.com

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

Technical Assistance

For technical assistance inside the United States, call Nova Biomedical Technical Services:

1-800-545-NOVA (6682)
1-781-894-0800
FAX: 1-781-894-0585

For technical assistance outside the United States, call your local Nova subsidiary or authorized distributor.

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1. Introduction

This manual provides all necessary instructions for the routine operation and upkeep of the Stat Profile Prime Plus 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 cartridges, etc.) with care. Gloves and protective clothing are recommended. When performing maintenance and troubleshooting procedures, also use protective eye wear.***

This section introduces the Stat Profile Prime Plus 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 Plus Analyzer. The manual uses the following definitions:

- ***NOTE:*** Especially important information
- ***CAUTION:*** Information that is critical to avoid instrument damage or incorrect results
- ***WARNING:*** 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.

1.2.1 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. Do not stare into the scanner laser beam.

12. The analyzer should be cleaned only as recommended by the manufacturer.
13. Route power cords so they are unlikely to be walked on or pinched by items placed upon or against them. Pay particular attention to cords at plugs, at power sockets, and at the point where they exit the analyzer.
14. Take care not to let objects or liquids fall into the analyzer.
15. Do not attempt to service the analyzer beyond that described in the operating instructions. All other servicing should be referred to qualified service personnel.
16. Take care not to reach into the analyzer or sample probe area while the instrument is busy.

1.2.2 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 57005 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.

1.2.3 Barcode Scanner Safety

WARNING: Do not stare into the laser beam.

Barcode Scanner Safety

A Class 2 laser is incorporated into the barcode scanner.

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.

1.2.4 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.

1.2.5 Cleaning Prime Plus Surfaces

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.

1.3 Installation and Use

This section covers the installation requirements for the analyzer. Prior to using the analyzer, you should be familiar with Chapter 2, Getting Started, and Chapter 3, Sample Analysis.

NOTE: *Under the Warranty, an authorized Nova service representative will install and service this equipment.*

1.3.1 Lifting the Analyzer

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.***

1. Stand facing the front of the analyzer.
2. Place your hands under each side of the analyzer.
3. Lift the analyzer.
4. Place the analyzer onto a clean, flat surface.

1.4 Requirements

The working area must be free of dirt, corrosive fumes, vibration, and excessive temperature changes. Table 1.1 shows additional requirements.

Table 1.1 Prime Plus Analyzer Requirements

Electrical	
Operating Voltage Range	100 to 240 VAC
Operating Frequency	47 to 63 Hz
Power Consumption	<100 Watts
Ambient Operating Temperature	15°C to 32°C (59°F to 89.6°F)
Operate at Humidity	20% to 85% without condensation
Operate at Altitude	Up to 12,000 feet/3650 meters
Dimensions	
Height	18.5 in (45.7 cm)
Width	14.0 in (35.6 cm)
Depth	15.0 in (38.1 cm)
Weight	
Without Calibrator or QC Packs	35 lb (15.9 kg)

1.5 Intended Use, Tests Performed, and Clinical Utility

The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of pH, Partial Pressure of Carbon Dioxide (pCO_2), Partial Pressure of Oxygen (pO_2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, Lactate, Creatinine, Blood Urea Nitrogen, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.

It is also indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of pH, Partial Pressure of Carbon Dioxide (pCO_2), Partial Pressure of Oxygen (pO_2), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate in heparinized capillary whole blood.

1.5.1 Measured Parameters

Table 1.2 shows the whole-blood parameters measured directly by the analyzer:

Table 1.2 Prime Plus Measured Parameters

pH	Potassium (K)	Blood Urea Nitrogen (BUN)
Partial Pressure of Carbon Dioxide (pCO_2)	Chloride (Cl)	Total Hemoglobin (tHb)
Partial Pressure of Oxygen (pO_2)	Ionized Calcium (iCa)	Oxyhemoglobin (O_2Hb)
Oxygen Saturation (SO_2%)	Ionized Magnesium (iMg)	Carboxyhemoglobin (COHb)
Hematocrit (Hct)	Glucose (Glu)	Methemoglobin (MetHb)
Sodium (Na)	Lactate (Lac)	Deoxyhemoglobin (HHb)
	Creatinine (Creat)	

1.5.2 Calculated Parameters

The parameters in Table 1.3 are calculated by the Prime Plus Analyzer based on results of the directly measured parameters:

Table 1.3 Prime Plus Calculated Parameters

Alveolar Oxygen (A)	Capillary Oxygen Content (CcO_2)	Oxygen Saturation (SO_2%)
Anion Gap (Gap)	Estimated Glomerular Filtration Rate (eGFR)	Oxygenation Index (OI)
Arterial Alveolar Oxygen Tension Gradient (A-aDO_2)	Estimated Plasma Volume (ePV)	P_{50}
Arterial Alveolar Oxygen Tension Ratio (a/A)	Serial or ΔPlasma Volume (ΔPV)	pH corrected to patient temperature: pH(TC)
Arterial Oxygen Content (CaO_2)	Fractional Oxyhemoglobin (FO_2Hb)	PCO_2 corrected to patient temperature: PCO_2(TC)
Arterial-Venous Oxygen Content Difference ($C(a\text{-}v)O_2$)	Mean Corpuscular Hemoglobin Concentration (MCHC)	PO_2 corrected to patient temperature: PO_2(TC)
Base Excess of Blood (BE-b)	nCA to nMg Ratio (nCa/nMg)	PO_2 to FIO_2 Ratio (PO_2/FIO_2)
Base Excess of Extracellular Fluid (BE-ecf)	Normalized Calcium (nCa)	Qsp/Qt (Physiological Shunt—requires mixed venous and arterial samples)
Bicarbonate Level (HCO_3)	Normalized Magnesium (nMg)	Respiratory Index (RI)
Blood Osmolality (OSM)	Oxygen Capacity (O_2Cap)	Standard Bicarbonate Concentration (SBC)
BUN/Creat Ratio (BUN/Creat)	Oxygen Content (O_2Ct)	Total Carbon Dioxide (TCO_2)
Hemoglobin (Hb)		Venous Oxygen Content (CvO_2)

1.5.3 Clinical Utility

Whole blood measurements obtained by this system are used as follows[1]:

- **pH, pCO_2, pO_2** measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- **Hematocrit (Hct)** measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.
- **Sodium (Na)** measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
- **Potassium (K)** measurements are used in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
- **Chloride (Cl)** measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
- **Ionized Calcium (iCa)** 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).
- **Ionized Magnesium (iMg)** measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).
- **Glucose (Glu)** measurements are used in the diagnosis and treatment of carbohydrate metabolism disturbances, including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell tumor.
- **Lactate (Lac)** measurements are used to evaluate the acid-base status of patients suspected of having lactic acidosis.
- **Creatinine (Creat)** measurements are used in the diagnosis and treatment of certain renal conditions and for monitoring adequacy of dialysis.
- **Blood Urea Nitrogen (BUN)** measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
- **Oxygen Saturation (SO_2)** measurements are used to assess the oxygenation of the hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Measurements are also used to diagnose and treat cyanosis.
- **Total Hemoglobin (tHb)** measurements are used in the evaluation of chronic and acute anemia as well as the oxygen transport capability of the hemoglobin.
- **Oxyhemoglobin (O_2Hb)** measurements are used to assess pulmonary function in combination with Deoxyhemoglobin and are also used in the diagnosis and treatment of cyanosis.
- **Carboxyhemoglobin (COHb)** measurements are used to determine if and to what level carbon monoxide has been inhaled by the patient. High levels of carbon monoxide can lead to tissue anoxia and death.
- **Deoxyhemoglobin (HHb)** measurements are used to assess pulmonary function in combination with Oxyhemoglobin.

- **Methemoglobin (MetHb)** measurements are used to determine congenital methemoglobinemia or determine the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. High levels of methemoglobin can lead to cyanosis and death.

1.6 The Sample

Lithium heparin or balanced heparin venous and arterial whole blood samples from syringes and open tubes can be used on the Stat Profile Prime Plus Analyzer. The minimum sample size for analysis is 135 µL.

Capillary whole blood samples from lithium heparin or balanced heparin capillary tubes can be used on the analyzer. The minimum sample size for analysis is 90 µL.

1.6.1 Handling Requirements

- **pH, pCO_2, pO_2**

Correct sample handling is critical to ensure that the blood gas values 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 that the 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]

- **Total Hemoglobin and Hematocrit**

Correct sample mixing is critical to ensure that measured Hematocrit and Total Hemoglobin values accurately reflect the in vivo state. To ensure a homogeneous mixture of red blood cells within the specimen, it is particularly important to ensure that samples are well mixed before introduction into the analyzer.

1.6.2 Acceptable Anticoagulants

- **Lithium or balanced heparin** is the **acceptable anticoagulant** for use with the analyzer.
- EDTA, citrate, oxalate, sodium heparin, and sodium fluoride **HAVE NOT** been evaluated.
- 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.

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

1.6.3 Sample Limitations

The system has not been evaluated for use with patients with polycythemia, hypochromia, or sickle cell disease.

1.6.4 Limitations

WARNING: ***The following analytes have been shown to exhibit clinically significant interferences in the presence of the compounds listed in Table 1.4. Refer to Section A.4 for additional details on Analytical Specificity.***

Table 1.4 Limitations: Interfering Substances Causing Clinically Significant Effects on Test Results

Parameter	Interfering Substance	Interference Observed at Concentrations Above
Chloride	Bromide	2.5 mmol/L
	Thiocyanate	3.4 mmol/L
COHb	Evans Blue	0.25 mg/dL
	Sulfhemoglobin	0.803%
Creatinine	Hydroxyurea	0.06 mg/dL
	Thiocyanate	1.7 mmol/L
Glucose	Hydroxyurea	0.2 mg/dL
	Oxalate	125 mg/dL
	Thiocyanate	3.4 mmol/L
Hematocrit	Albumin	2.8 g/dL
	Hemolysis	5.0%
	Triglycerides	335.5 mg/dL
Ionized Calcium	$MgCl_2$	3.75 mmol/L
Ionized Magnesium	Perchlorate	0.06 mmol/L
	Thiocyanate	0.4 mmol/L
	$ZnCl_2$	0.163 mg/dL
Lactate	Glycolic Acid*	0.0 mmol/L
	Hydroxyurea	0.0 mg/dL
MetHb	Evans Blue	0.125 mg/dL
	Intralipid	1.0%
	Methylene Blue	Interference at all Concentrations
	Patent Blue	1.875 mg/dL
	Sulfhemoglobin	0.63%
O_2Hb	Evans Blue	0.125 mg/dL
	Intralipid	1.0%
	Sulfhemoglobin	0.63%
tHb	Evans Blue	0.25 mg/dL
	Intralipid	1.0%

*Glycolic Acid, a metabolite of ethylene glycol that may be present in blood samples following ingestion of ethylene glycol (found in antifreeze fluid, de-icing solutions, certain cleaners), can cause falsely high lactate results.

2. Getting Started

The Stat Profile Prime Plus Analyzer's exterior (Figure 2.1) has a touch-screen display, sampler assembly with probe, and thermal printer. The front-panel door provides access to the analytical compartment (Figure 2.2).

Figure 2.1 Prime Plus Front Panel

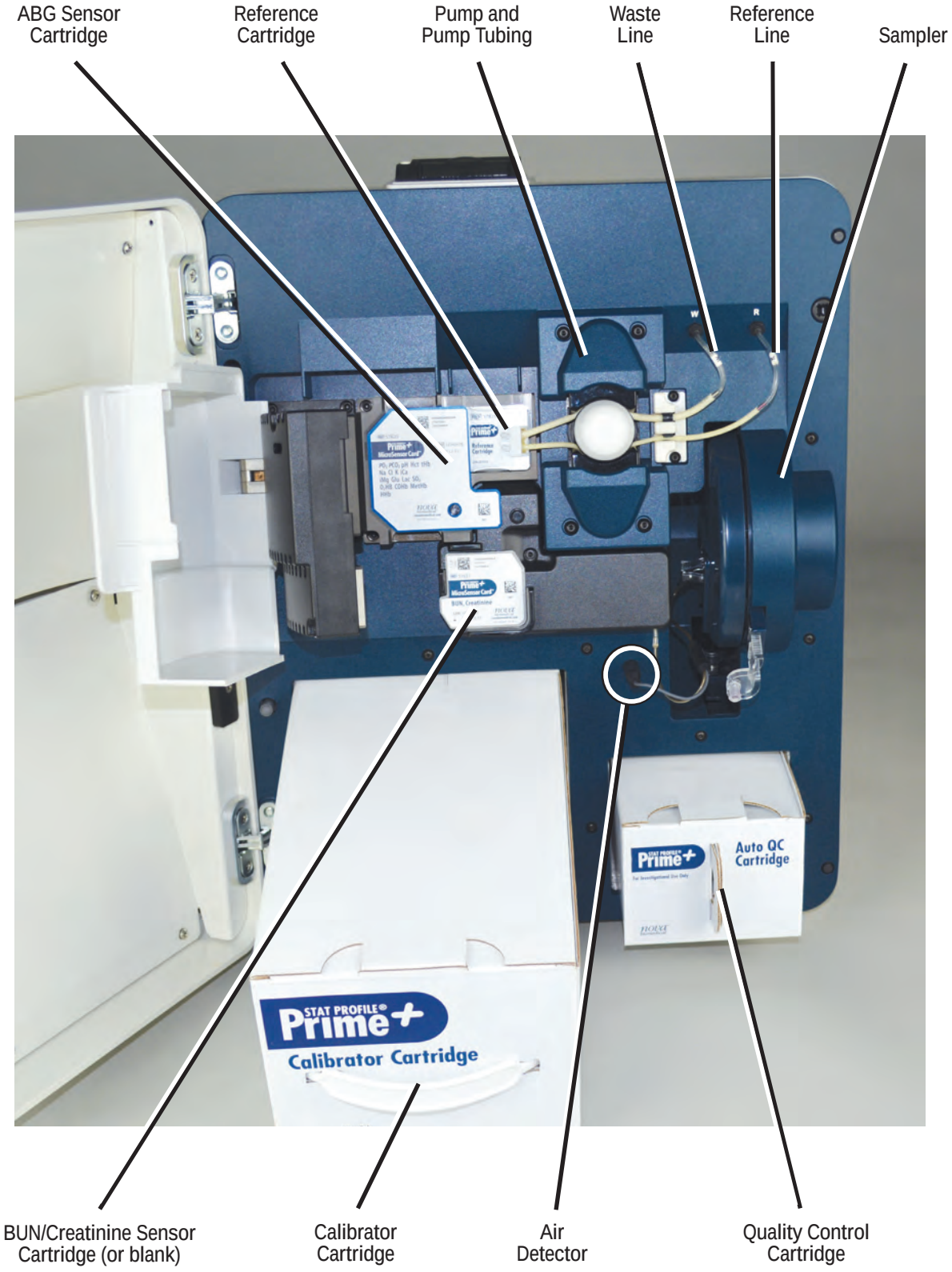

Figure 2.2 Prime Plus Analytical Compartment

2.1 Power-Up Procedure

A Power On Self Test (POST) runs automatically when you plug in the analyzer. Any errors encountered during the POST are displayed on the analyzer's screen.

After successfully completing the POST, the Home Screen status message displays Initializing. Initialization includes an internal diagnostic sequence that determines the remaining use life in the Sensor Cartridge, Reference Cartridge, BUN/Creatinine Sensor Cartridge, and the level of fluids in the Calibrator and QC Cartridges. The analyzer then runs a prime cycle and performs a CO-Ox Light Initialization sequence. Once complete, a System and Air Detector Calibration sequence is initiated.

2.2 The Home Screen

The Home Screen comprises a Header Bar, Selection Area, and Menu Bar (Figure 2.3).

2.2.1 Header Bar

The Header Bar (Figure 2.4) includes the following:

- Analyzer status: Status messages indicate the state of the analyzer (e.g., Ready or Busy) or actions required (e.g., Calibration Needed or Position Sample).
- Analyzer ID: An alpha-numeric identifier.
- Current date and time. A countdown clock displays during in-process operations.
- Login status and operator ID (analyzer can, however, run with no login required). Scan or enter the user ID via keyboard.

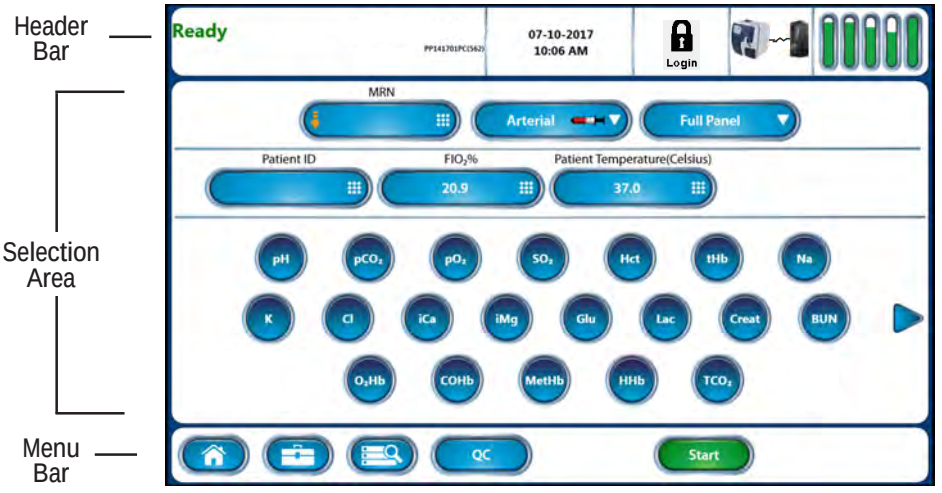

Figure 2.3 Home Screen Sections

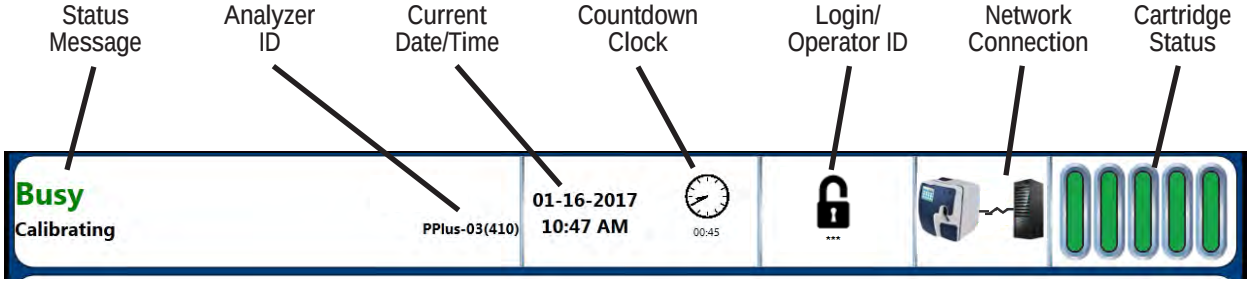

Figure 2.4 Header Bar Elements

- Network connection status.
- Cartridge status. The Prime Plus uses five consumables in the form of Sensor, Calibrator, and QC Cartridges. They are represented by five vertical green bars in the upper right corner:
  - Sensor Cartridge
  - Calibrator Cartridge
  - Auto QC Cartridge
  - BUN/Creatinine Sensor Card
  - Reference Cartridge

To see the status of any consumable, touch the cartridge status icon  .

2.2.2 Selection Area

Patient identifier and analyte details display in the Selection Area (Figure 2.5):

- Patient identifier
- Sample type selection
- Test panel selection
- Analyte status:
  - ***Blue*:** Analyte available and selected for analysis (press analyte icon to deselect).
  - ***Gray:*** Analyte available but unselected (press icon to select).
  - ***Orange:*** Analyte unavailable (press icon for details).
  - ***White*** Analyte unavailable (sensor failed under warranty).

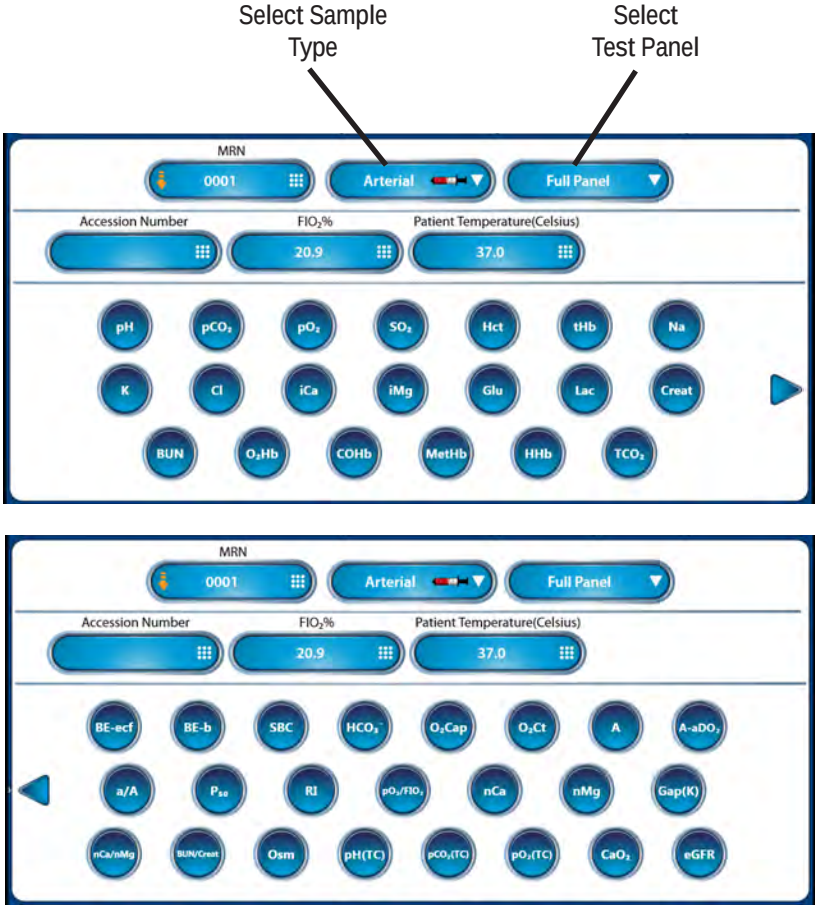

Figure 2.5 Selection Area Elements on Home Screen (top); Analytes continue on Screen 2 (bottom)

Press any button containing  to display a keyboard for data entry.

Press any button containing  to make a selection from a popup menu.

Press  and  to toggle between analyte screens.

2.2.2.1 Sensor Status Screen

Analytes displayed in **orange** are unavailable for analysis. Press an orange analyte to display the Sensor Status Screen. Sensor errors and QC Lockout conditions display. The following actions can be taken from the Sensor Status Screen:

- Touch Calibrate (Calibrate) to initiate a Calibration sequence. When the sequence is complete, the Home Screen displays.
- Touch QC (QC) to display the QC menu.
- Touch Fix to attempt to correct any indicated errors. The analyzer will first recalibrate and then rerun any level of internal QC that failed to recover within the expected ranges. If External QC is required, the analyzer will display the Analyze QC screen.
- Touch Home to return to the Home Screen.

2.2.3 Menu Bar

The Menu Bar (Figure 2.6) contains icons and buttons for navigation to, and initiation of, the following screens and functions:

- Home Screen
- System and Setup menus
- Stored patient test results
- QC functions

Buttons that appear on the right side of the Menu Bar (e.g., Start) allow you to initiate processes and analyses.

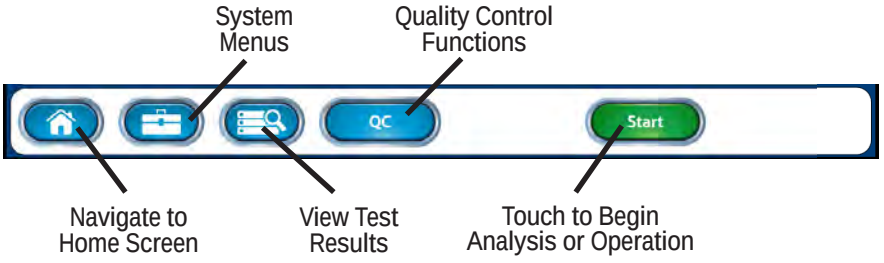

Figure 2.6 Menu Bar Elements

2.3 Login to Analyzer

NOTE: *The analyzer can be configured to require no login.*

1. From the Home Screen, press Login
2. If required, enter or scan your Operator ID.
3. Press Enter
4. If required, enter your Password.
5. Press Enter

2.4 Analyzer Calibration

The Prime Plus analyzer utilizes a replaceable internal Calibrator Cartridge to calibrate the Blood Gas, Electrolyte, Metabolite, and CO-Ox sensors contained in the analyzer. Calibrations are initiated by the analyzer automatically but can also be started manually, if necessary.

2.4.1 Automatic Calibrations

After startup, the analyzer performs a CO-Ox Light Initialization sequence and, once complete, initiates a System Calibration and an Air Detector Calibration sequence. The System Calibration performs a 2-point calibration of the Blood Gas, Electrolyte, and Metabolite sensors, and a 1-point optical calibration of the CO-Oximeter module. The Air Detector Calibration sequence calibrates the internal air detectors that position fluids in the analyzer correctly.

- 2-point calibrations are repeated every 2 hours to ensure the analyzer continues to perform optimally.
- A 1-point calibration is performed with every sample analysis.
- During the first System Calibration to occur after midnight each day, the analyzer also performs a CO-Ox Light Initialization sequence and an Air Detector Calibration.

2.4.2 Manual Calibrations

A System Calibration or Air Detector Calibration can be initiated manually, if needed. Manual calibrations may be necessary after certain maintenance functions or in response to unexpected error conditions.

Use the following button sequence to begin a manual System Calibration or a manual Air Detector calibration:

- From the Home screen, press the Calibrate button 

if it is displayed on the menu bar.
  - If 

is not displayed on the menu bar: From the Home screen, press the toolbox icon  and then press 

- From the Calibrate screen, choose either Calibrate System 

or Calibrate Air Detector 

3. Sample Analysis

When the analyzer is at **Ready** status (Figure 3.1), you can begin testing.

The analyzer measures samples from these containers:

- Syringes
- Capillary Tubes
- Blood Collection Tubes

Ampules are used for external Quality Control (QC) material. An internal Auto-QC Cartridge contains internal QC material.

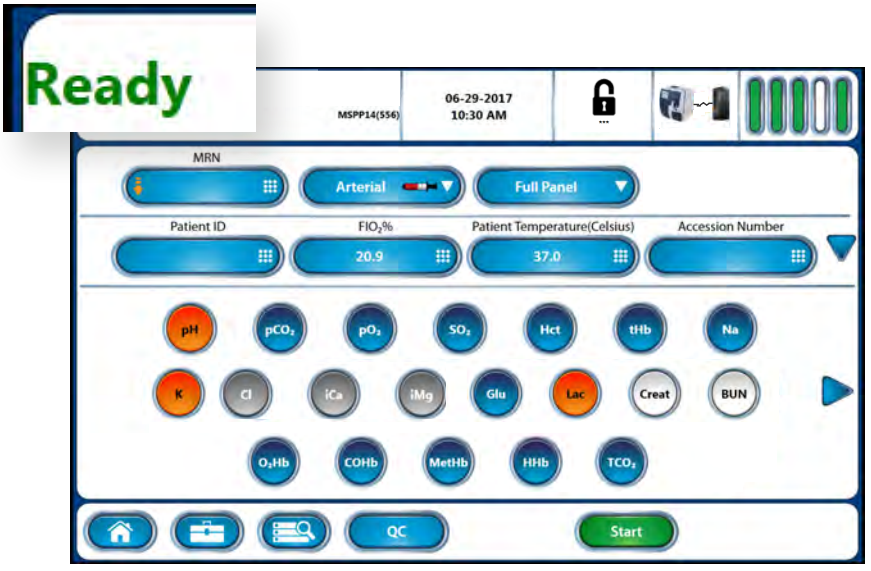

Figure 3.1 Ready Screen Showing Analytes and their Status

Analyte status indicators:

- **Orange:** Unavailable; corrective action required. Press analyte icon for additional information.
- **Blue:** Available; selected for testing.
- **Gray:** Available, but unselected; press the icon to select the analyte for testing.
- **White**: Unavailable; sensor failed and warranty credit was applied.

Before analyzing a patient or QC sample, confirm the following:

- Analyzer is at Ready status.
- Desired analytes display in **Blue**.

The analyzer can be configured such that specific information fields must be completed. Information is required when the word **Required** appears in the field.

In some configurations, the user may need to enter Required information before an analysis can be initiated—the analysis Start button is disabled until all Required fields are completed.

In other configurations, the user may initiate an analysis prior to entering all Required information. However, the Required information must be entered before the user is able to access test results. In this case, no test results can be viewed, printed, or transmitted until all Required fields are completed. If a sample analysis has been started but Required information is unavailable, press Cancel . No results will be displayed, printed, or transmitted.

WARNING: ***Do not perform glucose and lactate testing on patients taking the drug hydroxyurea. See Appendix A for additional interference information.***

3.1 Analyzing Whole-Blood Syringe Samples

1. Ensure that the analyzer is at Ready status.
2. Ensure desired analytes are **Blue.**
3. Enter all required information.
4. On the Home Screen, press the Sample Type button (see Figure 2.5).
5. Select the appropriate syringe type from the popup list (Figure 3.2).
6. On the Home Screen, press the Test Panel button (see Figure 2.5).
7. Select a Test Panel (Figure 3.3). from the popup list. Or select specific analytes to build a Custom Panel.
8. Prepare the sample for analysis.
9. Press Start 

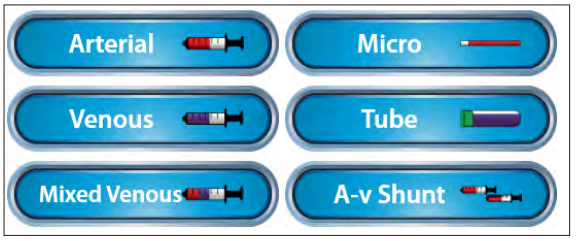

Figure 3.2 Sample Type Popup List

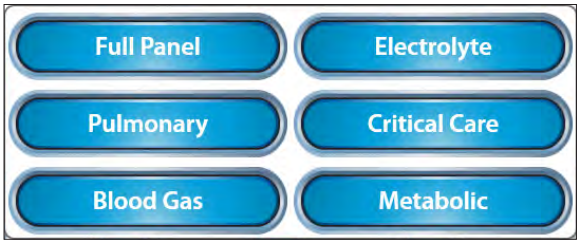

Figure 3.3 Test Panel Popup List

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

The sample probe extends. The analyzer displays Position Sample (Figure 3.4).

10. Insert the probe into the syringe (see Figure 3.6).
11. Press Aspirate 

The analyzer aspirates sample as necessary. Then, the probe retracts.

12. Remove the syringe.
13. Enter additional information as required or desired during analysis. Test results are not displayed until all required fields are completed.

Figure 3.4 Screen Prompt to Position Sample

Results of measured tests appear after analysis.

14. If displayed, press the right arrow ▶ to view calculated results.
15. Press Accept 

to accept and save the results
16. Press Print  to accept sample and print results.
17. Press Reject 

to reject the sample. Rejected samples are saved but cannot be printed or transmitted. Rejected samples appear in the sample list with an orange *X* over the container icon .

3.2 Using the Safety Sample Port

The Safety Sample Port (Figure 3.5) provides a means of attaching a syringe to the analyzer without manually positioning the sample probe in the syringe.

When under-filled syringes are in use, you can prevent the sample probe from bottoming out on the syringe plunger by using the Nova Syringe Clot Catcher in conjunction with the Safety Sample Port; use both to ensure correct sample positioning. When no clot catcher is used, fill the syringe with sufficient sample for the probe to travel approximately 1 inch (26 mm) into the syringe.

Figure 3.5
Safety Sample Port

Follow this procedure to analyze a sample from a syringe using the Safety Sample Port:

1. Ensure that the analyzer is at Ready status.
2. Ensure desired analytes are **Blue.**
3. Enter all required information.
4. Select the appropriate syringe Sample Type (see Figure 3.2).
5. Select a Test Panel (see Figure 3.3). Or select specific analytes to build a Custom Panel.
6. Prepare the sample for analysis.
7. Secure the syringe in the Safety Sample Port.
8. Press Start (Start)

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

The probe extends through the Safety Sample Port and into the syringe.

9. When the probe is in position, Press Aspirate (Aspirate)

The analyzer aspirates sample as necessary. Then, the sample probe retracts.

10. Remove the syringe from the Safety Sample Port.
11. Enter additional information as required or desired while the analysis runs. Test results are not displayed until all required fields are completed

Figure 3.6
Syringe in Safety Sample Port

Results of measured tests appear when analysis is complete.

12. If displayed, press the right arrow ▶ to view calculated results.
13. Press Accept (Accept) to accept and save the results.
14. Press Print (🖶) to accept the sample and print the results.
15. Press Reject (Reject) to reject the sample. Rejected samples are saved but cannot be printed or transmitted. Rejected samples appear in the sample list with an orange *X* over the container icon

3.3 Analyzing Whole Blood in a Blood Collection Tube

To analyze a Blood Collection Tube sample:

1. Ensure that the analyzer is at Ready status.
2. Ensure desired analytes are **Blue.**
3. Enter all required information.
4. On the Home Screen, press the Sample Type button (see Figure 2.5).
5. Select Tube 

6. On the Home Screen, press the Test Panel button (see Figure 2.5).
7. Select a Test Panel (see Figure 3.3) from the popup list. Or select specific analytes to build a Custom Panel.
8. Press 

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

The sample probe extends; the analyzer displays Position Sample.

9. Prepare the sample for analysis.
10. When prompted, position the Sample Probe in the Blood Collection Tube (Figure 3.7).
11. Press Aspirate 

The analyzer aspirates sample as necessary. Then, the sample probe retracts.

12. Remove the tube.
13. Enter additional information as required or desired during analysis. Test results are not displayed until all required fields are completed

Results of measured tests appear when analysis is complete.

Figure 3.7 Blood Collection Tube Sample over Probe

14. If displayed, press the right arrow  to view calculated results.
15. Press Accept 

to accept and save the results.
16. Press Print  to accept the sample and print the results.
17. Press Reject 

to reject the sample. Rejected samples are saved but cannot be printed or transmitted. Rejected samples appear in the sample list with an orange ***X*** over the container icon 

3.4 Analyzing Whole Blood in a Capillary Tube

To analyze a capillary whole blood specimen, collect a minimum of 90 µL of capillary whole blood in a lithium or balanced heparin capillary tube, ensuring sufficient volume in the tube and that there is no visible air in the blood specimen. Discard the tube and repeat sample collection if the blood specimen contains visible air.

To analyze a Capillary Tube sample:

1. Ensure that the analyzer is at Ready status.
2. Ensure desired analytes are **Blue**.
3. Enter all Required information.
4. On the Home Screen, press the Sample Type button (see Figure 2.5).
5. Select the Micro 

button.
6. Press the Start button.

NOTE: *When a Micro mode (Capillary) analysis runs, only pO_2, pCO_2, pH, Hct, Na, K, Cl, iCa, iMg, Glu, and Lac will be reported.*

WARNING: ***When the Micro Capillary is in the Capillary Adapter, do not open or close the analyzer door.***

The Adapter is rotated to the front of the Sampler. The analyzer displays Position Sample.

7. Prepare the sample for analysis.
8. Secure the Micro Capillary in the Capillary Adapter (Figure 3.8).
9. Press Aspirate.

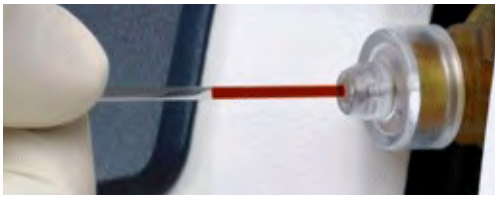

Figure 3.8
Micro Capillary in Capillary Adapter

The analyzer aspirates sample as necessary.

10. Remove the sample when prompted.
11. Press Enter 

The Adapter is returned to its position inside the Sampler.

12. If desired, press  to cancel the analysis.
13. Enter additional information as required or desired. Test results are not displayed until all required fields are completed
14. Press 

Results of measured tests appear when analysis is complete.

15. If displayed, press the right arrow  to view calculated results.
16. Press Accept to accept and save the results.
17. Press Print  to accept the sample and print the results.
18. Press Reject to reject the sample. Rejected samples are saved but cannot be printed or transmitted. Rejected samples appear in the sample list with an orange *X* over the container icon: 

3.5 The Sample Results Display

Results appear on the Sample Results screen (Figure 3.9). The test name, sample result, and unit of measure are displayed.

