At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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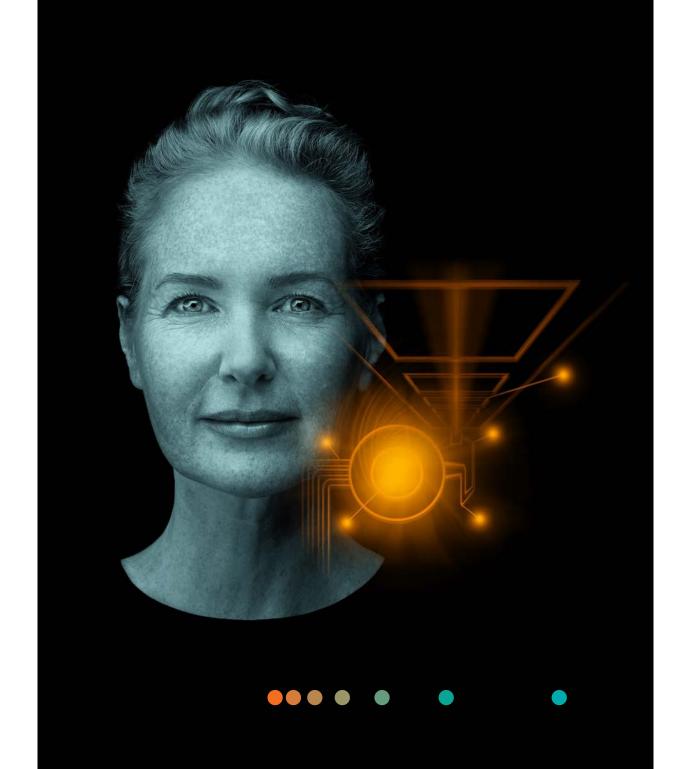
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## Inspired by patients. **Empowered** by technology.

Transforming care delivery by elevating your blood gas solution.

siemens-healthineers.com/rapidpoint500e



# ② P 14.43 2019.05.10 ADD OF VAN VGIU The Voco, VK. Viac pH pCO<sub>2</sub> pO<sub>2</sub> ✓ Na\* K\* Ca\*\* CI Healthineers ..

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#### RAPIDPoint 500e Blood Gas System

# Elevating Critical Testing to the Next Level

Healthcare professionals are increasingly under pressure to deliver quality care in busy critical care settings.

Any delay, distraction, or concern in the generation and reporting of test results physicians rely on can add to the operational burden and take time and focus away from the patient.

Siemens Healthineers' RAPIDPoint® 500e Blood Gas System\* helps you focus your care and attention where it matters most: the patient. We've enhanced and refined our leading blood gas solution, leveraging proprietary Integri-sense™ Technology to enable robust accuracy from sample to sample and confidence in every result. An intuitive user interface helps reduce daily operator interaction to a minimum, while onboard software defenses run efficiently in the background to provide a reassuring level of protection against cyber attacks and confidential data theft.

Realize higher standards in the sample-to-sample integrity, IT security, and operational simplicity of your blood gas testing. Transform care delivery with the RAPIDPoint 500e Blood Gas System—enabling you to deliver high value care for your patients.



Integri-sense Technology



Data

Security



Simplicity

#### Optimize your Day-to-day Blood Gas Operations

### Generate Results without Interruptions or Delays



Maintenance-free operation allows you to spend more time improving patient outcomes and less time acquiring results.



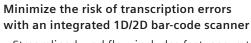
#### Generate results from a simple screen touch

- One-touch analyzer operation: Simply press Start after inserting a sample.
- Results in 60 seconds are displayed on-screen, automatically printed, and sent to the data manager/LIS/HIS.
- Custom panels can be configured to make frequently used tests easier to review.
- Includes a refreshed user interface, with large and easily accessible icons.

Eliminate the need for adapters with a

# standardized sampling procedure Small 100 µL sample is sufficient for a full panel. Universal sample port requires only one sampling procedure, regardless of the syringe or capillary type and manufacturer.

