Originating Department: Clinical Laboratory **Department:** Harrisburg Medical Center Clinical Laboratory	**Title:** RAPIDPoint® 500 System Blood Gases, Metabolites, and Co-Oximetry **Manual:** Blood Gas	**Page: 1 of 33** **Revision Date:** **Review Date:** **Review Date:** **Review Date:** **Review Date:**
Author: Gloria Bonin **Effective Date:** 11/25/2013	**Medical Director Approval:** Richard Cachia, M.D. 11/27/13	**Administrative Laboratory Director Approval:** Gloria Bonin 11/25/2013 **Technologist Review:** Helen Pritchett, MT (AAB) MT(AAB)

SCOPE

This policy applies to the clinical laboratory at Harrisburg Medical Center.

PURPOSE

The purpose of this policy is to provide guidelines for performing testing using the RAPIDPoint® 500 System for blood gases, metabolites and co-oximetry in whole blood.

NOTE: The RAPIDPoint® 500 System has the capability of measuring other analytes. The information regarding these tests has not been included in the procedure at this time but may be referenced at various points in the procedure.

PRINCIPLE

The RAPIDPoint 500 system uses electrochemical sensors for the direct measurement of pH, partial pressure of carbon dioxide, partial pressure of oxygen, sodium, potassium, ionized calcium, chloride, glucose, and lactate.

The electrochemical sensors are designed using a thick-film hybrid technology and solid-state design and are well suited for the compact measurement cartridges used in the RAPIDPoint 500 system. The sensors require only a small volume of sample for analysis and require no maintenance, since they are replaced when the measurement cartridge is replaced.

Concentration of analyte in the sample is measured by means of an electrochemical interaction between the analyte and the sensor for that analyte, which generates an electrochemical signal that is proportional to the amount of analyte in the sample. The signal is then detected using either potentiometry (difference in potential between two electrodes in a solution without applied current), amperometry (current generated when applying voltage across two electrodes), or conductance (readiness with which a conducting substance transmits electrical current).

The method that is used by each sensor for detecting the electrochemical reaction is summarized in the following table:

Sensor	Detection Method
pH	Potentiometric method using standard ion selective electrode (ISE) technology.
pCO2	Modified potentiometric method based on the principles of the Severinghaus electrode.
pO2	Amperometric measurement based on the principles of the Clark electrode.

CO-Oximetry of Whole Blood

The RAPIDPoint 500 system uses optical measurement technology for testing hemoglobin and its derivatives. These compounds each have characteristic optical absorbance spectra, where hemoglobin and each derivative absorb light differently at different wavelengths and interfering substances absorb light at known wavelengths.

The RAPIDPoint 500 system measures the absorbance of light through whole blood at several wavelengths. The measurement module then determines the concentration of total hemoglobin, the percentages of oxyhemoglobin (*F*O2Hb), carboxyhemoglobin (*F*COHb), methemoglobin (*F*metHb), deoxyhemoglobin (*F*HHb), and oxyhemoglobin (*F*O2Hb), and the concentration of neonatal bilirubin (nBili) in the sample.

> **NOTE**: Refer to *Appendix F: Principles of System Operation* in the *RAPIDPoint 500 System Operator's Guide* for additional details regarding principles of the tests.

Clinical Application and Usefulness

The RAPIDPoint 500 system is intended for *in vitro* diagnostic use and is designed to provide the determination in whole blood for the following parameters:

- pH
- pCO2
- pO2
- Na+
- K+
- Ca++
- Cl-
- glucose
- lactate
- tHb
- *F*O2Hb
- *F*COHb
- *F*metHb
- *F*HHb
- nBili

This system also tests pH in pleural fluid samples. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

By providing timely results, the system enables medical personnel to make faster decisions about patient treatment and improve the quality of patient care.

NOTE: As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but must be made by the physician after all clinical and laboratory findings are evaluated.

Specimen Collection and Handling

Whole Blood Specimen Collection and Patient Preparation

BIOHAZARD

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

NOTE: Refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide* for recommended precautions when working with biohazardous materials.

- Collect blood samples under proper medical supervision when selecting a site and performing the collection procedure. Use sterile technique at all times to avoid infecting the sample site.
- Use sample devices containing lithium heparin (dry lithium heparin is recommended) as the anticoagulant.
  CAUTION: Other anticoagulants such as benzalkonium heparin, EDTA, citrate, oxalate, and fluoride significantly affect blood pH, sodium, potassium, chloride, ionized calcium, and CO-oximetry results. Refer to *Interfering Substances* on page 33 for more information about substances that interfere with analyte measurement.

The following sample devices and sample sources are acceptable for collecting whole blood:

Sample Device	Sample Source	Collection Procedure
Capillary Tube	Capillary	• Fill the tube completely and cap it securely. • Do not use clay or cork to cap the tube. • Do not use capillary tubes containing mixing fleas.
Syringe	Arterial	• Expel air from the syringe and cap it immediately after obtaining the sample. • Do not use clay or cork to cap the tube.
Syringe	Venous	
Syringe with Catheter	Mixed Venous	

CAUTION: Because mixed venous samples collected from some pulmonary artery catheters can contain potentially interfering substances (such as the

benzalkonium ion) that significantly affect the results of some parameters, only certain results are reported.

- Plastic syringes should be kept at room temperature (not iced), as long as the blood is analyzed within 30 minutes of collection.
- If a prolonged time delay of more than 30 minutes before analysis is anticipated, the use of a glass syringe and storage in ice water are recommended.
- Syringes stored in ice water should not be used for electrolyte determinations, as room temperature effects on diffusion in and out of the red blood cells can cause unreliable potassium results. Storage in ice water is applicable to blood gas measurements.
- Although the system uses only 100 µL of sample for analysis, always use the recommended fill volumes for the sample devices. This ensures that the system can aspirate sufficient sample for analysis. The minimum fill volume for sample collection devices is listed in the following table:

Sample Device	**Minimum Fill Volume**
Capillary tube	100 µL
1 mL Syringe	200 µL
3 mL Syringe	800 µL
5 mL Syringe	1.5 mL

- Ensure that samples are free of particulate matter and bubbles.
- Before you analyze the sample, roll the syringe or the capillary tube between your palms and gently invert it several times to mix the sample thoroughly. Mix all samples using a consistent technique.
- Analyze the sample as soon as possible to minimize oxygen consumption.
- Position any labels toward the back of the syringe barrel near the plunger so the label does not block the syringe from entering the system and cause it to fall off.
- Cap the sample device immediately after you collect the sample to avoid room air contamination.
- If the sample is chilled, increase the mixing time to ensure that the sample is thoroughly mixed.
- Dispose of used sample devices according to your institution's infection control policy.

Specimen Rejection Criteria

Criteria For Specimen Rejection

- Evidence of clotting
- Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin (or EDTA for BNP or glucose cartridges).
- Syringe for pH, PCO_2, PO_2 and TCO_2 with air bubbles in sample.

- Incompletely filled vacuum tube for the measurement of ionized calcium, PCO_2, HCO_3 or TCO_2.
- Other sample types such as urine, CSF, and pleural fluid

Precautions: Avoid the Following Circumstances

- Drawing a specimen from an arm with an I.V.
- Stasis (tourniquet left on longer than one minute before venipuncture)
- Extra muscle activity (fist pumping)
- Hemolysis (alcohol left over puncture site, or a traumatic draw)
- Icing before filling cartridge
- Exposing the sample to air when measuring pH, PCO_2, PO_2 and TCO_2.