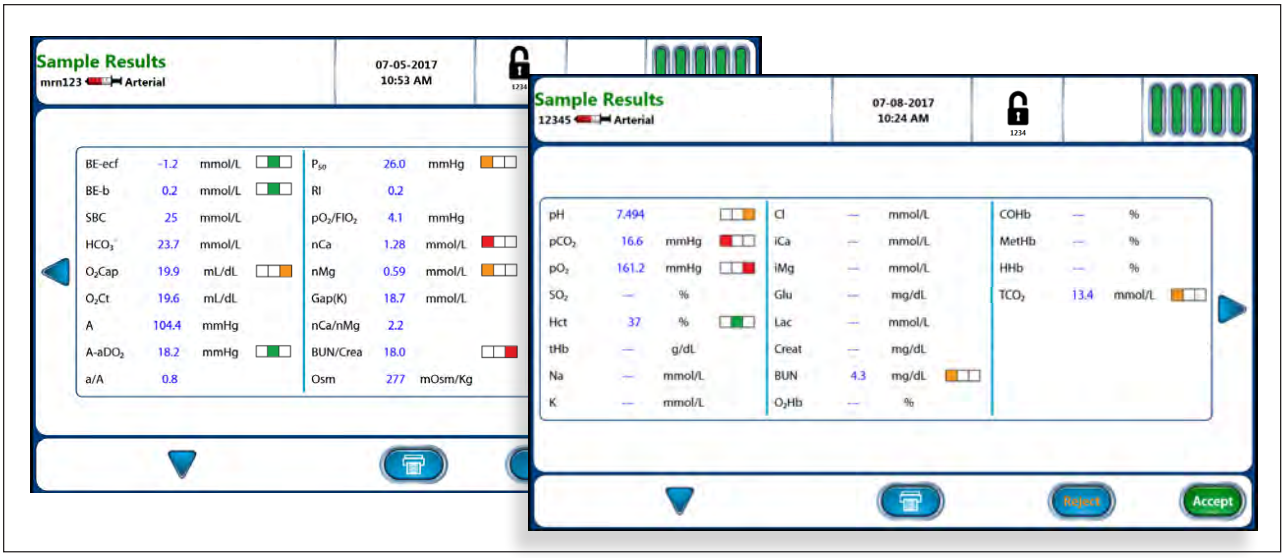

Figure 3.9 Sample Results for Calculated Analytes (left) and Measured Analytes (right) (U.S. Units of Measure Shown)

- Press the right arrowhead ▶ to display the calculated Sample Results screen.
- Press the left arrowhead ◀ to display the measured Sample Results screen.
- Use the down arrowhead ▼ to display the Sample Information screen (Figure 3.10). Fields displayed in blue may be edited; fields that are grayed out are locked and cannot be changed.
- Use the up arrowhead ▲ to return to the Sample Results screen.
- Press the Accept button Accept on the Sample Results screen to accept and save the results.
- Press Print to accept the sample and print the results.

Press Reject Reject to reject the sample. Rejected samples are saved but cannot be printed or transmitted. Rejected samples appear in the sample list with an orange *X* over the container icon  .

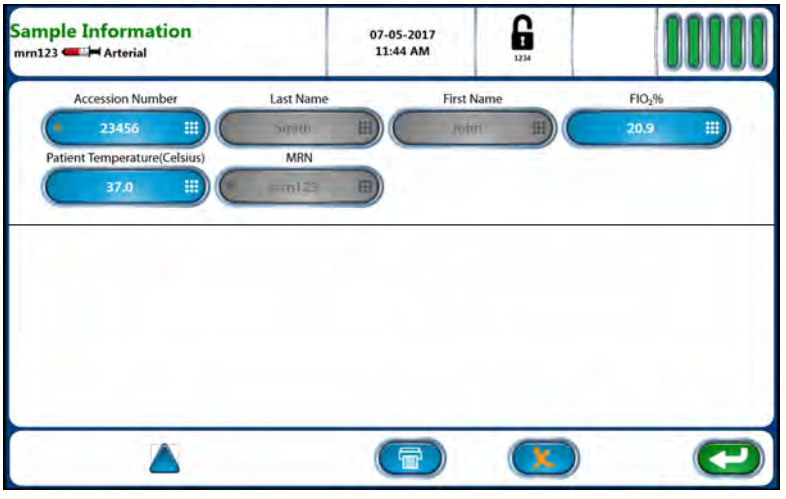

Figure 3.10 Sample Information Screen

The analyzer can be configured to display a 3-segment bar (Table 3.1) that indicates how a test result compares generally to ranges previously entered by the user.* A color in the left, middle, or right segment of the bar indicates at a glance whether a test result is below, within, or above range, respectively:

- **Red**: Results are outside of user-entered *Alert Range* limits.
- **Orange:** Results outside user *Reference Range* limits.
- **Green:** Results within user *Reference Range*.

Table 3.1 Test Result Bars

Lower Than Low Alert:	
Low Normal to Low Alert:	
Normal:	
High Normal to High Alert:	
Higher Than High Alert:	

Sample results displayed as **– –** are outside the analytical measurement range.

3.5.1 Sample Results Printout

The Sample Results printout contains a customizable header followed by the measured or calculated test results. Each test result contains the test name, the result value, and the unit of measure.

Some event codes prevent a test result from being printed. In such cases, the event code is printed in place of the test result. Results printed as – – are outside of the analytical measurement range.

3.5.1.1 Flags

A result flag consisting of one or more up (↑) or down (↓) arrows may also appear on the printout. Up arrows print when a test result value exceeds the upper end of a user-entered range (Reference, Alert, or Reportable range*). Down arrows print when a test result is less than the lower limit of an entered range (Table 3.2).

Table 3.2 Sample Results Printout Flags

↑	Measured value > High end of *Reference* Range
↑↑	Measured value > High end of *Alert* Range
↑↑↑	Measured value > High end of *Reportable* Range
↓	Measured value < Low end of *Reference* Range
↓↓	Measured value < Low end of *Alert* Range
↓↓↓	Measured value < Low end of *Reportable* Range

3.6 Analyzing QC and Proficiency Samples

3.6.1 Analyzing Auto Cartridge QC Samples Manually

1. Ensure the analyzer is at Ready status.
2. From the Home screen, press the QC button 

3. Select Analyze QC 

4. Press Select QC Level.
5. From the popup list, select the Internal (Auto QC) level to be analyzed.
6. Enter a QC comment, if desired.
7. Press Start 

Test results appear when the analysis is complete.

8. Press Accept 

to accept and save results and return to the Analyze QC screen.
9. Press Print  to accept and print the QC results.
10. Press Reject 

to reject the results and return to the Analyze QC screen. Rejected QC samples are deleted.

3.6.2 Analyzing External QC Samples

1. Ensure the analyzer is at Ready status.
2. From the Home screen, press the QC button 

.
3. Press Analyze QC 

.
4. Press Select QC Level.
5. From the popup list, select the External QC Level to be analyzed.
6. If applicable, select the lot number of the External QC Level.
7. Enter a QC comment, if desired.
8. Press Start 

.
9. Wait for the Sample Probe to fully extend.
10. Prepare the External QC sample for analysis.
11. Position ampule over the probe (Figure 3.11).
12. Press Aspirate 

. The analyzer aspirates the External QC sample.
13. When the Sample Probe retracts, remove the ampule.

Results appear when the analysis is complete.

14. Press Accept 

to accept and save the QC results, and return to the Analyze QC screen.
15. Press Print  to accept the sample and print the results.
16. Press Reject 

to reject the sample and return to the Analyze QC screen.

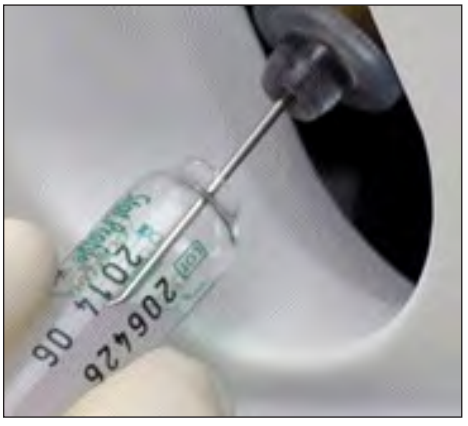

Figure 3.11
QC Ampule Positioned over Probe

3.6.3 Analyzing Proficiency Samples

NOTE: *Analyzing a specimen as a Proficiency sample reports test results with all user-defined Slope and Intercept (offsets) adjustments removed from the reported results to be consistent with recommendations from Proficiency Test providers.*

1. Ensure the analyzer is at Ready status.
2. From the Home screen, press QC
3. Press Analyze Proficiency
4. Press the Panel button.
5. Select a test panel from the popup list.
6. If desired, press the Identifier button and enter a sample identifier
7. If desired, press the Comment button and enter a sample comment
8. Press Start
9. Wait for the Sample Probe to fully extend.
10. Position the Proficiency sample over the probe.
11. Press Aspirate

The analyzer aspirates the sample. If desired, press Cancel to cancel the Proficiency analysis.

12. When the Sample Probe retracts, remove the sample.

Proficiency results display (Figure 3.12).

13. Press Accept Accept to accept and save the displayed Sample Results and Sample Information, and return to the Analyze QC screen.
14. Press Print to accept the sample and print the results.
15. Press Reject Reject to reject the sample and return to the Analyze QC screen.

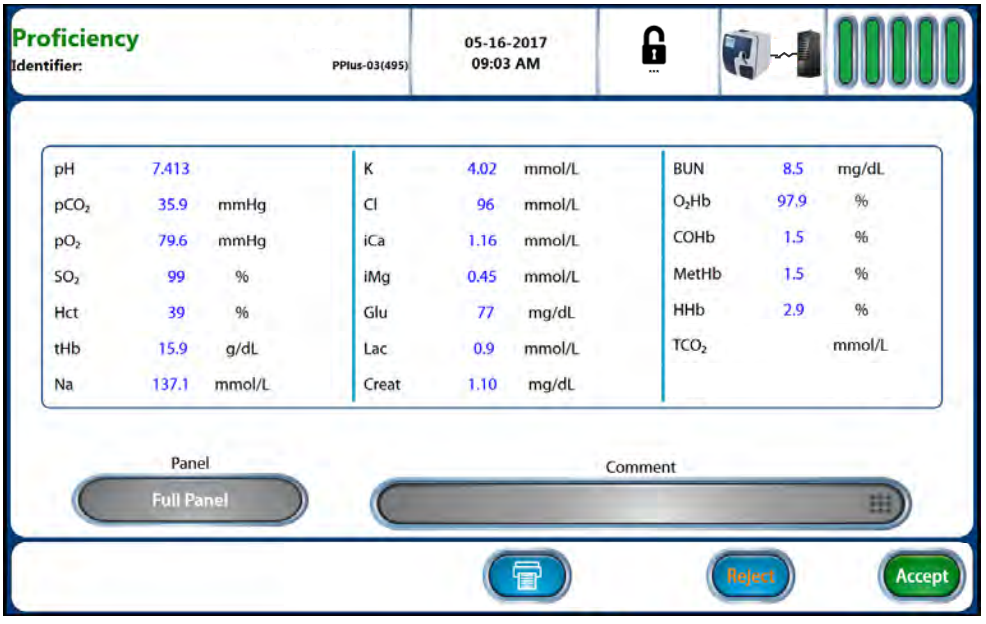

Figure 3.12 Proficiency Analysis Results
(U.S. Units of Measure Shown)

4. Patient and QC Data Review

Patient and QC Data are stored on the analyzer for review at any time. This section describes how to find and display the data.

4.1 Recalling Patient Results

From the Home Screen, press the Sample Results button to access the Results screen, which displays a list of the current day's tests (if any).

Tests are displayed in descending order, with the most recent at the top of the list (Figure 4.1). If the list contains more than one page of tests, a scroll bar is used to navigate the list of tests.

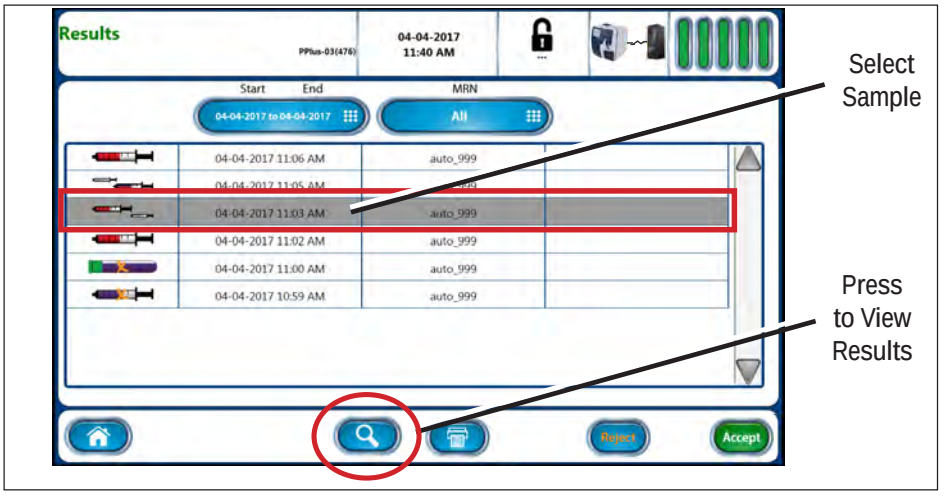

Figure 4.1 Results Screen

- To display results for a specific timeframe, press the Start/End button on the Results screen. Then press the Select button Select... Choose the desired timeframe (Figure 4.2). Press Enter
- To display results for a custom timeframe, press the Start/End button. Then scroll the Start and End date selectors (Figure 4.3) to the desired start and end dates. Press Enter.
- If known, a sample identifier (i.e., MRN, Patient ID, or Accession Number) can be entered to help quickly find a result. From the Home Screen, select the corresponding identifier button and enter the information. Only samples containing the entered identifier are displayed.

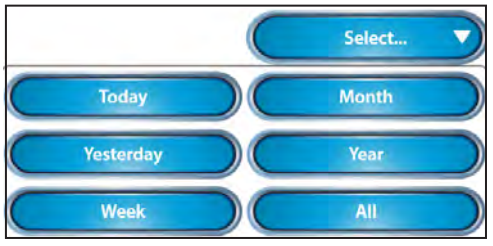

Figure 4.2 Specific Timeframe Selections

Figure 4.3 Custom Timeframe Selectors

4.1.1 Viewing Sample Results

1. From the Results screen, select the sample to be viewed (see Figure 4.1).
2. Press View

The Sample Results screen displays. Measured results appear on the first screen that displays (Figure 4.4, left); press the right arrow (if available) to view calculated results (Figure 4.4, right).

Information about a sample is displayed by pressing the page down button

Sample information may be reprinted and retransmitted by pressing Print or Transmit

Press Back to go back to the previous screen. Press Home to go to the Home screen.

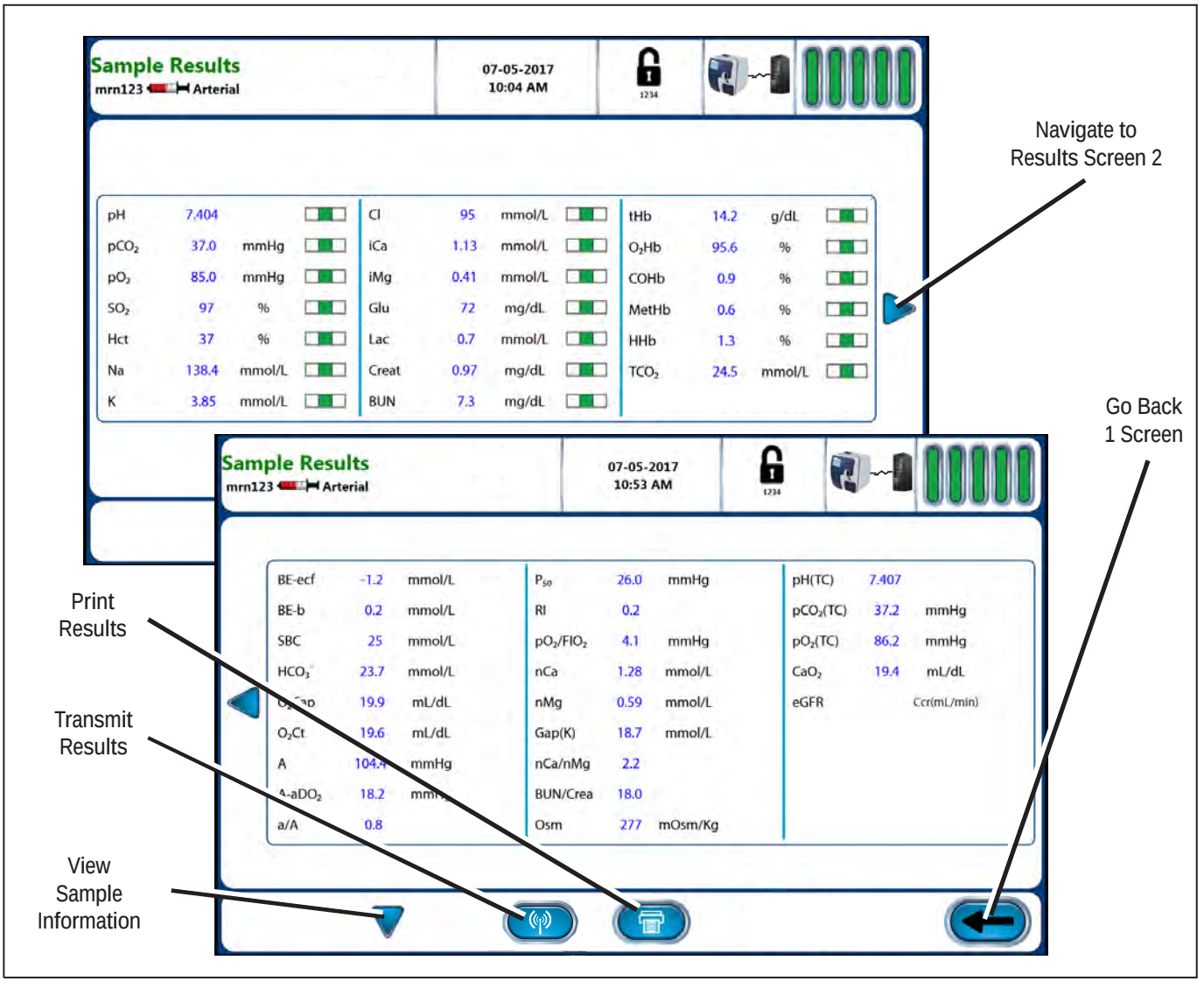

Figure 4.4 Sample Results Screens: Measured Results (top) and Calculated Results (bottom). (U.S. Units of Measure Shown)

4.2 Recalling QC Results

Existing QC results may be recalled for review from the QC menu.

1. From the Home screen press the QC button 

2. Press the View QC Data button 

The View QC data screen displays the current day's QC results. Results are presented in descending order, with the most recent at the top of the list. If the list contains more than one page of results, a scroll bar is used to navigate the list of results.

To display QC results from a specific timeframe:

1. From the View QC Data screen, select the Start/End button.
2. Press the Select button 

3. Choose the desired timeframe from the popup list (see Figure 4.2)
4. Press Enter 

To display QC results for a custom timeframe:

1. From the View QC Data screen, select the Start/End button.
2. Scroll the Start and End date selectors to the desired start and end dates.
3. Press Enter 

To limit the number of results displayed, select one or both of the following options:

1. Press the QC Level button. Then select the desired QC level from the popup list.
2. Press the Lot Number button. Then enter the lot number of the QC level to be displayed.

4.2.1 Viewing QC Results

1. From the View QC Data screen, select the sample to be viewed.
2. Press View  to display the QC results.

Results may be reprinted and retransmitted by pressing Print  or Transmit 

Press Back  to go back to the previous screen. Press Home  to go to the Home screen.

4.3 Recalling Proficiency Sample Results

Existing Proficiency sample results may be recalled from the QC menu.

1. From the Home screen, press QC 

2. Press the View Proficiency Data button 

The current day's Proficiency results display. Results are displayed in descending order, with the most recent sample at the top of the list. If the list contains more than one page of results, a scroll bar is used to navigate the list of results.

To display Proficiency results from a specific timeframe:

1. From the View Proficiency Data screen, select the Start/End date button.
2. Press the Select button 

3. Choose the desired timeframe from the popup list (see Figure 4.2).
4. Press Enter 

To display Proficiency results for a custom timeframe:

1. From the View Proficiency Data screen, select the Start/End date button.
2. Scroll the Start and End date selectors to the desired start and end dates.
3. Press Enter 

To limit the number of results displayed, select one or both of the following options:

1. Press the Panel button. Then select the desired panel from the popup list.
2. Press the Identifier button. Then enter an identifier to be displayed.

4.3.1 Viewing Proficiency Results

1. From the View Proficiency Data screen, select the sample to be viewed.
2. Press View  to display the results.

Results may be reprinted and retransmitted by pressing Print  or Transmit 

Press Back  to go back to the previous screen. Press Home  to go to the Home screen.

4.4 Reviewing QC Statistics

Statistics are kept for each level of QC material configured for use by the analyzer.

To view QC statistics:

1. From the Home screen, press QC 

2. Select QC Statistics 

The QC Statistics screen displays. The analyzer displays statistics for all available tests for the first level of configured QC material. A scroll bar is active to navigate the list of tests, if necessary.

To view statistics for a different level of QC:

1. Press the QC Level button (Figure 4.5).
2. Select desired level from the popup list.

When multiple lot numbers of a control level are available, press the Lot Number button and select the desired lot.

The test name, unit of measure, Mean, SD, CV%, N, and QC Range are displayed for the current day's results.

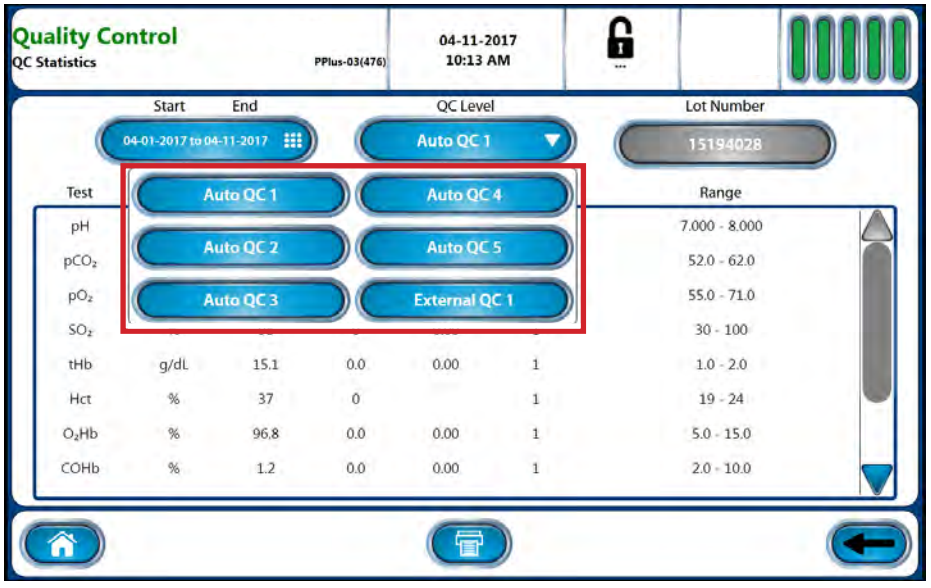

Figure 4.5 QC Level Selections on QC Statistics Screen (U.S. Units of Measure Shown)

Statistics are recalculated whenever the selected timeframe is changed.

To display QC statistics from a specific timeframe:

1. From the QC Statistics screen, select the Start/End date button.
2. Press the Select button 

3. Choose the desired timeframe from the popup list.
4. Press Enter 

To display QC statistics for a custom timeframe:

1. From the QC Statistics screen, scroll the Start and End date selectors to the desired start and end dates.
2. Press Enter 

Press Print  to print the displayed statistics. Press Back  to go back to the previous screen. Press Home  to go to the Home screen.

4.5 Levey Jennings Charts

Levey Jennings charts for each test can be viewed from the QC Menu:

1. From the Home screen, press QC 

2. Select the Levey Jennings button 

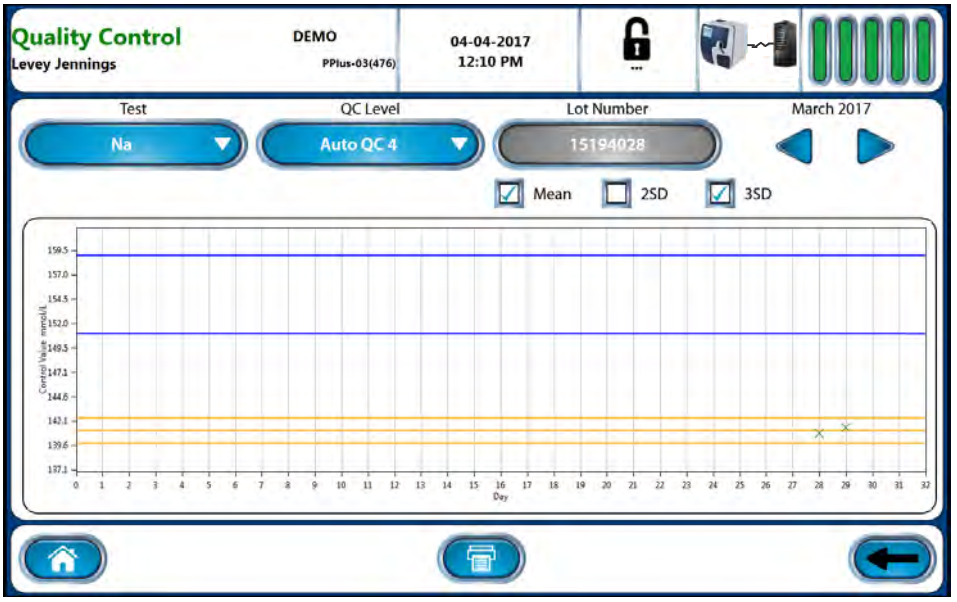

Figure 4.6 Levey Jennings Chart (U.S. Units of Measure Shown)

The analyzer displays a Levey Jennings chart (Figure 4.6) for the first test on the first QC level for the current calendar month.

To select a Levey Jennings chart by test:

1. From the Levey Jennings screen, press the Test button.
2. Select the desired test from the popup list (Figure 4.7).
3. Press the QC Level button.
4. Select the desired QC level from the popup list.

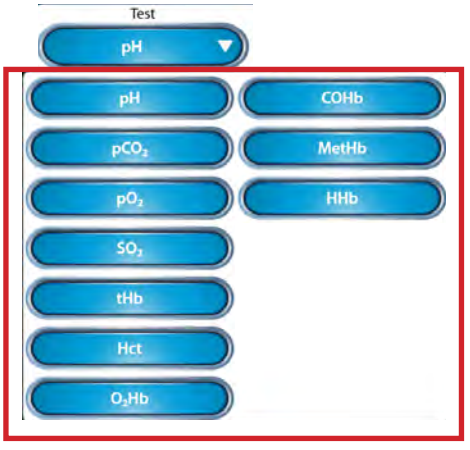

Figure 4.7 Levey Jennings Test Selections

To select a Levey Jennings chart from a previous month:

1. Press the left and right arrow buttons to select charts from a particular month.
2. Press the Test button.
3. Select the desired test from the popup list.
4. Press the QC Level button.
5. Select the desired QC level from the popup list.

When multiple lot numbers of a control level are available, press the Lot Number button and select the desired lot from the popup list. A gray Lot Number button indicates there is no other lot number to select.

Check and uncheck the Mean, 2SD, and 3SD boxes (Mean 2SD 3SD) to include Mean, 2SD, and 3SD data on the displayed chart.

5. Consumables Replacement

The following sections provide information for maintaining the Prime Plus Analyzer.

WARNING: ***Blood samples and blood products are potential sources of infectious agents. Handle all blood products and Flow Path components (waste-line, probe, sensor cartridges, etc.) with care. Gloves and protective clothing are recommended. When performing replacement and troubleshooting procedures, also use protective eye wear.***

Status information about consumables can be viewed at any time by pressing the Cartridge Status icon on the Home Screen, or on any screen where the icon appears. The Cartridge Status popup screen (Figure 5.1) appears and displays date of installation, lot number and expiration date, use life expiration date and time, samples remaining, and percentage use life remaining.

Consumables cartridges are arranged as status bars as shown in Figure 5.2.The status bars use color to display their states (Figure 5.3).

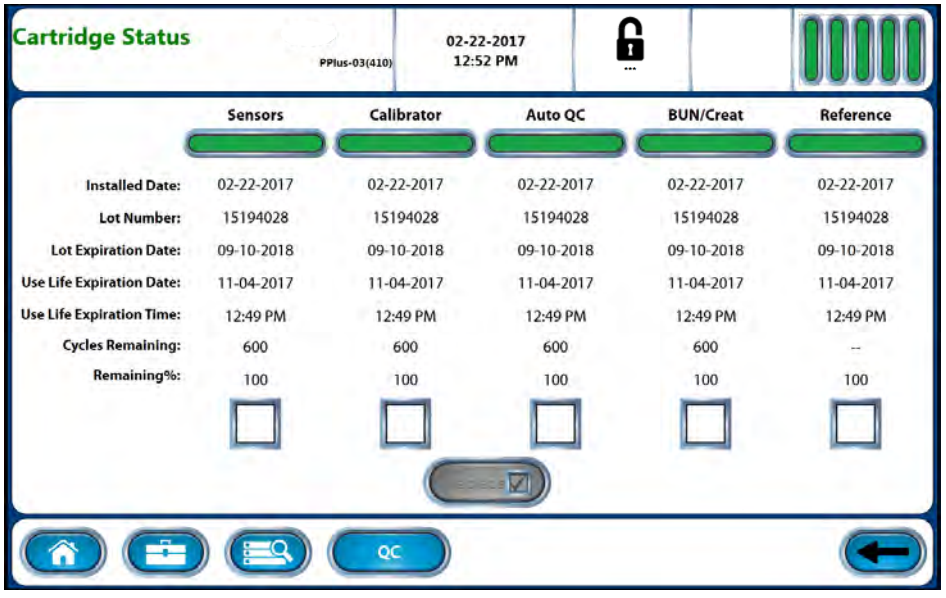

Figure 5.1 Cartridge Status Screen

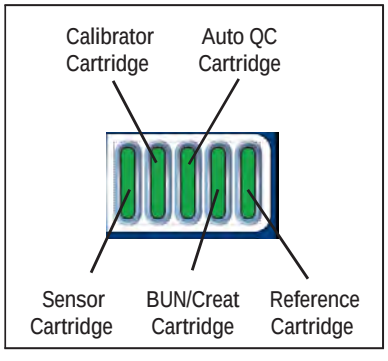

Figure 5.2 Cartridge Representation

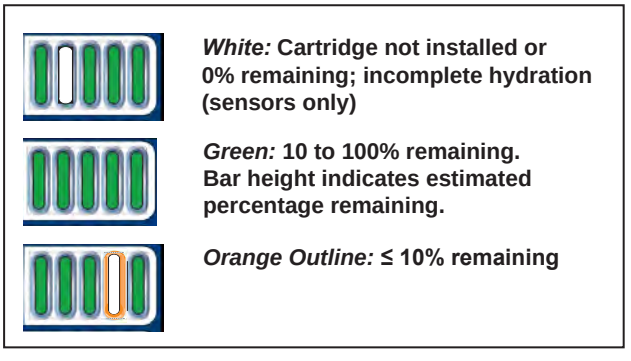

Figure 5.3 Consumables Cartridge Status

5.1 Replacing Cartridges

To replace any cartridge:

1. From any screen, press the Cartridge Status icon
2. Touch the checkbox ☐ at the bottom of the column or columns representing the cartridge or cartridges to be replaced (Figure 5.4). Selected cartridges will display a checkmark in the selection box.

The Replace button activates.

3. Press Replace

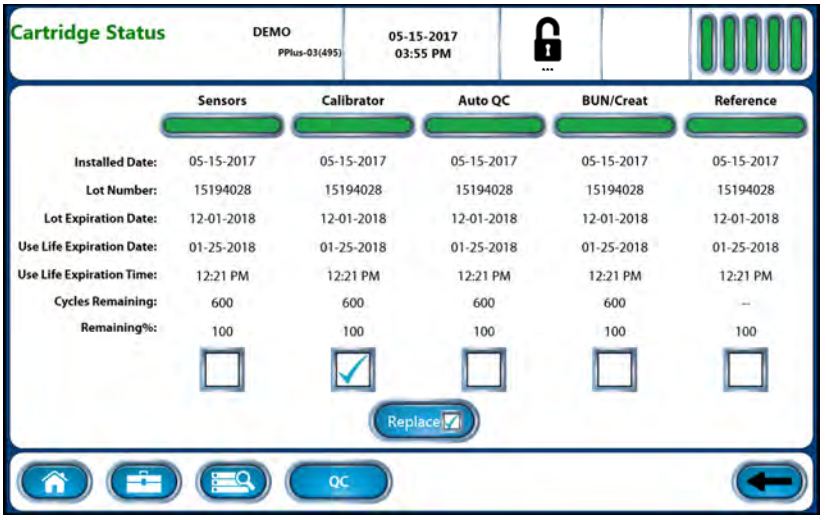

Figure 5.4 Cartridge Status Screen

NOTE: *When multiple cartridges are being replaced, the analyzer determines the order in which they should be replaced.*

4. Use the on-screen instructions and the steps provided in the following sections to replace a cartridge.
5. Use the on-screen video if unfamiliar with the replacement procedure. The Start and Stop buttons permit playing and pausing the video.

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

5.1.1 Replacing the Calibrator Cartridge

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

1. Press the Cartridge Status
2. In the Calibrator column of the Cartridge Status screen, select checkbox ☐
3. Press Replace
4. Open the analyzer door.
5. Remove Calibrator Cartridge (Figure 5.5).
6. If needed, charge the new cartridge using the Creatinine Charging Kit (included with the Calibrator Cartridge).
7. Mix the new Calibrator Cartridge thoroughly by gentle inversions.
8. Insert the new Calibrator Cartridge.
9. Remove the Capillary Adapter (Figure 5.6) by sliding it off the probe.

10. Install the new Capillary Adapter (included with the Calibrator Cartridge).

CAUTION: ***The probe moves when you press*** Continue.

11. Press Continue.
12. When the probe stops moving, close the door.

5.1.2 Replacing the Auto QC Cartridge

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

1. From any screen, press the Cartridge Status icon
2. In the Auto QC column, press the checkbox ☐
3. Press Replace
4. Open the analyzer door.
5. Remove the Auto QC Cartridge (Figure 5.7).
6. If needed, charge the cartridge using the Creatinine Charging Kit (included with the Calibrator Cartridge).
7. Insert the new Auto QC cartridge.
8. Press Continue

5.1.3 Replacing the ABG Sensor Cartridge

1. From any screen, press the Cartridge Status icon
2. In the Sensors column of the Cartridge Status screen, press the checkbox ☐
3. Press Replace
4. Open the analyzer door.
5. Open the Sensor Cartridge door to access the sensor cartridges.

NOTE: *Hold sensor cartridges by the edges.*

6. Remove the old ABG Sensor Cartridge.
7. Insert a new cartridge (Figure 5.8).
8. Close the Sensor Cartridge door.
9. Close the analyzer door.
10. Press Continue

Figure 5.5 Remove Calibrator Cartridge

Figure 5.6 Capillary Adapter

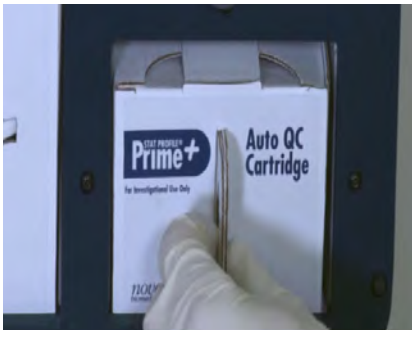

Figure 5.7 Remove Auto QC Cartridge

Figure 5.8 Replace ABG Sensor

5.1.4 Replacing the BUN/Creatinine Sensor Cartridge

WARNING: ***Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP).***

1. From any screen, press the Cartridge Status icon
2. In the BUN/Creat column, press the checkbox ☐
3. Press Replace
4. Open the analyzer door.
5. Open the Sensor Cartridge door.

NOTE: *Hold sensor cartridges by the edges.*

6. Remove the old BUN/Creat Sensor Cartridge (Figure 5.9).
7. Insert a new BUN/Creat Sensor Cartridge.
8. Close the Sensor Cartridge door.
9. Close the analyzer door.
10. Press Continue

Figure 5.9
Replace BUN/Creatinine Sensor Cartridge

5.1.5 Replacing the Reference Cartridge

WARNING: ***Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP).***

1. From any screen, press the Cartridge Status icon
2. In the Reference column, press the checkbox ☐
3. Press Replace
4. Follow the on-screen instructions.
5. Wait for the pump to stop.
6. Open the analyzer door.
7. Open the Sensor Cartridge door.

NOTE: *Hold sensor cartridges by the edges.*

8. Remove the ABG Sensor Cartridge (Figure 5.10).
9. Disconnect the Waste (W) and Reference (R) tubes (Figure 5.11).
10. Remove each tube from its collar and pump roller (Figure 5.12).