- Sample probe is self-cleaning and safely contained within the measurement cartridge to minimize operator exposure to biohazards.
- Operator variability is eliminated with handsfree automatic sample aspiration.



- Streamlined workflow includes fast, accurate capture of patient data, operator IDs, and OC information.
- Helps provide a reliable audit trail for compliance purposes.



#### Maximize analyzer uptime

- Measurement cartridge replacement and initialization, which includes a new sensor module CO-ox sample chamber and sample probe, takes approximately 24 minutes—one of the shortest initialization times in the industry.
- Measurement cartridge has a 28-day onboard use life.
- A variety of measurement cartridge test sizes provides analytical flexibility.



#### Rely on always-ready QC and calibration

- Independent Automatic Quality Control cartridge verifies system performance, providing consistent accuracy without operator interaction.
- You can schedule QC when most convenient and depending on your local QC protocol, so your analyzer is ready when you are.
- Three levels of independent AQC, multiple calibration routines, and advanced software algorithms enable the analyzer to be ready to generate reliable, clinically actionable test results.





# Integri-sense Technology: Redefining System and Sample Integrity at Every Analytical Stage



Integri-sense technology is the guardian of patient results. It performs frequent quality and sample integrity checks before, during, and after every patient sample. Automatic quality control, comprehensive calibrations, and advanced software algorithms combine to enable the analyzer to be ready to generate reliable, clinically actionable results each and every time, delivering confidence with every result.

#### **Automatic quality control**

The AQC cartridge enforces specific levels of external QC at specified time intervals and is fully programmable as hospital requirements mandate. Separately contained Level 1, Level 2, and Level 3 QC materials span the clinically significant ranges. Measurement of control analytes confirms that analyzers report acceptable patient test results.

The QC materials and patient samples follow exactly the same pathway in the measurement cartridge. The same expected analyte ranges apply across every test setting. Fixed or absolute QC limits are designed to be consistent with the medical needs of clinicians, minimizing false rejections caused by erroneous QC signals. The RAPIDPoint 500e Blood Gas System\* complies with CLIA, CLSI guidelines, and ISO 15189, with onboard review of Levey-Jennings charts.

Month-on-month and year-on-year results are always comparable

#### Advanced sample management

The universal sample port enables analyzer operation to be biohazard protected and the results independent of operator technique.

The system employs a standardized sampling procedure using both syringes and capillaries, with no sample adapters needed. The fast sample port replacement occurs in approximately 90 seconds. Automatic, hands-free sample aspiration and advanced clot management and clearance facilitate ease of use.

Sample port facilitates consistently accurate results with a minimum of downtime.







#### Clot and Bubble Checks

Patient sample integrity is continuously monitored for clots and bubbles, triggering an automatic clot clearance sequence to protect the sensors.

#### Readiness Checks

Deep-system health, calibration, and fluidics checks provide analytical quality before, during, and after sample measurement.

#### **Temperature Checks**

Three preheaters maintain every sample at 37°C throughout the sample pathway to enable the analysis to be performed at the correct temperature.

#### **Wash Sequence Checks**

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

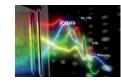
#### **Automatic system calibration**

Routine calibrations at set intervals adjust the slope and offset drift for each analytical parameter without operator involvement.

Full auto-calibration includes measurement of zero and slope for total hemoglobin. Prevent erroneous results by turning off an individual parameter in the event of an unsuccessful calibration. Calibration can be temporarily deferred to allow a STAT sample to run. Retrospective calibration (Retrocal) auto-commences when a measurement cartridge initializes or when excessive drift is detected in sensors. Retrocal minimizes potential effects of interfering substances such as benzalkonium chloride on sensors. If this interferent is detected, the system will present a real-time warning flag to notify the operator and recommend caution when interpreting sodium results.

Analyzers perform and report within specifications.