PROCEDURE FOR ANALYSIS

Equipment, Reagents, and Materials

Equipment RAPIDPoint 500 System

Reagents Measurement Cartridge

- AutomaticQC Cartridge Kit (for the Automatic QC option)
- Siemens RAPIDQC controls (for the Required QC or Unscheduled QC options)
- Wash/Waste Cartridge

Materials

- Syringes (for whole blood, pleural fluid, and controls)
- Capillary Tubes (for whole blood)
- *Quick*™ Adaptor (for control ampules)
- Storage and Stability, and Equipment Maintenance

Equipment

RAPIDPoint 500 System

- Ambient Operating Conditions: 18° to 30°C (64° to 86°F) with 5% to 85% relative humidity
- Clean the analyzer as needed, as described in the *RAPIDPoint 500 System Operator's Guide.*

Reagents

Measurement Cartridge

The measurement cartridge contains the sensors, reagents, and electronic and fluidic components neededto analyze patient and QC samples and to calibrate the RAPIDPoint 500 system. The sensors in the cartridge for RAPIDPoint 500 systems are capable of measuring pH, partial pressure of oxygen (pO2), partial pressure of carbon

dioxide (pCO2), sodium (Na+), potassium (K+), ionized calcium (Ca++), chloride (Cl-), glucose, lactate, total hemoglobin (tHb), oxyhemoglobin (*F*O2Hb), deoxyhemoglobin (*F*HHb), methemoglobin (*F*MetHb), carboxyhemoglobin (*F*COHb), and neonatal bilirubin (nBili).

Cartridges are available for 100, 250, 400, and 750 patient and QC sample analyses. Cartridges are also available in different configurations with regard to the type of parameters available on the cartridge.

BIOHAZARD

Handle expired measurement cartridges as contaminated with potential infectious materials. Always use universal precautions when handling contaminated equipment or potentially infectious materials. Refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide* for recommended precautions when working with biohazardous materials.

CAUTION! Do not install the measurement cartridge with the system powered off.

- Store measurement cartridges refrigerated between 2° to 8°C. Cartridges can also be stored at room temperature, not to exceed 25°C for up to 7 days.
- Each measurement cartridge is stable for 28 days after installation on the system when the cartridge is installed by the date on the label.
  NOTE: The Install-by date indicates the last date on which the cartridge can be installed and still have 28 days of use before expiration. If a cartridge is installed after the Install-by date, it is stable for the number of days remaining before expiration, that is, 28 days minus the number of days past the Install-by date.
- Siemens Healthcare recommends that you mark the date received on each measurement cartridge every time you receive new cartridges and use the oldest cartridge whenever you need to replace the measurement cartridge.
- Refer to the *RAPIDPoint 500 System Operator's Guide* for instructions for installing a measurement cartridge.

Wash/Waste Cartridge

The Wash/Waste cartridge contains the wash reagent, which cleans the sample path after analysis and calibration, and it also stores liquid waste. The biohazardous waste fluid contacts only the replaceable cartridges of the RAPIDPoint 500 systems and never comes in contact with other components of the system. The waste fluid is completely enclosed in the Wash/Waste cartridge when you replace the cartridge.

BIOHAZARD

Handle expired Wash/Waste cartridges as contaminated with potential infectious materials. Always use universal precautions when handling contaminated equipment or potentially infectious materials. Refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide* for recommended precautions when working with biohazardous materials.

- Store Wash/Waste cartridges refrigerated or at room temperature (between 2° to 25°C).
- Each Wash/Waste cartridge is stable for ten days after installation on the system. The system prompts the operator when the cartridge needs replacement.
- Refer to the *RAPIDPoint 500 System Operator's Guide* for instructions for loading a Wash/Waste cartridge.

AutomaticQC Cartridge Kit

- Store AutomaticQC cartridges refrigerated between 2° to 8°C.
- Each AutomaticQC cartridge is stable for 28 days after installation on the system when the cartridge is installed by the date on the label.
- **NOTE**: The Install-by date indicates the last date on which the cartridge can be installed and still have 28 days of use before expiration. If a cartridge is installed after the Install-by date, it is stable for the number of days remaining before expiration, that is, 28 days minus the number of days past the Install-by date.
- Siemens Healthcare recommends that you mark the date received on each AutomaticQC cartridge every time you receive new cartridges and use the oldest cartridge whenever you need to replace the measurement cartridge.
- An AutomaticQC cartridge contains sufficient QC material to perform at least one sample analysis of each level three times per day for the life of the AutomaticQC cartridge.
- The AutomaticQC cartridge provides the target ranges for each level of QC material when you replace the cartridge.
- Refer to the *RAPIDPoint 500 System Operator's Guide* for instructions for installing an AutomaticQC cartridge.

Reagent Ingredients

Measurement Cartridge

The measurement cartridge contains the reagents described in the following table. Electrolytes, pH, glucose, and gases are NIST traceable.

Reagent	Ingredients	Volume
Zero	gases (oxygen, carbon dioxide, nitrogen), salts (alkali halides), organic buffers, catalyst, and surfactant	75 mL
RCx	gases (oxygen, carbon dioxide, nitrogen), salts (alkali halides), organic buffers, dye, surfactant, and preservative	60 mL
200	gases (oxygen, carbon dioxide, nitrogen), salts (alkali halides), organic buffers, glucose, lactate, surfactant, and preservative	230 mL
Reference	potassium chloride, silver chloride, and surfactant	16 mL

Wash/Waste Cartridge

The Wash/Waste cartridge contains the reagents described in the following table. Electrolytes, pH, glucose, and gases are NIST traceable.

Reagent	Ingredients	Volume
Wash	gases (oxygen, carbon dioxide, nitrogen), salts (alkali halides), surfactant, and preservative	250 mL

AutomaticQC Cartridge

The quality control material that is contained in the AutomaticQC cartridge is uniquely formulated to provide verification of performance at several points in the clinical range for the RAPIDPoint 500 system.

The AutomaticQC cartridge contains the reagents described in the following table:

Level	Ingredients	Volume
1	buffered bicarbonate solution with Na+, K+, Ca++, Cl-, carbon dioxide, oxygen, nitrogen, dye, glucose, lactate, surfactant, and preservative	75 mL
2	buffered bicarbonate solution with Na+, K+, Ca++, Cl-, carbon dioxide, oxygen, nitrogen, dye, glucose, lactate, surfactant, and preservative	115 mL
3	buffered bicarbonate solution with Na+, K+, Ca++, Cl-, carbon dioxide, oxygen, nitrogen, dye, glucose, lactate, surfactant, and preservative	155 mL
A	buffered bicarbonate solution with Na+, K+, Ca++, Cl-, carbon dioxide, oxygen, nitrogen, surfactant, and preservative	60 mL
B	buffered bicarbonate solution with Na+, K+, Ca++, Cl-, carbon dioxide, oxygen, nitrogen, surfactant, and preservative	60 mL

Reagents Special Preparation

No special preparation of the measurement cartridge, Wash/Waste cartridge, or AutomaticQC cartridge is required.

Calibration

Calibration Points

The following table lists the calibration points for each analyte in the reagents.

Analyte	High Calibration Point	Low Calibration Point
pH	7.4	6.8
*p*CO2	70 mmHg	35 mmHg
*p*O2	154 mmHg	0 mmHg
tHb	15 g/dL	0g/dL

Calibration Frequency

Calibration verification will be performed every six (6) months.

- Material for calibration verification of blood gas, electrolyte, total hemoglobin, and metabolite systems. Catalog number 116189 includes the following:
  - Siemens CVM Levels 1-5. (four 2.5 ampules for each level).
  - Adapters
  - Siemens Data Collection and recording forms.

The system performs calibrations automatically at prescribed intervals and with each sample if necessary.

The system automatically calibrates the sensors as follows:

- One-point calibrations are scheduled to occur regularly at 30-minute intervals between calibrations. A one-point calibration adjusts either the offset or the slope drift for a parameter by measuring one reagent of known concentration.
- Every fourth scheduled calibration is a two-point calibration, and every fourth two-point calibration is a full calibration. A two-point calibration adjusts both the offset and the slope drift for a parameter by measuring two reagents of known concentration.
- Every two-point calibration also measures the zero for tHb, and every full calibration measures the zero and slope for tHb. If the zero calibration exceeds drift limits, then one-point calibrations measure for zero until the drift error is cleared.

The system performs additional calibrations during sample analysis for the first several hours after you install a new measurement cartridge. These calibrations ensure that the cartridge is ready for sample analysis. If necessary, the system can defer a calibration to analyze a sample. In this case, the message informing you that the system is busy contains a **STAT** button that lets you interrupt the calibration. However, if the maximum

time between automatic calibrations has elapsed, the system must complete the calibration before allowing sample analysis. The message that appears informing you the system is busy does not allow you to interrupt the calibration.

If the system detects a problem for a parameter during calibration, the system repeats the calibration for as many as two times. The *Additional Cal Required* message appears on the printed report and in the events log. If the calibrations are not successful, the system turns the parameter off. You can continue to obtain results for the other parameters, but the failed parameter is not available until it passes a calibration. You can perform a calibration or you can wait for the parameter to pass the next calibration. If the parameter does not pass calibrations successfully, you must replace the cartridge to obtain results for the parameter the system turned off.

Also, under certain circumstances, the system performs additional calibrations during sample analysis to minimize the effects to the sensors from interfering substances. The results for these additional calibrations do not appear on the screen, are not printed, and do not appear in the *Results* screen. The system returns to the automatic calibration schedule when the sensors recover from the interference. When these additional calibrations are required, sample results do not update during analysis, analysis time is prolonged due to the additional calibration, and all printed calibration reports are status reports.

Calibration Procedure

Use this procedure to perform a one-point, a two-point, or a full calibration.

NOTE: Only operators with level **1** or **2** security access can calibrate the system.

1. If prompted, enter your password, or scan your password with the barcode scanner.
2. At the *Analysis* screen, select the **System** button.
3. Select *Calibrate*.

NOTE: You cannot perform calibrations for at least three hours after installing a new measurement cartridge. During this period, the system performs automatic calibrations and the **Restart Cartridge** button displays in place of the **Calibrate** button. The **Restart Cartridge** button enables you toinitiate a cartridge reinitialization in the event a cartridge fails calibration.

Some calibration types may not be available because an automatic calibration is scheduled to begin shortly. For example, a one-point calibration is not available if a two-point calibration is scheduled to start within 30 minutes.

4. Select the calibration type and select **Start**. The calibration begins, the system displays a message indicating that the system is busy, and the time until the calibration completes is shown. If you want to interrupt the calibration to analyze a priority sample, select **STAT**.

5. If a parameter fails the calibration, the calibration repeats. When the calibration is finished, the *Analysis* screen appears.

Reviewing Calibration Results

The RAPIDPoint 500 system offer two calibration report formats. Depending on the options selected in Setup, the system prints a **full calibration report** or a **system status report**. You can also select not to print a report:

- The **full calibration report** shows the measurement and drift values and the legend that explains the result symbols.
- The **system status report** describes the calibration results as passed or failed and identifies any failed parameters.
- **NOTE:** If the system cannot report a value during a calibration, the result is blank on the full calibration reports. If the system is connected to a RAPIDComm data management system or to an LIS, the system automatically sends the calibration data to these computer systems.

Quality Control (QC)

Quality control (QC) materials (controls) are substances with known expected values that cover the clinically significant range for each parameter.

Follow these guidelines to ensure the most accurate QC results:

- Treat all QC materials as you treat patient samples.
- Quality control procedures are part of an overall quality assurance program. United States federal regulations state that each laboratory must establish QC procedures to document and evaluate system performance, thus ensuring the accuracy and reliability of patient results and reports. Monitoring the results of QC analyses can alert you to possible system performance problems. More frequent use of controls may be required to evaluate system performance during troubleshooting operations.
- In addition to daily QC monitoring, participation in interlaboratory QC survey programs lets you compare your system performance with systems in other laboratories. Participation in interlaboratory QC survey and proficiency testing programs can identify systematic errors not detected by intralaboratory QC testing alone.

QC Options

The RAPIDPoint 500 system supports three options for performing quality control. The option that is enabled in your laboratory is specified during system setup and can only be changed by an operator with appropriate access privileges.

> **NOTE:** Refer to the *RAPIDPoint 500 System Operator's Guide* for system setup instructions.

- **AutomaticQC:** The AutomaticQC cartridge contains liquid controls and the components needed to automatically transfer aliquots of the liquid controls to the measurement cartridge. The system displays the *AQC Pending* message 15 minutes before QC is automatically performed. The system compares QC results with target ranges and will automatically repeat the analysis if any parameters are out of range if this feature is specified during system setup. If a parameter fails the second analysis, the system automatically turns off the parameter to prevent further analysis.

  The system also displays the levels of QC to be analyzed and indicates the progress of analysis for scheduled levels. The current level being analyzed is highlighted, any level that has completed analysis is indicated by an underscore bar, and any level which is scheduled for this time but has not yet been analyzed displays the number of the level only.

- **Required QC:** Liquid controls are used for the Required QC option. When this option is enabled, the system displays the *Required QC Due* message with the time remaining before QC must be performed. The system also compares QC results with the target ranges (if they are defined in system setup) and prompts you to repeat the analysis if any parameters are out of range. If a parameter fails the second analysis, the system automatically turns off the parameter to prevent further analysis.

- **Unscheduled QC:** Liquid controls are used for the Unscheduled QC option. When this option is enabled, QC testing is neither scheduled nor monitored by the RAPIDPoint 500 system and parameter status is not affected by QC results. The system neither turns off parameters that do not pass QC analysis nor turn on a parameter that has previously failed QC analysis if it passes for the failed level.

QC Materials

Siemens RAPIDQC Complete

- Level 1: Siemens Reference Number 02017464 (108860)
  - Ten (10) 2.5 ml ampules
- Level 2: Siemens Reference Number 07519905 (108868)
  - Ten (10) 2.5 ml ampules
- Level 3: Siemens Reference Number 07182730 (108869)
  - Ten (10) 2.5 ml ampules

IMPORTANT: When performing QC analysis on the RAPIDPoint 500 system, either install the AutomaticQC cartridge (see page 16) or use the RAPIDQC® Complete liquid controls. Use of other QC materials may adversely affect parameter performance.

Prepare and handle RAPIDQC® Complete liquid controls as instructed in the package insert that comes with the control product.

IMPORTANT: AQC cartridges available prior to the release of System Software version 2.0 do not support lactate testing on the RAPIDPoint 500 System. AQC cartridges that support lactate testing are identified by a label on the top of the AQC cartridge.

QC Frequency

Analyze three (3) levels of external quality control material every 30 days and when the AQC cartridge is replaced.

QC Procedure

Performing AutomaticQC

- **NOTE:** Frequency of AutomaticQC analysis is defined during system setup. Refer to the*RAPIDPoint 500 System Operator's Guide* for system setup instructions. Although AutomaticQC will be automatically performed at the defined intervals, it can also be performed at any time byfollowing the procedure below.

  You can also specify that the system analyzes AutomaticQC samples before operators can analyze patient sample, and you can interrupt AutomaticQC between levels if you need to analyze an urgent patient sample.

1. If prompted, enter your password or scan your password with the barcode scanner.
2. Select the **AutomaticQC** sample type button, and then select the **Start** button. A screen is displayed allowing you to select the level for your AutomaticQC sample. The *FailedQC* table on this screen shows any failed QC results.
3. Select the level that you want to analyze and then select **Start**.
4. If prompted, enter your operator ID and then select the **Continue** button.
5. The *Results* screen is displayed with the results for the selected parameters when the analysis is complete. Use the *Print* icon to print the results.
   NOTE: The report may be automatically printed if specified during system setup.
6. Select the **Continue** button when you finish viewing and/or printing the results.

