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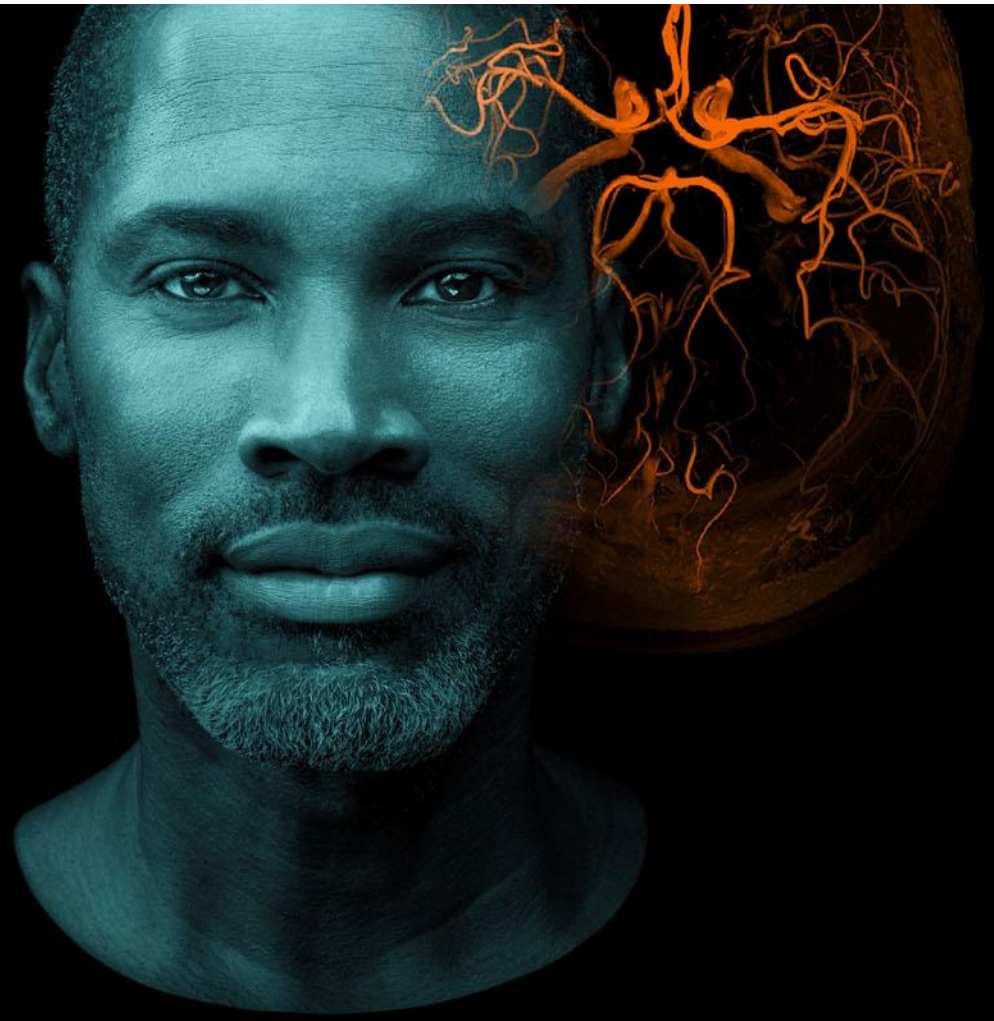
Mitigating Errors in Blood Analysis with POC Informatics



Marcy Anderson, Northeast Zone Head for
POC Customer Experience

Objectives

- Define sources of error in point of care testing
- Recognize design attributes that mitigate risk in point of care testing
- Demonstrate the features and benefits of a comprehensive POC informatics system

Mitigating Risk in POCT

The Food and Drug Administration (FDA) regulates medical devices and provides guidance on risk mitigation.

FDA Risk Control

Potential sources of error for consideration:

- Operator error/human factors
- Specimen integrity and handling
- Reagent integrity (reagent viability)
- Hardware, software, and electronics integrity
- Stability of calibration and internal controls
- Environmental factors

Failsafes and Failure Alerts

Lockout functions that do not allow output of results if:

- Controls or system checks are not successfully completed.
- The device detects damage during internal electronic system checks.
- Expired reagents are used.

Internal procedural controls to flag procedural problems such as:

- Improper sample flow
- Incorrect use of components
- Improper addition of specimen

1. Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver applications for manufacturers of in vitro diagnostic devices: guidance for industry and Food and Drug Administration staff. U.S. