Integri-sense Technology Handbook/Reference Guide

Comprehensive Quality Assurance Providing Sample Integrity at Each Analytical Stage

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Preface

Blood gas testing is one of the most important diagnostic tools for evaluating and diagnosing respiratory and metabolic imbalances that often can be a matter of life and death. For this reason, it is performed in nearly every hospital in the world. In addition to the blood gas values, these critical care analyzers also provide patient test results that include electrolytes, metabolites, total hemoglobin, CO-oximetry, and neonatal total bilirubin.

Clinicians look to the medical industry to provide blood gas systems that offer a comprehensive menu in an easy-to-use analyzer that consistently delivers fast patient test results with the accuracy that the medical profession demands.

Siemens Healthineers is dedicated to delivering a critical care portfolio that transforms care delivery by offering the right test in the right place at the right time. Offering lab-quality testing solutions, the RAPIDPoint® 500e Blood Gas System enables increased efficiency and shorter time to diagnosis for improved patient outcomes. To enable robust sample-to-sample accuracy and confidence in every blood gas result, the RAPIDPoint 500e system employs built-in, proprietary Integri-sense™ Technology.

What Is Integri-sense Technology?

Integri-sense Technology is the guardian of patient results.

Through a comprehensive series of functional checks and balances, Integri-sense Technology delivers accurate patient results. These frequent quality and sample checks are automatically performed before, during, and after every patient sample. Three levels of independent, automatic quality control solutions, covering the medical decision levels for all parameters, contribute to the integrity of and confidence in the RAPIDPoint 500e system. Multiple calibration routines and advanced software algorithms combine to ensure that the RAPIDPoint 500e analyzer produces reliable and clinically actionable test results, each and every time, delivering confidence with every patient result.

Fully Automated

Automatic Calibrations
Routine calibrations are performed for each analytical parameter without operator involvement.

Automatic Quality Control
Three levels of truly independent automatic quality control span the clinically significant ranges.

System Algorithm Checks
Advanced software algorithms enable the analyzer to be ready to generate reliable, clinically actionable test results.

Checks and Balances

60 Seconds to Results
Provides clinically actionable results in 60 seconds.

24-Minute Cartridge Initialization Time
Includes a new sensor module, CO-ox chamber, and sample probe with every new cartridge.

Advanced Sample Management
Sample port design facilitates sample handling, maximizing analyzer uptime.

Workflow Efficiencies

Temperature Checks
Sample is maintained at 37°C, representative of the human body.

Clot Detection
Patient sample integrity is continuously monitored for clots, triggering an automatic clot clearing sequence to protect the sensors.

Bubble Detection
Patient sample integrity is continuously monitored for bubbles.

CO-oximetry
Supports assessment of a patient's oxygenation status.

Figure 1. Integri-sense Technology overview.

Before we explore the details of Integri-sense Technology, it is important to have a basic understanding of the RAPIDPoint 500e blood gas system–its components and overall operating characteristics.

RAPIDPoint 500e Blood Gas System Overview

The RAPIDPoint 500e system (Figure 2) delivers accurate results quickly, provides efficient and flexible quality control and calibration options, requires no maintenance, and is designed for ease of use. In addition, the system is designed to minimize the potential introduction of clots into the analyzer, enforce advanced operator and data security measures, ensure greater operator safety, and provide clear troubleshooting guidance. Analysis with the RAPIDPoint 500e system offers a full menu of critical care parameters, including blood gas and pH, electrolytes, metabolites, total hemoglobin, CO-oximetry, and neonatal total bilirubin.

Measurement cartridge

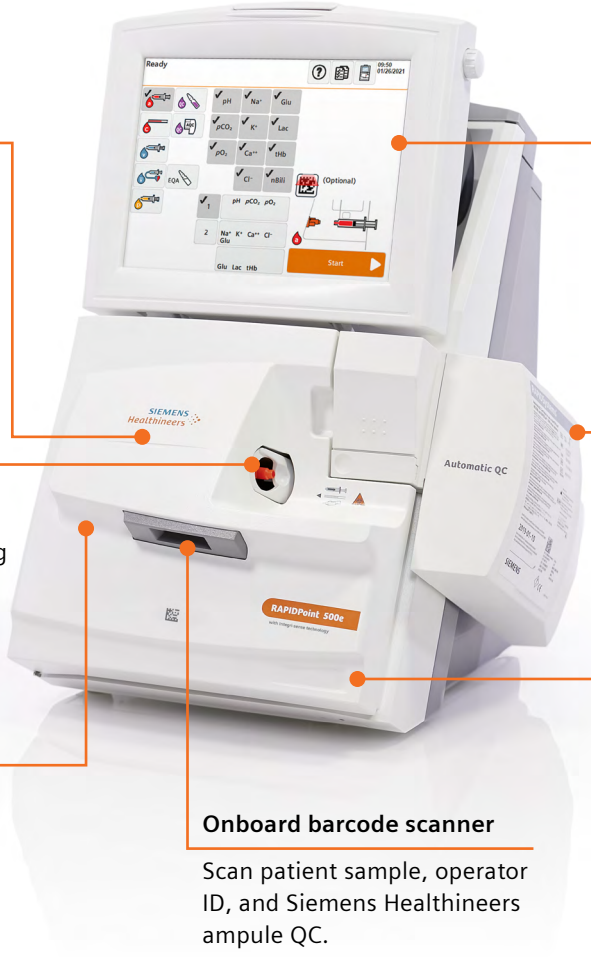
Accommodate different workloads with a variety of measurement cartridges, all with a 28-day onboard use life.

Universal sample port for hands-free sampling

Eliminate operator variability with hands-free, automatic sample aspiration while avoiding risk of biohazard exposure.

CO-oximetry

Measure total hemoglobin, CO-ox fractions, and neonatal total bilirubin on whole blood.



Easy-to-navigate display

Easily access system functions using the icons on the large, intuitive touchscreen display.

Onboard AQC cartridge

Verify analyzer performance with three independent QC solutions covering the medical decision levels.

Wash/waste cartridge

Reduce exposure to potential biohazards with the "closed" wash/waste cartridge.

Onboard barcode scanner

Scan patient sample, operator ID, and Siemens Healthineers ampule QC.

Figure 2. RAPIDPoint 500e Blood Gas System components.

Maintenance-free Cartridge Technology

The RAPIDPoint 500e system is a cartridge-based blood gas analyzer offering the simplicity of operation required in most critical care testing environments. Maintenance-free operation allows the clinician to spend more time dedicated to patient care and managing patient outcomes and less time acquiring test results.

Three cartridges are used with the RAPIDPoint 500e system:

- The **measurement cartridge** includes the planar sensors, sample probe and sample port, calibration solutions, and CO-oximeter chamber.
- The **wash/waste cartridge** cleans the sample pathway after every analysis and collects the waste.
- The **automatic quality control (AQC) cartridge** contains three independent QC solutions and is fully programmable according to hospital requirements.