Performing Required QC

NOTE: Frequency of Required QC analysis is defined during system setup. Refer to the *RAPIDPoint 500 System Operator's Guide* for system setup instructions. Follow the procedure below to analyze liquid controls when the *Required QC Due* message appears on the banner to indicate that QC analysis is now scheduled or if prompted after you install a new measurement cartridge.

1. If prompted, enter your password or scan your password with the barcode scanner.
2. Select the **Perform QC** button.
3. When prompted, introduce the level of the control shown on the screen:
   a. Scan the barcode on the liquid control ampule.
   b. Open the ampule using the ampule breaker.

c. Attach a *Quick* adapter to the ampule.
d. Insert the *Quick* adapter with the attached ampule into the sample port as shown on the screen.
e. Select the **Continue** button. The system aspirates the sample.

4. When prompted, remove the *Quick* adapter from the sample port and then select the **Continue** button.
5. If prompted, enter your operator ID and then select the **Continue** button.
6. The *Results* screen is displayed with the results for the selected parameters when the analysis is complete. Use the *Print* icon to print the results.
NOTE: The report may be automatically printed if specified during system setup.
7. Select the **Continue** button when you finish viewing and/or printing the results.

Performing Unscheduled QC

NOTE: Follow the procedure below to analyze liquid controls if you are not using either AutomaticQC or Required QC or if you need to perform additional testing of liquid controls. When Unscheduled QC is enabled, the system neither turns off parameters that do not pass QC analysis nor turns on a parameter that has previously failed QC analysis if it passes for the failed level.

1. If prompted, enter your password or scan your password with the barcode scanner.
2. Select the button for the QC sample type.
3. Introduce the liquid control sample:
   a. If necessary, scan the barcode on the liquid control ampule.

   NOTE: If you do not scan the barcode on the liquid control ampule, the system analyzes all parameters, even parameters not included in the control. For example, if you analyze a hematocrit control, the system shows blood gas, electrolyte, and glucose results.
   b. Open the ampule using the ampule breaker.
   c. Either attach a *Quick* adapter to the ampule or draw the contents of the ampule into a syringe.
   d. Insert the *Quick* adapter with attached ampule or the syringe into the sample port as shown on the screen.
   e. Select the **Start** button. The system aspirates the sample.
   f. When prompted, remove the *Quick* adapter or syringe from the sample port and then select the **Continue** button.
4. If prompted, enter your operator ID and then select the **Continue** button.
5. The *Results* screen is displayed with the results for the selected parameters when the analysis is complete. Use the *Print* icon to print the results.
   NOTE: The report may be automatically printed if specified during system setup.
6. Select the **Continue** button when you finish viewing and/or printing the results.

Reviewing Quality Control Results

Results of the quality control test are displayed on the *Results* screen and can be printed. The printed report provides the following information:

- Identifies the control.
- The target ranges that are defined in system setup.
- A legend explains result symbols.
  NOTE: The system automatically prints the report if the *Auto Print* option is enabled during system setup. Depending on the options that are enabled during system setup and the parameters you analyze, the report may be different for your system.

The following symbols may appear with the results on the screen and in the report:

Symbol	Description
↑	The result is above the target range.
↓	The result is below the target range.
-----↑	The result is above the reporting range.
-----↓	The result is below the reporting range.
-----?	The system has an atypical response when measuring this parameter.

1. If any results are not within the expected range, **DO NOT** test patient specimens. Troubleshoot and rerun the controls. Test and report patient specimens **ONLY** when control results are acceptable.
   NOTE: Refer to the *Troubleshooting* section of the *RAPIDPoint 500 System Operator's Guide* for information on resolving failed quality control tests.
2. To display control comments, print details of the quality control test, or to send the details to the LIS, select the appropriate function button.

Replacing an AutomaticQC Cartridge

The *AutomaticQC Cartridge* symbol appears on the banner when ten or fewer samples remain for any level of QC material, or when less than 24 hours remain before the cartridge expires. This enables you to replace the AutomaticQC cartridge at a time when the system is not busy. The system automaticallydisplays a message if you must replace the cartridge before you can perform any other tasks.

CAUTION! Do not install the AutomaticQC cartridge with the system powered off.
NOTE: You can reinstall an AutomaticQC cartridge that was previously removed if the following criteria apply:

- The cartridge is reinstalled within six hours on the system from which it was removed,
- The cartridge contains at least one sample left for all levels of AQC testing, and
- The cartridge has at least one day of use-life before expiration.

NOTE: If a message is displayed indicating that the cartridge needs replacing, go to Step **4** in the following procedure:

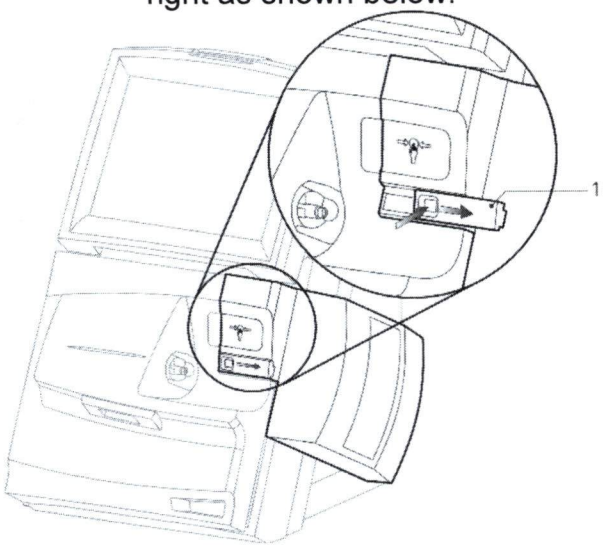
1. If prompted, enter your password or scan your password with the barcode scanner.
2. At the *Analysis* screen, select the **System** button.

NOTE: The *AutomaticQC Cartridge* symbol appears in the *Analysis* screen when the cartridge nears expiration.

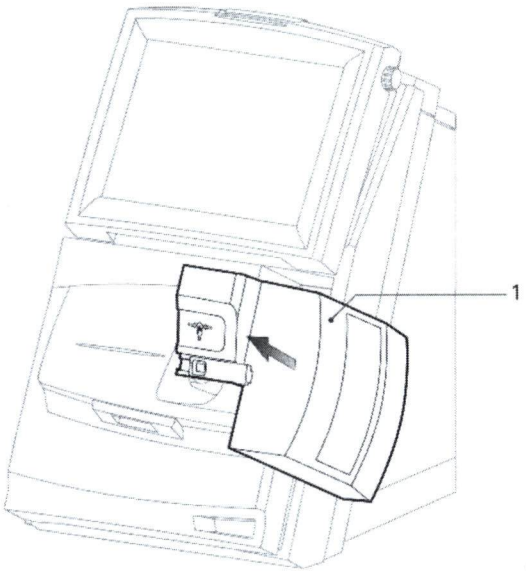
3. At the *System* screen, select the **AutomaticQC Cartridge** button.
4. Select **Replace**. The system plays a video that shows how to perform this procedure. View the video before you begin if required.

NOTE: Select the **Video** button to play the video again if you need help while replacing the cartridge.

5. Push in and then slide the connector (1) on the AutomaticQC cartridge to the right as shown below:



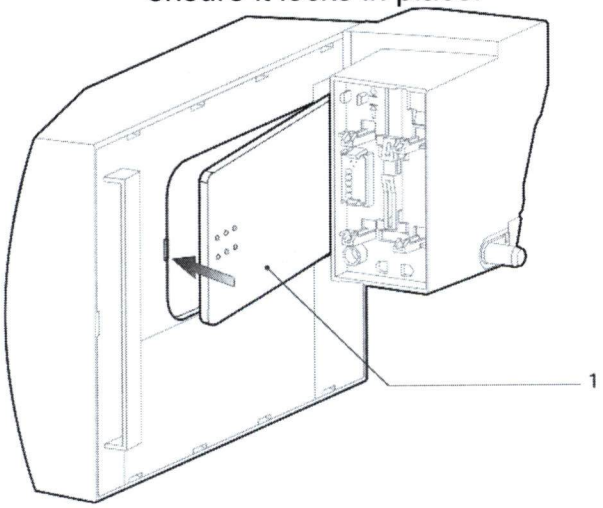
6. Wait for the AutomaticQC cartridge to eject from the system.
7. Remove the AutomaticQC cartridge as shown below and dispose of it according to hospital policy.