#### Comprehensive CO-oximetry



Precise optical measurement and reporting of sample hemoglobin moieties and oxygen saturation provide clinicians with vital diagnostic information.

Sample hemolysis is not required. Absorbance measurement at multiple wavelengths across a short optical path generates a precise spectral blueprint. The analyzer automatically detects and corrects for deviations caused by common interferences. Algorithms auto-correct for light scatter from erythrocyte membranes. The analyzer reports tHb, sO<sub>2</sub>, O<sub>2</sub>Hb, HHb, COHb, MetHb, and neonatal total bilirubin with accuracy equivalent to hemolyzed methods.

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

#### Proper pre-analytical technique for the blood draw and subsequent sample handling facilitates the delivery of quality patient results.

Siemens Healthineers helps its blood gas users generate consistent, dependable results with a mix of education and training initiatives designed to improve blood collection and sample handling skills. Our website¹ features instructional video and educational materials demonstrating correct procedure for the collection and manipulation of a blood gas sample prior to analysis. Testing should be completed within 10 minutes and no longer than 30 minutes after patient draw.

Correct sample collection, handling, mixing, and time to analysis collectively enhance test accuracy.

- Use an appropriate sampling device for blood gas analysis.
- The sampling device should contain a dry, electrolyte-balanced lithium heparin anticoagulant to reduce the potential for clots and dilution errors.
- Proper use of a filter cap allows for safe removal of any air bubbles in the syringe, minimizing gas dissolution into the sample.
- Mix the sample thoroughly for a minimum of 20 seconds after collection. Remix by rotating and repeatedly rolling the sampling device immediately before testing.
- Present a clot-free sample to the analyzer and start analysis.



1. https://www.siemens-healthineers.com/blood-gas/bloodgassystems/rapidpoint-500-systems (accessed August 19, 2019).

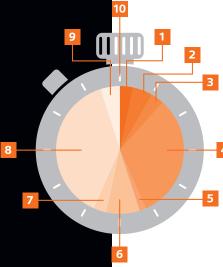
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# 60 seconds in the life of a sample

Automated Integri-sense technology means you can have confidence in the analytical capabilities of your blood gas analyzers. You can depend on RAPIDPoint 500e systems\* to conduct meticulous quality checks in the background, at every stage of analysis.

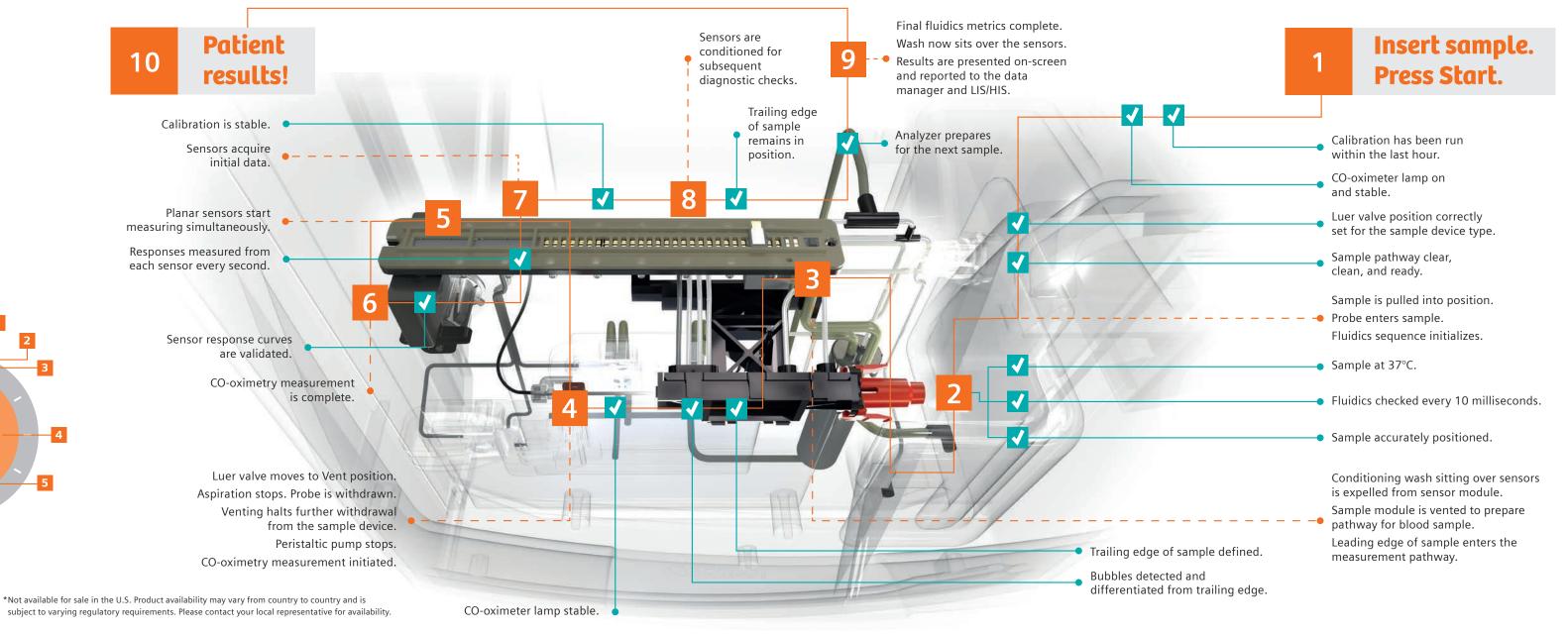
You can test with confidence, knowing that your analyzers will report accurate results clinicians can rely on when making patient treatment decisions.

