White Paper

Point-of-care blood analysis

Meeting the need for accurate, quality testing in critical care

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SIEMENS Healthineers

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Meeting the need for accurate, quality testing in critical care

Point-of-care testing (POCT), laboratory testing conducted close to the site of patient care, has been possible for over 4 decades.[1,2] Numerous studies support how a patient-side testing approach can reduce turnaround time and lead to operational efficiencies while maintaining the accuracy and quality of a laboratory-based process.[3-5]

Clinical staff, the laboratory, and healthcare institutions can benefit by streamlining patient testing workflows to enhance patient care and deliver the most cost-effective and efficient use of hospital resources, allowing them to focus on delivering the most value to patients.[6]

These benefits are driving factors for POCT adoption and market growth. In 2020, the global POC diagnostic market was reported to be $34.49 billion USD, with North America accounting for $14.09 billion of the market. Based on the prevalence of acute and chronic diseases worldwide, the demand for POC products is expected to continue.[7]

Point-of-care testing is a widely adopted diagnostic tool in various locations in the hospital, especially in critical care settings such as the intensive care unit (ICU), operating room (OR), and emergency department (ED).[8] One of the most frequently ordered tests in critical care is blood gas analysis.[9] A blood gas test measures the amount of oxygen and carbon dioxide in the blood. It is also used to determine the pH and acidic content of the blood. Imbalances in the oxygen, carbon dioxide, and pH levels of the blood are indicative of numerous cardiopulmonary and metabolic diseases, making blood gas analysis a key measurement in the diagnosis of conditions including kidney failure, heart failure, uncontrolled diabetes, hemorrhage, chemical poisoning, drug overdose, shock, asthma, and chronic obstructive pulmonary disorder.[10,11]

The first commercially available blood gas analyzers were introduced into clinical laboratories in the 1960s.[12] Over the past four decades, technological advances have translated into improvements in the performance and design of blood gas analyzers.[12-14] Modern analyzers can measure a broad menu of critical analytes and enable the testing of blood gas, electrolytes, and metabolites from a single patient sample.[14,15] These analyzers are now the mainstay of critical care patient management throughout hospital systems.[13]

Due to technological advancements, blood gas analysis can now be done not only in the laboratory but also at the patient bedside, with point-of-care testing systems.[13] Availability of point-of-care blood analysis systems in critical care settings can rapidly inform clinical decisions, enabling expedited intervention and leading to improved patient outcomes. However, to realize these benefits, POCT systems must also provide strong analytical performance and rigorous quality assurance measures (QC/QA) as well as demonstrated user-friendliness and workflow efficiency.[13] Lastly, these systems must have IT security features to provide data protection in this world of increasing cybersecurity concerns.[13]

epoc Blood Analysis System[15]

Overview

The epoc® Blood Analysis System (Siemens Healthineers USA, Tarrytown, NY) is a patient-side test system that meets these requirements. This system has provided the benefit of POC testing across the critical care continuum since it first launched in 2006.

This testing solution offers a full menu of laboratory-accurate tests, including blood gases, a basic metabolic panel, hematocrit, and lactate. In addition to 13 measured analytes, the system provides 18 calculated parameters from only 92 µL of arterial, venous, or capillary whole blood.

Results are generated in less than 1 minute after sample insertion, making it ideal for acute patient populations.

The epoc system consists of three primary components: the epoc Reader; epoc NXS Host; and epoc blood gas, electrolyte, and metabolite (BGEM) Test Card. Each Test Card is bar-coded with lot number and expiration date for error-free test panel recognition. The Reader interprets electronic signals from the Test Card that are transferred via BLUETOOTH to the epoc NXS Host. The epoc NXS Host serves as a mobile primary user interface and analytical engine that generates test results and securely integrates with the LIS/HIS.

epoc Blood Analysis System with NXS Host
The epoc NXS Host is the first handheld diagnostic instrument to leverage the power of ANDROID, with enhanced processing power and performance, 2 GB of memory, and long battery life. The system has a vibrant, HD-resolution touchscreen that can be used with gloved fingers and features a large on-screen keyboard. The Host's user interface is designed to support both expert and novice operators and delivers a streamlined, intuitive, prompt-based testing workflow. The Host provides audio and visual prompts when action is required and offers a "Show me how" prompt where the screen expands and shows a large animation that demonstrates the appropriate technique for the particular process step.

13 Critical Tests on a Single Card

Blood gas

- pH
- pCO_2
- pO_2

Hematocrit

- Hct

Lactate

- Lac

Basic metabolic panel

- TCO_2
- Na^+
- K^+
- Ca^{++}
- Cl^-
- Glu
- Crea
- BUN

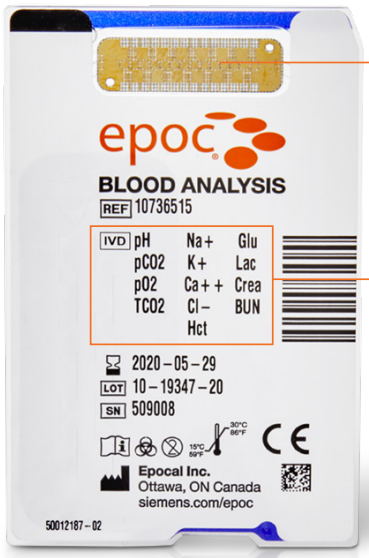
Additional calculated values

AGao	BE(b)	eGFRckd‡
AGapK	c502	eGFRckd-a‡
$cHCO_2$	cHeb	eGFRswz§
$cTCO_2$	eGFRmdr†	BUN/Crea
BE(ecf)	eGFRmdr-a†	Urea/Crea

†IDMS–traceable MDRD type
‡CKD-EPI equation
§Bedside Schwartz equation

Values >60 will be reported as>60 mL/min/1.73 m2

Test Card



Sensor Module:
Contact surface

Test Panel Type

- Blood gas
- Basic metabolic panel
- Lactate
- Hematocrit

Test Card Features

- Room-temperature storage
- Bar-coded with lot and expiration for error-free test panel recognition
- 92 uL sample syringe/90 uL sample capillary
- Arterial, venous, or capillary whole-blood samples
- Simplified inventory management

Testing process

In a few simple steps, a clinician can have clinically actionable test results without leaving the patient's bedside, from a solution that simplifies the testing process, automates quality assurance, and provides comprehensive, connected care. The process steps are described below:

Step 1: Test initiation. To initiate a test, the operator simply detaches the Host from the Reader and scans their user credentials to verify authorization to use the system. The Host is then returned to the Reader, and a series of electronic checks occurs to verify the system is ready.

Step 2: Test Card insertion and calibration. The system prompts the operator to insert a Test Card to initiate the calibration cycle. After insertion, the epoc system automatically checks the Test Card expiration date. If it is expired, the operator is prompted to insert a new, valid Test Card before continuing. This eliminates erroneous results caused by expired reagents. The system also performs a calibration process that ensures the quality of the Test Card. This key step mitigates the risk of losing a valuable patient sample and avoids sample redraws. Test Card calibration takes only 3 minutes, during which the patient ID and other information can be entered and the sample drawn.

The epoc system is integrated for patient safety, with a positive patient ID feature, automated quality assurance, and a simplified operating process. The operator scans the patient ID using the integrated 1D/2D bar-code scanner, and the system wirelessly matches the scanned ID with patient data in the LIS, positively confirming the patient ID. Ensuring a reliable match to the patient and result mitigates the risk of error and potential misidentification and gives caregivers confidence. Then the operator enters important information about the patient, sample, and tests to be run. A series of dropdown menu options facilitates entering the information, including patient demographics, sample type, and the types of tests to be run.

Step 3: Sample injection. The system prompts the operator to inject the sample into the Test Card, providing visual prompts and guidance regarding the appropriate sample injection technique. Following injection, the system analyzes the sample and displays results in less than 1 minute after sample introduction.

Step 4: Obtaining test results. When sample analysis is complete, blood test results are displayed in three groups: Gases+, Chem+, and Meta+. It is important to note that test results from the epoc Blood Analysis System correlate with those from leading benchtop blood gas and laboratory chemistry analyzers, demonstrating analytical precision, performance, and comparability to traditional laboratory methods as well as other near-patient and handheld systems on the market.[16]

Color-coded results

- **Normal**
- **Outside Reference Range**
- **Critical**

Results on the epoc NXS Host are color-coded so the operator can easily identify those that are critical or out of range. Red denotes a critical result, yellow indicates a result out of range, and white indicates a normal result. If critical results need to be documented, the system prompts the operator, indicating at the top of the screen where critical results can be documented. With the push of a button, a screen appears from which the operator can notify the attending physician or other caregiver. The functionality to reject a test, if required, is also available.

Connectivity
The epoc system leverages a secure, wireless connection to instantly transmit results via data management software to the LIS/HIS. This ensures that current test results from each department are available to the care team and connects the patient, actionable test results, the care team, and the therapy delivered.

Bidirectional communication between the epoc system and the data management software enables remote, centralized management of devices, operators, inventory, and quality control and allows the proactive and secure management of data across the hospital, providing centralized control of decentralized testing

Conclusion

Point-of-care testing brings results to the patient bedside, simplifying the testing process and shortening the time to clinical results.[17] POCT systems combine convenience and ease of use with resulting workflow efficiency for the staff and cost savings for hospital systems.[6] In critical care environments, accurate blood gas, electrolyte, and metabolite testing at the patient bedside, like that provided by the epoc Blood Analysis System with epoc NXS Host, enables clinicians to provide immediate, potentially lifesaving intervention. Technological innovation in this diagnostic arena has and will continue to improve the quality of patient care and lead to better patient outcomes.[6,17]

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Further information is available at www.siemens-healthineers.com.

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