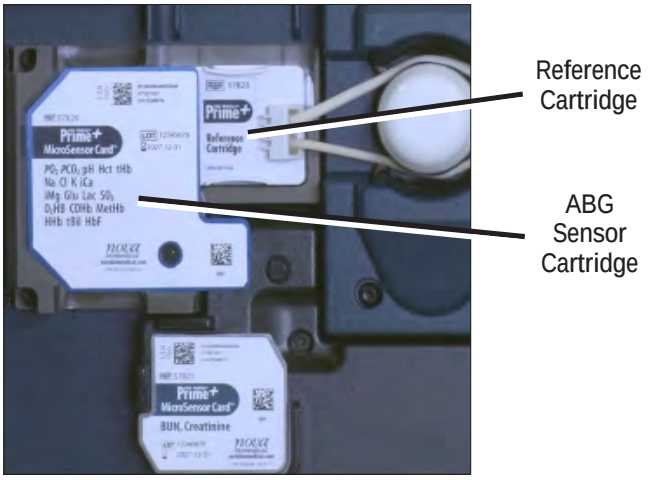

Figure 5.10 Reference Cartridge Positioned Behind ABG Sensor Cartridge

11. Remove the Reference Cartridge with attached tubing by sliding the cartridge up and taking it out (Figure 5.13).
12. Insert the new Reference Cartridge with tubing by positioning the cartridge above its cutout and sliding it down into place.
13. Feed the tubing through the pump rollers.
14. Feed the tubing through the tube collars.
15. Connect the W and R tubes to their respective ports on the chassis.
16. If you are also replacing the Sensor Cartridge and BUN/Creat Sensor Cartridge at this time, remove the used sensor cartridges and insert the new cartridges.
17. Close the Sensor Cartridge door.
18. Close the analyzer door.
19. Press Continue 

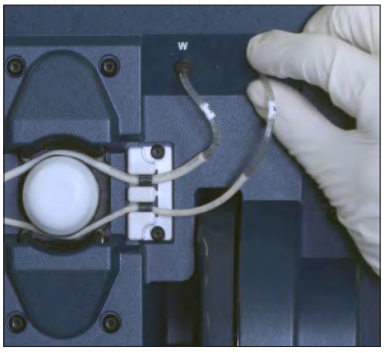

Figure 5.11 Remove W and R Tubes

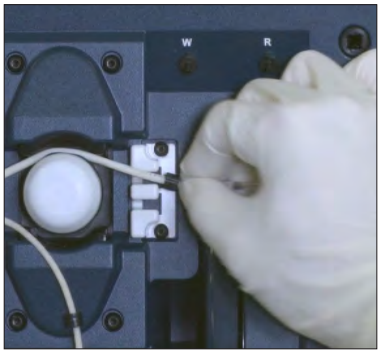

Figure 5.12 Remove Tubing from Pump Roller

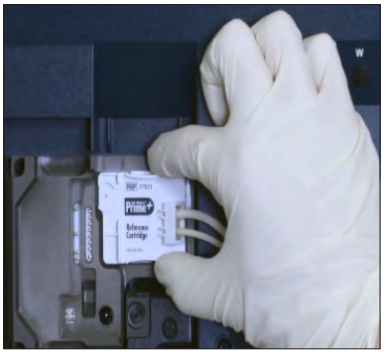

Figure 5.13 Remove Reference Cartridge

5.2 Sensor Warranty Claims

The micro-sensor cards used in the analyzer are covered by a prorated manufacturer warranty throughout the sensor card expected use life.

If one or more sensors fails to meet its minimum performance specifications, it is automatically disabled by the analyzer. The failed sensor's test button, and those of any dependent tests, appear on the analyzer Home screen with an orange background to indicate the sensor is currently disabled (Figure 5.14).

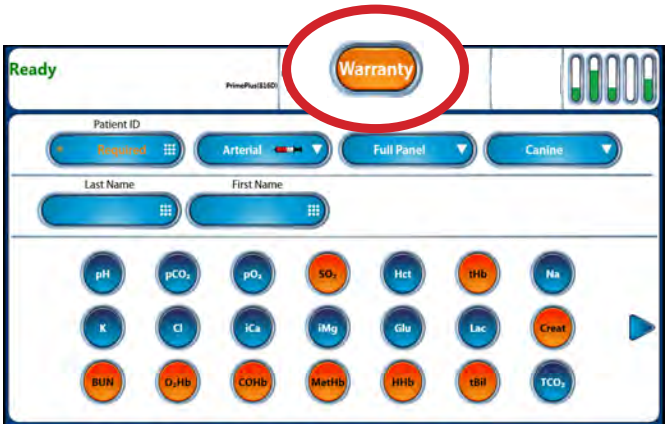

Figure 5.14 Home Screen Showing Warranty Claim Button; Affected Analytes Appear in Orange

NOTE: *An analyte button that has an orange background indicates that a sensor is disabled and cannot report test results. User intervention (e.g., recalibration, or a QC analysis that yields a passing result) may correct the problem without the need to replace the sensor card. If corrective action does not resolve the problem, you then must decide whether to continue testing using the sensor card with one or more sensors disabled, or to replace the sensor card, re-enabling the unavailable sensors.*

If a sensor fails to meet its expected use life, the orange Warranty button 

appears near the top of the Home Screen.

Press the button to display the sensor card screen, from which you can choose to claim credit for the individual sensor(s) or for the entire sensor card. The amount of the credit is based on several factors:

- The number of sensors that failed.
- The number of samples analyzed using that sensor card.
- The length of time the sensor card has been installed on the analyzer.

The test button for any sensor that has been claimed for warranty credit displays on the Home screen with a white background (Figure 5.15). The white background indicates the sensor has been permanently disabled on the current sensor card. Any dependent tests display with an orange background, indicating they also have been disabled.

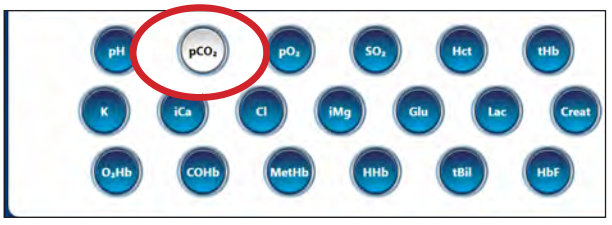

Figure 5.15
A White Button Indicates a Disabled Sensor

To resume reporting test results for these sensors, a new sensor card must be installed. Results for all remaining sensors continue to be available.

5.2.1 Claiming Warranty Credit for a Sensor or Sensor Card

To claim a warranty credit for one or more sensors, press the orange Warranty button at the top of the screen. The Warranty claim screen displays.

The name of any sensor that fails within the warranty period appears centered on the claim screen in orange text, above the claim option checkboxes (Figures 5.16 and 5.17).

To claim warranty credit, choose one of the following options:

- Claim credit for the indicated sensor(s) and continue to use the sensor card to report results from all remaining sensors (“Claim Sensor” in Figure 5.16, bottom).
- Claim credit for the entire sensor card and replace the card (“Claim Sensor Card” in Figure 5.16, top).

When you have made your choice, press Enter  to continue. Or press Cancel  to decide later.

Press Enter again to confirm your choice. Or press Cancel to exit without saving.

Sensors claimed under warranty display on the Home screen with a white background, indicating they are permanently disabled. The analyzer generates and prints a 16-digit warranty code for each sensor claimed.

Contact Nova Biomedical or your local Nova distributor to request credit for the claimed sensor(s) or sensor card.

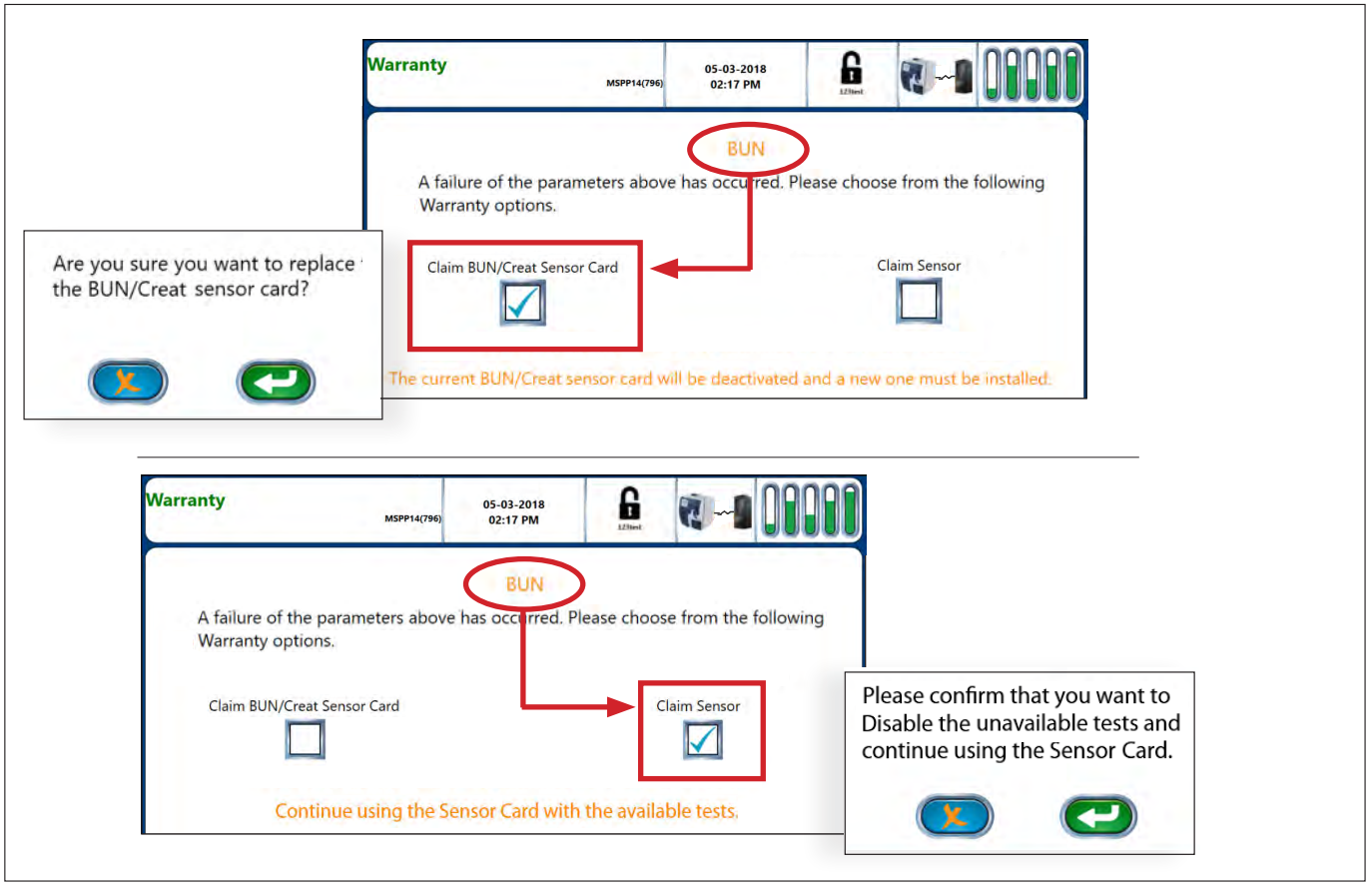

Figure 5.16 Warranty Failure Screens and User-selected Credit Claims, with Confirmation Pop-up Screens, for Sensor Card Credit (top) and Sensor Only Credit (bottom)

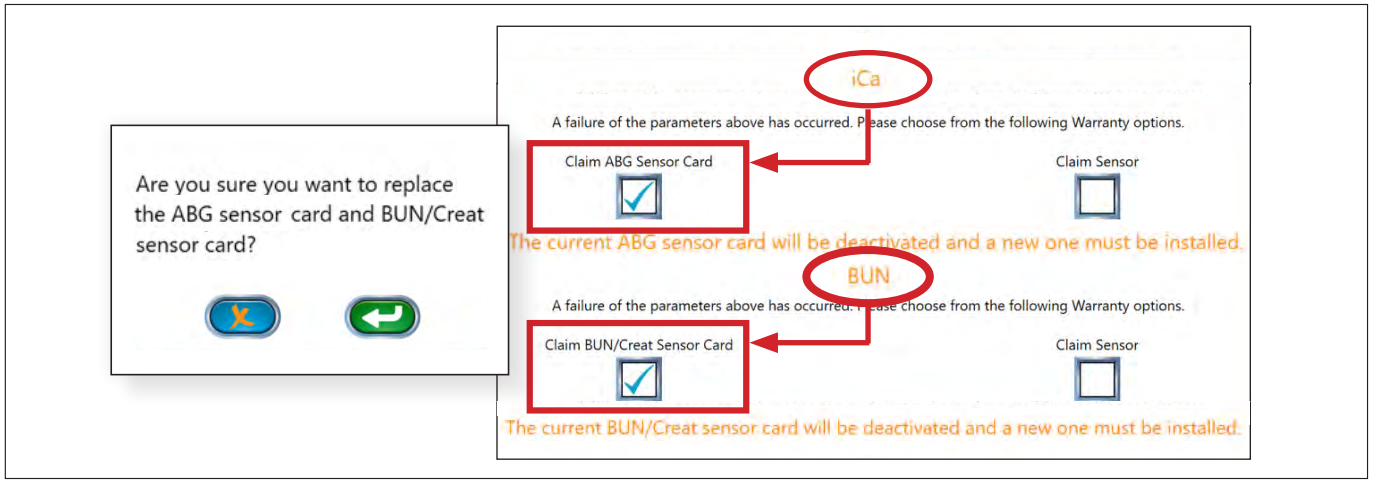

Figure 5.17 Simultaneous Warranty Failures and User-selected Credit Claims for the Associated Sensor Cards (with Confirmation Pop-up Screens)

5.2.2 Automatic Warranty Claims

The analyzer may, in certain circumstances, permanently disable the entire sensor card and claim warranty credit for the failure automatically. Should this occur, you must replace the sensor card to continue using the analyzer.

NOTE: *Because the warranty was claimed automatically, the warranty button is not displayed.*

The analyzer may also permanently disable an individual sensor, including any dependent sensors, and automatically claim warranty credit for the failed sensor(s) while leaving the remaining sensors available for testing.

If the failed sensor is a required parameter, the sensor card must be replaced. However, before replacing the sensor card, you must claim warranty credit for the remaining sensors as follows:

1. On the Home screen, press the button (with white background) for the sensor that has been permanently disabled

The Warranty screen displays.

2. Select Claim Sensor Card to permanently disable the remaining sensors. Follow the prompts to confirm your decision to claim the sensor card.

Warranty codes are then generated and printed for credit for the failure. Contact Nova Biomedical Technical Support.

For Technical Assistance, Call Toll Free	
USA	1-800-545-6682 (NOVA)
Canada	1-800-263-5999
Other Countries	Contact the local Nova Biomedical Sales Office or Authorized Nova Biomedical Distributor

5.2.3 Accessing Stored Credits

1. From the Home Screen, select the toolbox 
2. Select the Service button
3. Select the Credits button.
4. Use the date selector to specify the desired date range to view.

Credits generated during the selected date range are displayed with the date and time the warranty credit was created, the lot number of the sensor card, and the 16-digit warranty code (Figure 5.18).

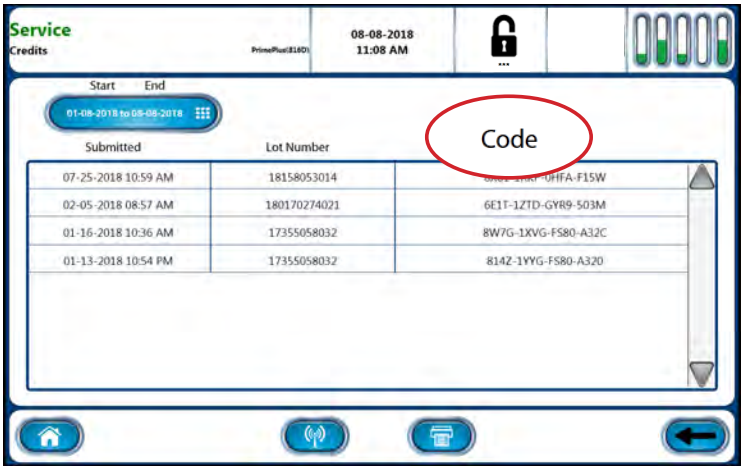

Figure 5.18 Credit Screen
Listing Credit Claims and Warranty Codes

6. Periodic Replacements

The following consumables require occasional replacement:

- Sample Probe
- Printer Paper
- Safety Sample Port

6.1 Replacing the Sample Probe

WARNING: ***Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP).***

1. From the Home Screen, press the System Menu button
2. Press Replace
3. Select Replace Probe
4. Wait for the pump to stop.

The probe extends.

5. Open the analyzer door.
6. Remove the Capillary Adapter (Figure 6.1).
7. Squeeze the tabs on the Sample Probe latch.
8. Slide the Sample Probe left.
9. Remove the Sample Probe.
10. Disconnect the Probe cable plug.
11. Disconnect the Probe tubing.
12. To install the new Probe, insert the Sample Probe latch into position until you hear it click into place.
13. Install the Capillary Adapter by aligning the adapter center hole with the probe and sliding the adapter over the probe.
14. Connect the probe air detector cable and tubing.
15. Press Enter

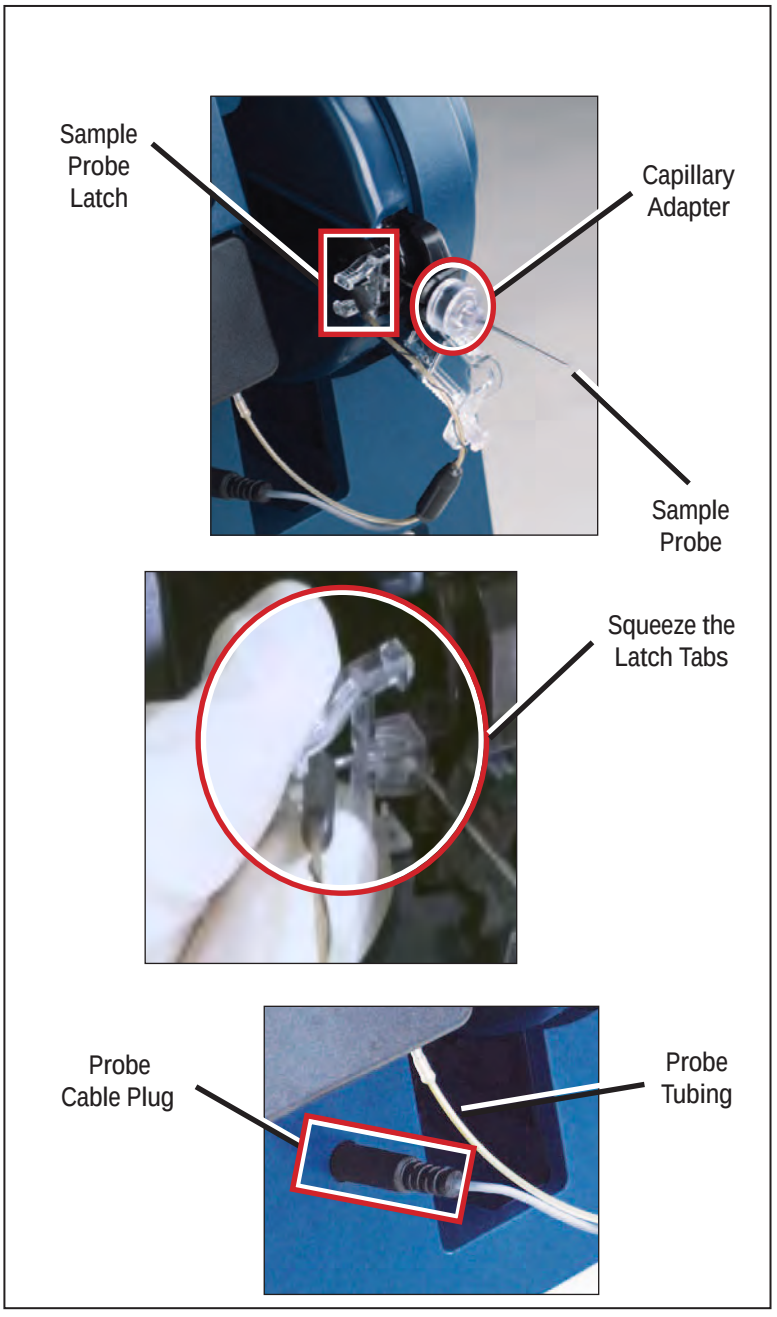

Figure 6.1 Sample Probe Replacement

6.2 Replacing Printer Paper

1. On the top of the analyzer, insert a finger into the printer cover's finger catch (Figure 6.2).
2. Pull the catch to release the cover.
3. Raise the cover until it rests open.
4. Remove the depleted paper roll.
5. Orient a new roll of paper so the loose end will feed from the bottom of the roll.
6. Insert the roll of paper into the opening with the loose end pointed toward the front of the analyzer.
7. Pull the loose end over the row of plastic cutting teeth so the paper extends outside the printer cover.
8. Close the printer door.
9. Press until the cover clicks shut.

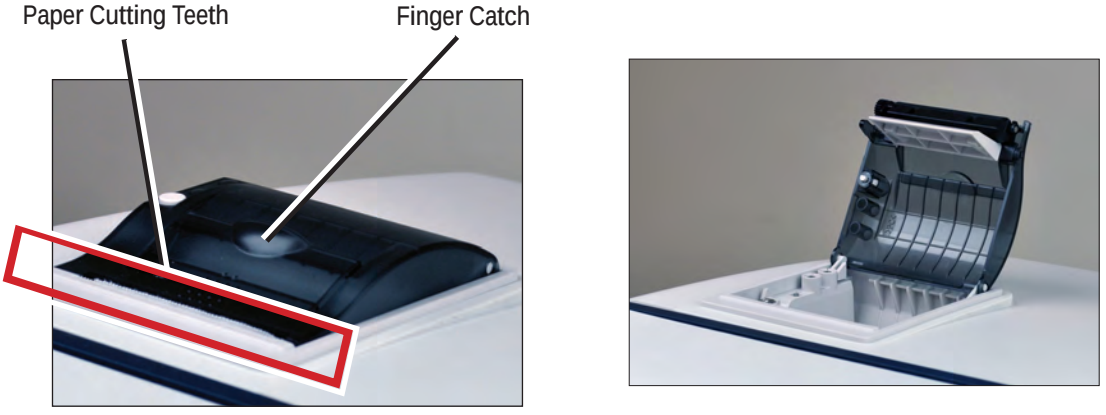

Figure 6.2 Printer Cover Closed (left) and Open (right)

6.3 Replacing the Safety Sample Port

WARNING: Exposure to Blood Borne Pathogens. Follow established Good Laboratory Practices (GLP).

1. Open the analyzer door.
2. Squeeze the ribbed tabs on the upper and lower edges of the Safety Sample Port (Figure 6.3).
3. Slide the Safety Sample Port toward the front of the analyzer to remove it from the analyzer.
4. Slide in a new Safety Sample Port.
5. Close the analyzer door.

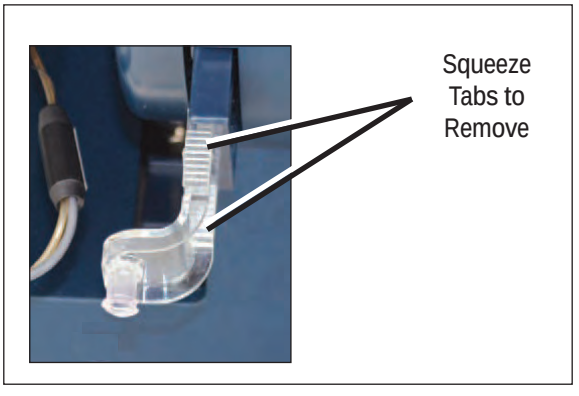

Figure 6.3 Safety Sample Port Tabs

7. Troubleshooting

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

For Technical Assistance, Call Toll Free	
USA	1-800-545-6682 (NOVA)
Canada	1-800-263-5999
Other Countries	Contact the local Nova Biomedical Sales Office or Authorized Nova Biomedical Distributor

WARNING: ***Blood samples and blood products are potential sources of infectious agents. Handle all blood products and Flow Path components (e.g., Waste Line, Capillary Adapter, Sample Probe, Sensor Cartridge, etc.) with care. Gloves and protective clothing are recommended. When performing maintenance and troubleshooting, also use protective eye wear.***

7.1 Event Log

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

 > Service > Logs > 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 timeframe 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, a description of the event, the event ID, the cause and processor. To print the Event Log, press the Print button.

7.2 Resolving Event Codes

Event Codes comprise 5 categories:

- Sensor Card Errors
- CO-Oximeter Errors
- Flow Errors
- Calibrator and Auto QC Cartridge Errors
- Electromechanical Errors

Use the following troubleshooting steps to resolve the listed codes. If a displayed code is unlisted, contact Nova Biomedical Technical Support for assistance.

Table 7.1 Event Codes	
Sensor Cartridge Errors	
Code	**Description and Corrective Action**
pH Slope pCO_2 Slope pO_2 Slope Na Slope K Slope Cl Slope Ca Slope Mg Slope Glu Slope Lac Slope Creat Slope BUN Slope Hct 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. If the problem persists, replace the appropriate Sensor Cartridge. 3. Replace the Calibrator Cartridge. 4. Replace the Reference Sensor. 5. Call Nova Biomedical Technical Support or your local distributor.
pH Overload pCO_2 Overload pO_2 Overload Na Overload K Overload Cl Overload Ca Overload Mg Overload Glu Overload Lac Overload Creat Overload BUN Overload Hct Overload	During the last calibration or analysis sequence, the indicated analytes' sensor reading exceeded the software limits. Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.
pH Acquisition pCO_2 Acquisition pO_2 Acquisition Na Acquisition K Acquisition Cl Acquisition Ca Acquisition Mg Acquisition Glu Acquisition Lac Acquisition Creat Acquisition BUN Acquisition Hct Acquisition	During the last calibration or analysis sequence, the indicated analytes' sensor reading could not be taken. Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.

Table 7.1 Event Codes (Continued)	
Sensor Cartridge Errors (Cont'd)	
Code	**Description and Corrective Action**
pH Calculation pCO_2 Calculation pO_2 Calculation Na Calculation K Calculation Cl Calculation Ca Calculation Mg Calculation Glu Calculation Lac Calculation Creat Calculation BUN Calculation Hct Calculation	During the last calibration or analysis sequence, the indicated analytes' sensor reading could not be calculated. Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.
pH Stability pCO_2 Stability pO_2 Stability Na Stability K Stability Cl Stability Ca Stability Mg Stability Glu Stability Lac Stability Creat Stability BUN Stability Hct Stability	During the last calibration or analysis sequence, the indicated analytes' sensor reading did not reach a stable endpoint. Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.
pH E-zero Drift pCO_2 E-zero Drift pO_2 E-zero Drift Na E-zero Drift K E-zero Drift Cl E-zero Drift Ca E-zero Drift Mg E-zero Drift Glu E-zero Drift Lac E-zero Drift Creat E-zero Drift BUN E-zero Drift Hct E-zero Drift	During the last analysis sequence, the indicated analytes' performance changed significantly from successful 2-point calibration. Recommended Solution 1. Recalibrate the analyzer. 2. If the problem persists, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.

Table 7.1 Event Codes (Continued)	
Sensor Cartridge Errors (Cont'd)	
Code	**Description and Corrective Action**
pH A to A Drift pCO_2 A to A Drift pO_2 A to A Drift Na A to A Drift K A to A Drift Cl A to A Drift Ca A to A Drift Mg A to A Drift Glu A to A Drift Lac A to A Drift Creat A to A Drift BUN A to A Drift Hct 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, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.
pH Slope Drift pCO_2 Slope Drift pO_2 Slope Drift Na Slope Drift K Slope Drift Cl Slope Drift Ca Slope Drift Mg Slope Drift Glu Slope Drift Lac Slope Drift Creat Slope Drift BUN Slope Drift Hct 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, replace the appropriate Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.
pCO_2 Slope Drop pCO_2 Slope Time Check	During the last 2-point calibration, the PCO_2 sensor did not meet the minimum specifications for a properly performing sensor. Recommended Solution 1. Replace the Sensor Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.

Table 7.1 Event Codes (Continued)	
Sensor Cartridge Errors (Cont'd)	
Code	**Description and Corrective Action**
Sensor Card Invalid Part Number BUN/Creat Sensor Card Invalid Part No. Reference Invalid Part Number	The sensor card RFID tag is programmed with a part number that is not intended for use with the analyzer. Recommended Solution 1. Replace the appropriate Sensor Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.
Sensor Card Lot Expiration BUN/Creat Sensor Card Lot Expiration	The indicated sensor card has exceeded its shelf life expiration date. Recommended Solution 1. Replace the appropriate Sensor Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.
Sensor Card Days Expiration BUN/Creat Sensor Card Days Expiration Reference Days Expiration	The indicated sensor card has exceeded its use life expiration date. Recommended Solution 1. Replace the appropriate Sensor Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.
Sensor Card Sample Use Expiration BUN/Creat Sensor Card Sample Use Expiration	The indicated sensor card has exceeded its maximum number of cycles (samples). Recommended Solution 1. Replace the appropriate Sensor Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.
ABG Sensor Card Void Warranty BUN Sensor Card Void Warranty	The manufacturer's warranty for the indicated sensor card has been voided. This will occur if: • The Sensor Cartridge has exceeded its warranty use life. • The Sensor Cartridge has been removed from the analyzer for more than two hours. • The analyzer has been powered off for more than two hours. • The Reference Sensor has exceeded its Use Life Expiration Date. Recommended Solution 1. Replace the appropriate Sensor Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor..

Table 7.1 Event Codes (Continued)	
CO-Oximeter Errors	
Code	**Description and Corrective Action**
Failed to XCalibrate Spectrometer	The CO-Oximeter module was unable to successfully complete an X axis optical calibration. Recommended Solution 3. Repeat the calibration. 4. If the problem persists, clean the CO-Oximeter optics lenses. 5. Call Nova Biomedical Technical Support or your local distributor.
Contamination Detected	The CO-Oximeter optics readings indicate the cuvette is contaminated. Recommended Solution 1. Flush the sample flowpath (refer to section 7.4) 2. Perform Check Cuvette 3. If the problem persists, replace the Sensor Cartridge. 4. Call Nova Biomedical Technical Support or your local distributor.
Invalid CO-Ox Calibration Absorbance Value	The CO-Oximeter optics readings exceed the allowable software limits. Recommended Solution 1. Clean the CO-Oximeter optics lenses. 2. If the problem persists, replace the Sensor Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor..
SulfHb Interference	During the last sample analysis the SulfHb value was measured as >1.5%. Recommended Solution 1. Repeat the analysis. 2. Verify the result on an alternate reference method. 3. Contact Nova Biomedical Technical Support if the problem exists on all samples.
CO-Ox Data Suspect	During the last sample analysis, the CO-Oximeter measured fractions exhibited an unknown interference; therefore, the results were determined to be potentially erroneous. Recommended Solution 1. Repeat the analysis. 2. Verify the result on an alternate reference method. 3. Contact Nova Technical Support if problem exists on all samples.

Table 7.1 Event Codes (Continued)	
Flow Errors	
Code	**Description and Corrective Action**
No Flush When Required No Air When Required No Standard A When Required No Standard B When Required No Standard C When Required No Standard D When Required	During the last calibration or sample analysis, the expected calibration standard, flush solution or room air was not detected when required. Recommended Solution 1. Flush the sample flowpath (refer to section 7.4) 2. Verify the % remaining in the Calibrator Cartridge. If the pack indicates less than 10% remaining, replace the Calibrator Cartridge. 3. Call Nova Biomedical Technical Support or your local distributor.
Short Sample No Sample When Required Sample Position	During the last sample analysis, no sample was detected at one or more air detectors when expected. Recommended Solution 1. Flush the sample flowpath (refer to section 7.4) 2. Repeat the sample analysis. 3. Calibrate the Air Detectors. 4. Call Nova Biomedical Technical Support or your local distributor.
Insufficient Sample	During the last sample analysis, not enough sample was aspirated into the analyzer to produce accurate results. Recommended Solution 1. Repeat the sample analysis. 2. Flush the sample flowpath (refer to section 7.4) 3. Call Nova Biomedical Technical Support or your local distributor.

Table 7.1 Event Codes (Continued)	
Calibrator and Auto QC Cartridge Errors	
Code	**Description and Corrective Action**
Calibrator Invalid Part Number Auto QC Invalid Part Number	The indicated cartridge is programmed with a part number that is not intended for use with the analyzer.. Recommended Solution 4. Replace the Cartridge. 5. Call Nova Biomedical Technical Support or your local distributor.
Calibrator Lot Expiration Auto QC Lot Expiration	The indicated cartridge has exceeded its shelf life expiration date. Recommended Solution 1. Replace the Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.
Calibrator Days Expiration Auto QC Days Expiration	The indicated cartridge has exceeded its use life expiration date. Recommended Solution 1. Replace the Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.
Calibrator Sample Use Expiration Auto QC Sample Use Expiration	The indicated cartridge has exceeded its maximum number of cycles (samples). Recommended Solution 1. Replace the Cartridge. 2. Call Nova Biomedical Technical Support or your local distributor.

Electromechanical Device Errors	
Code	**Description and Corrective Action**
Probe Failed To Home Sampler Failed Reaching Top Sensor Sampler Homing Failed Sampler Positioning Failed	The sampler was unable to move the sample probe to a required position. Recommended Solution 3. Open the analyzer door. Remove any obstructions that may impede sampler movement. 4. If no obstructions are found and the problem persists, power down the analyzer for 30 seconds, then restart. 5. Call Nova Biomedical Technical Support or your local distributor.

Table 7.1 Event Codes (Continued)	
Electromechanical Device Errors (Cont'd)	
Code	**Description and Corrective Action**
Rotary Valve Failed To Home	The rotary valve was unable to move to a required position. Recommended Solution 1. Power down the analyzer for 30 seconds, then restart. 2. Contact Nova Biomedical Technical Support or your local distributor.
Clamp Positioning Failed	The peristaltic pump clamp assembly failed to open or close correctly during the reference cartridge replacement procedure. Recommended Solution 1. Power down the analyzer for 30 seconds, then restart.. 2. Contact Nova Biomedical Technical Support or your local distributor.
Scanner Communications Scanner Timeout	The system bar code scanner did not respond or did not respond correctly when expected. Recommended Solution 1. Power down the analyzer for 30 seconds, then restart. 2. Contact Nova Biomedical Technical Support or your local distributor.
Printer Out Of Paper	The analyzer's thermal printer paper sensor does not detect an available roll of paper. Recommended Solution 1. Install printer paper if required 2. Power down the analyzer for 30 seconds, then restart. 3. Contact Nova Biomedical Technical Support or your local distributor.
Printer Door Open	The analyzer's thermal printer door sensor indicates the printer door is open. Recommended Solution 1. Ensure the printer door is closed securely. 2. Power down the analyzer for 30 seconds, then restart. 3. Call Nova Biomedical Technical Support or your local distributor.

7.3 Calculation Dependencies

Table 7.2 Prime Plus Calculation Dependencies

Sensor	Dependency	Calibration Calculation Error	Sample Calculation Error
PCO_2	pH	pH fails calibration	pH result has any error pH is uncalibrated
Hct	Na	Na fails calibration	Na result has any error Na is uncalibrated
iMg	iCa	iCa fails calibration	iCa result has any error iCa is uncalibrated
BUN	Na, K	Na or K fails calibration	Na or K result has any error Na or K is uncalibrated
Creat	Creatine	Creatine fails calibration Creat/Creatine fails post-flush check	Creatine result has any error Creatine is uncalibrated
PO_2	None	PO_2 sensor fails Delta Flush checks	N/A

7.4 Flushing the Flowpath

7.4.1 Flush Flowpath

CAUTION: Use of a device other than the Flowpath Flush Tool may damage the Sensor Cards.

The analyzer Flowpath can be flushed to remove clots and debris from the sensor card and cuvette. Use of a device other than the Flowpath Flush Tool (Figure 7.1) to flush the Flowpath is not recommended.

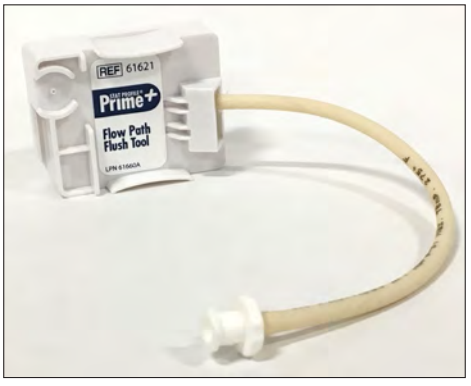

Figure 7.1 Flowpath Flush Tool

Use these steps to flush the Flowpath:

1. On the Home Screen, press Toolbox button > Flush (Figure 7.2).
2. Install the Flush Tool:
   - 2a. Wait for the Peristaltic Pump to stop turning.
   - 2b. Open the Sensor Module Door.
   - 2c. Remove the MicroSensor Card.
   - 2d. Remove the Reference Cartridge (Figure 7.3) by sliding it up.

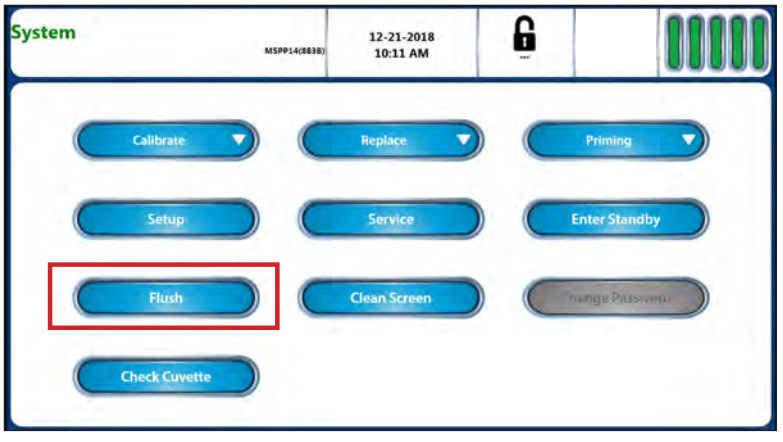

Figure 7.2 Flush Button on System Screen

2e. Install the Flush Tool by sliding it into the Reference Cartridge space.