All components required to measure critical analytes are contained in a single, longlife cartridge—without gas tanks and reagent bottles. The measurement cartridge incorporates the sample probe, industryproven planar sensors and is entirely maintenance-free over a 28-day onboard use life. The RAPIDPoint 500e analyzer is ready for use in approximately 24 minutes after cartridge installation.



## Integri-sense Technology Provides Accurate, Error-free Results—Sample after Sample





# Heightened System Security and Data in a Connected World



Healthcare providers are subject to highly sophisticated malware intrusion attempts on a daily basis.

Cyber criminals are constantly seeking to harvest IDs and patient information to commit medical fraud or even compromise an entire healthcare IT infrastructure and hold an organization at ransom. Medical devices are acknowledged as the weakest entry points into hospital networks.



RAPIDPoint 500e analyzers\* are comprehensively protected against threats from hackers. Robust, automated defenses help maintain and safeguard your institution's IT security, allowing you to focus on patients without worrying about device intrusion or data theft.

RAPIDPoint 500e System software upgrades represent a step change in data protection, guarding against risk of analyzer infection and unauthorized access to sensitive information.

#### Minimize system vulnerability with the latest operating software

- MICROSOFT WINDOWS 10 operating system enhances analyzer security.
- Software allows you to perform secure installations and encrypt setup and restore.

#### Prohibit unauthorized access with a discriminating firewall

- Blocks Trojans, intrusions, hacking attempts.
- Monitors traffic and defines/limits the specific analyzer ports that are allowed to accept or export data.

\*Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

#### Mitigate targeted attacks with MCAFEE embedded anti-malware

- Whitelists allow only trusted programs necessary for daily operations to reduce the potential attack surface.
- Blocks unauthorized programs and prevents inadvertently downloaded code from running.

#### Secure the privacy of patient data transfer

- Create an encrypted password when downloading data from an analyzer.
   The same password must be used to decrypt and view the data when transferred to a device or data manager.
- Configurable (on/off) USB port to meet hospital requirements.

#### Block unauthorized external connections

• Permit/deny a local subnet's remote viewer access, LIS/HIS access, or both.

#### Prevent operation by untrained staff

 Two-step authentication provides the option to configure analyzers with a second layer of protection, requiring the operator to enter an ID in addition to a password upon log-in.