The system's use of three separate cartridges provides several advantages:

- If a clot is detected, enters the analyzer, and is unrecoverable, you need only replace the affected cartridges.
- There are a variety of measurement cartridges to accommodate different workloads and menu requirements, all with a 28-day onboard use life.
- The AQC cartridge is positioned such that the quality control solutions follow the same sample pathway as the patient's whole blood.
- The AQC cartridge is fully automated and simply requires replacement every 28 days.
- The wash/waste cartridge is replaced as needed or once every 10 days, with no interruption in testing workflow.

Figure 3. RAPIDPoint 500e system cartridges: measurement cartridge, wash/waste cartridge, AQC cartridge.

Measurement cartridge

All the components required to measure the critical analytes are contained in a single, long use-life cartridge—without the need for separate sensors, reagent bottles, or gas tanks. The measurement cartridge includes the sample probe and sample port, industry-proven planar sensors, the CO-oximeter sample chamber, calibration solutions, and electronic and fluidic components needed to analyze patient and QC samples and calibrate the RAPIDPoint 500e system. The cartridge is entirely maintenance-free over its 28-day onboard use-life.

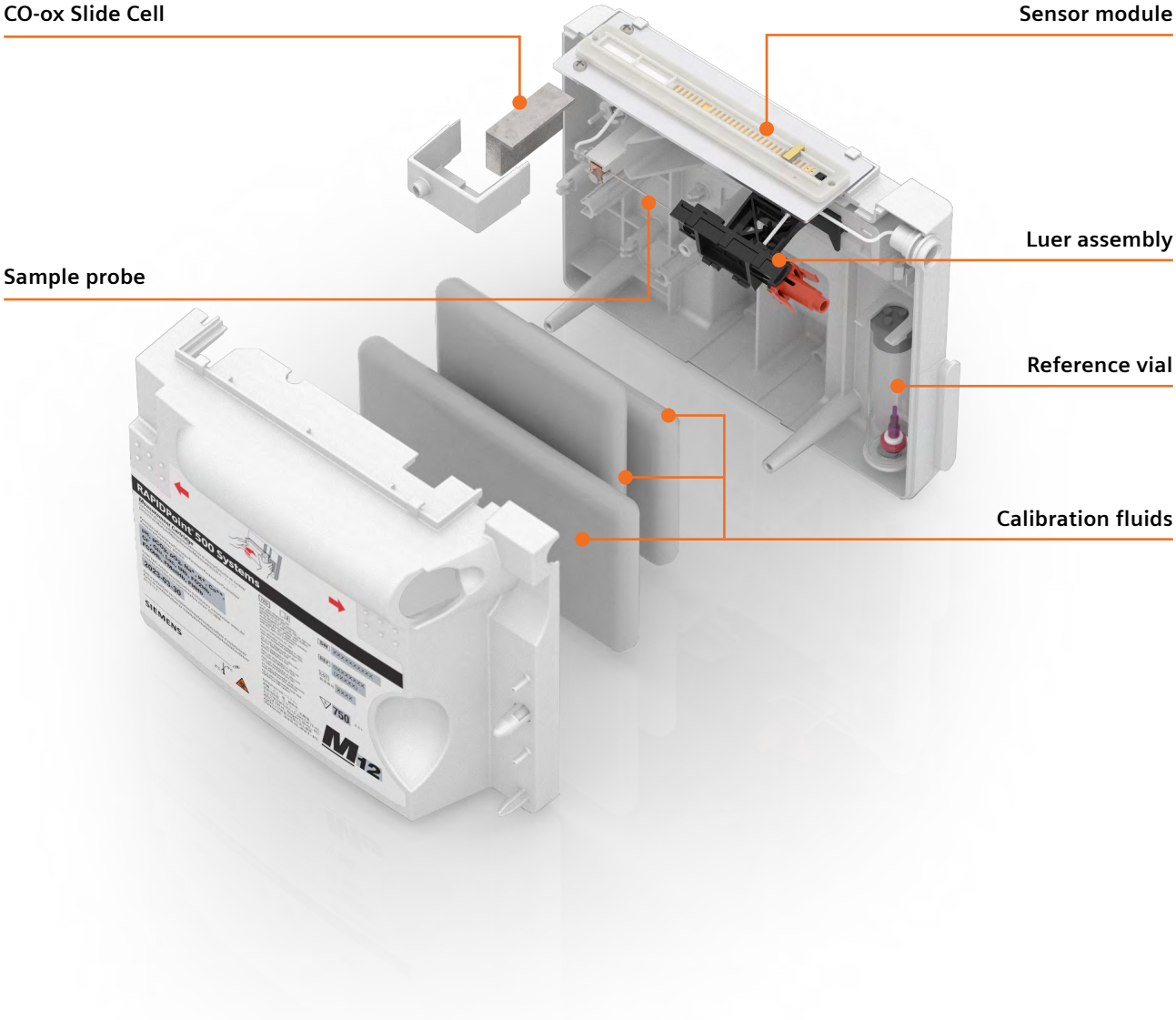


Figure 4. RAPIDPoint 500e system measurement cartridge.

Table 1. RAPIDPoint 500e system measured analytes.

Blood Gas	Electrolytes	Metabolites	CO-oximetry
• pH • Partial pressure of oxygen (pO_2) • Partial pressure of carbon dioxide (pCO_2)	• Sodium (Na^+) • Potassium (K^+) • Ionized calcium (Ca^{++}) • Chloride (Cl^-)	• Glucose • Lactate	• Total hemoglobin (tHb) • Oxyhemoglobin (FO_2Hb) • Deoxyhemoglobin (*F*HHb) • Methemoglobin (*F*MetHb) • Carboxyhemoglobin (*F*COHb) • Neonatal bilirubin (nBili)

Table 2 describes the traceability methods for the calibration solutions contained in each measurement cartridge. Most are traceable to NIST SRM standards.

Table 2. Calibrator traceability methods.

Parameter	Traceability Method
pH	Traceable to NIST SRM186 reference materials via the IFCC blood reference method.
pCO_2	Traceable to tonometered aqueous standards prepared using NIST-traceable temperature and pressure standards and gravimetrically prepared precision gas standards.
pO_2	Traceable to tonometered aqueous standards prepared using NIST-traceable temperature and pressure standards and gravimetrically prepared precision gas standards.
K^+	Traceable to NIST SRM 918 reference materials using flame photometry.
Na^+	Traceable to NIST SRM 919 reference material using flame photometry.
Ca^{++}	Traceable to gravimetrically prepared internal standards using NIST SRM 915 and ISE methods embodied in Siemens Healthineers blood gas analyzers.
Cl^-	Traceable to NIST SRM 919 or 918 reference materials using a coulmetric reference method.
Glucose	Traceable to NIST SRM 917 reference materials using the hexokinase method.
Lactate	Traceable to high-purity lactate using the lactate dehydrogenase spectrophotometric method.
tHb	Traceable to internal standards calibrated against the CLSI cyanmethemoglobin method.
Neonatal Bilirubin	There is no unique calibrator for nBili. It is an optical measurement that is associated with tHb, which is traceable as noted above.

Benefits of Refrigerated Storage

Refrigerated storage of the measurement cartridge ensures the integrity of the calibration solutions and planar sensors.