2f. Return the MicroSensor Card to the nest.

2g. Close the Sensor Module Door.

3. Begin Flushing:

3a. Aspirate 10 cc of deionized water into the 30-cc flushing syringe.

3b. Insert the flushing syringe into the open tubing on the Flush Tool (Figure 7.4).

3c. Hold absorbent gauze below the probe to catch water and debris from the Flowpath.

3d. Depress the syringe plunger to flush the Flowpath and force debris out of the probe.

4. To clear any remaining fluid, flush the Flowpath using air in the syringe according to the sequence described in step 3.

5. When the flush is completed, re-install the Reference Cartridge:

5a. Open the Sensor Module Door.

5b. Remove the MicroSensor Card.

5c. Slide the Flush Tool up to remove it.

5d. Re-install the Reference Cartridge by sliding it into its space.

5e. Return the MicroSensor Card to the nest.

5f. Close the Sensor Module Door.

5g. Press the Continue button to return to the Home Screen.

6. For Sample Contamination errors, initiate a full light scan cuvette check:

6a. On the Home Screen, press the Toolbox button > Check Cuvette (Figure 7.5).

Figure 7.3 Reference Cartridge Removal

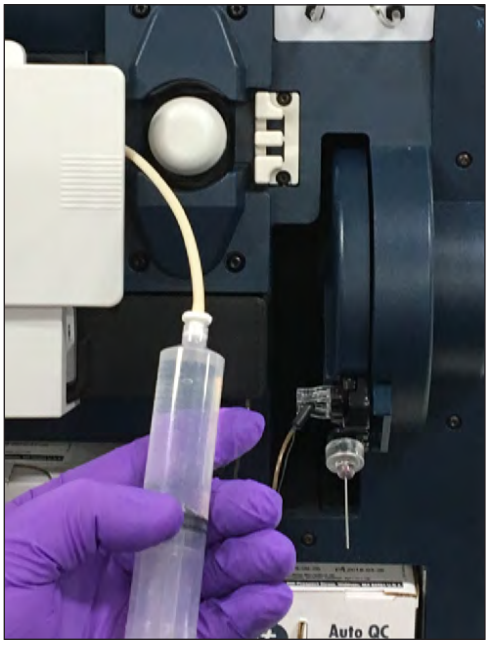

Figure 7.4 Tubing and 30-cc Syringe on Flush Tool

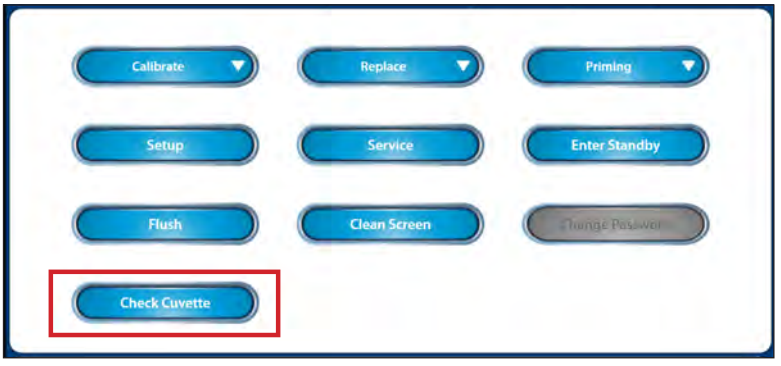

Figure 7.5 Check Cuvette Button on System Screen

7.4.1.1 Flush Sample Probe/S-Line

The Sample Probe may become obstructed by large clots or debris and require manual flushing. Here is the recommended procedure for clearing obstructions from the Sample Probe and S-line.

1. On the Home Screen, press Toolbox button > Flush.

The pump stops turning and the Sample Probe extends.

2. Open the analyzer door.
3. Use the Tube Removal Tool, if possible, to disconnect the Sample Probe/S-line tubing from the bottom of the Preheater.

NOTE: *Flushing the sample probe/S-line does not require use of the Flush tool. Disregard the instructions that appear on the screen.*

4. Draw deionized water into the 5-cc flushing syringe.
5. Slide the syringe tubing over the extended Sample Probe.
6. Use moderate pressure to flush water through the Sample Probe and out the open end of the S-line (Figure 7.6).
7. Refill the flushing syringe with air and repeat steps 5 and 6.
8. After the final flush, reconnect the S-line to the bottom of the Preheater.
9. Press the Continue button.

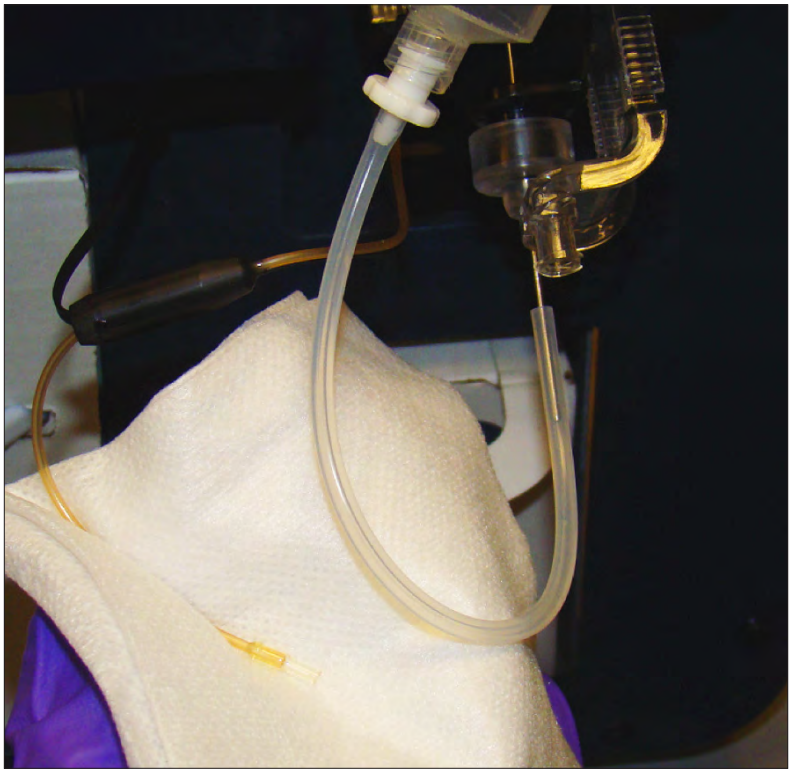

Figure 7.6 Flushing the S-Line

Appendix A: Instrument Specifications

Appendix A includes specifications, QC recommendations, and warranty information for the Stat Profile Prime Plus Analyzer.

A.1 Specifications

Table A-1 Analyte Measurement Ranges

Analyte	Default Units of Measure	Alternate Units of Measure
pH	6.500 – 8.000 (pH units)	316.2 – 10 nmol/L (H+ units)
PCO_2	3.0 – 200.0 mmHg	0.4 – 26.7 kPa
PO_2	5.0 – 765.0 mmHg	0.66 – 102.0 kPa
Hct	12 – 70 %	12 – 70 %
Na	80 – 200 mmol/L	80 – 200 mmol/L
K	1.0 – 20.0 mmol/L	1.0 – 20.0 mmol/L
Cl	50 – 200 mmol/L	50 – 200 mmol/L
iCa	0.1 – 2.7 mmol/L	0.40 – 10.80 mg/dL
iMg	0.1 – 1.5 mmol/L	0.24 – 3.65 mg/dL
Glu	15 – 500 mg/dL	0.8 – 28.0 mmol/L
BUN	3 – 100 mg/dL	1.07 – 35.71 mmol/L
Creat	0.2 – 12.0 mg/dL	0.02 – 1.06 mmol/L 18 – 1,061 µmol/L
Lac	0.3 – 20 mmol/L	2.7 – 180.1 mg/dL
SO_2%	30 – 100%	30 – 100%
tHb	5.0 – 25.0 g/dL	3.1 – 15.52 mmol/L 50 – 250 g/L
O_2Hb	1.8 – 100%	1.8 – 100%
COHb	0.3 – 60%	0.3 – 60%
MetHb	0.3 – 60 %	0.3 – 60%
HHb	0.4 – 40%	0.4 – 40%

Table A-2 Limits of Detection and Quantitation			
Analyte (Units)	**LoB**	**LoD**	**LoQ***
iCa (mmol/L)	0.04	0.05	0.05
iCa (mg/dL)	0.16	0.2	0.2
iMg (mmol/L)	0.05	0.1	0.1
iMg (mg/dL)	0.12	0.24	0.24
Glu (mmol/L)	0.22	0.28	0.67
Glu (mg/dL)	4.0	5.0	12.0
Lac (mmol/L)	0.00	0.1	0.2
Lac (mg/dL)	0.00	0.9	1.8
Creat (mmol/L)	0.008	0.01	0.011
Creat (µmol/L)	7.95	9.72	10.60
Creat (mg/dL)	0.09	0.11	0.12
BUN (mmol/L)	0.36	0.50	0.21
BUN (mg/dL)	0.5	0.7	0.3
tHb (g/dL)	2.9	3.2	3.2
tHb (g/L)	29	32	32
tHb (mmol/L)	1.8	2.0	2.0
O_2Hb (%)	0.4	1.8	1.8
COHb (%)	0.2	0.3	0.3
MetHb (%)	0.1	0.3	0.3
HHb (%)	0.2	0.4	0.4

*Calculated Total Error is less than the accuracy goal for Total Error, so LoQ = LoD as defined in NCCLS EP17-A2[4].

Table A-3.a Measurement Resolution: Measured Results		
Analyte	**Default Units of Measure**	**Alternate Units of Measure**
pH	0.001 (pH units)	1 nmol/L (H+ units)
PCO_2	0.1 mmHg	0.1 kPa
PO_2	0.1 mmHg	0.1 kPa
Hct	1%	N/A
Na	0.1 mmol/L	N/A
K	0.01 mmol/L	N/A
Cl	0.1 mmol/L	N/A
iCa	0.1 or 0.01 mmol/L	0.01 mg/dL
iMg	0.1 or 0.01 mmol/L	0.1 mg/dL
Glu	1 mg/dL	0.1 mmol/L
BUN	1 mg/dL	0.1 mmol/L
Creat	0.01 mg/dL	0.01 mmol/L 1 µmol/L
Lac	0.1 mmol/L	0.1 mg/dL
SO_2	1%	N/A
tHb	0.1 g/dL	1 g/L or 1.1 mmol/L
O_2Hb	0.1%	0.001 (decimal)
COHb	0.1%	0.001 (decimal)
MetHb	0.1%	0.001 (decimal)
HHb	0.1%	0.001 (decimal)

Table A-3.b Measurement Resolution: Calculated Results		
Test	**Default Units of Measure**	**Alternate Units of Measure**
A	0.1 mmHg	0.1 kPa
a/A	N/A	N/A
A-aDO	0.1 mmHg	0.1 kPa
Actual Bicarbonate (HCO_3)	0.01 mmol/L	N/A
Anion Gap	0.1 mmol/L	N/A
Base Excess ECF (BE-ecf)	0.1 mmol/L	N/A
Base Excess Blood (BE-b)	0.1 mmol/L	N/A
BUN/Creatinine Ratio (BUN/Creat)	N/A	N/A

Table A-3.b *(continued)* Measurement Resolution: Calculated Results		
Test	**Default Units of Measure**	**Alternate Units of Measure**
eGFR	mL/min/1.73 m^2	N/A
Ratio of Ionized Calcium to Ionized Magnesium	N/A	N/A
Estimated Plasma Volume (ePV)	0.001 dL/g	N/A
Serial or ΔPlasma Volume (ΔPV)	1%	N/A
Normalized Ionized Calcium	0.01 mmol/L	0.01 mg/dL
Normalized Ionized Magnesium	0.01 mmol/L	0.1 mg/dL
Osmolality	1 mOsm/kg	N/A
Oxygen Capacity (O_2Cap)	0.1 mL/dL	0.1 Vol%
Oxygen Content (O_2Ct)	0.1 mL/dL	0.1 Vol%
Oxygenation Index (OI)	0.01 (no units of measure)	N/A
PO_2/FIO_2	0.1	N/A
P_{50}	0.1 mmHg	0.1 kPa
pH Corrected to Patient Temperature	0.001 (pH units)	1 nmol/L (H^+ units)
PCO_2 Corrected to Patient Temperature	0.1 mmHg	0.1 kPa
PO_2 Corrected to Patient Temperature	0.1 mmHg	0.1 kPa
Qsp/Qt (Mixed Venous Only)	0.01%	N/A
Respiratory Index (RI)	0.1	N/A
Standard Bicarbonate (SBC)	0.1 mmol/L	N/A
TCO_2	0.1 mmol/L	N/A

Table A-4 Sample Requirements	
Acceptable Samples	Whole Blood (Lithium or Balanced Heparin)
Sample Volume (Syringe/Open Tube)	135 µL
Sample Volume (Capillary)	90 µL
Barometer	400 to 800 ±1 mmHg, accurate to 1.5%

A.2 Quality Control

Healthcare facilities should follow national or international guidelines for testing quality control materials. At a minimum, Nova Biomedical recommends that all laboratories perform on each analyzer the following QC procedures (Auto-Cartridge QC, or External Ampule QC):

- Prime Plus Blood Gas/SO_2%/Hb/Hct/CO-Oximeter Controls, Levels 1, 2, and 3.
  - 1 level of Control during each 8 hours of operation.
  - All 3 levels of Control during each day of operation.
- Nova Prime Plus Chemistry Controls Levels 4, 5.
  - During each 24 hours of testing, analyze a normal and an abnormal level of Chemistry Controls.
- After performing system maintenance, follow Good Laboratory Practice guidelines for performing QC analysis.

CAUTION: Sensor performance may be affected by use of controls other than Stat Profile Prime Plus Controls. Contact Nova Biomedical or your local distributor 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.

A.3 Nova Recommendation (for new Auto-Cartridge QC Lots)

Nova's recommendation for conversion to a new Auto-Cartridge QC lot number is to use the factory-supplied range levels of the new lot for the first 30 days or until sufficient data are collected to establish the new target values. All Nova controls ship with a product insert sheet that specifies the target range for each level of QC contained in the pack.

After sufficient data collection, enter the established values and ranges into the analyzer per laboratory policy.

A.3.1 Alternate Method

If the method described in Section A.3 is inadequate, Nova recommends running the external controls in parallel, overlapping with the on-board product change-over. This method provides continuity in monitoring performance during the change-over period. The external QC monitoring can be done using the QC program on the analyzer.

A.4 Analytical Specificity

An interference study was performed according to CLSI guideline EP07-A2.[5] The study used spiked and diluted specimens containing potential interfering substances for pH, pCO_2, pO_2, Hematocrit (Hct), Na, K, Cl, Ca, Mg, Glucose (Glu), Lactate (Lac), Creatinine (Creat) and BUN (Urea Nitrogen), SO_2%, Total Hemoglobin (tHb), Oxyhemoglobin (O_2Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), and Deoxyhemoglobin (HHb) at normal physiological levels. Each sample containing the interfering substance was evaluated against a reference specimen containing none of the interfering substance. Potential interfering substances were selected for test based upon a known potential to interfere with the test methodology.

Table A-5 lists interfering substances that produced no clinically significant effects on test results. Table A-6 lists interfering substances that produced clinically significant effects on test results.

Table A-5
Interfering Substances Causing No Clinically Significant Effect on Test Results

Interfering Substance	Highest Concentration Tested	Analytes Tested
Acetaminophen	20mg/dL	Lac, Glu, Creat, BUN, pH,PCO_2, PO_2
Acetoacetate	2 mmol/L	Na, K, iCa, Cl, iMg, Glu, Creat, BUN, Lac
Acetylsalicylic Acid	3.62 mmol/L	Na, K, Cl, iCa, iMg, Glu, Creat, BUN, Lac
Ammonium Chloride	107 µmol/L	Na, K, iCa, Cl, iMg, Glu
Ascorbic Acid	50 mg/dL	Na, K, iCa, iMg, Cl, Glu, Creat, BUN, Lac
Benzalkonium Chloride	10 mg/L	pH, Na, K, iCa, Cl, iMg, Glu, BUN, Lac
β-Carotene	2 mg/L	tHb, O_2Hb, COHb, MetHb, HHb, SO_2
β-Hydroxybutyrate	2 mmol/L	Glu, BUN, Lac
Bilirubin (Conjugate)	342 µmol/L	pH, PCO_2, PO_2, Na, K, iCa, Cl, iMg, Glu, Creat, BUN, Lac, Hct, SO_2, tHb, O_2Hb, COHb, MetHb, HHb
Calcium Chloride	2 mmol/L	pH, PCO_2, PO_2, Na, K, iMg
Chlorpromazine Hydrogen Chloride	0.2 mmol/L	Creat, BUN
Creatine	5 mg/dL	Creat, BUN
Cyanocobalamin	0.1 g/L	tHb, O_2Hb, COHb, MetHb, HHb, SO_2
Cyanomethemoglobin (Drabkin's reagent)	10%	tHb, O_2Hb, COHb, MetHb, HHb, SO_2
Dextran	60 g/L	pH, PCO_2, PO_2
D-Galactose	1 mmol/L	Glu, Lac
Dobutamine	2 mg/dL	pH, Na, K, Cl, iCa, iMg, Glu, Lac
Dopamine	1 mmol/L	Creat, BUN
Dopamine Hydrochloride	5.87 µmol/L	Glu, Creat, BUN, Lac
EDTA	3 mmol/L	Glu, Creat, BUN, Lac
Ethanol	86.8 mmol/L	pH, PCO_2, PO_2, Glu, Creat, BUN
Evans Blue	1 mg/dL	HHb, SO_2
Fluorescein	0.4 mg/mL	pH, PCO_2, PO_2, tHb, O_2Hb, COHb, MetHb, HHb, SO_2

Table A-5 *(continued)*
Interfering Substances Causing No Clinically Significant Effect on Test Results

Interfering Substance	Highest Concentration Tested	Analytes Tested
Fluoride	105 µmol/L	Glu, Creat, Lac
Glucosamine	30 µmol/L	Glu, Lac
Glucose	1000 mg/dL	Creat, BUN, Lac
Glutathione	3 mmol/L	BUN
Glycolic Acid	1 mmol/L	Glu, Creat, BUN
Halothane	759 µmol/L	pH, PCO_2, PO_2
Hematocrit High	64%	Creat, BUN
Hematocrit Low	22%	Creat, BUN
Hemoglobin	2 g/L	pH, PCO_2, PO_2, Na, K, iCa, Cl, iMg, Glu, Hct, Lac
Hemolysis	10%	tHb, O_2Hb, COHb, MetHb, HHb, SO_2
High Protein	60 g/L	Creat
Hydroxybutyrate	2 mmol/L	pH, PCO_2, PO_2
Hydroxycobalamin	0.6 g/L	Hct, SO_2, tHb, O_2Hb, COHb, MetHb, HHb
Hydroxyurea	0.8 mg/dL	BUN, pH, PCO_2, PO_2
Ibuprofen	2.4 mmol/L	Na, K, iCa, Cl, iMg, Glu, Creat, BUN, Lac
Indocyanine Green/ Cardiogreen	10 mg/L	tHb, O_2Hb, COHb, MetHb, HHb, SO_2
Intralipid	4000 mg/dL	pH, PCO_2, PO_2, Na, K, iCa, Cl, iMg, Glu, Creat, BUN, Hct, Lac, SO_2, COHb
Lactic Acid	12 mmol/L	Glu, Creat, BUN
Lithium	3.2 mmol/L	pH, PCO_2, PO_2
Lithium Lactate	6.6 mmol/L	Na, K, iCa, iMg, Glu, Cl, Creat
Low pH	6.8	Creat, BUN
Maltose	13 mmol/L	Glu, Lac
Mannose	1 mmol/L	Glu, Lac
Methylene Blue	2 mg/dL	tHb, O_2Hb, COHb, HHb, SO_2
Magnesium Chloride	15 mmol/L	Na, K

Table A-5 *(continued)*
Interfering Substances Causing No Clinically Significant Effect on Test Results

Interfering Substance	Highest Concentration Tested	Analytes Tested
N-acetylcysteine	10.2 mmol/L	Creat, BUN, Glu, Hct
Nithiodote	0.0512 g/mL	BUN
Ofloxacin	48.6 mmol/L	pH, PCO_2, PO_2
Paracentamol-4-acetamidopenol	2 mmol/L	Creat, BUN
Patent Blue	2.5 mg/L	tHb, O_2Hb, COHb, HHb, SO_2
Perchlorate	1 mmol/L	K, iCa, Cl
Potassium Chloride	5 mmol/L	Na, pH, PCO_2, PO_2, iCa, iMg
Proline	0.5 mmol/L	Creat
Pyruvate	309 µmol/L	Glu, Creat, BUN, Lac
Salicylic Acid	4.34 mmol/L	Na, K, Cl, iCa, Glu, Creat, BUN, Lac
Sodium Bromide	37.5 mmol/L	pH, PCO_2, PO_2, K, iCa, iMg, Creat, Lac
Sodium Chloride	10 mmol/L	pH, PCO_2, PO_2, iCa, iMg
Sodium Citrate	12 mmol/L	K, Cl, Glu, BUN, Creat, Lac
Sodium Heparin	100 iU/mL	pH, PCO_2, PO_2, Glu, Creat, BUN, Hct, Lac
Sodium Iodide	2.99 mmol/L	K, Cl, iCa, iMg, pH, PCO_2, PO_2, Creat
Sodium Oxalate	500 mg/dL	K, Cl, Lac
Sulfhemoglobin	1.5%	tHb, HHb, SO_2
Thiocyanate	6.8 mmol/L	Na, K, iCa, BUN, Lac
Urea	43 mmol/L	Glu, Creat, Lac
Uric Acid	1.4 mmol/L	Glu, BUN, Creat, Lac
White Blood Cells	83116 WBC/µL	Hct, tHb, O_2Hb, COHb, MetHb, HHb
Xylose	25 mg/dL	Glu, Lac
Zinc Chloride	1.3 mg/dL	Na, K, iCa
Lithium Heparin	80 IU/mL	pH, PCO_2, PO_2, Na, K, iCa, Cl, iMg, Glu, Creat, BUN, Hct, Lac, SO_2, COHb, tHb, O_2Hb, MetHb, HHb, HbF

Table A-6
Interfering Substances Causing Clinically Significant Effects on Test Results

Parameter	Interfering Substance	Interference Observed at Concentrations Above
Carboxyhemoglobin	Evans Blue	0.25 mg/dL
	Sulfhemoglobin	0.803%
Chloride	Bromide	2.5 mmol/L
	Thiocyanate	3.4 mmol/L
Creatinine	Hydroxyurea	0.06 mg/dL
	Thiocyanate	1.7 mmol/L
Glucose	Hydroxyurea	0.2 mg/dL
	Oxalate	125 mg/dL
	Thiocyanate	3.4 mmol/L
Hematocrit	Albumin	2.8 g/dL
	Hemolysis	5.0%
	Triglycerides	335.5 mg/dL
Ionized Calcium	$MgCl_2$	3.75 mmol/L
Ionized Magnesium	Perchlorate	0.06 mmol/L
	Thiocyanate	0.4 mmol/L
	$ZnCl_2$	0.163 mg/dL
Lactate	Glycolic Acid	0.0 mmol/L
	Hydroxyurea	0.0 mg/dL
Methemoglobin	Evans Blue	0.125 mg/dL
	Patent Blue	1.875 mg/dL
	Intralipid	1.0%
	Sulfhemoglobin	0.63%
	Methylene Blue	Interference at all Concentrations
Oxyhemoglobin	Evans Blue	0.125 mg/dL
	Intralipid	1.0%
	Sulfhemoglobin	0.63%
Total Hemoglobin	Evans Blue	0.25 mg/dL
	Intralipid	1.0%

A.5 Healthcare Professional Analytical Performance Studies

Trained healthcare professionals in a clinical laboratory setting compared 3 Stat Profile Prime Plus analyzers to 2 Stat Profile pHOx Ultra Analyzers in a laboratory setting. The protocol consisted of the following:

- Method comparison studies comparing the performance of the Stat Profile Prime Plus Analyzers to the Stat Profile pHOx Ultra Analyzers
- Within-run precision runs
- Day-to-day precision runs

A.5.1 Method Comparison Study

A.5.1.1 Arterial and Venous Whole Blood Specimens

Discarded lithium heparinized arterial and venous whole blood specimens from hospital patients were analyzed in singlet on the 3 Stat Profile Prime Plus analyzers and the 2 Stat Profile pHOx Ultra Analyzers. The number of samples per run and the total number of runs depended on the availability of blood specimens on any given day.

To cover the hard-to-find sample range, venous whole blood samples from consenting male and female donors were tonometered, spiked, or diluted to cover the analytical measurement ranges for all analytes. These samples were identified and noted as altered samples in the data tables.

A.5.1.2 Bias Chart Results

The method comparison bias estimate was analyzed.[6] Figures A.1 through A.19 and Tables A-7 and A-8 provide bias plot data for each parameter. Each bias plot includes 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 Plus analyzers compared to the average result from 2 Stat Profile pHOx Ultra analyzers. Clinically relevant low and high concentrations are annotated.