# Control Blood Gas Operations across the Continuum of Care

Build an open, vendor-neutral testing environment powered by Siemens Healthineers' POC Informatics to reduce the complexity and improve the efficiency of your operations.

Easily connect multiple RAPIDPoint epoc®, and RAPIDLab® solutions to your existing IT infrastructure.

Manage, configure, control, and troubleshoot testing on RAPIDPoint and RAPIDLab Blood Gas Systems with our POC Ecosystem™ Solution. Enable the monitoring of information from every connected analyzer, including epoc Blood Analysis Systems and test devices from more than 40 manufacturers, with our POCcelerator™ Data Management System.

Whatever your device mix and wherever critical testing takes place, Siemens Healthineers' POC Informatics helps advance workforce productivity, improve clinical workflows, satisfy compliance and accreditation requirements, and optimize the management of resources.



### Remotely Manage Multiple Blood Gas Systems and Operators in Every Setting

Oversee testing with our POC Ecosystem Solution. Intervene when you need to.

- Keep analyzers online and operational.
- Standardize test protocols and reporting.
- Authorize and certify/recertify operators.
   Schedule their training and assessment.
- Enforce QC checks. Assign and record the completion of routine maintenance tasks.
- Check the status of reagents and consumables.



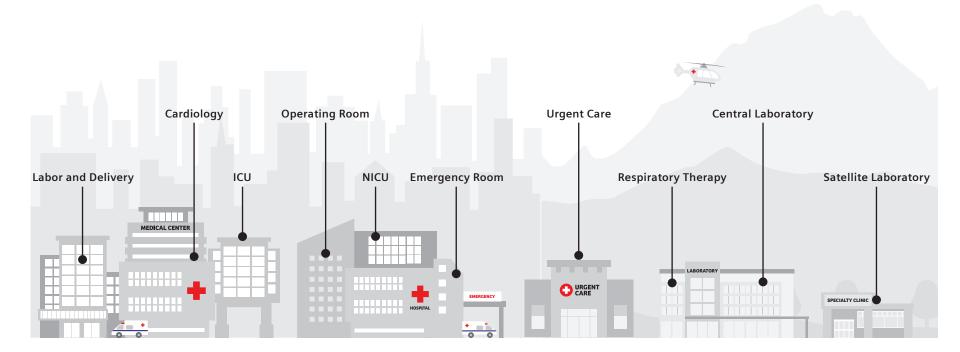
#### Aggregate Data from Blood Gas Systems Across your Network

Operationalize workflow with our POCcelerator Data Management System. Reduce the risk of errors and gain peace of mind through end-to-end data encryption.

- Address quality issues by proactively focusing on noncompliant data.
   Manage data for external quality assurance with the EQA Module.
- Standardize certification and compliance. Simplify operator training with the eTrainer Module.
- Improve operator tracking with technical validation checks for QC and patient results.
- Review and resolve linearity issues.

9

### Implement a Proven, End-to-end Blood Gas Solution



Regardless of the specific result required and wherever testing takes place, the RAPIDPoint 500e Blood Gas System generates high-quality, lab-accurate results clinicians can count on.

Comprehensive test results from a single sample are available when they are needed, allowing diagnosis and treatment to begin as guickly as possible. System operation is maintenance-free, so operators can stay productive and report urgent results to clinical decision makers without delays—even during the busiest of shifts.

The RAPIDPoint 500e Blood Gas System streamlines workflow and reduces testing complexity across the spectrum of care settings, freeing time to focus on what is most important: patients.

#### Analyze routine and specialty samples

• Whole arterial, venous or mixed venous, dialysate fluid\*, and pleural fluid pH test results from syringes and capillary samples.

#### Safeguard operators and samples

- Bio-safe, hands-free sampling and automatic sample aspiration.
- Integrated clot detection and clearance.