You can install the cartridge on the analyzer immediately after removing it from the refrigerator. The full menu measurement cartridge may be stored at room temperature for up to 24 hours before installation, while the blood gas and CO-ox only cartridge may be stored at room temperature for up to 7 days prior to installation. Each measurement cartridge is valid for up to a full 28 days (or the number of tests) after installation on the system. Note that the install-by date indicates the last date on which the cartridge can be installed and still have 28 days of use before expiration.

Wash/waste cartridge

The wash/waste cartridge contains the wash solution, which cleans the sample path after each analysis and calibration. When the analyzer is idle, the wash solution is in contact with all of the sensors. In addition, the wash solution is used to calibrate glucose, lactate, and the CO-oximeter during 2-point and full calibrations. The same wash/waste cartridge also stores all liquid waste, which is completely enclosed in the sealed cartridge for disposal. Biohazardous waste fluid contacts only the replaceable measurement and wash/waste cartridges and never comes in contact with other components of the system.

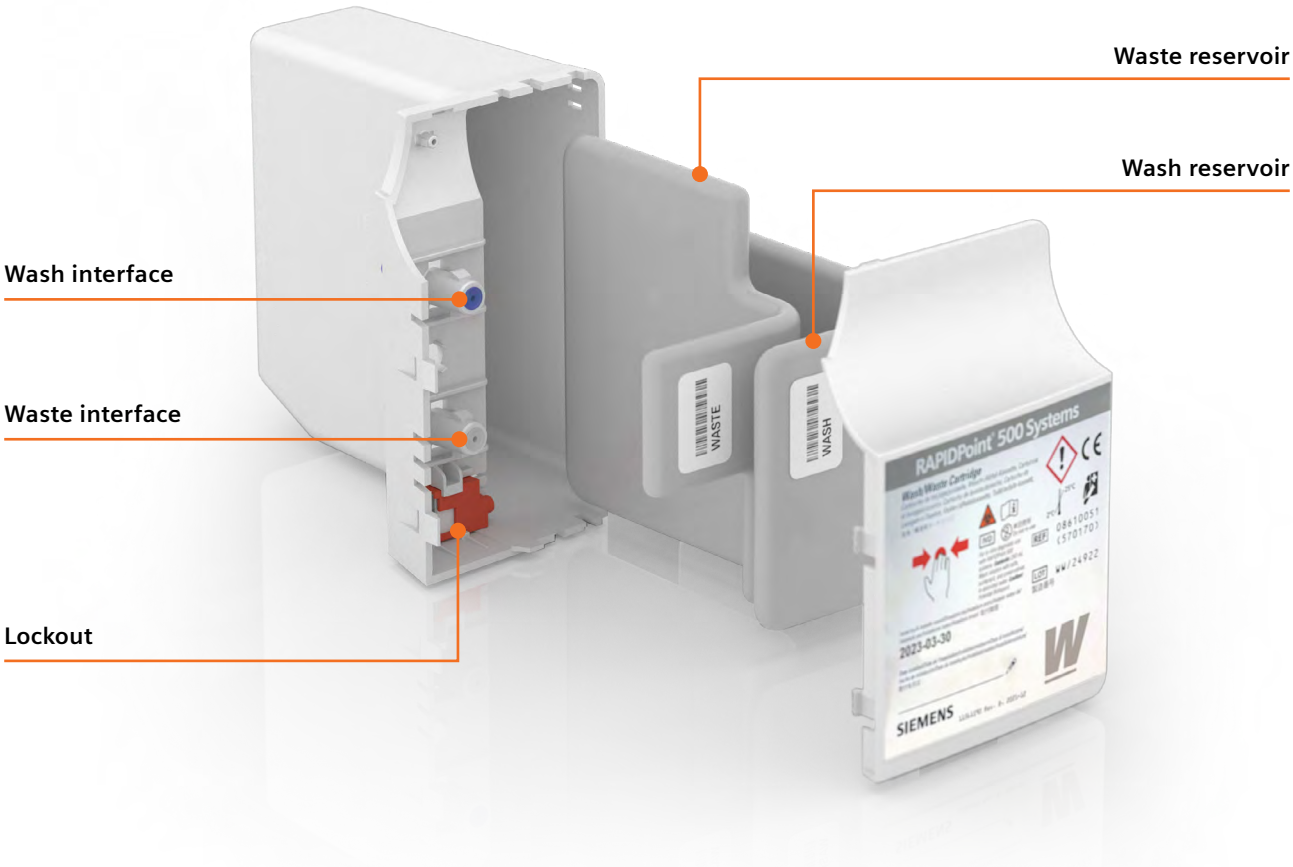


Figure 5. RAPIDPoint 500e system wash/waste cartridge.

Each wash/waste cartridge is valid for 10 days after installation on the RAPIDPoint 500e system, or until all wash reagent is consumed based on the number of samples analyzed.

Automatic quality control (AQC) cartridge

The AQC cartridge contains three separate levels of quality control solutions that span the clinically significant ranges for all analytes. The routine measurement of these control solutions helps to verify that the RAPIDPoint 500e system reports acceptable patient test results. In addition, each QC level is fully operator-programmable to be run at specific time intervals as hospital requirements mandate.