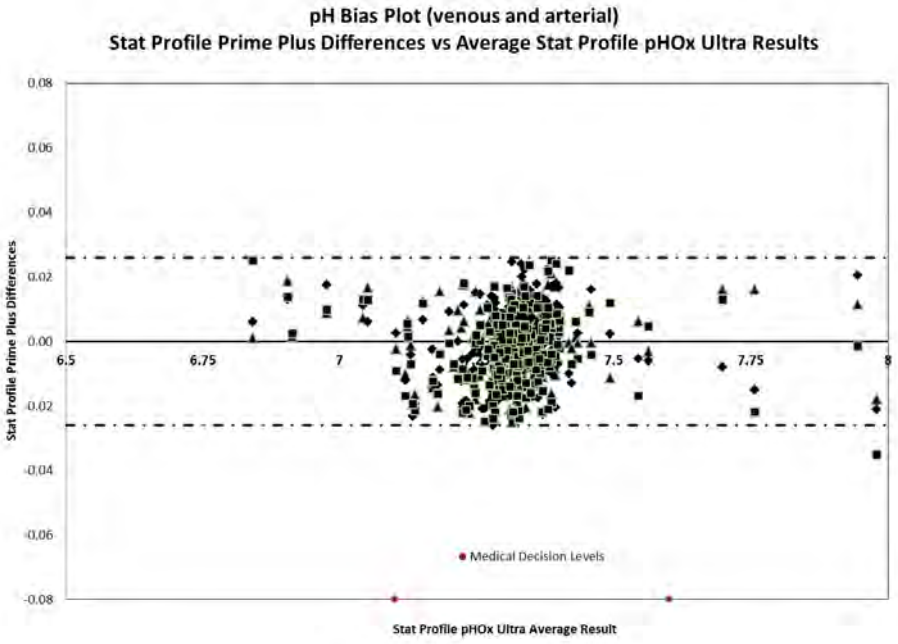

Figure A.1 pH Bias Plot

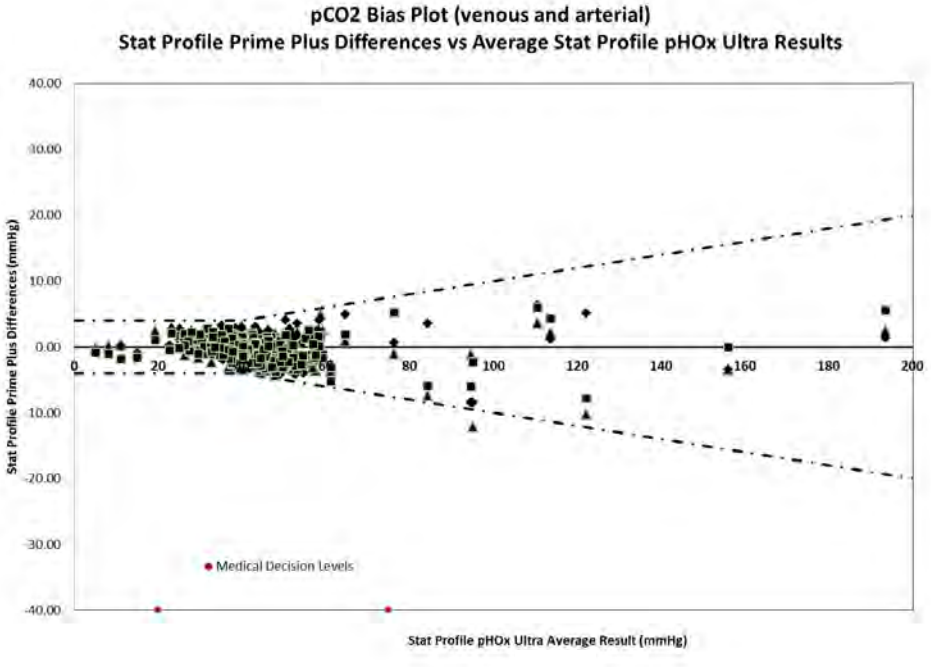

Figure A.2 pCO_2 Bias Plot

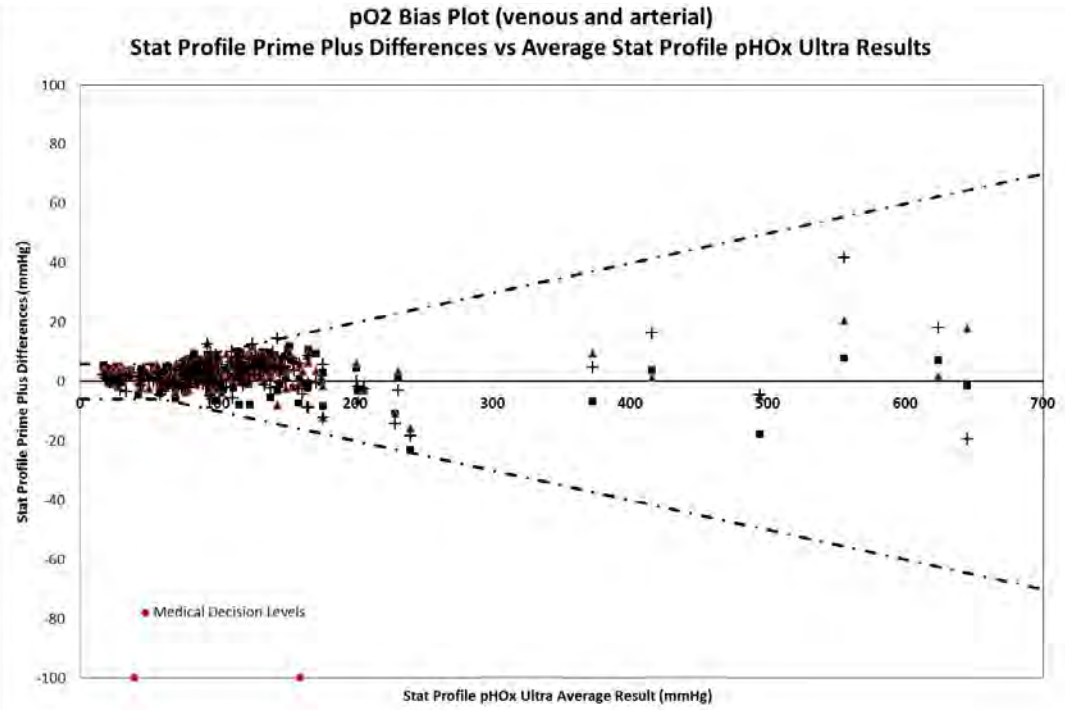

Figure A.3 pO_2 Bias Plot

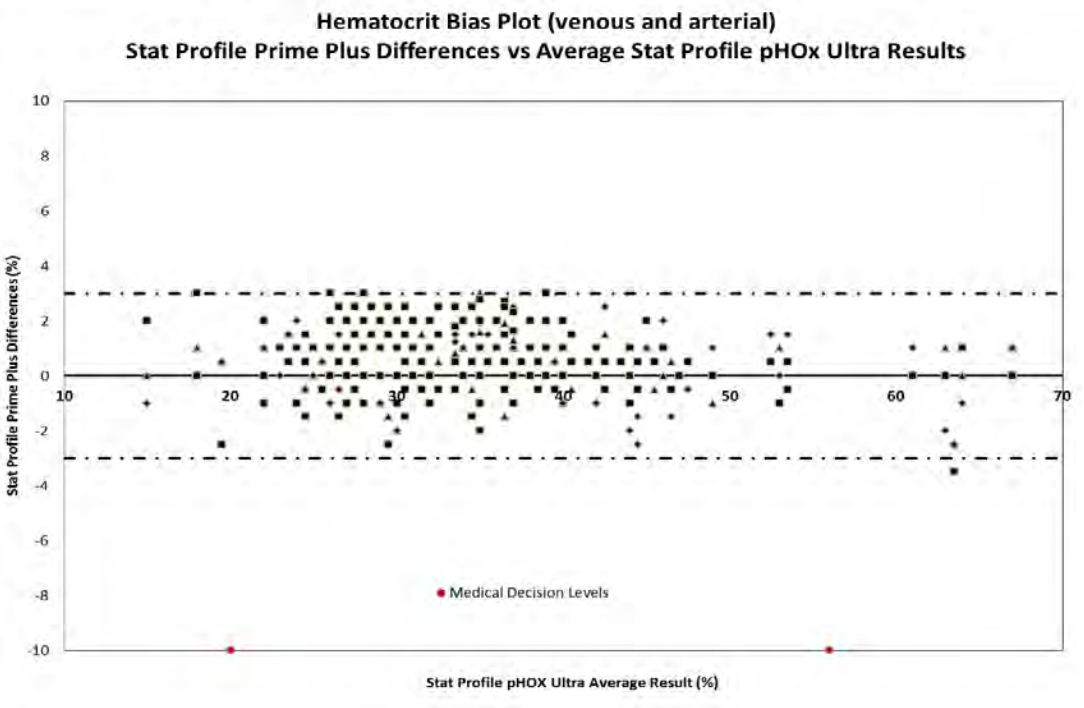

Figure A.4 Hct Bias Plot

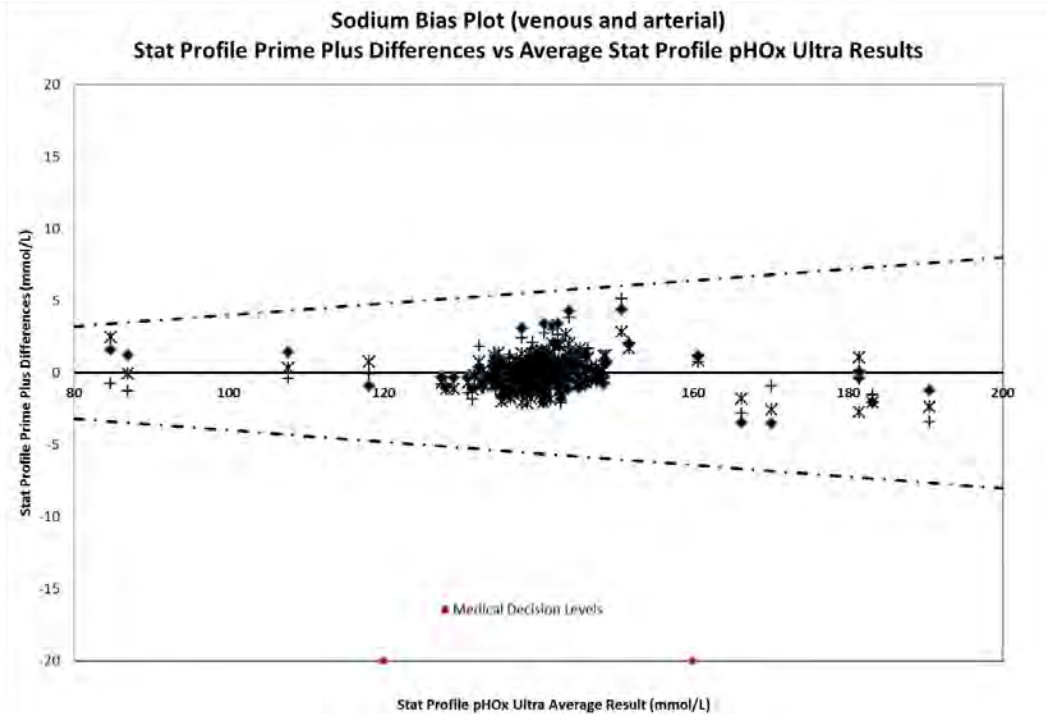

Figure A.5 Sodium Bias Plot

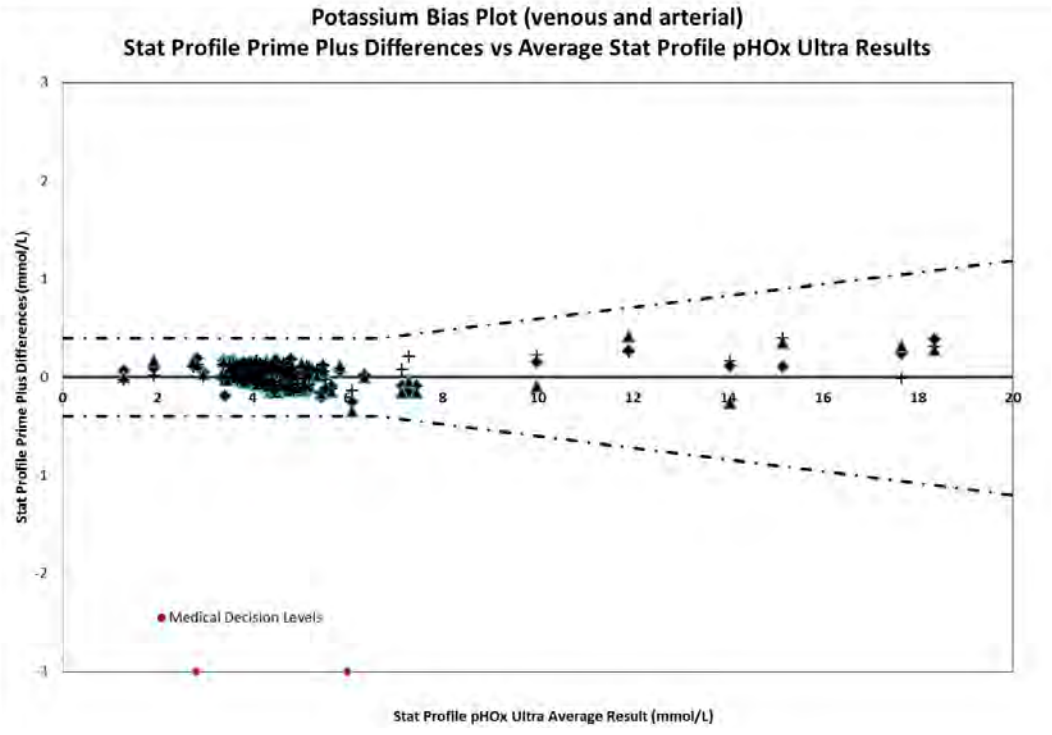

Figure A.6 Potassium Bias Plot

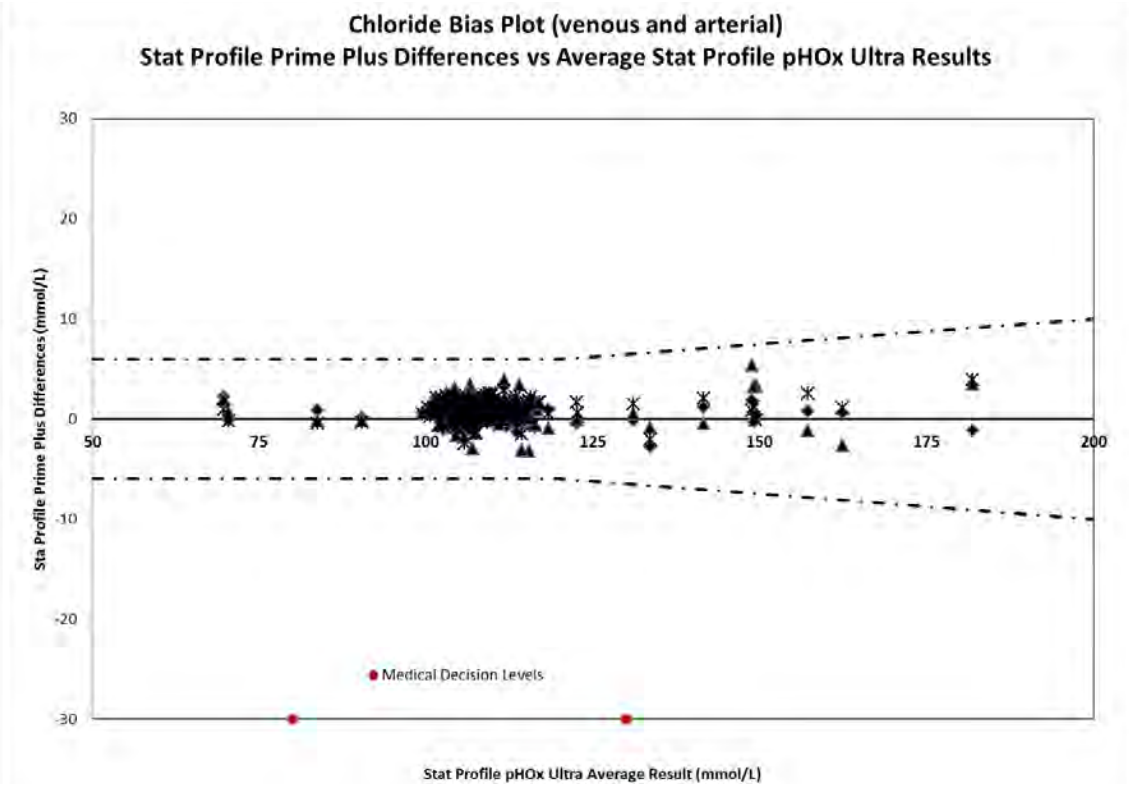

Figure A.7 Chloride Bias Plot

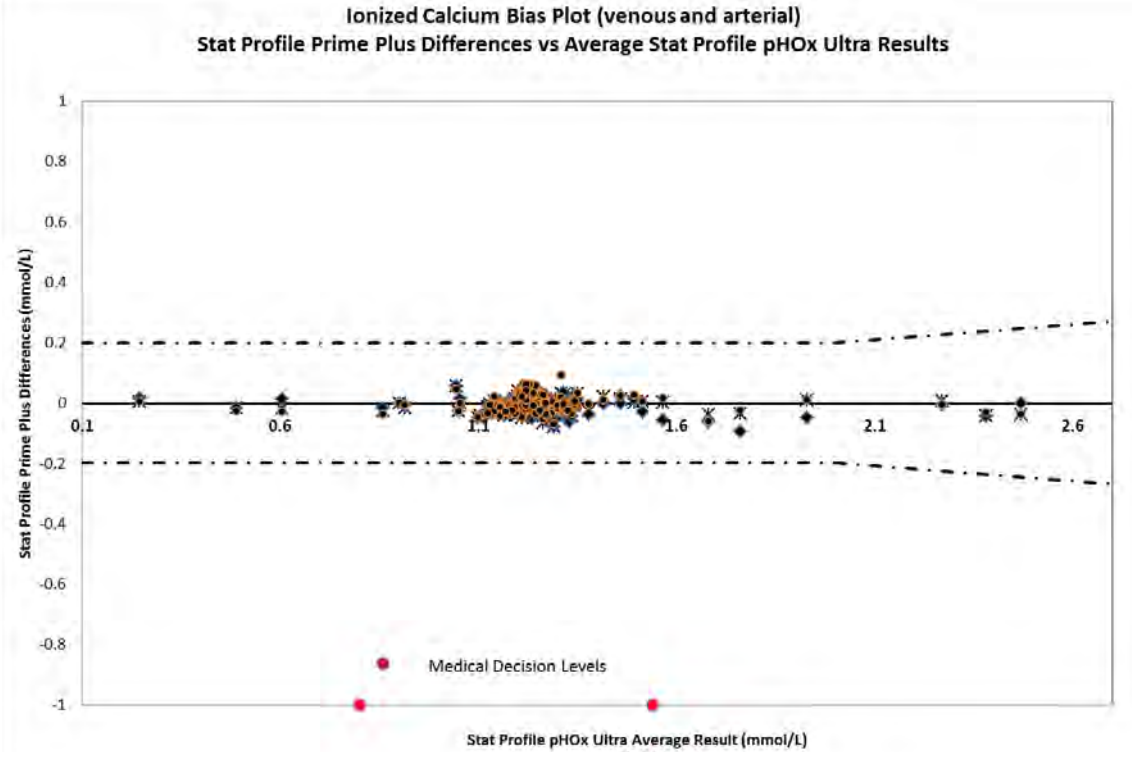

Figure A.8 Ionized Calcium Bias Plot

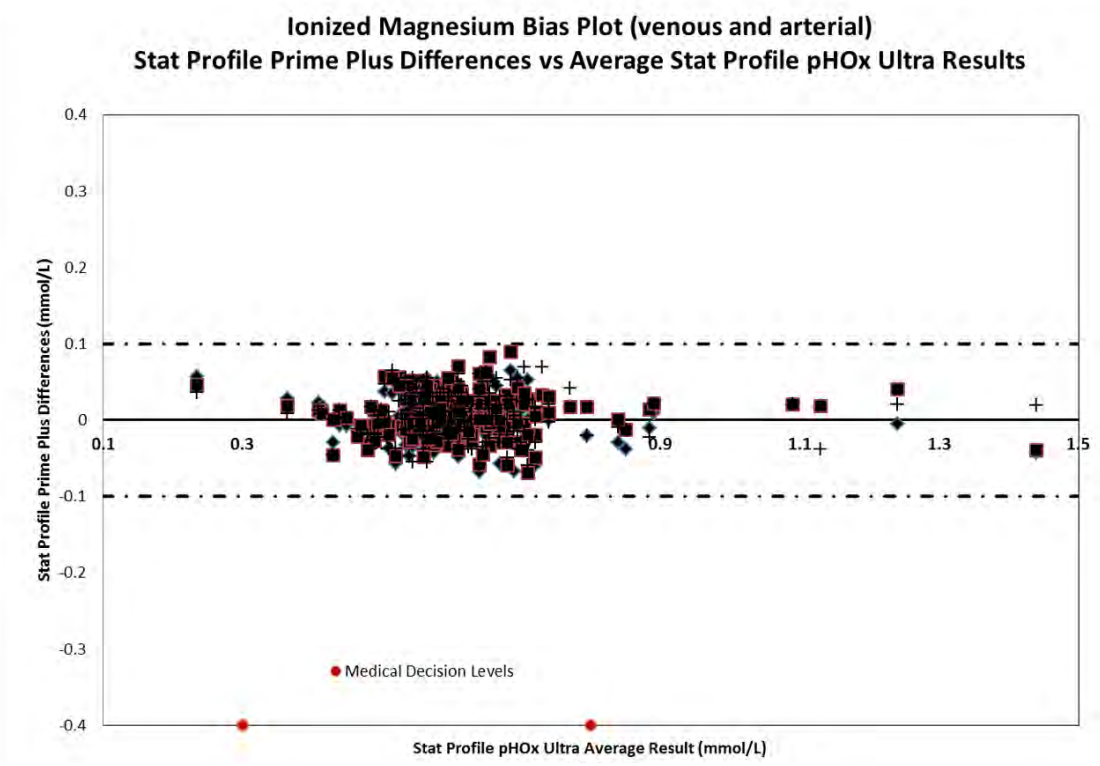

Figure A.9 Ionized Magnesium Bias Plot

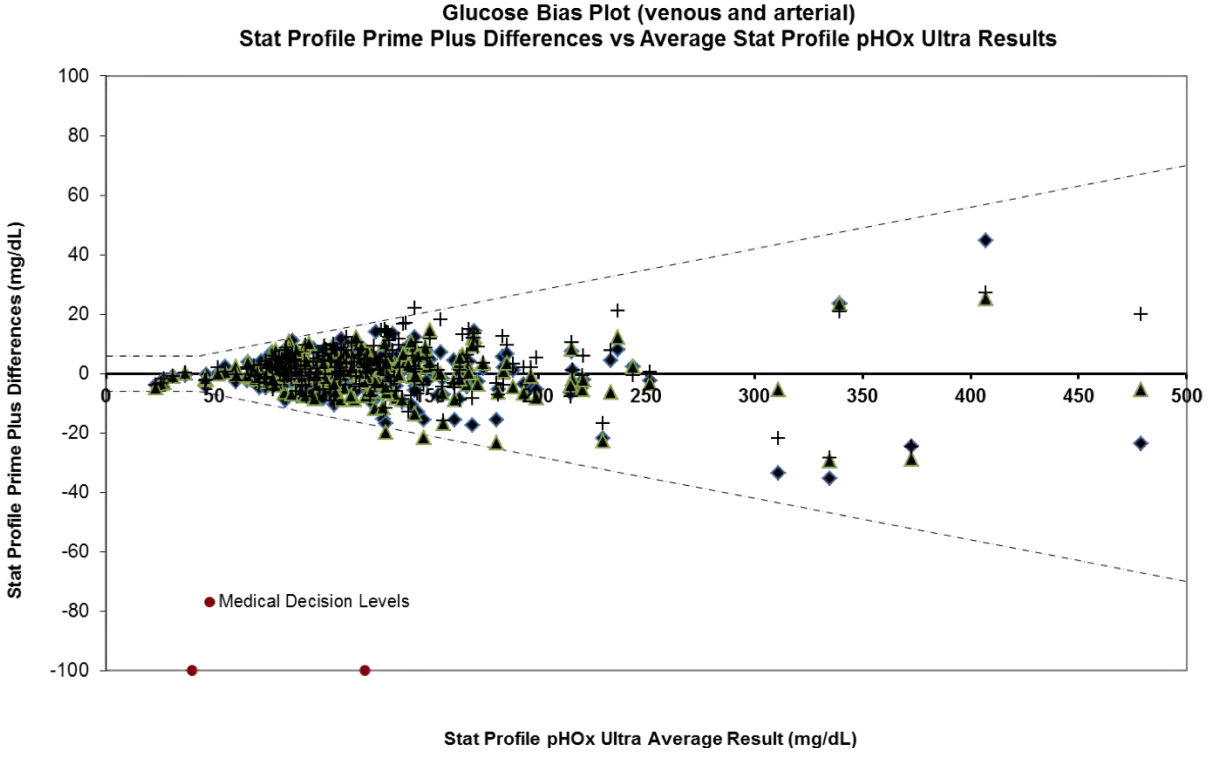

Figure A.10 Glucose Bias Plot

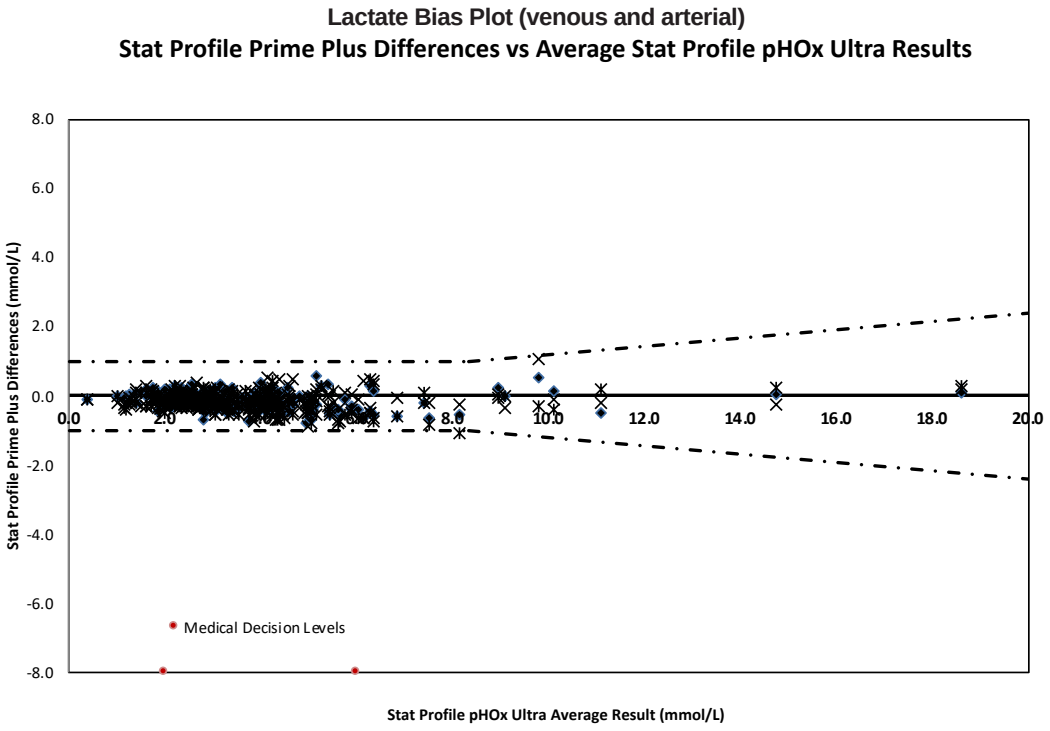

Figure A.11 Lactate Bias Plot

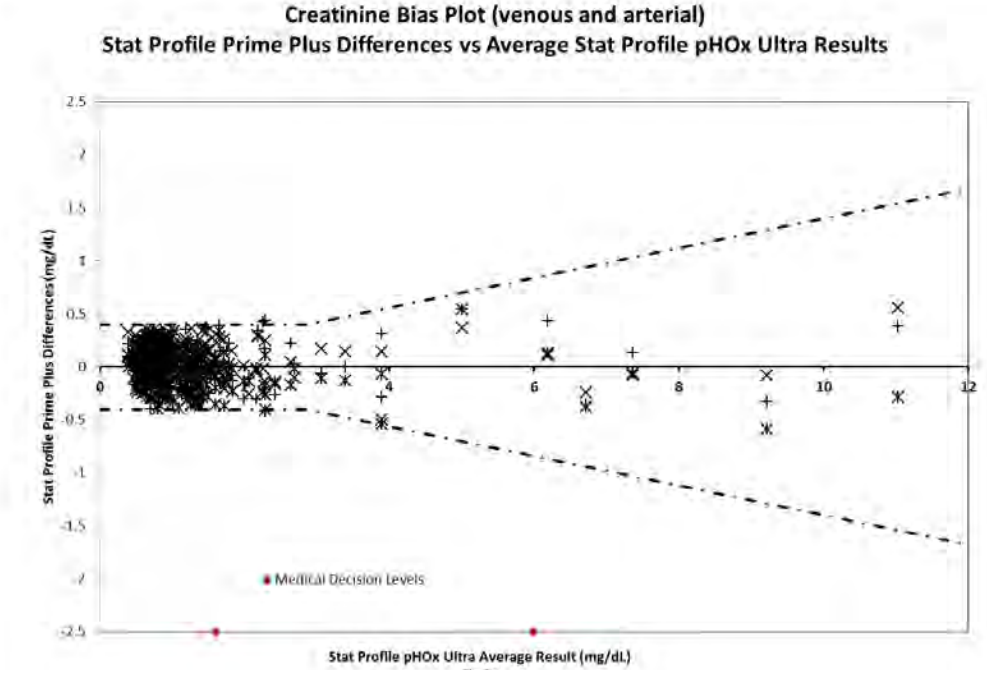

Figure A.12 Creatinine Bias Plot

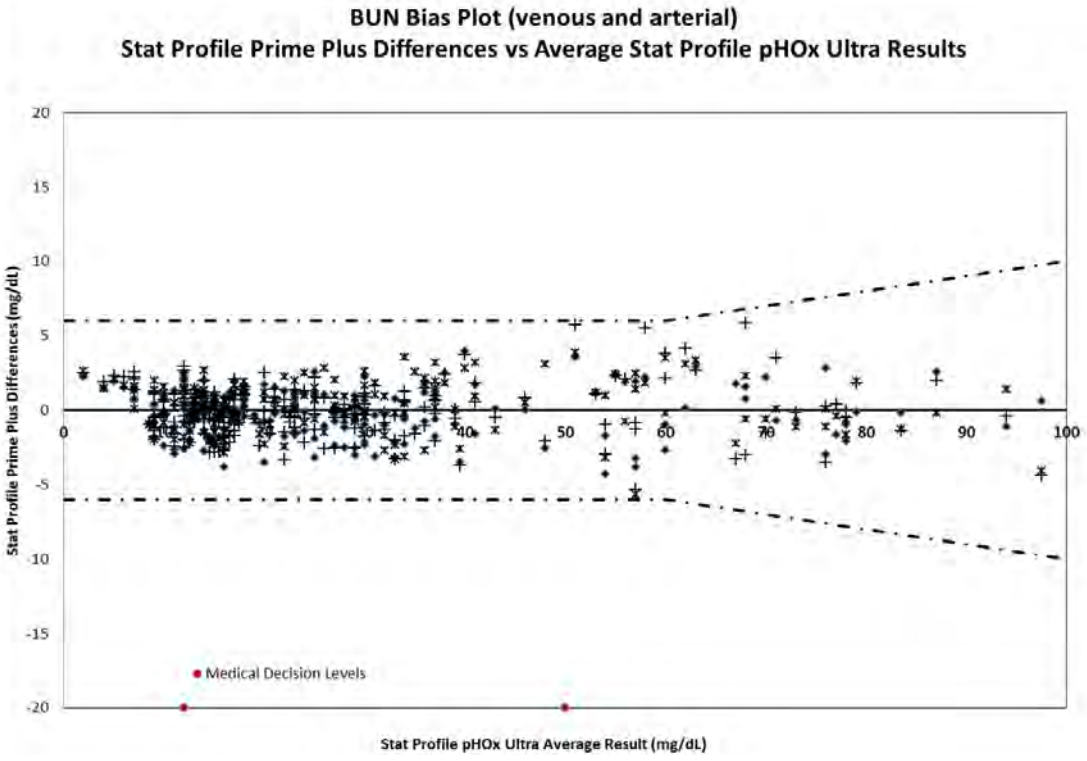

Figure A.13 BUN Bias Plot

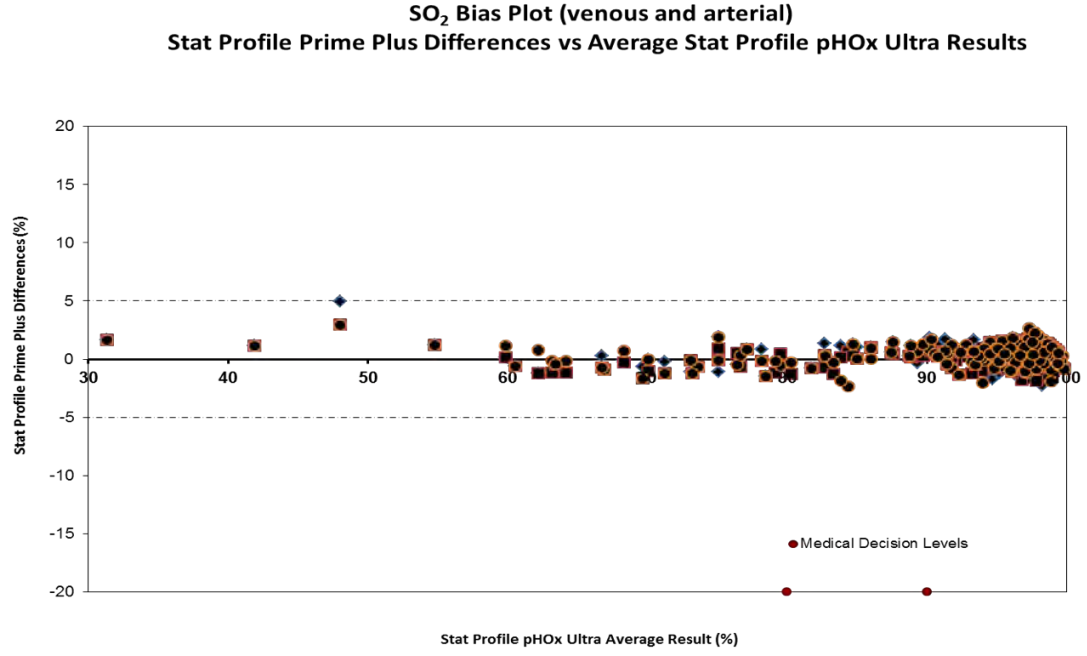

Figure A.14 SO_2 Bias Plot

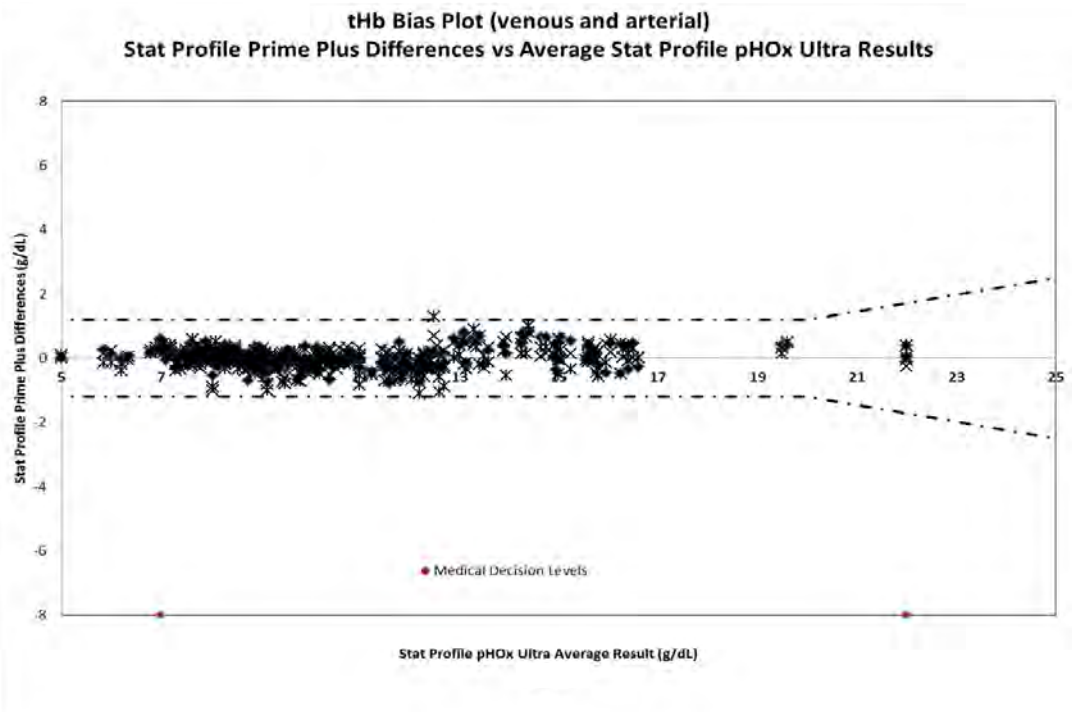

Figure A.15 tHb Bias Plot

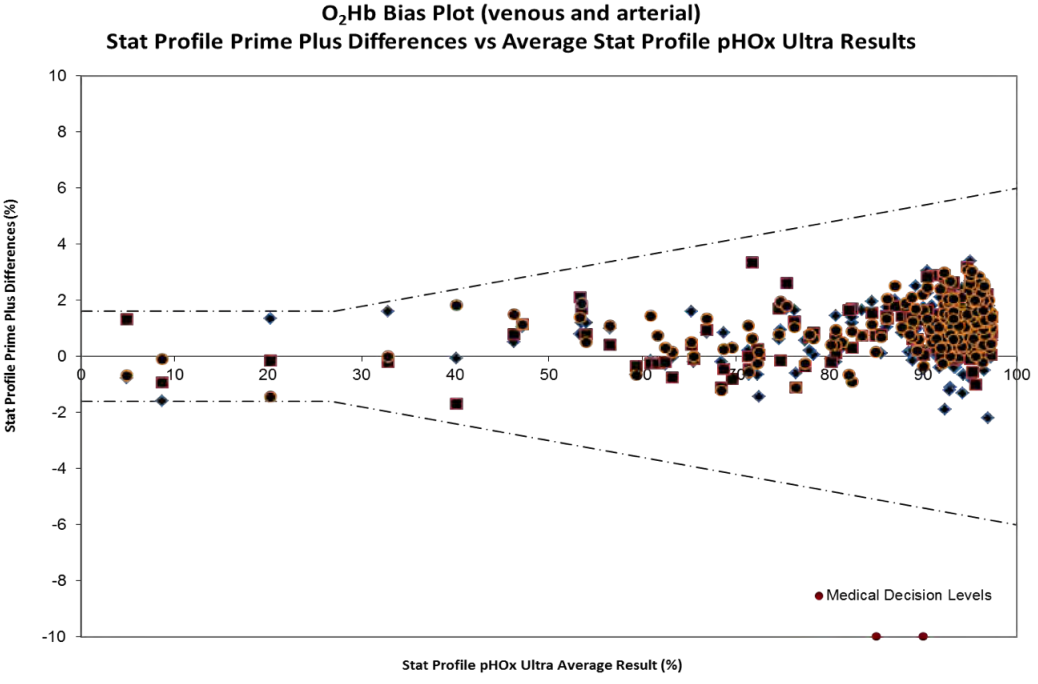

Figure A 16 O_2Hb Bias Plot

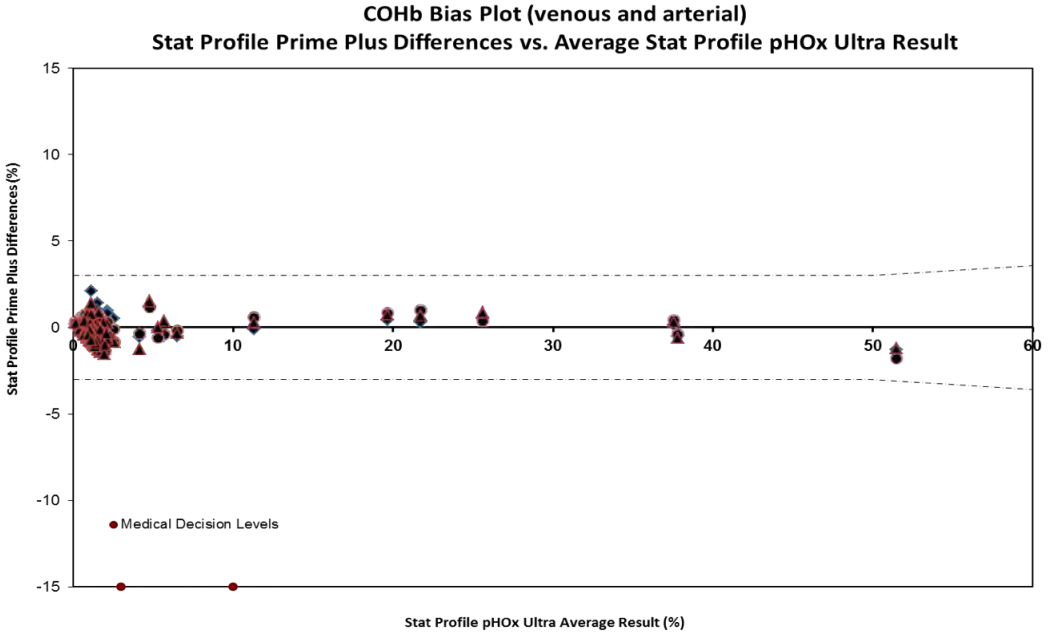

Figure A.17 COHb Bias Plot

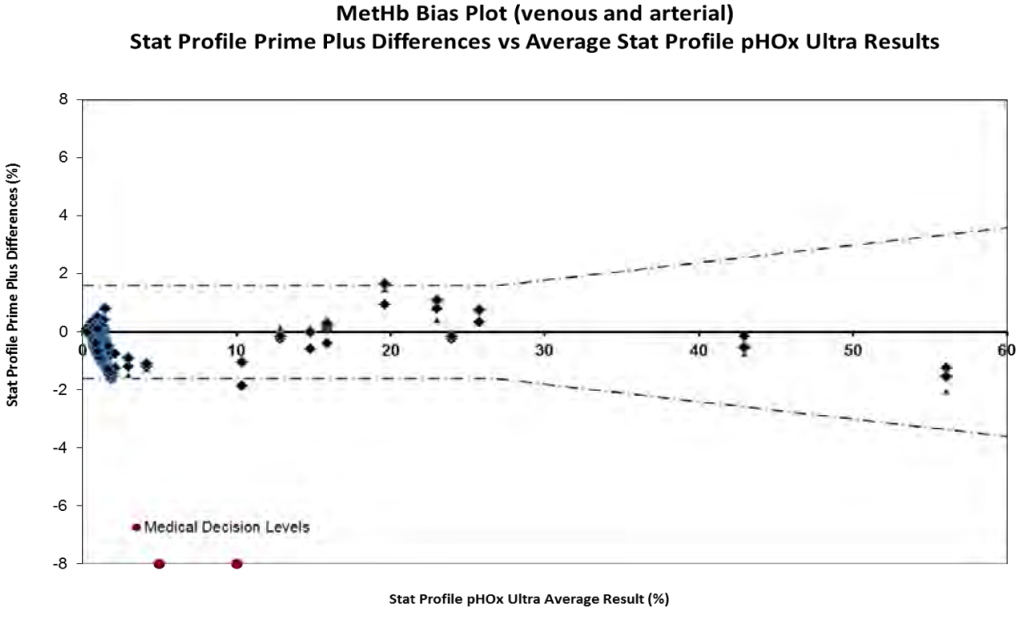

Figure A.18 MetHb Bias Plot

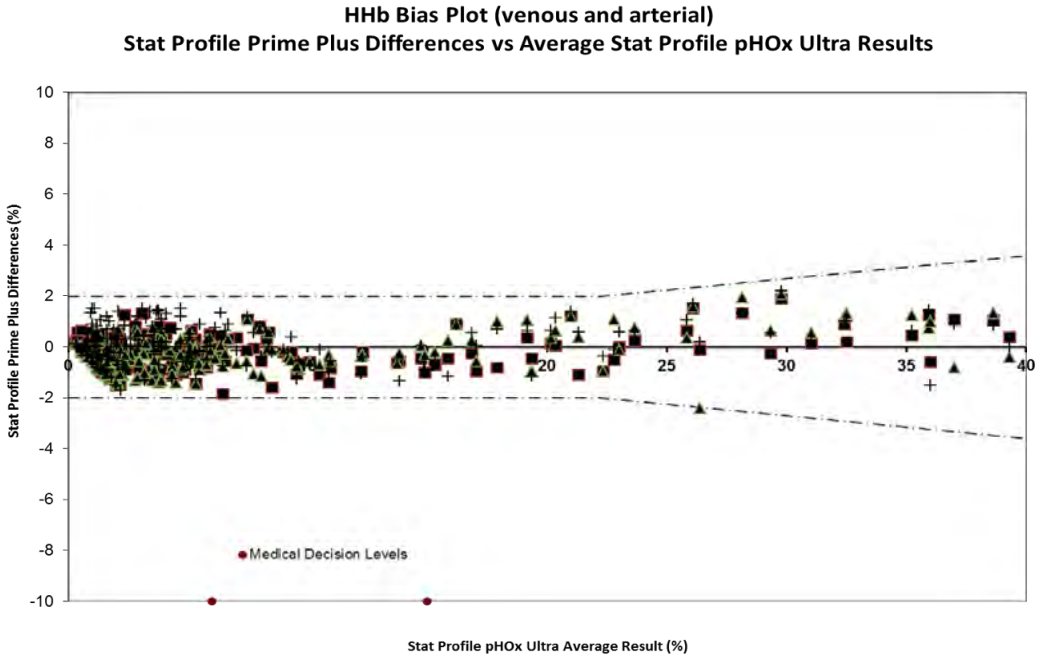

Figure A.19 HHb Bias Plot

Table A-7
Whole Blood Method Comparison: Syringe Samples
Stat Profile Prime Plus vs. pHOx Ultra

Analyte	Analyzer	N	# Altered Samples	Range	Slope	Intercept	r
pH	PP1	210	18	6.841 – 7.980	1.0053	–0.0396	0.9963
	PP2	210	18		0.9995	0.0024	0.9952
	PP3	210	18		0.9932	0.0465	0.9957
pCO_2 (mmHg)	PP1	209	17	5.1 – 193.5	0.9799	0.2799	0.9942
	PP2	209	17		0.9946	0.1253	0.9945
	PP3	209	17		1.0010	–0.6022	0.9955
pO_2 (mmHg)	PP1	204	12	17.2 – 645.1	0.9926	3.2768	0.9985
	PP2	204	12		1.0081	2.4631	0.9988
	PP3	204	12		1.0104	1.3563	0.9980
Hct (%)	PP1	209	17	15 – 67	0.9799	1.3661	0.9931
	PP2	209	17		0.9817	1.2540	0.9910
	PP3	209	17		0.9777	1.4149	0.9909
Na (mmol/L)	PP1	217	11	84.8 – 190.6	0.9836	2.2750	0.9944
	PP2	217	11		0.9834	2.2733	0.9950
	PP3	217	11		1.0024	–0.2753	0.9950
K (mmol/L)	PP1	219	13	1.30 – 18.37	1.0087	–0.0095	0.9988
	PP2	219	13		1.0065	–0.0030	0.9986
	PP3	219	13		1.0121	–0.0192	0.9991
Cl (mmol/L)	PP1	219	13	69.7 – 181.9	0.9829	2.5799	0.9971
	PP2	219	13		1.0050	0.2518	0.9946
	PP3	219	13		1.0154	–0.8345	0.9967
iCa (mmol/L)	PP1	222	16	0.25 – 2.47	0.9953	–0.0015	0.9941
	PP2	222	16		0.9778	0.0177	0.9925
	PP3	222	16		0.9973	–0.0014	0.9928
iMg (mmol/L)	PP1	214	8	0.24 – 1.44	0.9803	0.0139	0.9754
	PP2	214	8		0.9914	0.0135	0.9756
	PP3	214	8		0.9983	0.0079	0.9751
Glu (mg/dL)	PP1	224	18	23 – 479	0.9836	1.7417	0.9915
	PP2	224	18		0.9860	2.1406	0.9932
	PP3	224	18		1.0079	1.2756	0.9929
Creat (mg/dL)	PP1	216	10	0.4 – 11.0	0.9996	0.0474	0.9907
	PP2	216	10		0.9643	0.0222	0.9888
	PP3	216	10		1.0012	0.0393	0.9884
BUN (mg/dL)	PP1	209	14	2.0 – 98.0	1.0009	–0.2409	0.9968
	PP2	209	14		0.9993	0.2195	0.9968
	PP3	209	14		1.0051	–0.2758	0.9961
Lac (mmol/L)	PP1	206	7	0.4 – 18.6	0.9829	–0.0463	0.9932
	PP2	206	7		1.0017	–0.1117	0.9931
	PP3	206	7		0.9887	–0.1599	0.9934

Table A-8
Whole Blood Method Comparison: Syringe Samples (CO-Oximetery)
Stat Profile Prime Plus vs. pHOx Ultra CO-Oximetry

Analyte	Analyzer	N	# Altered Samples	Range	Slope	Intercept	r
SO_2 (%)	PP1	204	11	31 – 100	0.9967	0.5674	0.9971
	PP2	204	11		1.0020	–0.0581	0.9978
	PP3	204	11		1.0008	0.2589	0.9976
tHb (g/dL)	PP1	208	15	5.0 – 22.0	1.0175	–0.1682	0.9951
	PP2	208	15		1.0140	–0.1194	0.9953
	PP3	208	15		1.0088	–0.1675	0.9940
O_2Hb (%)	PP1	209	16	4.9 – 97.4	1.0147	–0.4523	0.9981
	PP2	209	16		1.0227	–0.8887	0.9987
	PP3	209	16		1.0222	–0.7820	0.9987
COHb (%)	PP1	205	12	0.1 – 51.5	0.9995	–0.2700	0.9960
	PP2	205	12		1.0000	–0.2127	0.9985
	PP3	205	12		1.0071	–0.3460	0.9959
MetHb (%)	PP1	208	15	0.2 – 56.1	1.0074	–0.7038	0.9983
	PP2	208	15		1.0119	–0.7047	0.9982
	PP3	208	15		1.0117	–0.5811	0.9974
HHb (%)	PP1	199	6	0.2 – 39.3	1.0203	–0.3452	0.9977
	PP2	199	6		1.0347	–0.4840	0.9979
	PP3	199	6		1.0166	–0.0026	0.9968

A.5.2 Analytical Precision or Repeatability

A.5.2.1 Quality Control Within-Run Precision Performance

The protocol consisted of 20 replicates per run for each of 3 different QC materials on each of the 3 Stat Profile Prime Plus Analyzers. The average, SD, CV%, and *n* for each analyzer for each QC level and parameter were calculated. The pooled average, SD, CV%, and *n* from all 3 analyzers for each QC level and parameter were calculated (Tables A-9 through A-13).