#### Employ a comprehensive test menu

Configure critical testing to be all-inclusive or as specific as the setting requires:

- Report blood gas, pH, electrolytes, metabolites, and full CO-oximetry (including neonatal total bilirubin and total hemoglobin) in approximately 60 seconds.
- Record key respiratory ventilator metrics.

### Improve Access to Care by **Customizing without Compromise**

The Siemens Healthineers critical care portfolio delivers solutions that transform care delivery by offering the right test in the right place at the right time. From handheld to robust central laboratory solutions, our portfolio enables increased efficiency and shorter time to diagnosis. Open, connected solutions let clinicians access shared data when and where it is needed for fast clinical decision making and more efficient management of resources. Decrease the time to diagnosis and intervention with a comprehensive menu of tests that fit your workflow. Order fewer retests and have more confidence in results with a customized configuration of analyzers whose results correlate, no matter where testing takes place.



#### RAPIDPoint 500e Blood Gas System\*

Elevate your blood gas solution.



Comprehensive, cartridge-based testing with heightened operational simplicity and system security. Integri-sense technology enables total confidence in every patient result. Sampling procedure is hands-free and standardized for both syringes and capillaries. Sample types include dialysate\* and pleural fluid pH applications.

#### **RAPIDLab 1200 Blood Gas Systems**

Meet high-throughput needs in labs and at the point of care.



Cartridge-based operation using one sampling procedure. Microsample mode is ideal for neonatal applications, with precise results available from as little as 35 µL of whole blood. Proven Ready Sensor® electrode technology assures measurement accuracy with reliable, long-life stability.

#### epoc Blood Gas Analysis System

Provide lab-quality results at the patient's side.



Handheld, maintenance-free determination of 13 critical parameters on single-use test cards. Automatic calibration takes place prior to every patient sample. Fast, wireless reporting of patient-side results.

#### RAPIDLab 348EX Blood Gas System

Deliver efficient critical care testing in labs and clinics.



Robust, reliable analytical performance on whole blood and dialysate fluid\* for the most essential parameters. Minimal maintenance, with convenient front-panel access to all sensors, reagents, and waste.

<sup>\*</sup>Feature not available for sale in the U.S.

<sup>\*</sup>Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability



#### RAPIDPoint® 500e\* Blood Gas System Product Specifications

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Integri-sense

#### siemens-healthineers.com/rapidpoint500e

nBili

System	Descri	ntion
Jystein	DCJCII	puon

Na+

Point-of-care blood gas analyzer		
System	Menu	
рН	K+	Lactate
$pCO_2$	Ca++	tHb
pO_	CI-	CO-oximetry

#### Glucose **Parameter Specifications**

Reporting Range
6.500-7.800
7.000-7.500
10.0–700.0 1.33–93.32
5.0–200.0 0.66–26.66
L 100.0-200.0
L 0.50-15.00
L 0.20-5.00 0.8-20.0
L 65.0-140.0
L 1.1-41.6 20-750
L 0.18–30.00 1.6–270.3

#### **CO-oximetry Parameters**

Units	Reporting Range
g/dL	2.0-25.0
g/L	20-250
mmol/L	1.2–15.5
mg/dL μmol/L	2.0-30.0 34-513
%	15.0-100.0
%	0.0-100.0
%	0.0-100.0
%	0.0-100.0
%	0.0-100.0
	g/dL g/L mmol/L mg/dL µmol/L % %

#### **Calculated Parameters**

pH(T)	BO <sub>2</sub>
pCO <sub>2</sub> (T)	pO <sub>2</sub> (A-a)(T)
$pO_2(T)$	pO <sub>2</sub> (a/A)(T)
HCO <sub>3</sub> act	p50
HCO <sub>3</sub> std	Ċsp/Ċt(T)
BE(B)	Ċsp/Ċt(T)(est)
BE(ecf)	RI(T)
ctCO <sub>2</sub>	$pO_2/F_1O_2$
Ca++(7.4)	$ctO_2(a), ctO_2(\nabla)$
AnGap	$ctO_2([a-\overline{v}]/a)$
Hct	$ctO_2(v), ctO_2(a-\nabla)$
$sO_2$	ctO <sub>2</sub> (Hb)
O <sub>2</sub> SAT(est)	VO <sub>2</sub>
mOsm	ĎΟ <sub>2</sub>