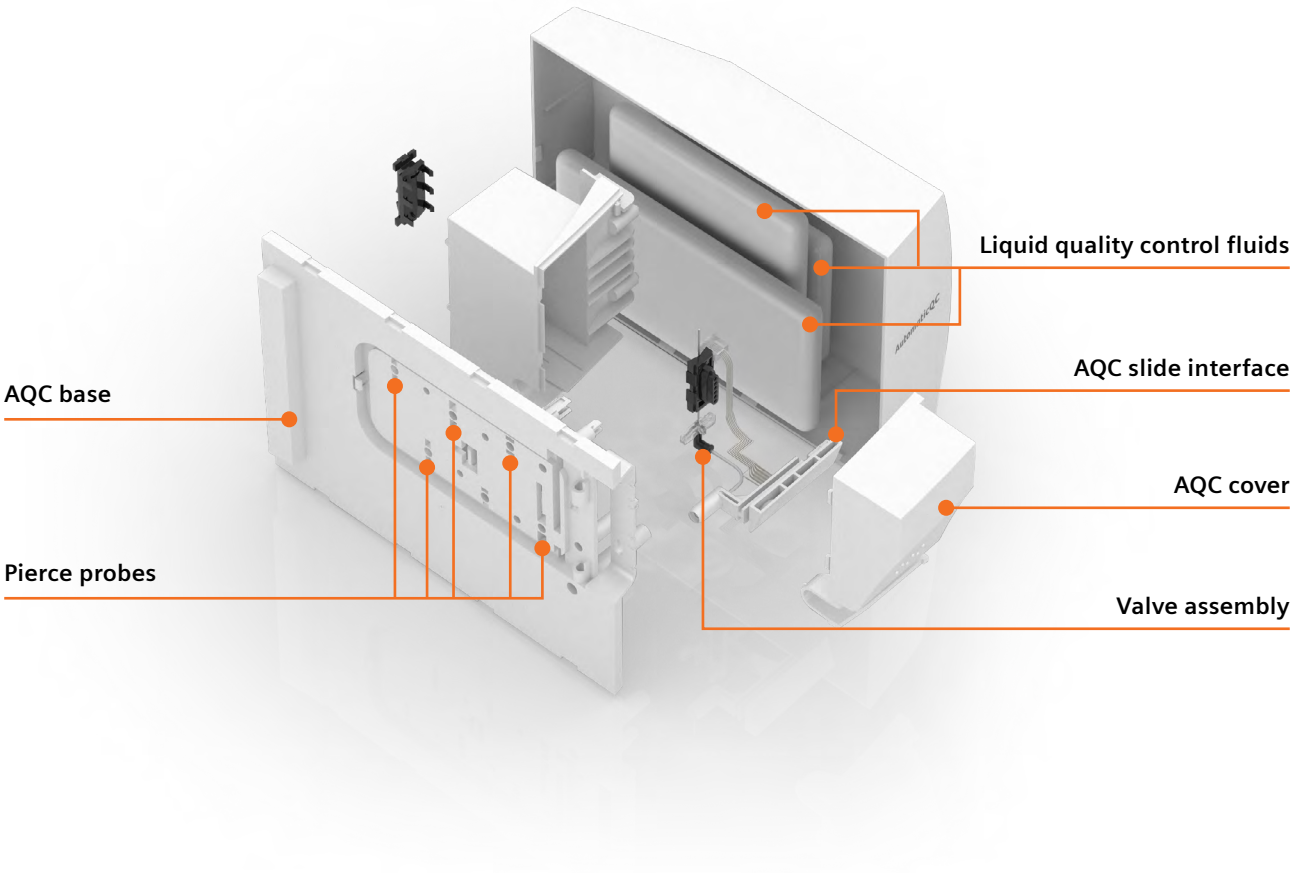


Figure 6. RAPIDPoint 500e system AQC cartridge.

Similar to the measurement cartridge, the AQC cartridge is stored refrigerated to ensure the integrity of the quality control solutions. You can install the AQC cartridge on the analyzer immediately after removing it from the refrigerator, and it is valid for a full 28 days after installation on the system. There is sufficient volume of quality control solution to run each level three times per 24 hours, with an additional percentage available for repeat testing.

More on the importance of the AQC cartridge with respect to Integri-sense Technology is described later in this document.

The Science behind Integri-sense Technology

There are many hardware, software, fluidic routines, detection, and reporting activities that comprise the integral workings of Integri-sense Technology. Each process contributes to the functional checks and balances necessary to ensure accurate patient results.

- **Automatic calibrations**
- **Advanced sample management**
- **Clot and bubble detection**
- **AQC**
- **CO-oximetry**
- **Managing interfering substances**
- **Additional automated checks**
- **Time to result**
- **Cartridge initialization time**

Automatic calibrations

Calibrations are performed automatically for accurate patient results.

The RAPIDPoint 500e system performs calibrations automatically at prescribed intervals and with each sample, if necessary. These routine calibrations at set intervals adjust the slope and/or offset drift for each measured parameter without any operator involvement. The automatic calibration schedule is as follows:

- 1-point calibrations are scheduled to occur regularly at 30-minute intervals. A 1-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 2-point calibration. The 2-point calibration adjusts both the offset and the slope drift for a parameter by measuring two reagents of known concentration.
- Every fourth 2-point calibration is a full calibration. A full calibration includes the 2-point calibration measurement and measures the zero and slope for total hemoglobin.

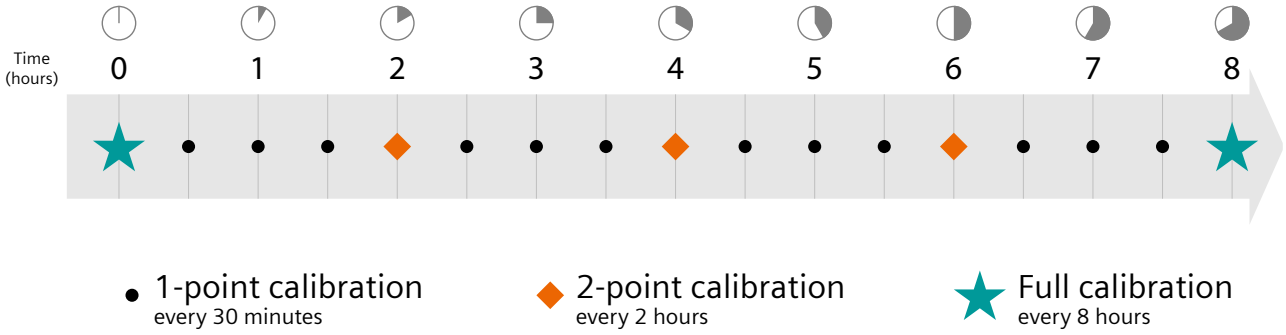


Figure 7. Routine calibration depicting 8-hour timeline.

During any calibration, if the RAPIDPoint 500e system detects a problem with a parameter, the system automatically repeats the calibration up to two times, if necessary. The *Additional Cal Required* message appears on the printed report and in the instrument's events log.

If the calibration is not successful, the system automatically turns off the affected parameter; however, results for the other parameters may continue to be reported. The failed parameter is not available until it successfully passes a subsequent calibration.

The operator can manually initiate a calibration or wait for the parameter to pass during the next routinely scheduled calibration. If the parameter does not pass calibration successfully, no results for the affected parameter will be reported.

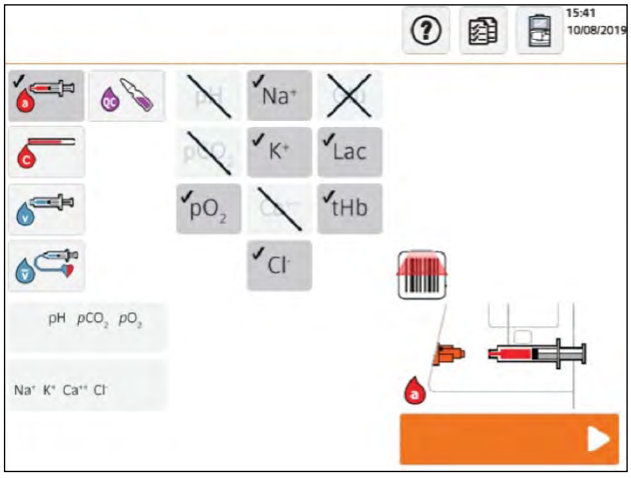


Figure 8. Display of successful and failed calibrations.

Retrospective calibration

In addition to the 1-point, 2-point, and full calibration routines, the RAPIDPoint 500e system performs retrospective calibration, also known as Retrocal. Retrocal is automatically initiated in response to two circumstances:

- During measurement cartridge initialization
- When excessive drift is detected in the measurement sensors

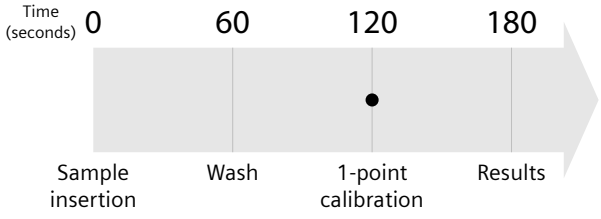


Figure 9. Retrospective calibration: 3-minute result turnaround time.