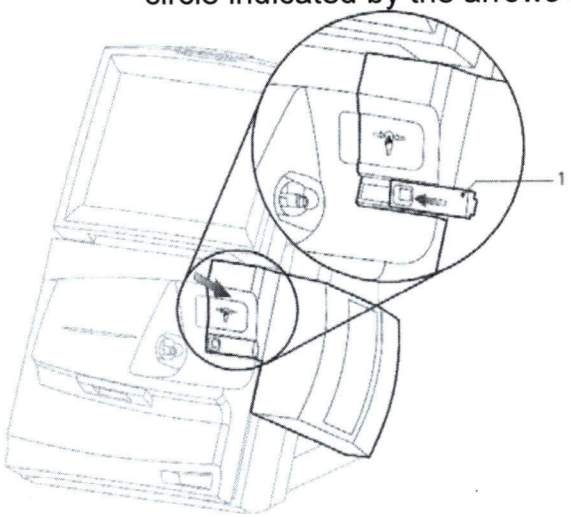
BIOHAZARD

In normal operation the AutomaticQC cartridge does not come in contact with biohazardous materials from the system. However, if you suspect that the cartridge is contaminated, dispose of it according to your hospital policy for biohazardous materials.

8. Obtain a new AutomaticQC cartridge and remove the yellow card from under the lever. Be sure the lever locks in place.
9. Press down on the lever firmly near the raised dots as shown below, to close and lock the lever in the cartridge. After you push the cartridge, release your hand and check to see if the cartridge moves forward. If it does, push again to ensure it locks in place.



10. Insert the cartridge in the system as shown below and then push firmly on the circle indicated by the arrows until you hear the cartridge lock in place.



11. Slide the cartridge connector to the left to close it. The *Wait* screen appears while the system prepares the cartridge, and the *Analysis* screen appears when the cartridge is ready for use.

Troubleshooting Out-of-Range QC Values

- Are the control solutions expired?
- Are the control solutions deteriorated? Try a fresh control solution.
- Was the proper control level tested? Rerun the correct level.
- Has the ambient room temperature changed by more than 5°C from the last calibration? Recalibrate and rerun controls.
- Has the measurement cartridge deteriorated? Load a new measurement cartridge and recalibrate.
- Is the Analyzer functioning properly? Refer to the *Troubleshooting* section of the *RAPIDPoint 500*
- *System Operator's Guide* for additional information on resolving failed quality control tests.
- Call Siemens Healthcare Diagnostics Customer Service at 1-877-229-3711.

Testing Patient Specimens

BIOHAZARD

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

NOTE: Refer to *Selecting Parameters and Units of Measurement* in the *RAPIDPoint 500 System Operator's Guide* for setting the parameters that are to be routinely measured and their units.

After a valid calibration has been performed and positive and negative controls have been successfully tested, you are ready to test patient samples.

Instrument Start-Up

After installation of the RAPIDPoint 500 system, the instrument should be left on at all times.

Powering the System On

1. Turn on the power switch.
2. After the RAPIDPoint 500 system title screen appears, the *Wait* screen displays the time remaining until you can use the system. The *Analysis* screen appears when the system is ready to use.

Replacing the Wash/Waste Cartridge

The *Wash/Waste Cartridge* symbol appears on the banner when 30 or fewer samples can be analyzed or when less than 24 hours remain before the cartridge expires. This enables you to replace the Wash/Waste cartridge at a time when the system is not busy. The system automatically displays a message if you must replace the cartridge before you can perform any other tasks.

NOTE: If you need to replace both the measurement cartridge and the Wash/Waste cartridge, refer to *Replacing the Measurement and Wash/Waste Cartridges* on page 20.

NOTE: If a message is displayed indicating that the Wash/Waste cartridge needs replacing, go to Step **4** in the following procedure.

1. If prompted, enter your password or scan your password with the barcode scanner.
2. At the *Analysis* screen, select the **System** button.

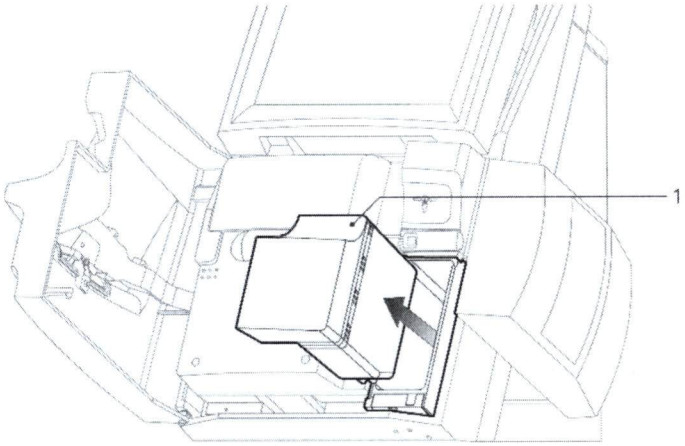
NOTE: The *Wash/Waste Cartridge* symbol appears in the *Analysis* screen when the Wash/Waste cartridge nears expiration.

3. At the *System* screen, select the **Wash/Waste Cartridge** button. Make sure that nothing is blocking the door at the front of the system.
4. Select **Replace**. The system plays a video that shows how to perform this procedure. View the video before you begin if required.

NOTE: Select the **Video** button to play the video again if you need help while replacing the cartridge.

5. Open the door at the front of the system.

Remove the Wash/Waste cartridge as shown below and dispose of it according to hospital policy.



BIOHAZARD

Handle expired Wash/Waste cartridges as contaminated with potential infectious materials. Always use universal precautions when handling contaminated equipment or potentially infectious materials. Refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide* for recommended precautions when working with biohazardous materials.

6. Obtain a new Wash/Waste cartridge.
7. Insert the Wash/Waste cartridge in the system and then push firmly on the dot until you hear the cartridge lock in place.
8. Close the door at the front of the system. The *Wait* screen is displayed, showing the time remaining until you can use the system. The *Analysis* screen appears when the system is ready to use.

Replacing the Measurement and Wash/Waste Cartridges

The *Replace Cartridges* symbol appears on the banner when 30 or fewer samples can be analyzed or when less than 24 hours remain before the measurement cartridge expires. This enables you to replace the measurement and Wash/Waste cartridges at a time when the system is not busy. The system automatically displays a message if you must replace the cartridges before you can perform any other tasks.

NOTE: When you replace a measurement cartridge, you must replace the Wash/Waste cartridge at the same time. If you need to replace only the Wash/Waste cartridge, refer to Replacing the Wash/Waste Cartridge on page 19.

CAUTION! Do not install the measurement cartridge with the system powered off.

NOTE: If a message is displayed indicating that the cartridge needs replacing, go to Step **4** in the following procedure.