#### **Input Parameters**

#### **Patient Demographics**

Patient ID	Sex
Last Name	Date of Birth
First Name	

#### **Sample Demographics**

Location	Temperature
Physician ID	tHb
Draw Date	$F_1O_2$
Draw Time	Flow
Accession No.	Resp Rate
Operator ID	pATM
Up to 10 custom demographic fields available	

#### **Ventilator Settings (optional)**

Ventilator Flow
Respiratory Rate
Continuous Positive Airway Pressure
Positive End Expiratory Pressure
Peak Inspiratory Pressure
Tidal Volume
Allen Test

<sup>\*</sup>Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.



Integri-sense $^{\text{\tiny{TM}}}$  technology is the guardian of patient results. It is a comprehensive series of analyzer functional checks and flagging mechanisms designed to deliver accurate test results.

## RAPIDPoint 500e\* Blood Gas System Product Specifications

**Sample Types** 

Whole blood (arterial, venous, mixed venous and capillary); pleural fluid; dialysate<sup>†</sup>

**Measurement Volume** 

Sample volume: 100 µL

Time to Result

Approximately 60 seconds

Cycle time: approximately 120 seconds

Measurement Cartridge

Use life: 28 days, or maximum number of tests

Size: 100/250/400/750 tests

Cartridge initialization time: approximately 24 minutes

Calibration

1-point calibration every 30 minutes; 2-point calibration every 2 hours; full calibration every 8 hours

**Quality Control** 

Automatic Quality Control (AQC) cartridge: three levels of independent quality control solutions; customizable QC schedule; ampule QC

**System Dimensions** 

Width: 30.0 cm (11.5 in.) Depth: 42.0 cm (16.0 in.)

Height: 55.0 cm (21.5 in., display at highest position)

Weight: 16.55 kg (36.5 lb, excluding cartridges)

Touchscreen: 21.1 x 15.8 cm (8.3 x 6.2 in.)

Integrated and External Barcode Scanner<sup>‡</sup>

For patient ID, operator ID, and ampuled QC

1D barcode symbologies: Code 128, Codabar, Code 39, Interleaved 2 of 5

2D barcode symbologies: PDF47, MicroPDF417, Datamatrix,

QR Code, Micro QR Code, Aztec and MaxiCode

#### **External Interfaces**

USB (3 ports); RS232; 10BASE-T Ethernet; barcode scanner

**Power Requirements** 

Rating: 150 VA Voltage: 100–240 VAC Freguency: 48–62 Hz

**Environmental Requirements** 

Temp: 15-30°C

Humidity: 5–85% noncondensing Barometric Pressure: 523–800 mmHg

Safety

TUV-listed, CSA, EN/IEC 61010-1, JIS

**EMC** 

61326-2-6: Class B

#### **Operating System**

MICROSOFT WINDOWS 10 IoT Enterprise (1809)

#### **Data Security**

Patient data encryption

MCAFEE enabled anti-malware

**Endpoint configuration** 

Firewall

Two-step operator authentification

No hard-coded password

USB on/off functionality

#### **Data Capacity**

Patient samples: 250

QC samples: 250 Operators: 5000

#### Communication

Wireless§

LIS

Dual-port transmission via Ethernet and serial port

 ${\sf POCcelerator^{TM},\,UniPOC^{TM},\,RAPIDComm^{@}-Data\,\,Management\,\,Systems}$ 

Features and specifications are subject to manufacturer change.

†Feature not available in the U.S

‡External scanner is optional and is not included with the analyzer.

§This feature applies only to facilities that implement an external wireless bridge between the RAPIDPoint 500e system and a DMS.

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