Table A-9
Within-Run Precision Summary
Auto-Cartridge QC Level 1

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
pH	Mean	7.175	7.177	7.175	7.176
	SD	0.001	0.001	0.002	0.002
pCO_2 (mmHg)	Mean	63.0	63.1	60.5	62.2
	SD	0.7	1.0	0.7	1.5
	CV%	1.1	1.6	1.2	2.3
pO_2 (mmHg)	Mean	57.9	56.5	56.5	57.0
	SD	0.7	1.0	1.0	1.1
	CV%	1.2	1.8	1.8	2.0
SO_2 (%)	Mean	50.1	48.8	51.1	50.0
	SD	0.1	0.1	0.1	0.9
Hct (%)	Mean	58	56	58	57
	SD	0.0	0.0	0.0	1.0
tHb (g/dL)	Mean	19	19	19	19
	SD	0.0	0.1	0.1	0.1
	CV%	0.2	0.4	0.3	0.3
O_2Hb (%)	Mean	20.6	20.1	20.5	20.4
	SD	0.1	0.1	0.2	0.3
	CV%	0.4	0.4	0.9	1.3
COHb (%)	Mean	29.8	29.8	28.6	29.4
	SD	0.1	0.2	0.1	0.6
	CV%	0.3	0.6	0.5	2.0
MetHb (%)	Mean	29.0	29.1	28.3	28.8
	SD	0.1	0.1	0.1	0.4
	CV%	0.3	0.3	0.5	1.2
HHb (%)	Mean	20.6	21.1	21.9	21.2
	SD	0.1	0.1	0.1	0.6
	CV%	0.4	0.6	0.4	2.7

Table A-10 Within-Run Precision Summary Auto-Cartridge QC Level 2					
Analyte	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
pH	Mean	7.391	7.391	7.391	7.391
	SD	0.001	0.001	0.001	0.001
pCO_2 (mmHg)	Mean	41.8	42.3	41.6	41.9
	SD	0.1	0.2	0.2	0.3
	CV%	0.2	0.4	0.4	0.8
pO_2 (mmHg)	Mean	90.7	91.1	94.0	91.9
	SD	0.5	0.4	0.5	1.5
	CV%	0.5	0.4	0.5	1.7
SO_2 (%)	Mean	82.8	83.1	83.3	83.1
	SD	0.1	0.1	0.1	0.2
Hct (%)	Mean	44	43	42	43
	SD	0.0	0.4	0.0	0.9
tHb (g/dL)	Mean	16	16	16	16
	SD	0.0	0.1	0.1	0.1
	CV%	0.2	0.4	0.4	0.6
O_2Hb (%)	Mean	52.1	52.5	52.8	52.5
	SD	0.0	0.1	0.1	0.3
	CV%	0.1	0.2	0.2	0.5
COHb (%)	Mean	18.0	18.0	18.5	18.2
	SD	0.1	0.1	0.1	0.3
	CV%	0.5	0.5	0.5	1.4
MetHb (%)	Mean	18.4	18.0	18.4	18.2
	SD	0.2	0.3	0.4	0.3
	CV%	1.0	1.5	2.1	1.9
HHb (%)	Mean	10.8	10.7	10.6	10.7
	SD	0.1	0.1	0.1	0.1
	CV%	0.9	0.9	0.6	1.2

Table A-11 Within-Run Precision Summary Auto-Cartridge QC Level 3					
Analyte	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
pH	Mean	7.598	7.597	7.603	7.599
	SD	0.001	0.001	0.002	0.003
pCO_2 (mmHg)	Mean	20.4	22.7	21.2	21.4
	SD	0.3	0.3	0.4	1.0
	CV%	1.3	1.2	1.7	4.7
pO_2 (mmHg)	Mean	135.0	132.0	135.2	134.1
	SD	0.3	1.5	0.3	1.7
	CV%	0.2	1.2	0.3	1.3
SO_2 (%)	Mean	92.9	92.2	92.6	92.5
	SD	0.1	0.1	0.1	0.3
Hct (%)	Mean	25.0	25.0	24.0	25.0
	SD	0.0	0.0	0.0	0.5
tHb (g/dL)	Mean	7	7	7	7
	SD	0.0	0.0	0.0	0.0
	CV%	0.2	0.3	0.3	0.5
O_2Hb (%)	Mean	82.5	81.7	81.9	82.0
	SD	0.1	0.2	0.1	0.3
	CV%	0.2	0.2	0.1	0.4
COHb (%)	Mean	5.3	5.4	5.5	5.4
	SD	0.1	0.2	0.1	0.2
	CV%	2.8	3.9	2.5	3.4
MetHb (%)	Mean	5.9	5.9	6.0	5.9
	SD	0.2	0.3	0.2	0.3
	CV%	3.9	5.5	4.1	4.5
HHb (%)	Mean	6.3	6.9	6.6	6.6
	SD	0.1	0.1	0.1	0.3
	CV%	1.8	2.0	1.7	4.2

Table A-12 Within-Run Precision Summary Auto-Cartridge QC Level 4					
Analyte	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
Na (mmol/L)	Mean	141.8	141.9	141.9	141.9
	SD	0.1	0.2	0.1	0.2
	CV%	0.1	0.2	0.1	0.1
K (mmol/L)	Mean	4.02	4.02	4.02	4.02
	SD	0.00	0.01	0.00	0.01
	CV%	0.1	0.2	0.1	0.1
Cl (mmol/L)	Mean	127.0	127.0	126.6	126.9
	SD	0.1	0.3	0.2	0.3
	CV%	0.1	0.2	0.1	0.2
iCa (mmol/L)	Mean	0.97	0.97	0.97	0.97
	SD	0.00	0.00	0.00	0.00
	CV%	0.4	0.3	0.2	0.3
iMg (mmol/L)	Mean	0.63	0.64	0.64	0.64
	SD	0.00	0.00	0.01	0.01
	CV%	0.7	0.5	0.9	0.9
Glu (mg/dL)	Mean	87	86	86	86
	SD	0.3	0.0	0.6	0.7
	CV%	0.4	0.0	0.7	0.8
BUN (mg/dL)	Mean	16.4	16.5	16.4	16.4
	SD	0.0	0.1	0.0	0.1
	CV%	0.3	0.4	0.3	0.5
Creat (mg/dL)	Mean	0.7	0.8	0.8	0.8
	SD	0.0	0.0	0.0	0.1
	CV%	0.2	1.3	0.5	7.4
Lac (mmol/L)	Mean	2.0	2.0	2.0	2.0
	SD	0.00	0.00	0.00	0.00
	CV%	0.00	0.00	0.00	0.00

Table A-13 Within-Run Precision Summary Auto-Cartridge QC Level 5					
Analyte	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
Na (mmol/L)	Mean	116.5	116.2	116.7	116.5
	SD	0.1	0.2	0.2	0.2
	CV%	0.1	0.1	0.2	0.2
K (mmol/L)	Mean	6.26	6.22	6.30	6.26
	SD	0.01	0.01	0.04	0.04
	CV%	0.1	0.2	0.7	0.7
Cl (mmol/L)	Mean	97.9	98.1	98.1	98.0
	SD	0.2	0.1	0.1	0.2
	CV%	0.2	0.1	0.1	0.2
iCa (mmol/L)	Mean	1.41	1.39	1.40	1.40
	SD	0.00	0.00	0.01	0.01
	CV%	0.3	0.2	0.6	0.7
iMg (mmol/L)	Mean	1.16	1.17	1.16	1.16
	SD	0.00	0.01	0.01	0.01
	CV%	0.4	0.5	0.9	0.7
Glu (mg/dL)	Mean	302	302	297	300
	SD	0.9	1.0	3.7	3.2
	CV%	0.3	0.3	1.2	1.1
BUN (mg/dL)	Mean	47.4	47.6	47.5	47.5
	SD	0.1	0.1	0.2	0.2
	CV%	0.3	0.3	0.4	0.4
Creat (mmol/L)	Mean	6.7	6.7	6.7	6.7
	SD	0.0	0.0	0.2	0.1
	CV%	0.4	0.5	2.3	1.4
Lac (mmol/L)	Mean	6.9	6.9	6.9	6.9
	SD	0.0	0.0	0.0	0.0
	CV%	0.0	0.0	0.7	0.4

A.5.2.2 Whole Blood Within-Run Precision Performance

Estimates of the whole blood within-run precision were determined in Syringe Mode. For each run, tonometered whole blood was analyzed 20 times on 3 Stat Profile Prime Plus analyzers for a total of 20 results per analyzer. Statistical analyses for each analyzer for Syringe Mode were calculated (Tables A-14 through A-16).

Table A-14
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
pH	Mean	7.114	7.144	7.134	N/A*
	SD	0.004	0.005	0.004	
pH	Mean	7.322	7.324	7.319	7.322
	SD	0.002	0.002	0.002	0.003
pH	Mean	7.323	7.325	7.328	7.325
	SD	0.002	0.001	0.002	0.002
pH	Mean	7.676	7.688	7.702	7.689
	SD	0.005	0.005	0.005	0.012
pCO_2 (mmHg)	Mean	14.8	16.5	16.6	N/A*
	SD	0.3	0.1	0.2	
	CV%	1.9	0.9	1.3	
pCO_2 (mmHg)	Mean	44.5	43.3	44.0	44.0
	SD	0.9	0.4	0.8	0.9
	CV%	2.1	0.9	1.7	2.0
pCO_2 (mmHg)	Mean	51.0	49.4	50.4	50.2
	SD	0.9	0.9	1.0	1.1
	CV%	1.7	1.9	2.0	2.3
pCO_2 (mmHg)	Mean	86.2	79.5	78.8	N/A*
	SD	1.4	0.8	1.1	
	CV%	1.6	1.1	1.4	
pO_2 (mmHg)	Mean	36.7	38.5	38.4	37.9
	SD	1.1	1.0	1.0	1.3
	CV%	3.1	2.7	2.6	3.4
pO_2 (mmHg)	Mean	67.8	64.7	66.5	66.3
	SD	0.9	1.0	1.3	1.7
	CV%	1.3	1.6	2.0	2.5
pO_2 (mmHg)	Mean	95.8	96.7	94.9	N/A*
	SD	0.3	1.0	0.4	
	CV%	0.3	1.0	0.4	
pO_2 (mmHg)	Mean	150.2	144.5	146.9	N/A*
	SD	1.1	0.5	0.6	
	CV%	0.7	0.3	0.4	

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-14 *(continued)*
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
Hct (%)	Mean	49	50	49	49
	SD	0.4	0.5	0.4	0.5
Hct (%)	Mean	42	44	44	N/A*
	SD	0.7	0.2	0.6	
Hct (%)	Mean	46	42	42	N/A*
	SD	0.5	0.4	0.6	
Hct (%)	Mean	28	28	27	28
	SD	0.5	0.8	0.2	0.7
Na (mmol/L)	Mean	160.3	160.4	159.9	160.2
	SD	0.7	0.8	0.4	0.6
	CV%	0.4	0.5	0.2	0.4
Na (mmol/L)	Mean	141.8	141.4	141.7	141.6
	SD	0.2	0.2	0.3	0.2
	CV%	0.1	0.2	0.2	0.2
Na (mmol/L)	Mean	142.4	142.6	142.4	142.5
	SD	0.4	0.3	0.4	0.4
	CV%	0.3	0.2	0.3	0.3
Na (mmol/L)	Mean	120.9	120.6	120.3	120.6
	SD	0.3	0.4	0.4	0.5
	CV%	0.3	0.3	0.4	0.4
K (mmol/L)	Mean	6.50	6.56	6.53	6.53
	SD	0.07	0.08	0.03	0.07
	CV%	1.0	1.2	0.4	1.0
K (mmol/L)	Mean	3.87	3.88	3.86	3.87
	SD	0.04	0.03	0.03	0.04
	CV%	0.9	0.9	0.8	0.9
K (mmol/L)	Mean	4.19	4.17	4.18	4.18
	SD	0.02	0.01	0.01	0.02
	CV%	0.4	0.3	0.3	0.4
K (mmol/L)	Mean	2.58	2.59	2.63	2.60
	SD	0.04	0.06	0.04	0.05
	CV%	1.5	2.4	1.4	2.0

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-14 *(continued)*
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
Cl (mmol/L)	Mean	147.2	147.3	145.7	146.7
	SD	0.7	1.9	1.3	1.6
	CV%	0.5	1.3	0.9	1.1
Cl (mmol/L)	Mean	103.1	103.6	103.3	103.3
	SD	0.3	0.2	0.2	0.3
	CV%	0.3	0.1	0.2	0.3
Cl (mmol/L)	Mean	106.5	107.6	107.3	107.2
	SD	0.5	0.4	0.8	0.7
	CV%	0.5	0.3	0.7	0.7
Cl (mmol/L)	Mean	74.8	72.8	73.7	73.8
	SD	0.7	0.9	0.6	1.1
	CV%	1.0	1.3	0.9	1.5
iCa (mmol/L)	Mean	1.66	1.68	1.67	1.67
	SD	0.01	0.01	0.01	0.01
	CV%	0.9	0.7	0.4	0.8
iCa (mmol/L)	Mean	1.17	1.17	1.18	1.17
	SD	0.00	0.00	0.01	0.01
	CV%	0.3	0.4	0.6	0.5
iCa (mmol/L)	Mean	1.14	1.15	1.13	1.14
	SD	0.00	0.01	0.01	0.01
	CV%	0.4	0.5	0.5	0.7
iCa (mmol/L)	Mean	0.78	0.75	0.78	0.77
	SD	0.01	0.01	0.01	0.01
	CV%	0.8	1.1	1.5	1.9
iMg (mmol/L)	Mean	1.13	1.13	1.14	1.13
	SD	0.02	0.01	0.01	0.01
	CV%	1.7	0.6	0.7	1.1
iMg (mmol/L)	Mean	0.64	0.63	0.64	0.64
	SD	0.01	0.01	0.00	0.01
	CV%	0.9	0.8	0.7	1.0
iMg (mmol/L)	Mean	0.64	0.65	0.65	0.64
	SD	0.01	0.01	0.01	0.01
	CV%	1.0	0.8	1.0	1.2
iMg (mmol/L)	Mean	0.24	0.22	0.24	0.24
	SD	0.01	0.01	0.01	0.01
	CV%	3.6	3.7	2.5	4.9

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-14 *(continued)*
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
Glu (mg/dL)	Mean	159	156	155	157
	SD	4.7	4.6	4.1	4.8
	CV%	2.9	2.9	2.7	3.0
Glu (mg/dL)	Mean	71	70	72	71
	SD	1.6	1.6	1.8	1.9
	CV%	2.3	2.2	2.5	2.6
Glu (mg/dL)	Mean	17	16	16	16
	SD	0.5	0.6	0.7	0.8
	CV%	3.0	4.1	4.4	4.7
Glu (mg/dL)	Mean	111	110	110	110
	SD	1.8	2.0	2.0	2.0
	CV%	1.7	1.9	1.8	1.8
Glu (mg/dL)	Mean	188	185	193	189
	SD	5.0	3.2	4.8	5.5
	CV%	2.6	1.7	2.5	2.9
Glu (mg/dL)	Mean	358	359	360	359
	SD	9.9	10.5	10.8	10.3
	CV%	2.8	2.9	3.0	2.9
BUN (mg/dL)	Mean	14.8	13.3	13.2	13.7
	SD	0.3	0.1	0.1	0.8
	CV%	2.3	1.0	0.9	5.6
BUN (mg/dL)	Mean	19.2	20.4	20.1	19.9
	SD	0.1	0.5	0.2	0.6
	CV%	0.5	2.3	0.8	3.1
BUN (mg/dL)	Mean	25.2	25.9	24.8	25.3
	SD	0.2	0.3	0.4	0.6
	CV%	0.7	1.0	1.5	2.2
BUN (mg/dL)	Mean	11.0	11.0	11.0	11.0
	SD	0.1	0.1	0.1	0.1
	CV%	0.5	0.6	0.7	0.6
BUN (mg/dL)	Mean	75.2	77.2	76.5	76.3
	SD	0.9	0.7	0.8	1.1
	CV%	1.2	0.9	1.0	1.5

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-14 *(continued)*
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
Creat (mg/dL)	Mean	0.5	0.5	0.5	0.5
	SD	0.0	0.0	0.0	0.0
	CV%	4.4	4.9	9.2	7.7
Creat (mg/dL)	Mean	0.7	0.7	0.8	0.8
	SD	0.1	0.1	0.1	0.1
	CV%	12.2	17.8	10.0	16.1
Creat (mg/dL)	Mean	0.4	0.4	0.4	0.4
	SD	0.04	0.00	0.04	0.04
	CV%	10.8	0.0	11.8	9.4
Creat (mg/dL)	Mean	3.2	3.3	3.4	3.3
	SD	0.07	0.07	0.08	0.09
	CV%	2.0	2.0	2.2	2.7
Creat (mg/dL)	Mean	9.2	8.6	8.9	8.9
	SD	0.16	0.14	0.15	0.28
	CV%	1.8	1.6	1.6	3.1
Lac (mmol/L)	Mean	2.0	2.1	2.3	2.2
	SD	0.1	0.1	0.1	0.2
	CV%	6.8	6.8	5.1	8.0
Lac (mmol/L)	Mean	4.8	4.7	4.7	4.7
	SD	0.2	0.1	0.1	0.1
	CV%	3.2	2.6	3.0	3.1
Lac (mmol/L)	Mean	7.4	7.7	7.5	7.5
	SD	0.2	0.2	0.2	0.2
	CV%	3.2	2.9	2.9	3.2
Lac (mmol/L)	Mean	11.0	11.1	10.8	11.0
	SD	0.3	0.2	0.2	0.3
	CV%	2.7	1.9	1.8	2.4
Lac (mmol/L)	Mean	16.7	16.7	16.5	16.6
	SD	0.2	0.3	0.3	0.3
	CV%	1.3	1.5	1.9	1.7

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-15
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
SO_2 (%)	Mean	100	100	100	100
	SD	0.1	0.1	0.1	0.1
SO_2 (%)	Mean	92	92	91	N/A*
	SD	0.2	0.5	0.5	
SO_2 (%)	Mean	80	80	80	N/A*
	SD	0.4	0.2	0.2	
SO_2 (%)	Mean	100	100	100	100
	SD	0.1	0.1	0.1	0.1
tHb (g/dL)	Mean	13.6	13.8	14.2	13.9
	SD	0.1	0.1	0.1	0.3
	CV%	1.1	1.0	0.5	1.9
tHb (g/dL)	Mean	15.1	15.5	15.6	N/A*
	SD	0.2	0.1	0.1	
	CV%	1.4	0.6	0.7	
tHb (g/dL)	Mean	16.3	15.1	14.7	N/A*
	SD	0.1	0.2	0.3	
	CV%	0.9	1.4	1.7	
tHb (g/dL)	Mean	20.3	20.0	20.9	20.4
	SD	0.1	0.1	0.1	0.4
	CV%	0.3	0.5	0.5	1.8
O_2Hb (%)	Mean	91.4	91.4	89.8	90.8
	SD	0.3	0.3	0.2	0.8
	CV%	0.3	0.3	0.3	0.9
O_2Hb (%)	Mean	78.5	79.5	78.7	N/A*
	SD	0.6	0.3	0.5	
	CV%	0.7	0.4	0.6	

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-15 *(continued)*
Within-Run Precision Summary
Whole Blood

Analyte	n = 20	Analyzer 1	Analyzer 2	Analyzer 3	Pooled
O_2Hb (%)	Mean	90.8	90.5	90.2	
	SD	0.5	0.4	0.4	N/A*
	CV%	0.6	0.4	0.5	
O_2Hb (%)	Mean	97.6	97.5	96.4	97.2
	SD	0.2	0.2	0.2	0.6
	CV%	0.2	0.2	0.2	0.6
COHb (%)	Mean	1.5	2.0	2.5	2.0
	SD	0.1	0.2	0.2	0.4
	CV%	9.9	8.4	6.9	21.4
COHb (%)	Mean	1.0	0.5	0.7	
	SD	0.3	0.2	0.3	N/A*
	CV%	29.8	36.9	34.7	
COHb (%)	Mean	0.8	0.7	1.0	
	SD	0.3	0.3	0.3	N/A*
	CV%	38.4	36.9	28.4	
COHb (%)	Mean	6.5	6.3	6.1	6.3
	SD	0.2	0.2	0.2	0.3
	CV%	2.5	3.2	3.6	4.1
MetHb (%)	Mean	0.4	0.4	0.6	0.4
	SD	0.1	0.1	0.1	0.1
	CV%	24.3	17.9	20.5	29.3
MetHb (%)	Mean	0.4	0.4	0.4	
	SD	0.1	0.1	0.1	N/A*
	CV%	18.7	21.9	19.1	
MetHb (%)	Mean	0.4	0.4	0.4	
	SD	0.1	0.1	0.1	N/A*
	CV%	20.2	18.7	21.5	
MetHb (%)	Mean	0.7	0.4	0.9	0.7
	SD	0.1	0.1	0.1	0.2
	CV%	11.6	22.7	13.1	35.6
HHb (%)	Mean	0.5	0.5	0.5	0.5
	SD	0.1	0.1	0.1	0.1
	CV%	13.9	13.9	15.7	14.8
HHb (%)	Mean	20.0	19.7	20.2	
	SD	0.4	0.3	0.3	N/A*
	CV%	1.9	1.5	1.7	

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-15 *(continued)* Within-Run Precision Summary Whole Blood					
Analyte	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
HHb (%)	Mean	8.0	8.4	8.4	N/A*
	SD	0.3	0.2	0.2	
	CV%	3.7	2.4	2.5	
HHb (%)	Mean	0.5	0.6	0.6	0.6
	SD	0.1	0.1	0.1	0.1
	CV%	22.1	18.2	19.3	21.2

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

Table A-16 Within-Run Precision Summary Neonatal Whole Blood					
Analyte	**n = 20**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**	**Pooled**
SO_2 (%)	Mean	99.0	99.1	99.2	99.1
	SD	0.0	0.2	0.4	0.3
tHb (g/dL)	Mean	16.1	15.7	16.6	16.1
	SD	0.1	0.1	0.1	0.4
	CV%	0.5	0.6	0.6	2.3
O_2Hb (%)	Mean	96.3	96.5	93.9	95.6
	SD	0.3	0.2	0.3	1.2
	CV%	0.3	0.3	0.3	1.3
COHb (%)	Mean	4.1	2.6	4.1	3.6
	SD	0.2	0.2	0.3	0.8
	CV%	5.7	8.4	7.6	21.3
MetHb (%)	Mean	0.9	0.4	1.4	0.9
	SD	0.1	0.1	0.1	0.4
	CV%	11.1	27.4	8.2	46.8
HHb (%)	Mean	0.5	0.5	0.5	0.5
	SD	0.0	0.1	0.3	0.2
	CV%	0.0	23.5	52.7	35.0

*Separate, tonometered, whole blood specimens were used for each analyzer; pooled statistics are not available.

A.5.3 Auto-Cartridge QC Solution Total Imprecision Performance

Estimates of the total imprecision were determined by analyzing the following QC solutions in duplicate over a period of 20 days, at 2 runs per day, for a total of 40 runs (Tables A-17 and A-18):

- 3 levels for pH, PCO_2, PO_2, Hct, SO_2, tHb, O_2Hb, COHb, MetHb, and HHb in QC mode.
- 2 levels for Na, K, Cl, iCa, iMg, Glu, BUN, Lac and Creat in QC mode.

Table A-17
Run to Run Imprecision—Auto-Cartridge QC

Sample (QC Level)	Pooled Mean	N	Within Run SD* (SR)	Within Run % CV*	Total Imprecision SD* (St)	Total Imprecision % CV*
pH						
QC Level 1	7.177	240	0.003	---	0.005	---
QC Level 2	7.390	240	0.001	---	0.003	---
QC Level 3	7.599	240	0.001	---	0.005	---
pCO_2						
QC Level 1	62.5	240	0.7	1.2	3.1	4.9
QC Level 2	42.0	240	0.3	0.7	1.6	3.9
QC Level 3	19.5	240	0.2	1.0	0.9	4.4
pO_2						
QC Level 1	61.2	240	1.8	3.0	2.6	4.2
QC Level 2	94.9	240	1.7	1.8	3.0	3.1
QC Level 3	130.4	240	1.8	1.4	2.2	1.7
Hct						
QC Level 1	58	240	0.1	---	0.1	---
QC Level 2	44	240	0.1	---	0.5	---
QC Level 3	25	240	0.2	---	0.2	---
Na						
QC Level 4	141.7	240	0.2	0.2	0.3	0.2
QC Level 5	116.5	240	0.2	0.2	0.3	0.3
K						
QC Level 4	4.02	240	0.01	0.2	0.01	0.2
QC Level 5	6.23	240	0.02	0.3	0.04	0.6
Cl						
QC Level 4	126.4	240	0.4	0.3	1.3	1.0
QC Level 5	99.3	240	0.4	0.4	1.3	1.3
iCa						
QC Level 4	0.97	240	0.00	0.4	0.00	0.0
QC Level 5	1.40	240	0.01	0.7	0.01	0.7

*Acceptance criterion for imprecision is either SD or CV%, whichever is greater.

Table A-17 *(continued)*
Run to Run Imprecision—Auto-Cartridge QC

Sample (QC Level)	Pooled Mean	N	Within Run SD* (SR)	Within Run % CV*	Total Imprecision SD* (St)	Total Imprecision % CV*
iMg						
QC Level 4	0.61	240	0.01	1.6	0.02	3.3
QC Level 5	1.14	240	0.01	0.9	0.03	2.6
Glu						
QC Level 4	87	240	0.8	0.9	1.9	2.2
QC Level 5	312	240	2.9	0.9	5.8	1.9
BUN						
QC Level 4	16.8	240	0.1	0.4	0.5	2.7
QC Level 5	48.7	240	0.4	0.7	1.7	3.6
Creat						
QC Level 4	0.8	240	0.0	1.2	0.0	4.9
QC Level 5	6.7	240	0.1	0.9	0.3	4.9
Lac						
QC Level 4	2.0	240	0.0	1.5	0.1	3.5
QC Level 5	7.0	240	0.1	1.0	0.1	1.4

*Acceptance criterion for imprecision is either SD or CV%, whichever is greater.

Table A-18
Run to Run Imprecision—Auto-Cartridge QC CO-Oximeter

Sample (QC Level)	Pooled Mean	N	Within Run SD* (SR)	Within Run % CV*	Total Imprecision SD* (St)	Total Imprecision % CV *
SO_2						
QC Level 1	49	240	0.6	---	0.8	---
QC Level 2	83	240	0.1	---	0.9	---
QC Level 3	93	240	0.1	---	0.6	---
tHb						
QC Level 1	19.0	240	0.4	2.1	0.5	0.9
QC Level 2	15.9	240	0.0	0.3	0.2	2.0
QC Level 3	6.9	240	0.0	0.3	0.1	1.4
O_2Hb						
QC Level 1	20.2	240	0.2	0.8	0.5	2.5
QC Level 2	52.5	240	0.1	0.1	0.4	0.8
QC Level 3	82.3	240	0.1	0.1	0.5	0.5

*Acceptance criterion for imprecision is either SD or CV%, whichever is greater.

Table A-18 *(continued)* Run to Run Imprecision—Auto-Cartridge QC CO-Oximeter						
Sample (QC Level)	**Pooled Mean**	**N**	**Within Run SD* (SR)**	**Within Run % CV***	**Total Imprecision SD* (St)**	**Total Imprecision % CV ***
COHb						
QC Level 1	29.9	240	0.5	1.5	0.7	2.0
QC Level 2	18.2	240	0.1	0.7	0.5	3.8
QC Level 3	5.4	240	0.1	2.4	0.3	3.9
MetHb						
QC Level 1	28.9	240	0.2	0.7	0.4	0.9
QC Level 2	18.4	240	0.2	0.9	0.3	1.3
QC Level 3	5.8	240	0.2	3.8	0.3	2.1
HHb						
QC Level 1	21	240	0.5	2.4	0.7	3.0
QC Level 2	10.9	240	0.1	0.7	0.6	2.6
QC Level 3	6.4	240	0.1	2.0	0.5	4.8

*Acceptance criterion for imprecision is either SD or CV%, whichever is greater.

Whole Blood Run-to-Run Precision Performance

Estimates of the whole blood run-to-run precision were determined in Syringe Mode (Tables A-19 and A-20). For each run, tonometered whole blood was analyzed in triplicate on 3 Stat Profile Prime Plus analyzers over 10 separate runs for a total of 30 results per analyzer. Statistical analyses for each analyzer for Syringe Mode were calculated.

Table A-19 Run-to-Run Imprecision Summary Whole Blood: Syringe				
Parameter	**n = 30**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**
pH	Mean	7.484	7.482	7.487
	SD	0.010	0.010	0.010
pCO_2 (mmHg)	Mean	29.3	29.7	29.2
	SD	0.6	0.5	0.8
	CV%	1.9	1.5	2.7
pO_2 (mmHg)	Mean	106.7	108.1	109.4
	SD	1.0	1.0	1.6
	CV%	0.9	0.9	1.4
Hct (%)	Mean	48	49	48
	SD	0.5	0.6	0.6
Na (mmol/L)	Mean	158.2	158.2	157.3
	SD	0.4	0.6	0.6
	CV%	0.3	0.4	0.4

Table A-19 *(continued)*
Run-to-Run Imprecision Summary
Whole Blood: Syringe

Parameter	n = 30	Analyzer 1	Analyzer 2	Analyzer 3
Na (mmol/L)	Mean	146.4	146.0	146.5
	SD	0.8	1.6	0.6
	CV%	0.6	1.1	0.4
Na (mmol/L)	Mean	118.9	119.5	119.7
	SD	0.4	0.3	0.7
	CV%	0.4	0.2	0.6
K (mmol/L)	Mean	4.85	4.84	4.85
	SD	0.05	0.08	0.05
	CV%	0.9	1.7	1.0
K (mmol/L)	Mean	3.49	3.48	3.39
	SD	0.08	0.08	0.04
	CV%	2.26	2.19	1.29
K (mmol/L)	Mean	2.55	2.53	2.57
	SD	0.04	0.03	0.03
	CV%	1.7	1.4	1.2
Cl (mmol/L)	Mean	121.3	121.2	120.5
	SD	0.6	0.8	0.7
	CV%	0.5	0.7	0.6
Cl (mmol/L)	Mean	103.5	103.6	103.7
	SD	0.3	0.5	0.3
	CV%	0.3	0.5	0.3
Cl (mmol/L)	Mean	89.4	90.0	90.3
	SD	0.4	0.8	0.4
	CV%	0.5	0.9	0.5
iCa (mmol/L)	Mean	1.62	1.61	1.60
	SD	0.01	0.02	0.01
	CV%	0.6	1.2	0.6
iCa (mmol/L)	Mean	1.19	1.19	1.18
	SD	0.01	0.01	0.01
	CV%	0.51	0.74	0.68
iCa (mmol/L)	Mean	0.96	0.96	0.96
	SD	0.00	0.01	0.00
	CV%	0.5	0.6	0.4
iMg (mmol/L)	Mean	0.90	0.88	0.87
	SD	0.01	0.01	0.01
	CV%	1.4	1.7	1.6
iMg (mmol/L)	Mean	0.64	0.63	0.64
	SD	0.00	0.01	0.01
	CV%	0.6	1.0	0.9

Table A-19 *(continued)*
Run-to-Run Imprecision Summary
Whole Blood: Syringe

Parameter	n = 30	Analyzer 1	Analyzer 2	Analyzer 3
iMg (mmol/L)	Mean	0.42	0.42	0.42
	SD	0.01	0.01	0.01
	CV%	1.5	1.2	1.3
Glu (mg/dL)	Mean	79	79	67
	SD	2.4	2.6	3.2
	CV%	3.0	3.3	4.8
Glu (mg/dL)	Mean	28	26	28
	SD	1.5	1.5	1.5
	CV%	5.3	5.7	5.3
Glu (mg/dL)	Mean	103	106	103
	SD	2.4	2.3	2.7
	CV%	2.4	2.2	2.7
Glu (mg/dL)	Mean	203	208	207
	SD	4.1	3.1	5.1
	CV%	2.0	1.5	2.5
Glu (mg/dL)	Mean	374	378	378
	SD	6.2	6.0	8.9
	CV%	1.7	1.6	2.4
BUN (mg/dL)	Mean	11.2	11.7	11.7
	SD	0.1	0.2	0.3
	CV%	0.9	1.3	2.1
BUN (mg/dL)	Mean	4.0	3.9	3.9
	SD	0.1	0.1	0.1
	CV%	1.3	2.0	1.5
BUN (mg/dL)	Mean	25.0	24.7	25.1
	SD	0.3	0.2	0.1
	CV%	1.1	0.9	0.5
BUN (mg/dL)	Mean	73.2	73.8	75.1
	SD	1.3	1.2	1.2
	CV%	1.8	1.7	1.7
Creat (mg/dL)	Mean	0.6	0.5	0.4
	SD	0.0	0.0	0.0
	CV%	4.1	4.4	2.6
Creat (mg/dL)	Mean	0.3	0.3	0.3
	SD	0.05	0.06	0.06
	CV%	17.0	16.6	18.2
Creat (mg/dL)	Mean	1.3	1.2	1.1
	SD	0.12	0.06	0.03
	CV%	9.0	5.5	2.3

Table A-19 *(continued)* Run-to-Run Imprecision Summary Whole Blood: Syringe				
Parameter	**n = 30**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**
Creat (mg/dL)	Mean	8.4	9.1	9.2
	SD	0.28	0.29	0.34
	CV%	3.4	3.2	3.7
Creat (mg/dL)	Mean	0.3	0.3	0.3
	SD	0.05	0.06	0.06
	CV%	17.0	16.6	18.2
Lac (mmol/L)	Mean	1.4	1.4	1.4
	SD	0.2	0.2	0.2
	CV%	13.3	14	14.7
Lac (mmol/L)	Mean	4.9	4.8	4.8
	SD	0.2	0.2	0.2
	CV%	4.7	4.1	4.1
Lac (mmol/L)	Mean	7.1	6.9	7.4
	SD	0.3	0.5	0.2
	CV%	4.5	7.4	3.1
Lac (mmol/L)	Mean	12.1	11.2	12.2
	SD	0.6	0.5	0.4
	CV%	4.6	4.8	3.1
Lac (mmol/L)	Mean	17.4	17.2	17.2
	SD	0.3	0.3	0.3
	CV%	2.0	1.7	1.5

Table A-20 Run-to-Run Imprecision Summary—CO-Oximeter Whole Blood (Syringe)				
Parameter	**n = 30**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**
SO_2 (%)	Mean	99.0	98.0	99.0
	SD	0.3	0.0	0.2
tHb (g/dL)	Mean	14.6	14.5	14.8
	SD	0.0	0.2	0.1
	CV%	0.3	1.1	0.7
O_2Hb (%)	Mean	98.0	96.6	97.6
	SD	0.3	0.3	0.4
	CV%	0.3	0.3	0.4

Table A-20 *(continued)* Run-to-Run Imprecision Summary—CO-Oximeter Whole Blood (Syringe)				
Parameter	**n = 30**	**Analyzer 1**	**Analyzer 2**	**Analyzer 3**
COHb (%)	Mean	0.6	0.9	1.0
	SD	0.2	0.3	0.2
	CV%	40.1	33.4	19.1
MetHb (%)	Mean	0.4	0.5	0.4
	SD	0.1	0.1	0.1
	CV%	20.9	21.1	22.1
HHb (%)	Mean	1.2	2.0	1.1
	SD	0.2	0.2	0.2
	CV%	20.5	11.5	21.1

A.5.4 Within-Sample Imprecision – Capillary Mode Fingerstick (Internal POC Site)

An internal precision study was performed in the Nova Customer Simulation Laboratory using a single Stat Profile Prime Plus analyzer. Capillary whole blood was collected via fingerstick puncture and run by two (2) point-of-care (POC) operators (Nurse and Respiratory Therapist).