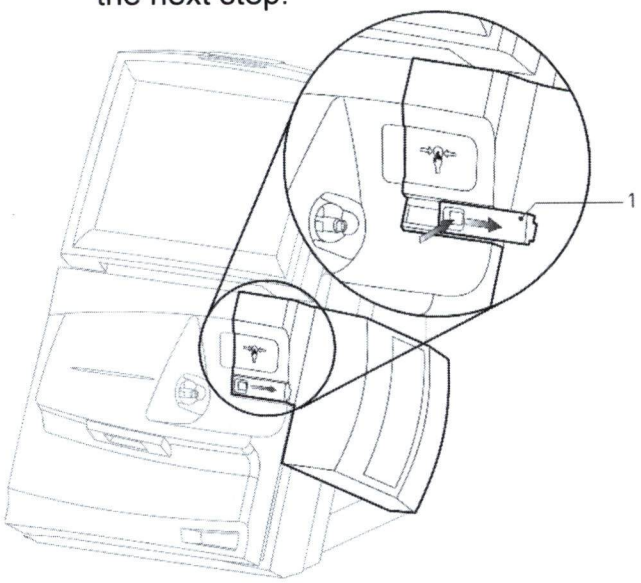
1. If prompted, enter your password or scan your password with the barcode scanner.
2. At the *Analysis* screen, select the **System** button.

NOTE: The *Replace Cartridges* symbol appears in the *Analysis* screen when the measurement cartridge nears expiration. At the *System* screen, select the **Measurement Cartridge** button. Make sure that nothing is blocking the door at the front of the system.

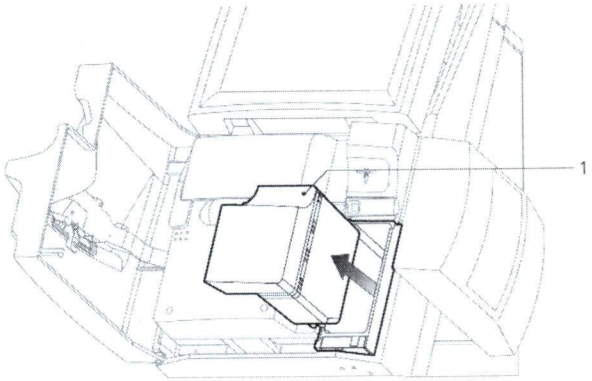
3. Select **Replace**. The system plays a video that shows how to perform this procedure. View the video before you begin if required.

NOTE: Select the **Video** button to play the video again if you need help while replacing the cartridge.

4. If an AutomaticQC cartridge is installed, push in and then slide the connector (1) on the AutomaticQC cartridge to the right as shown below. Otherwise, proceed to the next step.



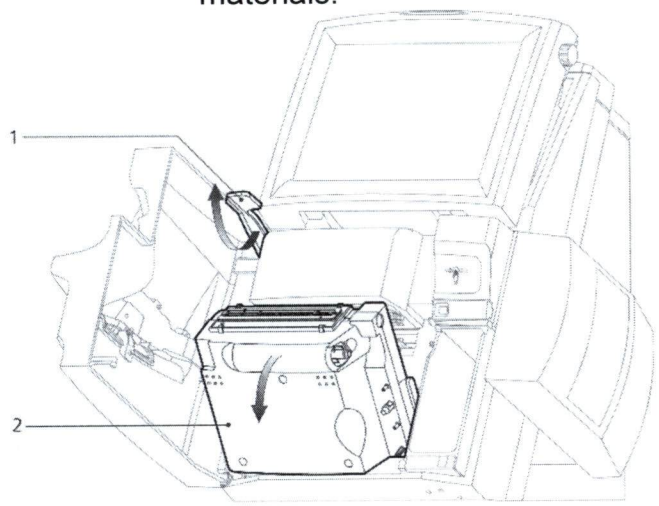
5. Open the door at the front of the system.
6. Remove the Wash/Waste cartridge as shown below and dispose of it according to hospital policy.



BIOHAZARD

Handle expired measurement cartridges and Wash/Waste cartridges as contaminated with potential infectious materials. Always use universal precautions when handling contaminated equipment or potentially infectious materials. Refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide* for recommended precautions when working with biohazardous materials.

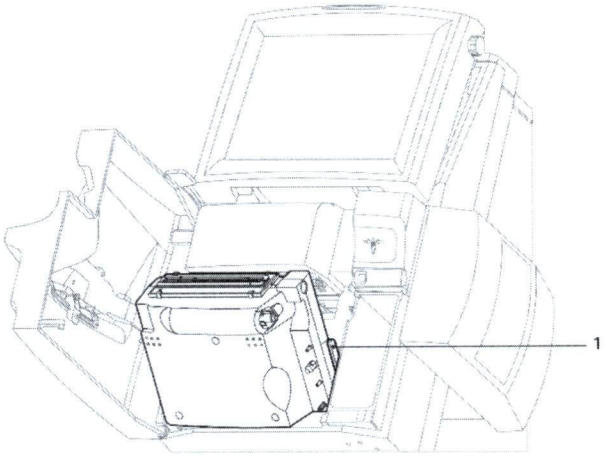
7. Lift up the latch:
   a. That secures the measurement cartridge as far as possible until the cartridge ejects from the system, then lift the measurement cartridge up and out of the system and
   b. Dispose of it according to hospital policy for working with biohazardous materials.



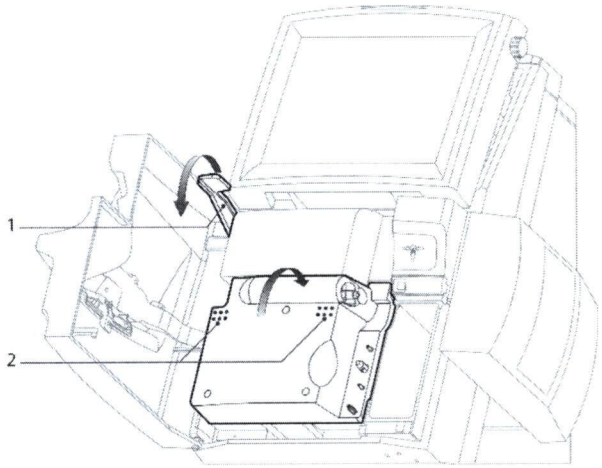
BIOHAZARD

Handle expired measurement cartridges and Wash/Waste cartridges as contaminated with potential infectious materials. Always use universal precautions when handling contaminated equipment or potentially infectious materials. Refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide* for recommended precautions when working with biohazardous materials.

8. Obtain a new measurement cartridge. Position the cartridge in the system as shown below, with the grooves on the sides of the cartridge (1) aligned with the grooves on the system.



9. Place your thumbs on the raised dots on the cartridge. Press in and upwards strongly and firmly to lock the cartridge in place, then lower the latch to secure he measurement cartridge.



10. Obtain a new Wash/Waste cartridge.

NOTE: A Wash/Waste cartridge is designed for single use only. If a Wash/Waste cartridge is removed from the system it cannot be inserted into the system again.

11. Insert the Wash/Waste cartridge in the system and then push firmly on the dot until you hear the cartridge lock in place.
12. Close the door at the front of the system.
13. If an AutomaticQC cartridge is installed, slide the connector on the AutomaticQC cartridge to the left to close it. Otherwise, proceed to the next step.
14. The *Wait* screen is displayed, showing the time remaining until you can use the system. The *Analysis* screen appears when the system is ready to use.
15. If prompted, analyze Required QC samples before analyzing patient samples.

Reinitializing the Measurement Cartridge

Each time a measurement cartridge is replaced, a cartridge initialization is automatically performed. During initialization measurement parameters are calibrated. This calibration is not always successful for all parameters, and takes a long time.

If a parameter failure shows in the events log of the System screen after initialization, or a parameter displays with a single diagonal line through it at the Ready screen, manually reinitialize the measurement cartridge.

> **NOTE**: Two lines through a parameter indicate a parameter failed calibration and a repeat calibration is unlikely to correct the problem.

1. Select **Restart Cartridge** at the *System* screen to perform a measurement cartridge reinitialization. A dialog box displays and you are asked if you want to restart cartridge initialization.
2. Select **Yes**. The *Wait* screen displays while cartridge initialization proceeds until completion.

Testing Patient Samples

After a valid calibration has been performed and positive and negative controls have been successfully tested, you are ready to test patient samples. The system is ready to perform this testing when the *Analysis* screen is displayed.