Retrocal is performed more frequently than the standard calibration routines, and it invokes a 1-point calibration with every sample tested. During Retrocal, the time to result is greater than the standard 60 seconds.

When a new measurement cartridge is installed on the RAPIDPoint 500e system, the planar sensors undergo rapid hydration and may experience increased drift. As a result, there is a cartridge initialization period in which Retrocal is performed in the background during sample analysis over a period of a few hours to ensure that sample measurements are accurate. When abnormal drift is detected in the sensors at any time during the life of the cartridge, Retrocal is initiated automatically.

Abnormal drift is often caused by an interfering substance such as a quaternary ammonium compound, for example, benzalkonium chloride. Retrocal minimizes the potential effects of interfering substances on the sensors. For example, mixed venous samples collected from pulmonary artery catheters frequently contain interfering substances that can negatively impact sensors, and therefore Retrocal is often automatically triggered when this sample type is tested. The system returns to the standard calibration schedule when cartridge initialization is complete or when the sensors have sufficiently recovered from the interfering substance.

Advanced sample management

Sample port simplifies sample introduction and minimizes instrument downtime.

The universal sample port provides protection from biohazards during system operation and ensures consistent sample aspiration independent of operator technique. Through a standardized sampling procedure, sample aspiration is automatic and hands-free for syringes, capillaries, ampules, and open-top tubes.*

Sample port

Sample port with syringe

Sample port with capillary

Figure 10. Examples of sample port with syringe and capillary sampling devices.

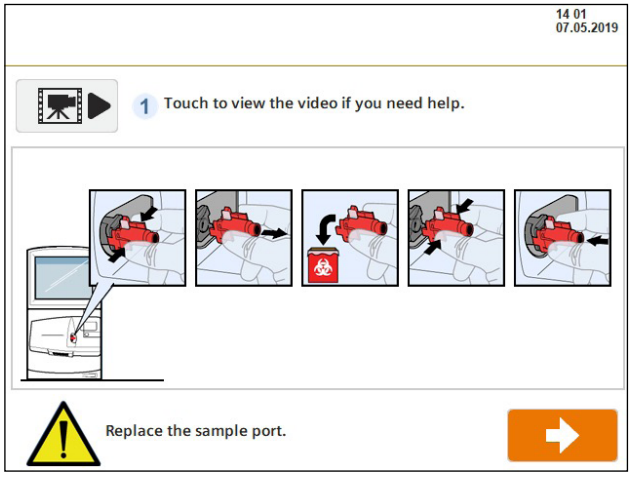


Figure 11. Sample port replacement notification.

One of the unique features of the sample port is its ability to capture larger clots and prevent them from entering the measurement cartridge. When a clot enters the sample port, the system performs a backflush and notifies the operator to replace the sample port.

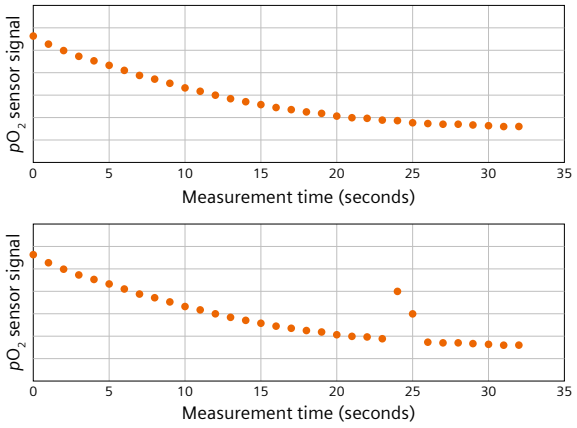
You can replace the sample port in as little as 90 seconds, so the system is available for sample analysis with minimal downtime.

Clot, bubble, and short-sample detection

Comprehensive software algorithm checks continually monitor sample integrity.

The patient sample is continuously monitored for clots and bubbles to help ensure accurate results and protect the measurement cartridge sensors from the potentially negative effect of excessive fibrin.

Figures 12a and Figure 12b show RAPIDPoint 500e system software maps of normal and abnormal pO_2 analyte response curves. Note the abnormal occurrence at the 25-second interval.



Figures 12a and 12b. Normal and abnormal whole-blood response curves.

**Open-top tubes can be sampled hands-free when used with the appropriate Siemens Healthineers adapter.*

System hardware and software are both designed to detect the presence of clots and minimize their impact on the analyzer when they occur. Possible causes of clots in the patient sample include improper mixing when the whole-blood sample was obtained and inadequate heparin levels, among others.

Both the measurement cartridge and sample probe are designed to minimize the aspiration of fibrin clots into the sample pathway. The first line of defense against clots is the sample port on the measurement cartridge.

A specialized wash cycle is initiated when the system detects a clot and indicates a *D39 Obstruction* error. This wash cycle reverses the sample pump and repeats the wash several times to remove any remaining sample as well as the clot, and the system prompts for the sample port to be replaced.

In addition to detecting and managing samples that contain clots, the system detects bubbles early in the sample pathway as well as in the CO-oximeter sample chamber. Bubbles can be present in the sample prior to being introduced to the sample port or may be created by an obstruction. The sample path over the planar sensors and through the CO-oximeter sample chamber is automatically monitored by fluid detectors that ensure the integrity of sample fluid flow throughout the entire sample aspiration process. The system will not analyze patient or QC samples when bubbles are detected. This is especially important because, in addition to pH, the system measures oxygen and carbon dioxide, which are adversely affected by exposure to room air.

Figure 13. Sample port location.

When the system detects bubbles, the *Bubbles in Sample* message appears in the events log. Also, when the system detects bubbles in the CO-oximeter, an *Excessive Bubbles in COox sample* message will post in the events log.