Sample Collection and Data Analysis

Capillary whole blood was collected from consenting donors via fingerstick puncture into two (2) 115uL balanced heparinized capillary tubes per donor.

The whole blood from each capillary pair was analyzed by the POC operators in capillary mode on one Prime Plus analyzer and the results compared.

The pooled average, SD, and CV% for all sample pairs was calculated and compared to the defined imprecision specifications (Table A-21).

Table A-21 Within-Sample Imprecision Summary				
Analyte	**Mean**	**N**	**Within-Sample SD**	**Within-Sample CV%**
pH	7.403	60	0.008	N/A
pO_2 (mmHg)	81.8	60	2.2	2.7
pCO_2 (mmHg)	32.0	60	1.0	3.0
Hct (%)	41	60	1.0	N/A
Na (mM)	139.5	60	0.8	0.6
K (mM)	4.75	60	0.17	3.5
Cl (mM)	109.9	60	0.6	0.6
Ca (mM)	1.20	60	0.01	0.9
Mg (mM)	0.54	60	0.01	1.1
Glu (mg/dL)	109	60	1.6	1.5
Lac (mM)	1.7	60	0.2	12.4

A.5.5 Within-Run Imprecision – Capillary Mode Fingerstick (External POC Site)

A precision study was performed at an external site – Tampa General Hospital, Florida. using discarded specimens transferred from a lithium heparin syringe to a capillary tube by POC (Point-of-Care) operators.

The study used one Prime Plus Analyzer, de-identified and discarded arterial blood specimens, Auto QC, Calibrator cartridge, sensor card/cartridge and 115 µL balanced heparin capillary tubes.

Sample Analysis

Each whole blood specimen was transferred from a syringe to three balanced heparin capillary tubes and analyzed in Capillary Micro mode on the Stat Profile Prime Plus Analyzer by one POC operator. The samples were recorded.

Data Analysis

The mean, standard deviation (SD) and coefficient of variation (CV%) of the triplicate results of each analyte in each sample were calculated (Table A-22).

Table A-22 Within-Run Imprecision Summary

Analyte	Unit	Grand Mean	Grand SD	Grand CV%
pH	pH units	7.357	0.008	N/A
pO_2	mmHg	37.2	0.7	1.9
pCO_2	mmHg	145.6	2.1	1.5
Hct	%	31.5	1.2	N/A
Na	mmol/L	135.1	0.8	0.6
K	mmol/L	3.94	0.04	0.9
Cl	mmol/L	110.1	0.8	0.8
Ca	mmol/L	1.14	0.01	1.2
Mg	mmol/L	0.51	0.01	2.5
Glu	mg/dL	128	1.8	1.4
Lac	mmol/L	3.1	0.1	4.6

A.6 Point-of-Care Usage Performance Studies

The Stat Profile Prime Plus analyzer may be used in point-of-care settings. The analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a Cardiothoracic Intensive Care Unit (CTICU), an Emergency Department (ED) and a Respiratory Therapy Lab (RT). A total of 61 respiratory care, 12 nursing, and 1 exercise physiology POC personnel participated in the testing within the 3 POC setting sites on 3 Stat Profile Prime Plus analyzers. The personnel represent trained, qualified staff found in typical POC sites where blood gas analyzers are utilized.

A.6.1 Within Run Precision/Reproducibility Study Design

The within run precision test data included in the following tables were obtained from different POC personnel running 20 replicates of test materials consisting of a combination of available Quality Control and Linearity materials to cover the analyte measurement ranges on a Stat Profile Prime Plus 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 are representative of the expected within run precision performance obtainable by POC personnel using the Stat Profile Prime Plus analyzer utilizing external quality control and linearity materials.

Table A-23 Within Run Precision/Reproducibility Results
Point-of-Care Study: CTICU
Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)

Parameter	Mean	SD	%CV	95% CI
Blood Gas Quality Control, Level 1				
pH	7.233	0.008	N/A	7.218 – 7.248
pCO_2 (mmHg)	56.7	1.5	2.6	53.7 – 59.6
pO_2 (mmHg)	73.5	2.7	3.7	68.1 – 78.9
Hct (%)	60	0.7	1.2	59 – 61
SO_2 (%)	48	0.9	1.8	46.4 – 49.9
tHb (g/dL)	19.7	0.3	1.7	19 – 20.4
O_2Hb (%)	21.0	0.4	2.0	20 – 22
COHb (%)	29.0	0.3	0.9	28.5 – 29.6
MetHb (%)	27.4	0.1	0.4	27.2 – 27.6
HHb (%)	22.6	0.2	0.9	22.2 – 23
Blood Gas Quality Control, Level 2				
pH	7.435	0.003	N/A	7.428 – 7.441
pCO_2 (mmHg)	37.7	0.4	1.0	36.9 – 38.4
pO_2 (mmHg)	114.0	0.8	0.7	112.5 – 115.5
Hct (%)	38	0.0	0.0	38 – 38
SO_2 (%)	78	0.0	0.0	78 – 78
tHb (g/dL)	12.9	0.1	1.0	12.6 – 13.1
O_2Hb (%)	47.3	0.1	0.3	47 – 48

Table A-23 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: CTICU Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
COHb (%)	21.7	0.2	1.0	21.3 – 22.1
MetHb (%)	17.5	0.3	1.7	16.9 – 18.1
HHb (%)	13.5	0.1	0.9	13.2 – 13.7
Blood Gas Quality Control, Level 3				
pH	7.619	0.012	N/A	7.595 – 7.644
pCO_2 (mmHg)	20.1	0.9	4.7	18.2 – 22
pO_2 (mmHg)	149.8	2.2	1.4	145.5 – 154.1
Hct (%)	27	0.5	1.9	25 – 28
SO_2 (%)	90	0.5	0.5	89.4 – 91.3
tHb (g/dL)	6.2	0.1	1.9	5.9 – 6.4
O_2Hb (%)	80.1	0.1	0.1	80 – 80
COHb(%)	6.6	0.1	1.6	6.4 – 6.8
MetHb(%)	5.0	0.2	4.0	4.6 – 5.4
HHb (%)	8.4	0.2	1.9	8.1 – 8.7
Linearity, Level 1				
pH	6.737	0.007	N/A	6.723 – 6.751
pCO_2 (mmHg)	130.4	4.1	3.1	122.3 – 138.5
pO_2 (mmHg)	33.7	1.4	4.2	30.8 – 36.5
Linearity, Level 4				
pH	7.725	0.012	N/A	7.701 – 7.749
pCO_2 (mmHg)	20.2	0.4	1.8	19.4 – 20.9
pO_2 (mmHg)	482.0	11.8	2.4	458.4 – 505.7
Linearity, Level 2				
Hct (%)	29	0.0	0.0	29 – 29
Linearity, Level 3				
Hct (%)	47	0.0	0.0	47 – 47

Table A-24 Within Run Precision/Reproducibility Results Point-of-Care Study: CTICU Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Chemistry Quality Control, Level 4				
Na (mmol/L)	137.0	0.0	0.0	137 – 137
K (mmol/L)	3.90	0.00	0.0	3.90 – 3.90
Cl (mmol/L)	120.3	0.9	0.8	118.5 – 122.1
Ca (mmol/L)	1.06	0.00	0.3	1.05 – 1.07
Mg (mmol/L)	0.62	0.00	0.0	0.62 – 0.62
Glu (mg/dL)	81	0.0	0.0	81 – 81
Lac (mmol/L)	1.4	0.1	8.5	1.2 – 1.7
BUN (mg/dL)	16.0	0.0	0.0	16 – 16
Creat (mg/dL)	1.2	0.03	2.6	1.1 – 1.3
Linearity, Level 1				
Na (mmol/L)	89.0	2.0	2.2	85.1 – 92.9
K (mmol/L)	1.57	0.05	3.0	1.48 – 1.66
Cl (mmol/L)	58.5	1.6	2.7	55.3 – 61.7
Ca (mmol/L)	2.40	0.02	0.7	2.37 – 2.44
Mg (mmol/L)	1.46	0.02	1.4	1.42 – 1.5
Glu (mg/dL)	428	3.5	0.8	421.2 – 435.1
Lac (mmol/L)	0.4	0.0	0.0	0.4 – 0.4
Linearity, Level 4				
Na (mmol/L)	171.6	0.8	0.4	170 – 173.1
K (mmol/L)	11.83	0.08	0.7	11.67 – 11.99
Cl (mmol/L)	131.8	0.5	0.4	130.8 – 132.8
Ca (mmol/L)	0.46	0.01	1.3	0.45 – 0.48
Mg (mmol/L)	0.23	0.00	1.6	0.22 – 0.24
Glu (mg/dL)	34	0.5	1.5	33.4 – 35.5
Lac (mmol/L)	17.3	0.3	1.7	16.7 – 17.9

Table A-24 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: CTICU Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Linearity, Level 2				
BUN (mg/dL)	49.9	0.9	1.7	48.2 – 51.6
Creat (mg/dL)	7.2	0.11	1.5	7 – 7.5
Linearity, Level 3				
BUN (mg/dL)	24.8	0.4	1.7	24 – 25.6
Creat (mg/dL)	5.1	0.07	1.3	5 – 5.3

Table A-25 Within Run Precision/Reproducibility Results Point-of-Care Study: Emergency Department Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Blood Gas Quality Control, Level 1				
pH	7.227	0.008	N/A	7.211 – 7.244
pCO_2 (mmHg)	63.2	2.2	3.4	58.9 – 67.6
pO_2 (mmHg)	78.2	1.1	1.5	75.9 – 80.5
Hct (%)	61	0.0	0.0	61 – 61
SO_2 (%)	47	0.6	1.4	45.8 – 48.4
tHb (g/dL)	19.9	0.2	1.0	19.5 – 20.3
O_2Hb (%)	20.3	0.3	1.5	20 – 21
COHb(%)	29.2	0.2	0.6	28.9 – 29.6
MetHb(%)	27.8	0.1	0.2	27.7 – 27.9
HHb (%)	22.7	0.2	0.7	22.4 – 23
Blood Gas Quality Control, Level 2				
pH	7.420	0.003	N/A	7.414 – 7.426
pCO_2 (mmHg)	38.9	0.7	1.9	37.4 – 40.3
pO_2 (mmHg)	115.0	1.2	1.0	112.6 – 117.3
Hct (%)	38	0.0	0.0	38 – 38

Table A-25 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: Emergency Department Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Blood Gas Quality Control, Level 2 (Continued)				
SO_2 (%)	78	0.0	0.0	78 – 78
tHb (g/dL)	13.0	0.2	1.3	12.7 – 13.4
O_2Hb (%)	47.0	0.2	0.4	47 – 47
COHb(%)	21.3	0.2	0.9	20.9 – 21.7
MetHb(%)	18.5	0.2	0.8	18.2 – 18.8
HHb (%)	13.2	0.1	0.8	13 – 13.4
Blood Gas Quality Control, Level 3				
pH	7.616	0.006	N/A	7.605 – 7.627
pCO_2 (mmHg)	20.2	0.2	1.0	19.8 – 20.6
pO_2 (mmHg)	145.7	2.5	1.7	140.7 – 150.7
Hct (%)	27	0.2	0.8	27 – 27
SO_2 (%)	91	0.0	0.0	91 – 91
tHb (g/dL)	6.6	0.1	2.0	6.3 – 6.8
O_2Hb (%)	80.1	0.1	0.1	80 – 80
COHb(%)	6.2	0.1	1.4	6 – 6.4
MetHb(%)	5.7	0.1	2.4	5.5 – 6
HHb (%)	7.9	0.1	1.5	7.7 – 8.2
Linearity, Level 1				
pH	6.754	0.012	N/A	6.729 – 6.778
pCO_2 (mmHg)	118.6	3.9	3.3	110.8 – 126.4
pO_2 (mmHg)	44.7	2.2	4.9	40.3 – 49.1
Linearity, Level 4				
pH	7.726	0.004	N/A	7.718 – 7.735
pCO_2 (mmHg)	18.7	0.1	0.5	18.5 – 18.9
pO_2 (mmHg)	476.4	6.4	1.3	463.6 – 489.1

Table A-25 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: Emergency Department Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Linearity, Level 2				
Hct (%)	29	0.0	0.0	29 – 29
Linearity, Level 3				
Hct (%)	47	0.0	0.0	47 – -47

Table A-26 Within Run Precision/Reproducibility Results Point-of-Care Study: Emergency Department Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Chemistry Quality Control, Level 4				
Na (mmol/L)	137.1	0.3	0.2	136.5 – 137.7
K (mmol/L)	3.93	0.04	1.1	3.84 – 4.01
Cl (mmol/L)	122.9	0.4	0.4	122 – 123.8
Ca (mmol/L)	1.06	0.02	1.6	1.03 – 1.09
Mg (mmol/L)	0.61	0.01	1.0	0.59 – 0.62
Glu (mg/dL)	81	1.4	1.7	78.1 – 83.5
Lac (mmol/L)	1.7	0.0	2.9	1.6 – 1.8
BUN (mg/dL)	16.5	0.5	3.1	15.4 – 17.5
Creat (mg/dL)	1.2	0.04	3.1	1.1 – 1.3
Linearity Level 1				
Na (mmol/L)	90.8	1.0	1.0	88.9 – 92.7
K (mmol/L)	1.69	0.03	1.8	1.63 – 1.75
Cl (mmol/L)	61.1	1.1	1.8	58.9 – 63.3
Ca (mmol/L)	2.28	0.02	0.9	2.23 – 2.32
Mg (mmol/L)	1.27	0.04	3.4	1.18 – 1.35
Glu (mg/dL)	446	5.5	1.2	434.6 – 456.8
Lac (mmol/L)	0.4	0.0	9.5	0.3 – 0.5

Table A-26 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: Emergency Department Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Linearity Level 4				
Na (mmol/L)	170.8	0.4	0.2	170 – 171.6
K (mmol/L)	11.83	0.06	0.5	11.71 – 11.94
Cl (mmol/L)	132.8	0.4	0.3	132 – 133.6
Ca (mmol/L)	0.47	0.00	1.0	0.46 – 0.48
Mg (mmol/L)	0.24	0.00	1.4	0.23 – 0.25
Glu (mg/dL)	34	0.5	1.5	32.8 – 34.8
Lac (mmol/L)	16.9	0.1	0.8	16.6 – 17.2
Linearity, Level 2				
BUN (mg/dL)	49.2	0.9	1.8	47.4 – 51
Creat (mg/dL)	7.5	0.08	1.1	7.4 – 7.7
Linearity, Level 3				
BUN (mg/dL)	24.5	0.5	2.1	23.4 – 25.5
Creat (mg/dL)	4.8	0.05	1.0	4.7 – 4.9

Table A-27 Within Run Precision/Reproducibility Results Point-of-Care Study: RT Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Blood Gas Quality Control, Level 1				
pH	7.221	0.005	N/A	7.211 – 7.231
pCO_2 (mmHg)	59.6	1.1	1.9	57.4 – 61.9
pO_2 (mmHg)	75.9	1.1	1.5	73.7 – 78.1
Hct (%)	61	0.7	1.1	59 – 62
SO_2 (%)	48	0.3	0.7	47.4 – 48.6
tHb (g/dL)	20.0	0.1	0.7	19.7 – 20.3
O_2Hb (%)	21.0	0.2	0.9	21 – 21
COHb(%)	29.1	0.1	0.4	28.8 – 29.3

Table A-27 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: RT Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
MetHb(%)	27.3	0.1	0.3	27.2 – 27.5
HHb (%)	22.6	0.1	0.4	22.4 – 22.8
Blood Gas Quality Control, Level 2				
pH	7.430	0.002	N/A	7.425 – 7.434
pCO_2 (mmHg)	37.1	0.7	1.9	35.7 – 38.5
pO_2 (mmHg)	103.1	1.9	1.9	99.2 – 106.9
Hct (%)	38	0.3	0.0	37 – 39
SO_2 (%)	78	0.0	0.0	78 – 78
tHb (g/dL)	12.8	0.1	0.9	12.6 – 13
O_2Hb (%)	47.5	0.1	0.3	47 – 48
COHb(%)	21.7	0.1	0.6	21.4 – 22
MetHb(%)	17.3	0.2	0.9	16.9 – 17.6
HHb (%)	13.5	0.1	0.7	13.3 – 13.7
Blood Gas Quality Control, Level 3				
pH	7.636	0.003	N/A	7.63 – 7.641
pCO_2 (mmHg)	19.7	0.3	1.7	19 – 20.3
pO_2 (mmHg)	148.8	1.3	0.9	146.2 – 151.3
Hct (%)	26	0.6	2.3	25 – 28
SO_2 (%)	91	0.2	0.2	90.5 – 91.4
tHb (g/dL)	6.4	0.1	1.7	6.1 – 6.6
O_2Hb (%)	80.4	0.1	0.1	80 – 81
COHb(%)	6.4	0.1	1.4	6.2 – 6.6
MetHb(%)	4.9	0.1	3.0	4.6 – 5.2
HHb (%)	8.2	0.1	1.6	8 – 8.5

Table A-27 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: RT Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Linearity, Level 1				
pH	6.731	0.004	N/A	6.723 – 6.739
pCO_2 (mmHg)	144.3	1.7	1.2	140.9 – 147.7
pO_2 (mmHg)	27.9	1.3	4.6	25.3 – 30.4
Linearity, Level 4				
pH	7.732	0.005	N/A	7.722 – 7.742
pCO_2 (mmHg)	18.4	0.2	0.9	18 – 18.7
pO_2 (mmHg)	479.6	12.6	2.6	454.5 – 504.7
Linearity, Level 2				
Hct (%)	29	0.2	0.8	28.6 – 29.5
Linearity, Level 3				
Hct (%)	46	0.0	0.0	46 – 46

Table A-28 Within Run Precision/Reproducibility Results Point-of-Care Study: RT Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Chemistry Quality Control, Level 4				
Na (mmol/L)	136.6	0.6	0.4	135.4 – 137.8
K (mmol/L)	3.86	0.06	1.5	3.74 – 3.98
Cl (mmol/L)	122.8	0.6	0.5	121.6 – 124
Ca (mmol/L)	1.07	0.01	1.1	1.05 – 1.1
Mg (mmol/L)	0.60	0.05	8.8	0.49 – 0.7
Glu (mg/dL)	82	0.7	0.8	80.7 – 83.4
Lac (mmol/L)	1.8	0.0	2.5	1.7 – 1.9
BUN (mg/dL)	16.8	0.4	2.7	15.9 – 17.6
Creat (mg/dL)	1.2	0.00	0.0	1.2 – 1.2

Table A-28 Within Run Precision/Reproducibility Results *(continued)* Point-of-Care Study: RT Stat Profile Prime Plus External Quality Control & Linearity Materials (N=20)				
Parameter	**Mean**	**SD**	**%CV**	**95% CI**
Linearity, Level 1				
Na (mmol/L)	90.0	0.4	0.4	89.2 – 90.7
K (mmol/L)	1.60	0.02	1.4	1.55 – 1.64
Cl (mmol/L)	58.9	0.6	1.0	57.7 – 60
Ca (mmol/L)	2.39	0.01	0.5	2.37 – 2.42
Mg (mmol/L)	1.39	0.01	0.8	1.37 – 1.41
Glu (mg/dL)	385	4.9	1.3	374.8 – 394.5
Lac (mmol/L)	0.3	0.0	0.0	0.3 – 0.3
Linearity, Level 4				
Na (mmol/L)	171.0	0.3	0.2	170.4 – 171.6
K (mmol/L)	12.00	0.07	0.6	11.86 – 12.13
Cl (mmol/L)	132.4	0.9	0.7	130.6 – 134.2
Ca (mmol/L)	0.42	0.05	11.4	0.32 – 0.51
Mg (mmol/L)	0.23	0.01	2.2	0.22 – 0.25
Glu (mg/dL)	32	0.5	1.5	31.4 – 33.2
Lac (mmol/L)	16.9	0.2	1.2	16.5 – 17.3
Linearity, Level 2				
BUN (mg/dL)	47.1	0.8	1.7	45.5 – 48.7
Creat (mg/dL)	7.4	0.06	0.8	7.3 – 7.6
Linearity, Level 3				
BUN (mg/dL)	24.8	0.4	1.8	23.9 – 25.6
Creat (mg/dL)	4.3	0.05	1.1	4.2 – 4.4

A.6.2 Quality Control Total Imprecision Performance

The estimates for total imprecision were obtained from different POC personnel running 3 levels of Stat Profile Prime Plus Quality Control/Linearity Materials in duplicate each day for a total of 20 runs on 3 Stat Profile Prime Plus analyzers. The protocol was based on methods described in CLSI *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition*, CLSI EP5-A2T.[29] The total imprecision data from one representative POC site is shown in Table A-29 and exhibits the expected total imprecision performance obtainable by POC personnel using the Stat Profile Prime Plus analyzer using external quality control and linearity materials.

Table A-29 Total Imprecision Data, ED Site

Parameter	Pooled Mean	N	Within Run SD (Sr)	Within Run %CV	Total SD (St)	Total %CV
Blood Gas Quality Control, Level 1						
pH	7.223	40	0.004	N/A	0.008	N/A
pCO_2 (mmHg)	60.0	40	1.6	2.6	3.6	5.9
pO_2 (mmHg)	76.5	40	1.3	1.6	2.4	3.1
Hct (%)	61	40	0.5	0.8	0.6	0.9
SO_2 (%)	47.5	40	0.6	1.2	0.7	1.4
tHb (g/dL)	19.8	40	0.2	0.9	0.2	1.0
O_2Hb (%)	20.5	40	0.3	1.2	0.4	1.7
COHb (%)	29.2	40	0.1	0.5	0.2	0.7
MetHb(%)	27.7	40	0.1	0.4	0.1	0.4
HHb (%)	22.7	40	0.1	0.5	0.1	0.6
Blood Gas Quality Control, Level 2						
pH	7.428	40	0.003	N/A	0.006	N/A
pCO_2 (mmHg)	37.2	40	1.1	3.0	2.3	6.1
pO_2 (mmHg)	112.2	40	1.6	1.4	3.0	2.6
Hct (%)	38	40	0.2	0.6	0.3	0.8
SO_2 (%)	78.0	40	0.4	0.5	0.4	0.5
tHb (g/dL)	13.3	40	0.3	1.9	0.3	2.2
O_2Hb (%)	47.1	40	0.4	0.8	0.4	0.9

Table A-29 Total Imprecision Data, ED Site *(continued)*						
Parameter	**Pooled Mean**	**N**	**Within Run SD (Sr)**	**Within Run %CV**	**Total SD (St)**	**Total %CV**
COHb(%)	21.2	40	0.3	1.2	0.3	1.4
MetHb(%)	18.4	40	0.2	1.1	0.2	1.2
HHb (%)	13.2	40	0.2	1.2	0.2	1.2
Blood Gas Quality Control, Level 3						
pH	7.627	40	0.006	N/A	0.008	N/A
pCO_2 (mmHg)	20.1	40	0.6	3.1	1.0	4.8
pO_2 (mmHg)	148.9	40	1.6	1.1	3.4	2.3
Hct (%)	27	40	0.4	1.6	0.4	1.6
SO_2 (%)	91.0	40	0.0	0.0	0.0	0.0
tHb (g/dL)	6.6	40	0.1	1.9	0.1	2.2
O_2Hb (%)	80.1	40	0.1	0.2	0.2	0.2
COHb(%)	6.2	40	0.1	1.4	0.1	1.5
MetHb(%)	5.8	40	0.1	2.2	0.1	2.3
HHb (%)	7.9	40	0.1	1.5	0.1	1.7
Chemistry Quality Control, Level 4						
Na (mmol/L)	136.2	40	0.8	0.6	0.9	0.6
K (mmol/L)	3.88	40	0.05	1.4	0.08	2.2
Cl (mmol/L)	123.2	40	0.6	0.5	0.7	0.6
Ca (mmol/L)	1.07	40	0.02	1.7	0.02	2.1
Mg (mmol/L)	0.60	40	0.02	3.6	0.03	4.4
Glu (mg/dL)	81	40	1.1	1.4	1.1	1.3
Lac (mmol/L)	1.8	40	0.1	2.8	0.1	3.2
BUN (mg/dL)	15.7	40	0.6	3.6	0.8	4.8
Creat (mg/dL)	1.1	40	0.0	3.5	0.1	5.5

Table A-29 Total Imprecision Data, ED Site *(continued)*						
Parameter	**Pooled Mean**	**N**	**Within Run SD (Sr)**	**Within Run %CV**	**Total SD (St)**	**Total %CV**
Chemistry Quality Control, Level 5						
Na (mmol/L)	109.8	40	1.0	0.9	0.9	0.8
K (mmol/L)	6.24	40	0.06	1.0	0.12	1.9
Cl (mmol/L)	95.1	40	0.4	0.4	0.6	0.6
Ca (mmol/L)	1.56	40	0.04	2.8	0.04	2.7
Mg (mmol/L)	1.07	40	0.03	2.7	0.07	6.5
Glu (mg/dL)	298	40	4.4	1.5	5.2	1.7
Lac (mmol/L)	6.7	40	0.2	3.1	0.2	3.4
BUN (mg/dL)	49.8	40	2.2	4.4	2.5	5.1
Creat (mg/dL)	7.4	40	0.1	1.8	0.4	5.2
Linearity, Level 4						
Na (mmol/L)	168.6	40	1.5	0.9	2.0	1.2
K (mmol/L)	11.64	40	0.12	1.0	0.18	1.5
Cl (mmol/L)	132.7	40	1.0	0.8	1.2	0.9
Ca (mmol/L)	0.48	40	0.01	1.6	0.01	1.9
Mg (mmol/L)	0.24	40	0.01	2.3	0.01	5.4
Glu (mg/dL)	32	40	0.7	2.2	0.8	2.4
Lac (mmol/L)	16.5	40	0.2	1.0	0.4	2.2
BUN/Creat Linearity, Level 3						
BUN (mg/dL)	24.3	40	0.2	0.7	0.6	2.4
Creat (mg/dL)	4.9	40	0.1	1.1	0.3	6.4

A.6.3 Whole Blood Method Comparison Study

Method comparison studies on venous and arterial whole blood specimens were performed by POC participants from 3 POC settings including a Cardiothoracic Intensive Care Unit (CTICU), an Emergency Department (ED) and a Respiratory Therapy Lab (RT) on 3 Stat Profile Prime Plus analyzers. The studies included a minimum of 20 testing days, using methods described in CLSI *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*, CLSI EP9-A2.

Heparinized blood gas specimens were used to compare the whole blood results obtained by POC personnel in these settings to the whole blood results obtained by trained laboratory personnel on the same specimens on the same analyzer. The pooled method comparison test data included in the following tables was obtained by respiratory care, nursing, and exercise physiology POC personnel compared to results obtained by trained laboratory personnel on the same specimens. Spiked and tonometered specimens were needed to support the full reportable range. The method comparison test data is representative of the expected results obtained by POC personnel when compared to trained laboratory personnel using a Stat Profile Prime Plus analyzer on heparinized whole blood specimens on the same analyzer.

Table A-30 Venous and Arterial Whole Blood Method Comparison Point of Care vs Lab (Combined)

Parameter	Total Specimens	Altered Samples	Whole Blood Range	Slope	Intercept	r
pH	432	18	6.832 - 7.931	0.9930	0.0500	0.9976
pCO_2 (mmHg)	428	14	14.0 - 199.2	0.9848	0.9958	0.9963
pO_2 (mmHg)	432	18	11.5 - 565.2	1.0109	-1.5391	0.9989
Hct (%)	417	3	18 - 69	0.9997	0.1315	0.9929
SO_2 (%)	398	1	30 - 100	1.0084	-0.9664	0.9982
tHb (g/dL)	416	2	5.0 - 24.2	1.0042	-0.0058	0.9923
O_2Hb (%)	422	8	7.1 - 98.4	1.0072	-0.8636	0.9983
COHb (%)	425	11	0.3 - 50.5	1.0024	-0.0013	0.9986
MetHb (%)	437	23	0.3 - 56.7	1.0040	0.0006	0.9993
HHb (%)	422	8	0.4 - 92.1	1.0074	0.1507	0.9984
Na (mmol/L)	432	18	90.0 - 187.0	0.9964	0.4488	0.9949
K (mmol/L)	435	21	1.10 - 17.60	1.0158	-0.0678	0.9993
Cl (mmol/L)	434	20	56.0 - 173.0	0.9963	0.4416	0.9971
Ca (mmol/L)	434	20	0.51 - 2.48	0.9820	0.0239	0.9871
Mg (mmol/L)	426	13	0.24 - 1.36	1.0020	-0.0021	0.9910
Glu (mg/dL)	419	8	16 - 493	1.0102	-0.9232	0.9988
Lac (mmol/L)	413	0	0.5 - 16.5	1.0181	-0.0796	0.9975
BUN (mg/dL)	413	0	4.0 - 100.0	0.9969	0.0674	0.9990
Creat (mg/dL)	429	16	0.2 - 11.3	0.9984	-0.0025	0.9987

A.6.4 Capillary Whole Blood Specimens

A separate clinical study was conducted in Point-of-Care (POC) settings to demonstrate the clinical performance of capillary whole blood specimens on the Stat Profile Prime Plus analyzers. The study compared the Stat Profile Prime Plus analyzers to the Nova Stat Profile pHOx Ultra analyzers (predicate device) to assess the equivalence of the analyzers in the measurement of pH, blood gases, hematocrit, electrolytes, and metabolites in capillary whole blood specimens. The method comparison study was performed at two (2) external POC sites. Capillary whole blood specimens collected from consenting donors were analyzed on the Prime Plus and pHOx Ultra and the results compared using linear regression. The study was conducted in an Emergency Room (ER) with five (5) nurses and in a Hemodialysis Unit with four (4) nurses over a minimum of 20 days. Each site utilized a single Prime Plus analyzer and a single pHOx Ultra comparative analyzer. Some of the specimens were altered (typically less than 10%) to cover the full dynamic range. Combined data from both sites is shown below in the table.

Table A-31 Capillary Mode Method Comparison Stat Profile Prime Plus vs pHOx Ultra (Combined)

Parameter	N	Altered Samples	Whole Blood Range	Slope	Intercept	r
pH	249	18	6.790-7.729	0.989	0.074	0.994
pO_2 (mmHg)	251	20	7.5-567.1	1.001	0.832	0.998
pCO_2 (mmHg)	245	14	7.4-183.1	1.008	–0.597	0.997
Hct (%)	241	10	18-55	0.990	0.801	0.988
Na (mM)	243	12	83.0-195.6	1.013	–2.224	0.989
K (mM)	245	14	1.34-18.53	0.994	0.042	0.999
Cl (mM)	243	12	64.5-191.6	0.994	0.349	0.986
Ca (mM)	247	16	0.37-2.46	0.990	0.016	0.993
Mg (mM)	249	18	0.13-1.22	0.966	0.021	0.981
Glu (mg/dL)	245	14	28-452	0.995	0.904	0.997
Lac (mM)	243	12	0.4-17.6	1.000	0.012	0.999

A.7 Calibrator Cartridge

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

A.7.1 Traceability of Calibrators, Controls, and Standards

Concerning traceability, pH, electrolytes, and chemistry analytes are traceable to the Standard Reference Materials of the National Institute of Standards and Technology (NIST); pO_2, pCO_2, and SO_2 are traceable to tonometry.

A.8 Reference Values

Each laboratory should establish and maintain its own reference values. The values shown in Table A-32 should be used **only as a guide.**

Table A-32
Prime Plus Reference Values [1, 2, 3, 8, 11]

Analyte	Default (U.S.) Units of Measure	International (SI) Units of Measure
pH	7.350 – 7.450 (pH units)	44.67 – 35.48 (H^+ units)
PCO_2	35 – 45 mmHg	4.66 – 5.99 kPa
PO_2	83 – 108 mmHg	11.04 – 14.36 kPa
Hematocrit (Hct)	Male: 39 – 49%	Male: 39 – 49%
	Female: 35 – 45%	Female: 35 – 45%
Na	136 – 146 mmol/L	136 – 146 mmol/L
K	3.5 – 5.1 mmol/L	3.5 – 5.1 mmol/L
Cl	98 – 106 mmol/L	98 – 106 mmol/
iCa[6]	4.36 – 5.20 mg/dL	1.09 – 1.30 mmol/L
iMg (Whole Blood)[7]	1.09 – 1.45 mg/dL	0.45 – 0.60 mmol/L
Glu	65 – 95 mg/dL	3.61 – 5.27 mmol/L
BUN	7 – 14 mg/dL	5.0 – 10.0 mmol/L
Creatinine	Male: 0.7 – 1.3 mg/dL	Male: 0.06 – 0.11mmol/L
		Male: 61.9 – 114.9 µmol/
	Female: 0.6 – 1.1 mg/dL	Female: 0.05 - 0.10 mmol/L
		Female: 53.0 – 97.2 mmol/L
Lactate [9, 10]	0.7 – 2.5 mmol/L	6.3 – 22.5 mg/dL
SO_2 (Arterial Whole Blood)	95 – 98%	95 – 98%
Total Hemoglobin (tHb)	Male: 14.0 – 17.8 g/dL	Male: 8.7 – 11.0 mmol/L
		Male: 140 – 178 g/L
	Female: 12.0 – 15.6 g/dL	Female: 7.4 – 9.7 mmol/L
		Female: 120 – 156 g/L
O_2Hb (Arterial Whole Blood)	94 – 97%	94 – 97%
COHb (Nonsmoking)	0.0 – 1.5%	0.0 – 1.5%
MetHb	0.0 – 1.5%	0.0 – 1.5%
HHb	0.0 – 5.0%	0.0 – 5.0%
TCO_2	22 – 29 mmol/L	22 – 29 mmol/L
HCO_3^-	21 – 28 mmol/L	21 – 28 mmol/L
Base Excess of Blood (BE-B)	−2 – +3 mmol/L	−2 – +3 mmol/L

Table A-32 *(continued)* Prime Plus Reference Values [1, 2, 3, 8, 11]		
Analyte	**Default (U.S.) Units of Measure**	**International (SI) Units of Measure**
O_2Ct (Arterial Whole Blood)	Male: 18 – 24 mL/dL	Male: 18 – 24 vol%
	Female: 15 – 21 mL/dL	Female: 15 – 21 vol%
O_2Cap (Arterial Whole Blood)	Male: 18 – 25 mL/dL	Male: 18 – 25 vol%
	Female: 15 – 22 mL/dL	Female: 15 – 22 vol%
Osmolality	275 – 295 mOsmol/kg	275 – 295 mOsmol/kg

A.9 Cybersecurity

A.9.1 Cybersecurity Protection Overview

The Stat Profile Prime Plus system includes extensive safeguards to protect the system from outside cybersecurity attacks. A summary of the safeguards is found below. Professional laboratory and Information Technology users that require extensive information and details may contact Nova Biomedical Technical Support at 1-800-545-6682 in North America. Outside of the USA, contact your authorized Stat Profile Prime Plus distributor.

A.9.2 Software Updates

Stat Profile Prime Plus software updates are performed exclusively by factory trained Field Support Specialists. 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 Plus analyzer will not execute a software update if the image is questionable or the image does not pass the embedded CRC.

A.9.3 Operating System Patches

The Stat Profile Prime Plus analyzer main operating system has been custom tailored. It is an embedded version of Windows that has been “trimmed” to contain only applications and drivers that are pertinent to functionality of the analyzer. In certain instances, if it is deemed necessary to update the main operating system with security patches, security patch updates are performed exclusively by factor trained Field Support Specialists.