BIOHAZARD

Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, refer to *Appendix A: Safety Information* in the *RAPIDPoint 500 System Operator's Guide.*

1. If prompted, enter your password or scan your password with the barcode scanner.
2. Roll the syringe or the capillary tube between your palms and gently invert it several times to mix the sample thoroughly.

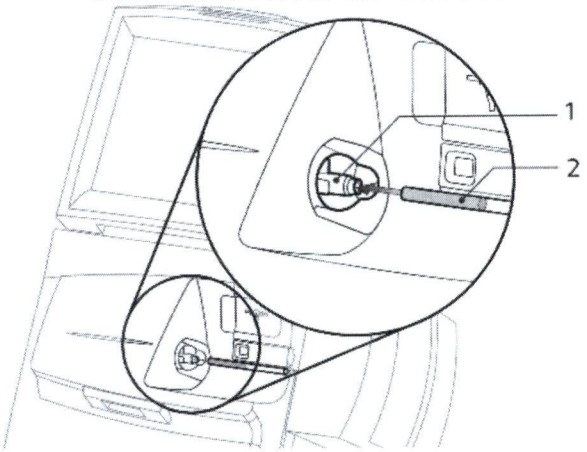
CAUTION! Ensure that labels attached to the syringe do not block the syringe from entering the system and cause it to fall off. Position the label toward the back of the syringe barrel near the plunger if required.

CAUTION! Always select the mixed venous sample button to analyze mixed venous samples. Samples collected from some pulmonary artery catheters can contain the benzalkonium ion that interferes with analysis and affects results. If you select

another sample type button for mixed venous samples containing the benzalkonium ion, the reported results will be unreliable.

NOTE: If you have a priority sample but a message appears indicating that the system is busy, select STAT to interrupt the system. Wait until the system is ready for analysis, and then analyze the patient sample. If the STAT button does not appear, wait until the message disappears to analyze the patient sample.

3. Select the button on the *Analysis* screen that corresponds with the type of sample being analyzed (arterial blood, venous blood, mixed venous blood, or pleural fluid) and the sample device (syringe or capillary tube). A checkmark is displayed in the currently selected button.
4. If necessary, scan the Patient ID barcode. The patient name, date of birth, and sex are automatically retrieved if they already exist on the system.
5. When prompted, introduce the sample device into the sample port (1) as shown below and select the **Start** button to aspirate the sample.



CAUTION! When using capillary tubes, hold the capillary tube at the end closest to the sample port when inserting the capillary tube into the sample port. Holding the capillary tube incorrectly can cause it to break. Also, to prevent damage to the sample port, introduce only the fire-polished end of a capillary tube into the sample port.

6. When prompted, remove the sample device from the sample port and select the **Continue** button.
7. If prompted, enter demographic information and select the **Continue** button.

NOTE: To enter the patient ID using the barcode scanner, select **Patient ID**, then scan the patient ID barcode. To enter the accession number using the barcode scanner, select **Accession No.**, then scan the accession number barcode.

8. The *Results* screen is displayed with the test results when the analysis is complete. Use the *Print* icon to print the results.
9.

NOTE: The report may be automatically printed if specified during system setup.

10. Select the **Continue** button when you finish viewing and/or printing the results.

Reviewing Patient Test Results

Results of the patient sample test are displayed on the *Results* screen and can be printed. The results are displayed in yellow when analysis is still in progress. Preliminary results will not display if the system is performing additional calibrations during analysis. A parameter is grayed out on the *Results* screen if a result cannot be reported because of system problems (for example, the parameter failed QC or is out of calibration). A parameter is not displayed on the *Results* screen if a required value (for example, temperature if a temperature corrected value was ordered) is not entered. If individual results do not appear on screens and reports, ensure that those parameters are not turned off because they failed Required QC or AutomaticQC, missed a Required QC analysis, or are out of calibration.

> **NOTE:** Refer to the *Troubleshooting* section of the *RAPIDPoint 500 System Operator's Guide* to identify other causes of missing results on screens and reports.

The following symbols identify results that are either out of range or need your attention. These symbols and results appear in red on the screen, and they also appear on the report.

Symbol	Description
↑	The result is above the patient range.
↓	The result is below the patient range.
-----↑	The result is above the reporting range.
-----↓	The result is below the reporting range.
-----?	The system has an atypical response when measuring this parameter and cannot report the result. Analyze the sample again if possible.
? <? >?	The reported result is questionable. The system has been set to use *Analytical Range* limits and the *Display Question Result* options, which should not be selected at the same time. Ensure *Analytical Range* limits, *Display Question Result*, or both are turned off, and analyze the sample again. The **?** symbol displays without a value in the patient list at the Results screen. The **<?** and **>?** symbols display with values in printed reports and the display.
>	The result is greater than the selected Analytical Range limit. **NOTE**: Analytical Range limits do not apply to QC results.
<	The result is less than the selected Analytical Range limit. **NOTE**: Analytical Range limits do not apply to QC results. **NOTE**: If a neonatal bilirubin (nBili) value falls below the 2.0 mg/dL (34 µmol/L) reporting range, a value of <2.0 (or <34) is reported.

Patient Sample Reports

The system automatically prints the patient sample report if the Auto Print option is enabled during system setup. A patient sample report can also be printed by selecting the **Print** button while the results are being displayed in the *Analysis* screen.

Typically, the patient sample report identifies the patient and sample and contains CO-oximetry results, temperature-corrected results, patient and sample demographics, patient ranges as defined in Setup, and a legend that explains results symbols. Messages regarding the patient results, system calibration, and/or other conditions may also be displayed in the patient report. The following table describes the messages that may appear.

NOTE: Refer to the *Troubleshooting* section of the *RAPIDPoint 500 System Operator's Guide* to resolve problems indicated by the message.

Message	Description
↓ or ↑ = Out of range	The result is above or below the patient range.
-----↓ or -----↑ = Out of reporting range	The result is above or below the reporting range.
-----? = Question result	The system has an atypical response when measuring this parameter.
D2 Excessive Drift:	The parameter exceeded calibration limits.
D3 Slope Error:	The parameter exceeded calibration limits.
D4 Offset Error:	The parameter exceeded calibration limits.
Temp Out of Range	Temperature of the sample is beyond the acceptable measurement range at the end of sample analysis.
Report data edited	Demographic data for the sample was edited.
D70 Optics Error:	An error occurred in the CO-ox optical measurement system. The number after the message indicates the type of error.
D75 Lamp Failure	The CO-ox halogen lamp has failed.
D76 COox	Electronics Error: An error has occurred in the CO-ox electronic components. The number after the message indicates the type of error.
D77 COox	Temperature Error An error has occurred in the CO-ox temperature control components.
COox Sample Temp Out of Range	Temperature of the sample is beyond the acceptable measurement range at the end of sample analysis.
Excessive Bubbles in COox Sample	The system was not able to analyze the CO-ox portion of the sample because of bubbles detected in the CO-ox sample chamber.
SulfHb > 1.5%	The system detects sulfhemoglobin with a concentration greater than 1.5%

Error Messages During Testing
The system displays an error message in the event of certain conditions or errors, as explained in the *Troubleshooting* section of the *RAPIDPoint 500 System Operator's Guide.*

NOTE: Refer to the *Troubleshooting* section of the *RAPIDPoint 500 System Operator's Guide* to resolve problems indicated by the message.

The system messages can appear as follows:

- Messages can appear in a message box over the *Analysis* screen or over the *System* screen. In a restricted system where operator access privileges are specified, some messages can appear at the *Sign-In* screen.
- Messages can appear in the events log at the *System* screen or in the events log that you access from the *Results* menu. For example, after you replace a depleted Wash/Waste cartridge, the message about the cartridge no longer appears at the *System* screen but remains in the events log that you access from the *Results* menu.