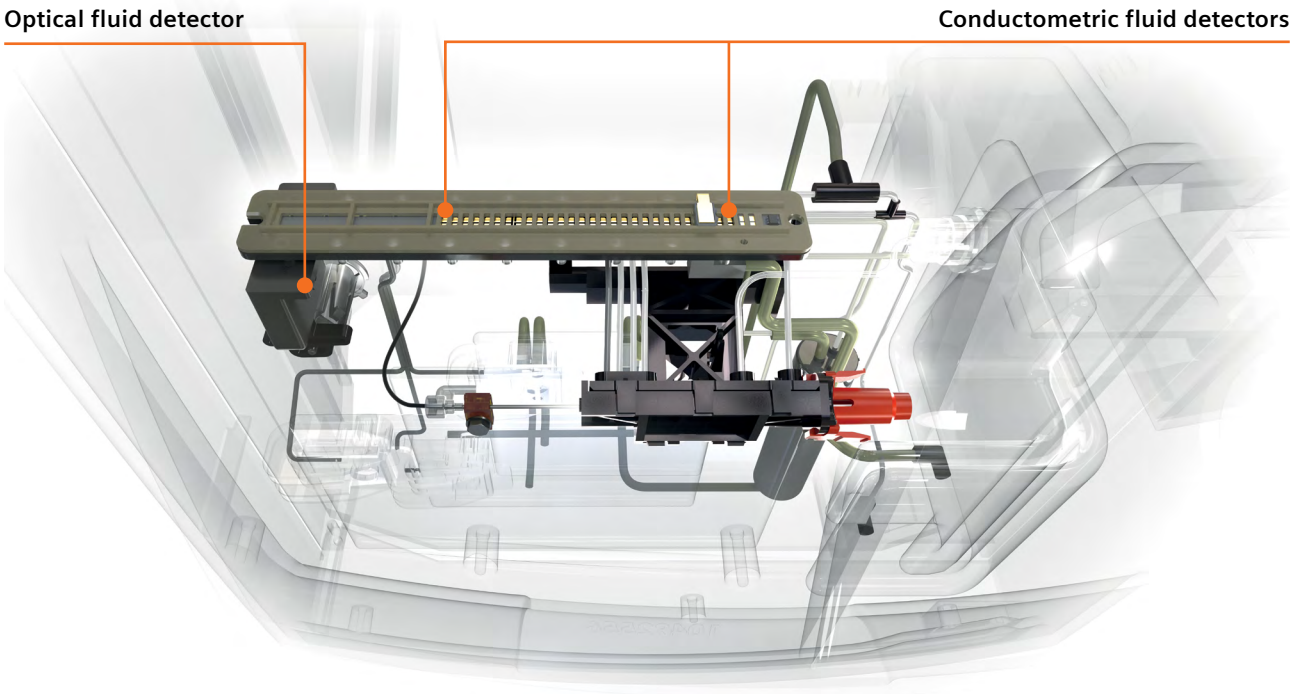


Figure 14. Fluid detectors detect obstruction and bubbles in the sample pathway.

To avoid introducing bubbles to patient samples, ensure that you use the recommended collection procedures, storage, sample handling, and proper mixing technique when obtaining a blood gas sample.

The RAPIDPoint 500e system cannot report results for a patient when there is not enough blood to complete the analysis. Short samples are detected by the same fluid detectors used for bubbles. A short sample can occur if the sampling device does not contain enough blood (insufficient sample) or if an obstruction prevents the system from aspirating enough blood for analysis (short sample aspiration). In either case, an *Insufficient Sample* message appears in the events log, and no patient results are reported.

Automatic quality control (AQC)

Three independent QC solutions span the clinically relevant medical decision levels.

Quality control runs are among the routine laboratory procedures that help to ensure accurate patient results. The level and frequency of analysis of quality control materials vary based on country regulations and hospital medical directives.

Figure 15. RAPIDPoint 500e system with AQC cartridge.

The RAPIDPoint 500e system's AQC cartridge contains the quality control solutions and the electronic, mechanical, and fluidic components needed to analyze QC samples. Each level of the quality control material is uniquely formulated to provide verification of performance at several points in the clinical range for each analyte. Plus, the QC material is presented to the analyzer in a standardized and unique manner that removes the need for operator intervention and ensures the running of specific levels of QC at specified time intervals, as dictated by regulatory requirements or according to individual hospital protocol.

AQC fluidics are designed so that the AQC manifold provides a fluid path for the QC materials to flow from the AQC cartridge to the patient sample entry probe of the RAPIDPoint 500e system's measurement cartridge.

Therefore, the AQC solutions and patient samples follow exactly the same pathway through the RAPIDPoint 500e system's measurement cartridge.

In Figure 16, the red line represents the patient's whole-blood sample flow path; the blue line represents the AQC flow path.

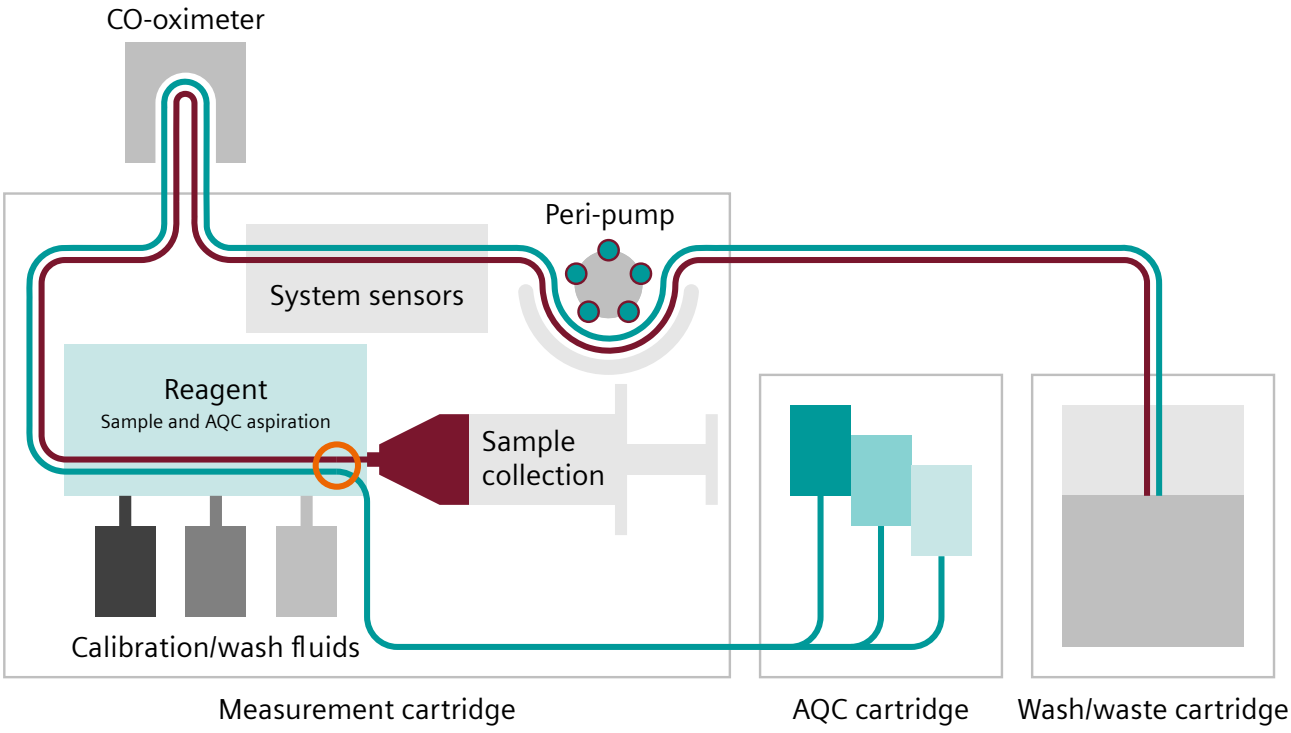


Figure 16. RAPIDPoint 500e system sample pathway.

AQC statistical application: Month-on-month and year-on-year, the quality control results are always comparable

The AQC cartridge is entirely external to the measurement system, and the three levels of the AQC controls are value-assigned to a master lot by Siemens Healthineers manufacturing. The consistency of the manufacturing process allows you to consider your AQC controls as having one continuous lot number with no expiration date.

Exposure to the atmosphere when using ampule QC tends to generate the most variability, and this exposure is eliminated with AQC. This technology allows all laboratories to apply the same expected ranges over time for each measured analyte on the RAPIDPoint 500e system (Table 3).

Table 3. AQC targets and acceptable ranges for each measured analyte.