The analyzer operating system has been locked down. A date dependent password must be entered to gain access to the file system. Windows AppLocker has been tuned to prevent the possibility of all executable and driver files from running off of a USB stick. Factory trained Field Support Specialists must follow proprietary instructions to upload and install patches from external media into the analyzer’s file system.

A.9.4 Malware Control

The Stat Profile Prime Plus 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.9.5 Creation of Software for Release

Stat Profile Prime Plus 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 Plus software.

A.9.6 Security Risks Related to Connectivity to LIS or HIS Systems

The Stat Profile Prime Plus analyzer offers three communication protocol options: POCT1A, HL-7, and ASTM, with Ethernet. All protocols using Ethernet can be optionally encrypted through a configuration selection

A.9.7 Security Risks Related to USB Ports

The Stat Profile Prime Plus analyzer contains two USB ports. There are three primary purposes for the USB ports:

A.9.7.1 Printing

Non-networked USB printers are generally not considered security risks.

A.9.7.2 Export/Import of Data

Configuration data and log files can be exported to a USB stick. The files exported are encrypted. Additionally, log file export can only be accessed after entering a password that changes daily and is available only after contacting Nova Biomedical Technical Support.

The analyzer checks the validity of a configuration file before importing from a USB stick. Files that have been altered are prevented from import.

Virus files on a USB stick generally require access to the operating system to spread from the USB stick to the computing system. The analyzer operating system has been locked down. A date dependent password must be entered to gain access to the file system. Windows AppLocker has been tuned to prevent all executable and driver files from running off of a USB stick.

A.9.7.3 HID Devices (e.g., keyboard and mouse)

The USB ports will support HID devices. HID devices are easily hacked and therefore pose security risks. Nova Biomedical recommends using the built in touch screen and onboard keyboard instead of adding external HID devices.

A.10 Ordering Information

Stat Profile Prime Plus Analyzer supplies and parts (Table A-33) are available from Nova Biomedical.

Table A-33
Stat Profile Prime Plus Analyzer Parts

Description	Part Number
Stat Profile Prime or Prime Plus Power Cord US 110V	01498
Stat Profile Prime or Prime Plus Power Cord Int 230V	14631
Stat Profile Prime Plus Cart	57811
Calibrator Flush Fixture	57458
Control Flush Fixture	57454
Power Supply	57005
Stat Profile Prime and Prime Plus 120V Backup Power Supply	53727
Stat Profile Prime and Prime Plus 230V Backup Power Supply	53726
Scanner Handheld DS8178 w/ Base & Cable Prime Plus	59696
Stat Profile Prime Plus MicroSensor Card with CO-Ox	61615
Stat Profile Prime Plus MicroSensor Card with CO-Ox (Low Volume)	61605
Stat Profile Prime Plus MicroSensor Card with CO-Ox (High Volume)	61614
Stat Profile Prime Plus MicroSensor Card	58642
Stat Profile Prime Plus MicroSensor Card (Low Volume)	64604
Stat Profile Prime Plus MicroSensor Card (High Volume)	58643
Stat Profile Prime Plus MicroSensor Card BUN, Creatinine	57821
Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card	58379
Stat Profile Prime Plus Calibrator Cartridge 100 Sample	57825
Stat Profile Prime Plus Calibrator Cartridge 200 Sample	57826
Stat Profile Prime Plus Calibrator Cartridge 300 Sample	57827
Stat Profile Prime Plus Calibrator Cartridge 400 Sample	57828
Stat Profile Prime Plus Calibrator Cartridge 500 Sample	57829
Stat Profile Prime Plus Calibrator Cartridge 700 Sample	65141
Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN	57831
Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN	57832
Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN	57833
Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN	57834
Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN	57835
Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat / BUN	65142
Stat Profile Prime Plus Reference Cartridge	57823
Stat Profile Prime Plus Auto QC Cartridge 160 Sample	57838
Stat Profile Prime Plus Auto QC Cartridge 320 Sample	57839
Stat Profile Prime Plus Auto QC Cartridge 480 Sample	57840
Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN	57841
Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN	57842
Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN	57843

Table A-33 *(continued)* Stat Profile Prime Plus Analyzer Parts	
Description	**Part Number**
Stat Profile Prime Plus Ampuled Controls BG, CO-Ox Levels 1, 2, 3	57844
Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5	57845
Prime Safety Sample Port 5 PK	52669
Linearity Set BUN Creat Hct	61656
Nova Calibration Verification Control 1-4	55229
Flow Path Flush Tool	61621

A.11 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 MERCHANDISABILITY 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.

Appendix B: Theory

B.1 Principles of Measurement

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

The parameters are measured by an Ion-Selective Electrode (ISE) that 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 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 E_r and E_j are the reference and junction potential respectively.

B.1.1.1 Calculating Sample Concentration

Equation 1 links the voltage of the cell (E_m) to the activity of the ion.

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

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.

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

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, plasma, and serum is relatively constant over the physiological range [12]. As a result, the activity coefficients of sodium, potassium, calcium, magnesium, 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 resulting in:

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

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, magnesium, and chloride ions in the sample.

B.1.2 pH Sensor

B.1.2.1 Definition of pH

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

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

where:

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

B.1.2.2 Principle of pH Measurement

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

B.1.3 Partial Pressure of Carbon Dioxide (PCO_2)

B.1.3.1 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.

B.1.3.2 Principle of PCO_2 Measurement

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

$$CO_2 + H_2O <=> H_2CO_3 <=> H^+ + [HCO_3^-] \qquad \text{Equation 8}$$

The pH of this internal solution varies with the *P*CO_2 according to the Henderson-Hasselbalch equation[13]:

$$pH = pK_a + \log \{HCO_3^- / PCO_2 * a\} \qquad \text{Equation 9}$$

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)

B.1.4.1 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. *P*O_2 provides an indication of the availability of oxygen in inspired air.

B.1.4.2 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:

$$\text{Glucose} + O_2 \xrightarrow{\text{Glucose Oxidase}} \text{Gluconic Acid} + H_2O_2 \qquad \text{Equation 10}$$

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 electrode is proportional to the glucose concentration of the sample.

B.1.7 BUN Concentration

The Prime Plus Analyzer uses urease, which has been chemically bonded to a membrane, to catalyze the conversion of urea present in the sample to ammonia and CO_2 according to the following overall reaction:

$$NH_2 - \overset{\overset{O}{\|}}{C} - NH_2 + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2 \qquad \text{Equation 12}$$

At the pH of the sample, ammonia converts predominantly to the ammonium ion:

$$NH_3 + H^+ \longrightarrow NH_4^- \qquad \text{Equation 13}$$

An ammonium ion selective electrode is used to detect the ammonium formed by the above reactions. This measurement is then related to the concentration of urea present in the original sample via the Nernst equation.

B.1.8 Creatinine Concentration

The Prime Plus Creatinine sensor uses 3 enzymes. These 3 enzymes catalyze the conversion of Creatinine, ultimately forming formaldehyde, glycine, and hydrogen peroxide. The relevant chemical reactions are shown below:

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine} \qquad \text{Equation 14}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidohydrolase}} \text{Sarcosine} + \text{Urea} \qquad \text{Equation 15}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Formaldehyde} + \text{Glycine} + H_2O_2 \qquad \text{Equation 16}$$

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

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

B.1.9 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:

$$\text{Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate Acid} + H_2O_2 \qquad \text{Equation 17}$$

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

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^- \qquad \text{Equation 18}$$

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

B.2 Principles of Measurement – CO-Oximeter

The Prime Plus CO-Oximeter subsystem is used to measure the hemoglobin parameters of whole blood such as total hemoglobin (tHb), carboxyhemoglobin (COHb), deoxyhemoglobin (HHb), oxyhemoglobin (O2Hb), and methemoglobin (MetHb) using chemometrics applied to optical absorbance.

Whole blood is drawn into a cuvette via a peristaltic pump. The analyzer then measures the light transmittance through the sample over a plurality of wavelengths in the 422 to 695 nm spectral region. This output signal is processed using a computational mapping function technique to determine the concentration of tHb, COHb, O_2Hb, and MetHb.

B.2.1 Total Hemoglobin (tHb)

Hemoglobin is a protein found in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues back to the lungs.

Total Hemoglobin is the sum of all measured hemoglobin fractions expressed as the amount of hemoglobin in a specified volume of whole blood.

Total Hemoglobin is calculated using the following equation:

$$tHb = O_2Hb + HHb + COHb + MetHb \qquad \text{Equation 19}$$

B.2.2 Oxyhemoglobin

Oxyhemoglobin is the combined form of hemoglobin and oxygen. Oxygen is bound reversibly and is readily given up to the tissues because of the lower tissue oxygen tension. Conversely in the lungs, there is a higher oxygen tension and greater oxygen uptake by hemoglobin.

The percentage of oxyhemoglobin is determined using the following equation:

$$O_2Hb\% = O_2Hb/tHb \times 100 \qquad \text{Equation 20}$$

B.2.3 Carboxyhemoglobin

Carboxyhemoglobin is the combined form of carbon monoxide and hemoglobin. The affinity of hemoglobin for carbon monoxide is approximately 210 times greater than for oxygen. Because of this high affinity, inhalation of large amounts of carbon monoxide can lead to death if left undiagnosed.

The percentage of carboxyhemoglobin is determined by using the following equation:

$$COHb\% = COHb/tHb \times 100 \qquad \text{Equation 21}$$

B.2.4 Methemoglobin

Methemoglobin is the form of hemoglobin in which the iron has been oxidized from the ferrous to the ferric state. Oxygen cannot bind with methemoglobin. Therefore, increased amounts can lead to cyanosis, tissue anoxia, and death. There are congenital and acquired forms of methemoglobinemia.

The percentage of methemoglobin is determined by using the following equation:

$$MetHb\% = MetHb/tHb \times 100 \qquad \text{Equation 22}$$

B.2.5 Deoxyhemoglobin

Deoxyhemoglobin is the form of hemoglobin that is not combined with oxygen but can easily uptake oxygen in the lungs.

The percentage of deoxyhemoglobin is determined by using the following equation:

$$HHb\% = HHb/tHb \times 100 \qquad \text{Equation 23}$$

B.2.6 Oxygen Saturation (SO_2%)

Oxygen saturation (SO_2%) represents the percent of hemoglobin bound to oxygen, expressed as a fraction of the amount of hemoglobin capable of binding to oxygen (oxyhemoglobin plus deoxyhemoglobin). As the level of SO_2% changes within a blood sample, the color of the whole blood changes. Oxygen Saturation is determined by using the following equation:

$$SO_2\% = (O_2Hb/(O_2Hb + HHb)) \times 100 \qquad \text{Equation 24}$$

B.3 Calculated Values

The analyzer uses the measured results to calculate other clinically valuable parameters. This section provides the equations used to calculate these values.

B.3.1 Temperature Correction for Measured Values

The Prime Plus Analyzer allows you to enter the patient temperature value when the value differs from 37°C, which occurs, for example, when a patient is having surgery under hypothermia. The pH, PCO_2, and PO_2 sample values, at the patient's actual temperature, are then calculated as follows:

$$pH_{(corrected)} = pH + [-0.0147 + 0.0065\,(7.400 - pH)](T - 37) \qquad \text{Equation 25}$$

$$PCO_{2(corrected)} = PCO_2 \times e\,(0.04375(T - 37)) \qquad \text{Equation 26}$$

$$PO_{2(corrected)} = PO_2 \times 10^{U} \qquad \text{Equation 27}$$

where:

$$U = \left([\frac{(5.49 \times 10^{-11})\,Y + 0.071}{(9.72 \times 10^{-9})\,Y + 2.30}] \times (T - 37)\right) \text{ and } Y = e\,[3.88 \times \ln(PO_2)] \qquad \text{Equation 28}$$

B.3.2 Calculated Bicarbonate Concentration [HCO_3^-] [20]

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

$$pH = pK + \log\frac{HCO_3^-}{\alpha\,(PCO_2)} \qquad \text{Equation 29}$$

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 29 gives:

$$Log_{10}[HCO_3^-] = pH + \log_{10}PCO_2 - 7.604 \qquad \text{Equation 30}$$

B.3.3 Total Carbon Dioxide Content (TCO_2) [14]

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

$$TCO_2 = [HCO_3^-] + \alpha\ (PCO_2) \qquad \text{Equation 31}$$

where:

PCO_2 is measured and $[HCO_3^-]$ is calculated from Equation 32.

B.3.4 Hemoglobin (Hb)

Hemoglobin is calculated based on the following equation:

$$\text{Hemoglobin g/dL} = \text{Measured Hematocrit}/3.0 \qquad \text{Equation 32}$$

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

B.3.5 Base Excess of Blood (BE-B; sometimes called In Vitro Base Excess) [14]

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 mmHg. Base excess of blood is calculated as follows:

$$BE - B = (1 - 0.014[Hb])\ ([HCO_3^-] - 24 + (1.43[Hb] + 7.7)(pH - 7.4)) \qquad \text{Equation 33}$$

B.3.6 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:

$$SBC = 24.5 + 0.9Z + Z\ (Z - 8\ )(0.004 + 0.00025\ [Hb]) \qquad \text{Equation 34}$$

where:

$$Z = [BE - B] - 0.19\ [Hb]\ ((100 - SO_2)/100 \qquad \text{Equation 35}$$

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

B.3.7 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:

$$BE - ECF = [HCO_3^-] - 25 + 16.2\ (pH - 7.40) \qquad \text{Equation 36}$$

B.3.8 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:

$$SO_2\% = \frac{[PO_2']^3 + 150[PO_2']}{[PO_2']^3 + 150[PO_2'] + 23{,}400} \times 100 \qquad \text{Equation 37}$$

Where:

$$[PO_2'] = [PO_2] \times e[2.3026 \times (0.48\,(pH - 7.4) - 0.0013([HCO_3^-] - 25))] \qquad \text{Equation 38}$$

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

B.3.9 Oxygenation Index (OI)

Oxygenation index (OI) is a calculated value used to assess the efficiency of oxygen exchange in the lungs. OI is used in critical care medicine to assess the severity of acute lung injury and to gauge the effectiveness of ventilator management strategies.

$$OI = \text{Mean Airway Pressure MAP} \times FiO_2 \times 100 \div PaO_2 \qquad \text{Equation 39}$$

B.3.10 Alveolar Oxygen (A)

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

$$A = \frac{\%FIO_2}{100}(B.P. - 0.045T2 + 0.84T - 16.5 - **PCO_2\ (\frac{\%FIO_2}{100} + (\frac{1 - (\%FIO_2/100)}{0.8})) \qquad \text{Equation 40}$$

where:

T = Patient Temperature

B.P. = Barometric Pressure

$\%FIO_2$ = Fraction Inspired Oxygen, as a Percentage

**Temperature corrected gas value

B.3.11 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:

$$Aa\ DO_2 = A - **PO_2 \qquad \text{Equation 41}$$

where:

**Temperature corrected gas value

B.3.12 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.

$$a/A = **PO_2/A \qquad \text{Equation 42}$$

where:
**Temperature corrected gas value

B.3.13 Arterial-Mixed Venous O_2 Content Difference ($a - \bar{v}\,DO_2$)

When 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 Arterial-Mixed Venous O_2 Content Difference 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 cardiac output. It is a nonspecific indication; even if, in some cases of completely relaxed patients with a constant metabolic rate, it can be related to the cardiac output.

$$a - \bar{v}DO_2 = CaO_2 - C\bar{v}O_2 \qquad \text{Equation 43}$$

B.3.14 Physiologic Shunt (AV Shunt) Calculation ($\dot{Q}\,sp/\dot{Q}\,t$)

The estimation of shunt flow can be performed when both mixed venous and arterial blood samples are sent and they are analyzed with the CO-Oximeter. The selection of syringe sample type analysis and the AV Shunt key is required. Analysis of the mixed venous sample is first followed by the arterial sample.

The Physiologic Shunt Calculation ($\dot{Q}sp/\dot{Q}t$) requires the calculation of the End Capillary Oxygen Content ($Cc'O_2$), Arterial Oxygen Content (CaO_2) and Mixed Venous Oxygen Content (CvO_2):

$$\dot{Q}sp/\dot{Q}t = \frac{Cc'O_2 - CaO_2}{Cc'O_2 - C\bar{v}O_2} \times 100 \qquad \text{Equation 44}$$

where:

$Cc'O_2 = 1.39 \times Hb \times 1.0$ Equation 45

$CaO_2 = 1.39 \times Hb \times SaO_2$ [from arterial sample] Equation 46

$C\bar{v}O_2 = 1.39 \times Hb \times S\bar{v}O_2$ [from mixed venous sample] Equation 47

$C(a\text{-}\bar{v})O_2 = CaO_2 - CvO_2$ Equation 48

B.3.15 P50 or PO_2 (0.5)

*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 mmHg PCO_2 for SO_2% values between 40% and 80%.

$$P50_{(\text{uncorrected})} = PO_2/(SO_2\%/(100 - SO_2\%))^{0.37} \quad \text{Equation 49}$$

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

$$P50_{(\text{uncorrected})} = 26.902 * \exp(1.121 *(y - x - 3.5z)/(1.87 * z^2 + z - 2.87)) \quad \text{Equation 50}$$

where:

$z = \tanh(0.5343 * x)$ Equation 51

$x = \ln(0.133 * PO2/7)$ SvO_2 [from mixed venous sample] Equation 52

$y = \ln(SO_2\%/(100-SO_2\%)) - 1.875$ Equation 53

The corrected equation is as follows:

$$\log P50_{(\text{corrected})} = \log P50_{(\text{uncorrected})} + 0.43\ (pH - 7.4) - 0.05(\log[PCO_2/40]) - 0.0131\ (T - 37) \quad \text{Equation 54}$$

B.3.16 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:

$$\log [Ca^{++}]_{7.4} = \log [Ca^{++}]_x - 0.24\ (7.4 - x) \quad \text{Equation 55}$$

where

x = measured pH of the sample

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

$[Ca^{++}]_x$ = ionized calcium concentration in the sample at the measured pH

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.3.17 Ionized Magnesium Normalized to pH 7.4

The activity and concentration of ionized magnesium in whole blood, plasma, and serum is pH dependent. On standing, the pH of plasma and serum samples rises due to the loss of CO_2. The samples of choice for ionized magnesium determination are anaerobically collected whole blood, plasma, or serum.

If an anaerobic sample is not available by measuring the actual pH of the sample at which the ionized magnesium concentration was measured, normalized ionized magnesium can be calculated. The normalized ionized magnesium represents what the ionized magnesium 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:

$$\log [Mg^{++}]_{7.4} = \log [Mg^{++}]_x - 0.1\,(7.4 - x) \qquad \text{Equation 56}$$

where
x = measured pH of the sample
$[Mg^{++}]_{7.4}$ = normalized concentration of ionized magnesium at pH 7.40
$[Mg^{++}]_x$ = ionized magnesium concentration in the sample at the measured pH

The equation assumes a normal concentration of total protein and may be used for measured values between pH 7.2 and 7.8. Between pH 6.9 and 7.2 a modified form of the equation is used. Normalized ionized magnesium values for samples with pH outside the range pH 6.9 to pH 7.8 are not displayed.

B.3.18 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:

$$\text{Anion Gap} = (Na^+ + K^+) - (Cl^- + [HCO_3^-]) \qquad \text{Equation 57}$$

Alternate choice:

$$\text{Anion Gap} = Na^+ - (Cl^- + [HCO_3^-]) \qquad \text{Equation 58}$$

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.3.19 Osmolality

Osmolality is calculated as a zero-order approximation consisting of only the most important contributors. The calculation[4] used is as follows:

$$\text{Osm (mOsm/kg)} = 1.86[Na^+] + ([Glu]/18) + ([BUN]/2.8) + 9 \qquad \text{Equation 59}$$

where:
Sodium units are mmol/L
Glucose units are mg/dL
BUN units are mg/dL.

B.3.20 BUN/Creatinine Ratio

The BUN/Creatinine ratio is as follows:

$$\text{BU/CR} = \frac{[\text{BUN}]}{[\text{Creatinine}]} \qquad \text{Equation 60}$$

The units for BUN and Creatinine are mg/dL. If alternate units are chosen, there is a conversion of units to BUN mg/dL and Creatinine mg/dL. The ratio has no units. If either concentration is not reported, the BUN/Creatinine ratio is not reported.

B.3.21 Estimated Plasma Volume (ePV)

Estimated Plasma Volume is the amount of intravascular fluid minus red blood cells, white blood cells, and platelets and is calculated using the Strauss Equation. Plasma volume represents the intravascular fluid compartment in the body and, thus, directly affects the patient's cardiovascular system. ePV is an important prognostic tool in patients with active Heart failure or a at risk of sepsis or septic shock. Higher estimated plasma volume values are associated with a more severe congestion status and higher risk of mortality.

$$ePV = \frac{1 - \text{Hematocrit}}{\text{Hemoglobin (g/dL)}} \times 0.01 \qquad \text{Equation 61}$$

B.3.22 Serial or ΔPlasma Volume (ΔPV)

Estimated Plasma Volume (ePV) may be most beneficial when measured serially, allowing for the change in plasma volume (ΔPV) to be assessed over time. Serial ePV or (ΔPV) monitoring has been shown to have prognostic ability in patients with congestive heart failure, sepsis or septic shock possibly resulting in acute kidney injury. This can be useful in guiding therapeutic diuresis, reducing a patients overall fluid load.

$$\Delta PV = 100 \times \frac{\text{Hemoglobin (T1)}}{\text{Hemoglobin (T2)}} \times \frac{1 - \text{Hematocrit (T2)}}{1 - \text{Hematocrit (T1)}} - 100 \qquad \text{Equation 62}$$

B.3.23 Fractional Oxyhemoglobin (FO_2Hb)

Fractional Oxyhemoglobin is defined as the concentration of oxyhemoglobin (O_2Hb) divided by the concentration of total hemoglobin (*T*Hb) where the total hemoglobin concentration is the sum of the concentrations of oxyhemoglobin (O_2Hb), deoxyhemoglobin (HHb), carboxyhemoglobin (COHb), and methemoglobin (MetHb). It is calculated as follows:

$$FO_2\,Hb = O_2Hb/tHb = O_2Hb/(O_2Hb + HHb + COHb + MetHb) \qquad \text{Equation 63}$$

B.3.24 Oxygen Content (O_2Ct)

Oxygen Content (O_2Ct) 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/mmol at standard temperature and pressure) can combine with 1 mole of hemoglobin (64,458 g/mol) so that oxygen capacity is equal to:

$$\frac{4\,(22393)}{64458} = 1.39 \text{ mL of } O_2 \text{ per gram of Hb} \qquad \text{Equation 64}$$

Therefore, for ABG only:

$$O_2 = 1.39[Hb](SO_2\%/100) + 0.0031[PO_2] \qquad \text{Equation 65}$$

For Co-Oximeter only:

$$O_2 = 1.39[Hb](SO_2\%/100) \qquad \text{Equation 66}$$

B.3.24.1 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 equations:

For ABG only:

$$O_2\ Cap = 1.39[tHb] \qquad \text{Equation 67}$$

For CO-Oximeter only:

$$O_2Cap\ = 1.39\ (O_2Hb\% + HHB\%/100) \times [tHb] \qquad \text{Equation 68}$$

B.3.25 Mean Corpuscular Hemoglobin Concentration (MCHC)

MCHC indicates the amount of hemoglobin per unit volume. MCHC correlates the hemoglobin content with the volume of the cell. It is expressed as g/dL of red blood cells. Normal value is 34±2 g/dL.

$$MCHC\ (\frac{g}{dL}) = \frac{Hemoglobin\ (g/dL)}{Hematocrit\ (\%)} \times 100 \qquad \text{Equation 69}$$

B.3.26 Calculated Parameters – eGFR

Estimated GFR (eGFR) calculations are as follows:

B.3.26.1 Cockcroft-Gault (CrCl (mL/min)) [15]

Males (mg/dL)

$$eGFR\ = ((140 - Age) \times Weight))/(S_{Cr} \times 72.0) \qquad \text{Equation 70}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years
Weight is in kg

Males (µmol/L)

$$eGFR\ = ((140 - Age) \times Weight \times (1.23))/S_{Cr} \qquad \text{Equation 71}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years
Weight is in kg

Females (mg/dL)

$$eGFR\ = ((140 - Age) \times Weight \times (0.85))/(S_{Cr} \times 72.0) \qquad \text{Equation 72}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years
Weight is in kg

Females (µmol/L)

$$eGFR = ((140 - Age) \times Weight \times (1.04))/(S_{Cr}) \quad \text{Equation 73}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years
Weight is in kg

Japanese Males (mg/dL)

$$eGFR = (0.789 \times (140 - Age) \times Weight)/(S_{Cr} \times 72.0) \quad \text{Equation 74}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years
Weight is in kg

Japanese Males (µmol/L)

$$eGFR = (0.789 \times (140 - Age) \times Weight \times (1.23))/S_{Cr} \quad \text{Equation 75}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years
Weight is in kg

Japanese Females (mg/dL)

$$eGFR = (0.789 \times (140 - Age) \times Weight \times (0.85))/(S_{Cr} \times 72.0) \quad \text{Equation 76}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years
Weight is in kg

Japanese Females (µmol/L)

$$eGFR = (0.789 \times (140 - Age) \times Weight \times (1.04))/S_{Cr} \quad \text{Equation 77}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years
Weight is in kg

B.3.26.2 MDRD (ml/min/1.73 m^2) [16]

Black Males ≥ 18 years (mg/dL)

$$eGFR = 186 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 1.210 \quad \text{Equation 78}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Black Males ≥ 18 years (µmol/L)

$$eGFR = 186 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 1.210 \quad \text{Equation 79}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Non-Black Males ≥ 18 years (mg/dL)

$$eGFR = 186 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \quad \text{Equation 80}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Non-Black Males ≥ 18 years (µmol/L)

$$eGFR = 186 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \quad \text{Equation 81}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Black Females ≥ 18 years (mg/dL)

$$eGFR = 186 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.210 \quad \text{Equation 82}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Black Females ≥ 18 years (µmol/L)

$$eGFR = 186 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.210 \quad \text{Equation 83}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Non-Black Females ≥ 18 years (mg/dL)

$$eGFR = 186 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.742$$ Equation 84

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Non-Black Females ≥ 18 years (µmol/L)

$$eGFR = 186 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.742$$ Equation 85

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Japanese Males ≥ 18 years (mg/dL)

$$eGFR = 194 \times (S_{Cr})^{-1.094} \times (Age)^{-0.287}$$ Equation 86

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Japanese Males ≥ 18 years (µmol/L)

$$eGFR = 194 \times (S_{Cr}/88.4)^{-1.094} \times (Age)^{-0.287}$$ Equation 87

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Japanese Females ≥ 18 years (mg/dL)

$$eGFR = 194 \times (S_{Cr})^{-1.094} \times (Age)^{-0.287} \times 0.739$$ Equation 88

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Japanese Females ≥ 18 years (µmol/L)

$$eGFR = 194 \times (S_{Cr}/88.4)^{-1.094} \times (Age)^{-0.287} \times 0.739$$ Equation 89

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Chinese Males ≥ 18 years (mg/dL)

$$eGFR = 186 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 1.333$$ Equation 90

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Chinese Males ≥ 18 years (µmol/L)

$$eGFR = 186 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 1.333$$ Equation 91

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Chinese Females ≥ 18 years (mg/dL)

$$eGFR = 186 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.333$$ Equation 92

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Chinese Females ≥ 18 years (µmol/L)

$$eGFR = 186 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.333$$ Equation 93

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

B.3.26.3 IDMS-Traceable MDRD (mL/min/1.73 m²) [17]

Black Males ≥ 18 years (mg/dL)

$$eGFR = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 1.210$$ Equation 94

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in Years

Black Males ≥ 18 years (µmol/L)

$$eGFR = 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 1.210$$ Equation 95

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in Years

Non-Black Males ≥ 18 years (mg/dL)

$$eGFR = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203}$$ Equation 96

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in Years

Non-Black Males ≥ 18 years (µmol/L)

$$eGFR = 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203}$$ Equation 97

where:
S_{cr} is Serum Creatinine (µmol/L)
Age is in Years

Black Females ≥ 18 years (mg/dL)

$$eGFR = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.210$$ Equation 98

where:
S_{cr} is Serum Creatinine (mg/dL)
Age is in Years

Black Females ≥ 18 years (µmol/L)

$$eGFR = 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.210$$ Equation 99

where:
S_{cr} is Serum Creatinine (µmol/L)
Age is in Years

Non-Black Females ≥ 18 years (mg/dL)

$$eGFR = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.742$$ Equation 100

where:
S_{cr} is Serum Creatinine (mg/dL)
Age is in Years

Non-Black Females ≥ 18 years (µmol/L)

$$eGFR = 175 \times S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.742$$ Equation 101

where:
S_{cr} is Serum Creatinine (µmol/L)
Age is in Years

Thai Males ≥ 18 years (mg/dL)

$$eGFR = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 1.129$$ Equation 102

where:
S_{cr} is Serum Creatinine ()
Age is in Years

Thai Males ≥ 18 years (µmol/L)

$$eGFR = 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 1.129$$ Equation 103

where:
S_{cr} is Serum Creatinine (µmol/L)
Age is in Years

Thai Females ≥ 18 years (mg/dL)

$$eGFR = 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.129 \quad \text{Equation 104}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in Years

Thai Females ≥ 18 years (µmol/L)

$$eGFR = 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.742 \times 1.129 \quad \text{Equation 105}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in Years

Japanese Males ≥ 18 years (mg/dL)

$$eGFR = 0.808 \times 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \quad \text{Equation 106}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in Years

Japanese Males ≥ 18 years (µmol/L)

$$eGFR = 0.808 \times 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \quad \text{Equation 107}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in Years

Japanese Females ≥ 18 years (mg/dL)

$$eGFR = 0.808 \times 175 \times (S_{Cr})^{-1.154} \times (Age)^{-0.203} \times 0.724 \quad \text{Equation 108}$$

where:
S_{Cr} is Serum Creatinine (mg/dL)
Age is in Years

Japanese Females ≥ 18 years (µmol/L)

$$eGFR = 0.808 \times 175 \times (S_{Cr}/88.4)^{-1.154} \times (Age)^{-0.203} \times 0.724 \quad \text{Equation 109}$$

where:
S_{Cr} is Serum Creatinine (µmol/L)
Age is in Years

B.3.26.4 Bedside Schwartz (mL/min/1.73 m²) [18]

For Serum Creatinine (S_{CR}) expressed as mg/dL:

$$eGFR = (\kappa \times Height)/ S_{Cr}$$ Equation 110

where:
Height units are cm
κ = 0.33 when age < 1 (Premature)
κ = 0.45 when age < 1 (Term)
κ = 0.55 when 1 ≤ age ≤ 12
κ = 0.55 when 13 ≤ age ≤ 17 (Female)
κ = 0.65 when 13 ≤ age ≤ 17 (Male)

For S_{CR} expressed as µmol/L:

$$eGFR = \kappa \times (Height)/(S_{Cr}/88.4)$$ Equation 111

where:
Height units are cm
κ = 0.33 when age < 1 (Premature)
κ = 0.45 when age < 1 (Term)
κ = 0.55 when 1 ≤ age ≤ 12
κ = 0.55 when 13 ≤ age ≤ 17 (Female)
κ = 0.65 when 13 ≤ age ≤ 17 (Male)

B.3.26.5 Counahan-Barratt (mL/min/1.73 m²) [19]

For S_{CR} expressed as mg/dL:

$$eGFR = (0.43 \times Height)/S_{Cr}$$ Equation 112

where:
Height units are cm

For S_{CR} expressed as µmol/L:

$$eGFR = 0.38 \times (Height)/(S_{Cr}/88.4)$$ Equation 113

where:
Height units are cm

B.3.26.6 CKD EPI equation (mL/min/1.73 m^2) [20]

Black Males ≥ 18 years (mg/dL)

$$eGFR = 141 \times \min((S_{Cr})/(\kappa), 1)^{\alpha} \times \max((S_{Cr}/(\kappa), 1)^{-1.209} \times 0.993^{Age} \times 1.159$$

Equation 114

where:
S_{Cr} is Serum Creatinine (mg/dL)
κ is 0.7 for Female; 0.9 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Black Males ≥ 18 years (µmol/L)

$$eGFR = 141 \times \min((S_{Cr}/88.4)/(\kappa), 1)^{\alpha} \times \max((S_{Cr}/88.4)/(\kappa)\ 1)^{-1.209} \times 0.993^{Age} \times 1.159$$

Equation 115

where:
S_{Cr} is Serum Creatinine (µmol/L)
κ is 61.9 for Female; 79.6 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Non-Black Males ≥ 18 years (mg/dL)

$$eGFR = 141 \times \min((S_{Cr})/(\kappa), 1)^{\alpha} \times \max((S_{Cr})/(\kappa), 1)^{-1.209} \times 0.993^{Age}$$

Equation 116

where:
S_{Cr} is Serum Creatinine (mg/dL)
κ is 0.7 for Females; 0.9 for Males
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Non-Black Males ≥ 18 years (µmol/L)

$$eGFR = 141 \times \min((S_{Cr}/88.4)/(\kappa), 1)^{\alpha} \times \max((S_{Cr}/88.4)/(\kappa), 1)^{-1.209} \times 0.993^{Age}$$

Equation 117

where:
S_{Cr} is Serum Creatinine (µmol/L)
κ is 61.9 for Female; 79.6 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Black Females ≥ 18 years (mg/dL)

$$eGFR = 141 \times \min((S_{Cr})/(\kappa), 1)^{\alpha} \times \max(S_{Cr}/(\kappa), 1)^{-1.209} \times 0.993^{Age} \times 1.018 \times 1.159$$

Equation 118

where:
S_{Cr} is Serum Creatinine (mg/dL)
κ is 0.7 for Female; 0.9 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Black Females ≥ 18 years (µmol/L)

$$eGFR = 141 \times \min((S_{Cr}/88.4)/(\kappa), 1)^{\alpha} \times \max((S_{Cr}/88.4)/(\kappa), 1)^{-1.209} \times 0.993^{Age} \times 1.018 \times 1.159$$

Equation 113

where:
S_{Cr} is Serum Creatinine (µmol/L)
κ is 61.9 for Female; 79.6 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Non-Black Females ≥ 18 years (mg/dL)

$$eGFR = 141 \times \min((S_{Cr})/(\kappa), 1)^{\alpha} \times \max(S_{Cr}/(\kappa), 1)^{-1.209} \times 0.993^{Age} \times 1.018$$

Equation 114

where:
S_{Cr} is Serum Creatinine (mg/dL)
κ is 0.7 for Female; 0.9 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Non-Black Females ≥ 18 years (µmol/L)

$$eGFR = 141 \times \min((S_{Cr}/88.4)/(\kappa), 1)^{\alpha} \times \max((S_{Cr}/88.4)/(\kappa), 1)^{-1.209} \times 0.993^{Age} \times 1.018$$

Equation 115

where:
S_{Cr} is Serum Creatinine (µmol/L)
κ is 61.9 for Female; 79.6 for Male
α is –0.329 for Female; –0.411 for Male
min indicates the minimum of S_{Cr}/κ or 1
max indicates the maximum of S_{Cr}/κ or 1
Age is in years

Japanese Males ≥ 18 years (mg/dL)

$$eGFR = 0.813 \times 144\ (S_{Cr}/\ 0.9)^{-0.411\ SCr < 0.9\ or\ -1.209\ SCr \geq 0.9} \times 0.993^{Age}$$ Equation 116

where:

S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Japanese Males ≥ 18 years (µmol/L)

$$eGFR = 0.813 \times 144\ ((S_{Cr}/88.4)/79.6)^{-0.411\ SCr < 0.9\ or\ -1.209\ SCr \geq 0.9} \times 0.993^{Age}$$ Equation 117

where:

S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

Japanese Females ≥ 18 years (mg/dL)

$$eGFR = 0.813 \times 144\ (S_{Cr}/\ 0.7)^{-0.329\ SCr < 0.7\ or\ -1.209\ SCr \geq 0.7} \times 0.993^{Age}$$ Equation 118

where:

S_{Cr} is Serum Creatinine (mg/dL)
Age is in years

Japanese Females ≥ 18 years (µmol/L)

$$eGFR = 0.813 \times 144\ ((S_{Cr}/88.4)/61.9)^{-0.329\ SCr < 0.9\ or\ -1.209\ SCr \geq 0.7} \times 0.993^{Age}$$ Equation 119

where:

S_{Cr} is Serum Creatinine (µmol/L)
Age is in years

B.3.26.7 CKD EPI (2021) equation (mL/min/1.73 m²) [31]

$$eGFR = 142 \times \min\ (S_{Cr})/(\kappa, 1)^{\alpha} \times \max\ (S_{Cr}/(\kappa, 1)^{-1.200} \times 0.9938^{Age} \times 1.012\ [\text{if female}]$$ Equation 120

where:

S_{Cr} is Serum Creatinine (mg/dL)
κ is 0.7 for Female; 0.9 for Male
α is –0.241 for Female; –0.302 for Male
$\min(S_{Cr}/\kappa, 1)$ is the minimum of S_{Cr}/κ or 1.0
$\max(S_{Cr}/\kappa, 1)$ is the maximum of S_{Cr}/κ or 1.0
Age is in years

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