Testing STAT Samples

If you have a priority sample but a message appears indicating that the system is busy, select STAT to interrupt the system. Wait until the system is ready for analysis, and then analyze the patient sample. If the STAT button does not appear, wait until the message disappears to analyze the patient sample.

Shutdown

Follow this procedure to remove power from the system:

1. If prompted, enter your password, or scan your password with the barcode scanner.
2. Select the **System** button.
3. Select **Shutdown**.
4. When prompted, select **Yes**. After you select **Yes**, a video automatically displays. Follow the procedure in the video to turn off the system.

NOTE: Be sure you wait until the screen is black before you turn off the power switch, as instructed in the video.

5. To restore power to the system, turn the power switch on.
6. After the *RAPIDPoint 500 system* title screen appears, the *Wait* screen displays the time remaining until you can use the system. The *Analysis* screen appears when the system is ready to analyze samples.

Reporting Results

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

Calculations

The operator is not required to perform any calculations.

Performance Parameters

Refer to *Appendix E: Specifications* in the *RAPIDPoint 500 System Operator's Guide* for specific performance characteristics. Refer to the *Interfering Substances* section in the *Appendix* for possible interfering substances.

Reference Intervals

The high and low limits of the patient range for each parameter are defined in the system and can be modified to meet the needs of your laboratory. The default range for each parameter and the default unit of measure are shown in the table below. The default ranges are the valid reporting ranges for the parameters.

NOTE: Refer to the Defining Patient Ranges section of the RAPIDPoint 500 System Operator's Guide to modify the high and/or low limit for a parameter.

Parameter	Reference Range	Reportable Range	Critical Test Value	Unit of Measure
pH (Whole Blood)	7.360-7.440	6.50-7.80	7.20-7.55	(pH units)
pCo2	35.0-48.0	5.0-200.0	<22->55	mmHg
pO2	83.0-108	10.0-700.0	<40	mmHg
tHb	12.0-18.0	2.0-25.0		g/dL
FO2Hb	94.0-97.0	-200-200		%
FCO2Hb	0.0-1.5	-200-200		%
FmetHb	-1.4-1.5	-200-200		%
FHHb	0.0-5.0	-200-200		%

Reporting Protocol for Abnormal Results
Call all critical results to the nurse or attending physician.

Out-of-range results appear in red on the screen with a red up or down arrow next to the result. An up or down arrow also appears next to the result on the patient report.

> **NOTE:** Refer to the *Selecting Parameters and Units of Measurement* section of the *RAPIDPoint 500 System Operator's Guide* to select alternate units for a parameter. The system automatically converts the ranges to the corresponding values for the selected units.
>
> **NOTE:** Refer to the *Selecting Parameters and Units of Measurement* section of the *RAPIDPoint 500 System Operator's Guide* to select additional calculated parameters for reporting and to determine which parameters and sample demographics must be selected and entered to obtain results for each calculated parameter.

Procedure Notes
Refer to the following sections of the *RapidPoint 500 System Operator's Guide* for additional information:

- **Troubleshooting/Diagnostics**: *Troubleshooting* section

Siemens cannot guarantee system performance when any of the following situations occur. Specific terms of warranty, service, and contract agreements may be invalidated if any of these situations occur.

- Expiration dates of cartridges are exceeded.
- Cartridges are not used according to the recommendations of Siemens.
- Standard laboratory practices are not followed.
- The procedures described in this guide are not followed.
- Environmental operating conditions and location recommendations are not followed.

Method Limitations

As with all diagnostic tests, do not base a definitive diagnosis on the results of a single test. A physician should make a diagnosis after all clinical and laboratory findings are evaluated. On whole blood, the total analytical error may be higher than the fixed limits of +/- 20%. The measured total analytical error includes many sources of error such as day-to-day variation, instrument-to-instrument differences, and variability in the reference method used for comparison.

Interfering Substances for Blood Gases and Metabolites

Serum or whole blood was spiked with a potentially interfering substance to the test concentrations shown when testing for interference. Interference was calculated using the difference between the medians of the spiked and unspiked samples.

> **NOTE:** Refer to the *Interfering Substances* section of the *RAPIDPoint 500 System Operator's Guide* for additional details concerning the methodology used when testing for interference to obtain the results shown in the following sections.

pO2 Sensor Interfering Substances

The following table lists the substances that were found not to interfere with the pO2 measurement. At the concentrations listed, these compounds produced less than a 2 mmHg error in the recovered pO2 values.

Substance Tested	Concentration Tested
Isoflurane	3%
Halothane	3%
Nitrous oxide	84%

pCO2 Sensor Interfering Substances

The following table lists the substances that were found not to interfere with the pCO2 measurement. At the concentrations listed, these compounds produced less than a 2 mmHg error in the recovered pCO2 values.

Substance Tested	Concentration Tested
Ibuprofen	40 mg/dL

pH Sensor Interfering Substances

The following table lists the substances that were found not to interfere with the pH measurement. At the concentrations listed, these compounds produced less than a 0.016 error in the recovered pH values.

Substance Tested	Concentration Tested
Acetaminophen	20 mg/dL

Interfering Substances for CO-Oximetry

Whole blood was spiked with a potentially interfering substance to the test concentrations shown when testing for interference. The interference was calculated by comparing the average difference between samples spiked with a substance and similar samples not spiked.

> **NOTE:** Refer to the *Interfering Substances* section of the *RAPIDPoint 500 System Operator's Guide* for additional details concerning the methodology used when testing for interference to obtain the results shown in the following sections.
>
> **CAUTION**: Any substance that absorbs light in the same regions as whole blood could potentially cause an interference or error in CO-oximetry measurements.

The following table lists substances that were found ***not*** to interfere with CO-oximetry measurements. At the concentrations listed, these compounds produced less than a 0.5 g/dL error in recovered tHb valuesand less than a 1.0% error in recovered *F*O2Hb, *F*COHb, *F*MetHb, and *F*HHb values.

Substance Tested	Concentration Tested
Beta carotene	40 mg/dL
Hemolysis	10% volume
Lipid	5% intra-lipid in serum
Indocyanine	Green 5 mg/L
Bilirubin	40 mg/dL
Fetal Hemoglobin	20%, 40%, 85%
Cyanmethemoglobin	10%
Evans Blue	5 mg/L

The substances listed in the following table interfered with CO-oximetry measurements.

Substance Tested	Concentration Tested	Level of Interference
Methylene Blue	25 mg/L	1.2% decrease in *F*O2Hb values 1.3% increase in *F*COHb values
Methylene Blue	40 mg/L	2.0% decrease in *F*O2Hb values 2.0% increase in *F*COHb values
Sulfhemoglobin	10%	0.8 g/dL decrease in tHb values 6.12% decrease in *F*O2Hb values 3.63% increase in *F*COHb values 1.4% increase in *F*MetHb values 1.7% increase in *F*HHb values

Supplies

- Measurement Cartridge, RAPIDPoint 405 system
- AutomaticQC Cartridge Kit
- Wash/Waste Cartridge
- Siemens RAPIDQC controls
- Syringes (for whole blood, pleural fluid, and controls)
- Capillary Tubes (for whole blood)
- *Quick*™ Adaptor (for control ampules)

References

1. RAPIDPoint 500 System Operator's Guide. Siemens Healthcare Diagnostics, Elkhart, IN 46515
2. Clinical and Laboratory Standards Institute, Blood Gas and pH Analysis and Related Measurements:
3. Approved Guidelines; CLSI Document C46-A; (Vol. 29, No. 8) 2009
4. Measurement Cartridge, RAPIDPoint 405 system package insert. Siemens Healthcare Diagnostics,
5. Elkhart, IN 46515
6. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals Third Edition (GP2-A3), 1996.
7. Gardner, Wendy. Siemens Healthcare. Email 11/19/2013. CLSI RAPIDPoint 500 Technical Procedure 2013.pdf.