		AQC Level 1		AQC Level 2		AQC Level 3	
Parameter	**Units**	**Target**	**Range (±)**	**Target**	**Range (±)**	**Target**	**Range (±)**
pH		7.150	0.020	7.350	0.020	7.550	0.026
H^+	nmol/L	70.8	3.2	44.7	2.1	28.2	1.7
pCO_2	mmHg	70.0	6.4	40.0	5.0	22.0	3.0
pCO_2	kPa	9.33	0.85	5.33	0.67	2.93	0.40
pO_2	mmHg	150.0	11.0	100.0	7.8	65.0	9.2
pO_2	kPa	20.00	1.47	13.33	1.04	8.67	1.23
Na^+	mmol/L	115.0	5.0	135.0	5.0	155.0	7.0
K^+	mmol/L	3.00	0.30	5.00	0.30	7.00	0.30
Ca^{++}	mmol/L	1.60	0.12	1.20	0.10	0.80	0.10
Ca^{++}	mg/dL	6.4	0.5	4.8	0.4	3.2	0.4
Cl^-	mmol/L	80	6	100	6	120	8
Glu	mg/dL	200	14	100	10	50	10
Glu	mmol/L	11.1	0.8	5.6	0.6	2.8	0.6
Lac	mmol/L	12.00	2.00	0.90	0.24	3.00	0.60
Lac	mg/dL	108.1	18.0	8.1	2.2	27.0	5.4
tHb	g/dL	18.0	1.6	14.0	1.4	8.0	1.0
tHb	g/L	180	16	140	14	80	10
tHb	mmol/L	11.2	1.0	87	0.9	5.0	0.6
O_2Hb	%	78.0	3.0	92.0	30	60.0	3.0
COHb	%	3.5	5.0	3.5	5.0	18.0	5.0
MetHB	%	16.0	3.6	2.0	46	6.0	3.6
HHb	%	2.500	4.000	2.500	4.000	16.000	4.000
nBili	mg/dL	20.0	4.0	12.0	2.8	5.0	2.4
nBili	umol/L	342	68	205	48	86	41

Siemens Healthineers recommends the evaluation method of 3SD (standard deviations) absolute limits for the RAPIDPoint 500e system when using onboard AQC. In simple terms, the QC recovery is either in or out of established default range limits. Since each measurement cartridge contains all new reagents, pump tubes, and fluidic pathways, when a cartridge replacement is implemented (maximum onboard use-life of 28 days), it is generally accepted that there will be variability and shifts associated with the change.

The suggested fixed or absolute QC limits are designed to be consistent with the medical needs of clinicians. These limits reduce to an absolute minimum the number of false rejections due to erroneous QC signals, as noted by comparing the small actual standard deviations to the absolute QC limits in Table 3. Absolute limits evaluation allows you to apply clinical decision making to the measurement process over extended periods of time, thereby avoiding overreaction and expenditure of time and energy in response to a change that is statistically, but not clinically, significant or relevant.

The RAPIDPoint 500e Blood Gas System complies with CLIA, CLSI guidelines, and ISO 15189, with onboard review of Levey-Jennings charts.

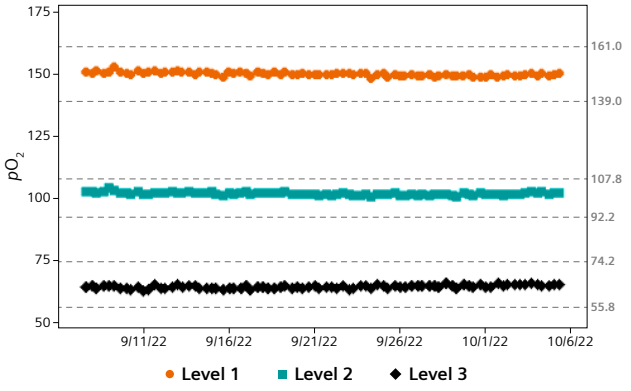


Figure 17. AQC scatter plot of QC performed over 28 days.

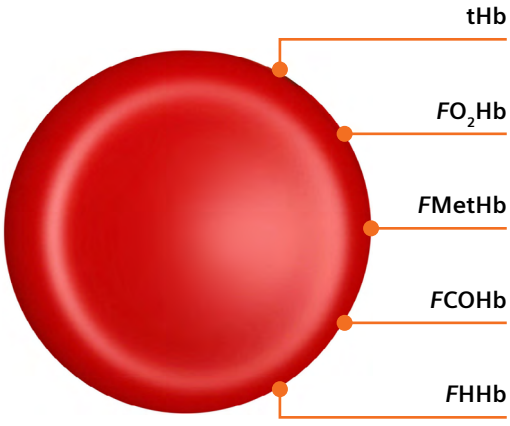
In summary, the fixed QC limits represent the largest possible error that may be present in a test result. These are sometimes referred to as “medical need” or “medical usefulness” limits. Because these fixed QC limits are much larger than the standard deviation of highly precise RAPIDPoint 500e system sample results, false positives and erroneous out-of-control signals are essentially eliminated.

Whole-blood CO-oximetry measurement

CO-oximetry supports the assessment of a patient's oxygenation status.

Precise optical measurement and reporting of sample total hemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, deoxyhemoglobin, neonatal total bilirubin, and oxygen saturation provide clinicians with vital diagnostic information.

Sample hemolysis is not required with the RAPIDPoint 500e system, as the CO-oximeter measurement is performed on whole blood. Absorbance measurements at multiple wavelengths across a short optical path generate a precise spectral blueprint. The analyzer automatically detects and corrects for deviations caused by common interferences. Algorithms auto-correct for light scatter caused by the erythrocyte membranes.



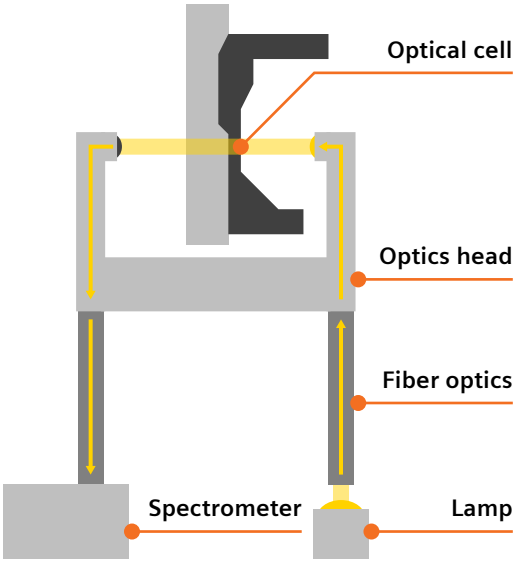


Figure 18. CO-oximeter optics assembly.

The CO-ox measurement module detects and quantitates the total hemoglobin and other related CO-oximeter quantities in the sample (Figure 19) by measuring the light through whole blood at multiple wavelengths (Figure 18). The CO-oximeter sample chamber is located in the measurement cartridge. The CO-oximeter sample chamber has a sliding cell design that opens and closes to allow for the measurement and continued flow of the sample to the measurement sensor module. It also contains a thermistor to control the temperature of the sample during measurement and a detector mechanism to sense the position of the chamber cell.

A halogen lamp in the back of the instrument provides the illumination. The light is guided to the optics head using fiber optic bundles. These multifiber bundles contain hundreds of fibers designed to deliver light that is uniformly distributed over the fiber face. The optics head transmits the light through the blood in the optical cell. Light passing through the blood is collected by the spectrometer. Light is guided to the polychromator using the fiber optic bundles. The polychromator separates the sample into its component wavelengths, measures the intensity of light at the different wavelengths, and converts the electrical signal to a digital value for processing.

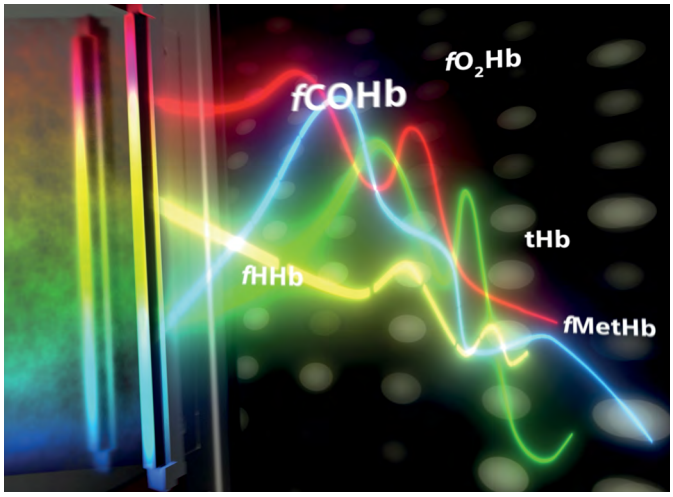


Figure 19. Sample component wavelengths.

Managing interfering substances

Constant monitoring of sensor response data identifies interferences.

Endogenous and exogenous substances present in the blood sample can cause interference during the measurement of the analyte by the planar sensors. The RAPIDPoint 500e system incorporates several methodologies to detect and/or correct for such interfering substances.

One method involves continuous monitoring of the sensor response data before, during, and after each sample. An integrity check of the sensor signal is performed at each stage of testing:

- **Pre-analytic:** Prior to each sample measurement, if an abnormality is detected, the system will automatically perform the sample measurement in Retrocal to correct for the abnormal sensor drift.
- **Analytic:** During each sample measurement, if an abnormality is detected, the system will automatically flag the relevant analyte with a Question Value instead of reporting an analyte result.
- **Post-analytic:** After each sample measurement, if an abnormality is detected, the system will automatically switch into Retrocal mode.

The metabolite sensors (glucose and lactate) present unique challenges due to endogenous interfering substances (such as uric acid) and exogenous interfering substances (such as acetaminophen). The metabolite planar sensors incorporate a correcting electrode that is identical to the measurement electrode, but without the active enzyme. The RAPIDPoint 500e system automatically uses the signal output from the correcting electrode during each sample measurement to remove the effect of the interfering substances from the reported analyte value.

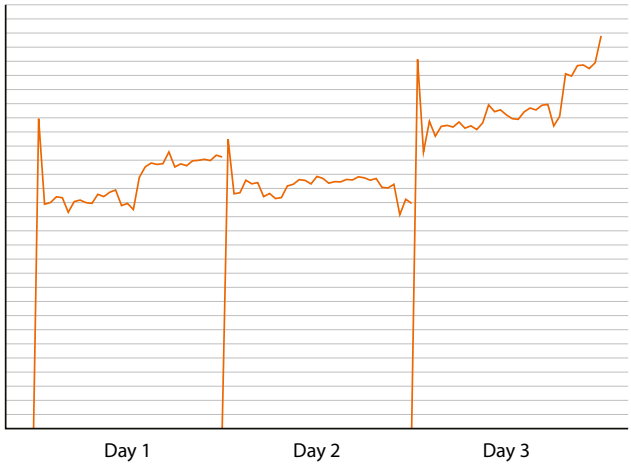


Figure 20. Representative response curves.

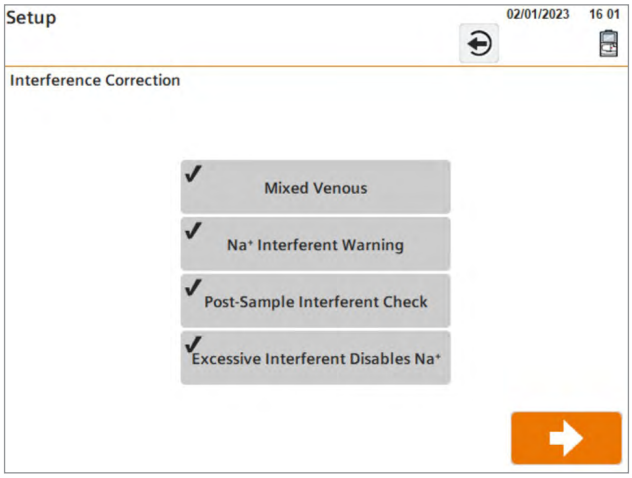


Figure 21. Sodium interference detection options.

Interference detection enhancements for sodium

Any quaternary ammonium compound (QAC) used to clean the area around the sample port and other parts of the RAPIDPoint 500e system can act as an interferent that adversely affects the sodium results. There are two options to consider (Figure 20) that will improve the reliability of sodium results when an interferent of this type is detected:

- **Post-sample interferent check:** If sodium interference is detected, results that may have been moderately affected by a QAC are reported as questionable. The sodium result displays as -----? without a numeric value, and an additional 2 minutes will be added to the time-to-result.
- **Excessive interferent disables sodium:** If excessive sodium interference is detected, you can have the sodium sensor disabled for the life of the current measurement cartridge. The *Excessive Interferent Disables Na^+* message indicates that the sodium sensor is no longer reliable due to intensive exposure to an interferent. The sodium sensor cannot be re-enabled, and sodium measurements can only proceed after a new measurement cartridge is installed.

Additional automated checks

There are several additional, fully automated system checks that occur continually to ensure efficient operation and generation of accurate results.

System temperature checks

Three separate heaters maintain every sample at 37.0°C throughout the entire sample pathway. This enables analysis to be performed at the correct temperature in both the sensor measurement module and the CO-oximeter sample chamber.

Wash sequence checks

Vigorous wash sequences cleanse the sample pathway and prevent carryover for accurate patient results and optimal sample throughput.

Readiness checks

Overall health, calibration, electronics, and fluidics checks provide analytical quality before, during, and after every sample measurement.

Cartridge checks

Automatic expiration checks and reagent integrity checks are performed for every measurement cartridge and AQC cartridge installation.

From a workflow perspective, the RAPIDPoint 500e system's internal checks and balances contribute to delivering both accurate patient results and efficient day-to-day operation.

Time to result

Clinically actionable patient results are available in approximately 60 seconds. Results are displayed on the RAPIDPoint 500e system display, automatically printed, and sent to the data manager/LIS/HIS.

Fast cartridge initialization time

24 Minutes

Measurement cartridge replacement and initialization, which include a new sensor module, CO-oximeter sample chamber, sample probe, calibration solutions, and fluidic pathways, take approximately 24 minutes—one of the shortest initialization times in the industry.

RAPIDPoint 500e Blood Gas System with Integri-sense Technology...

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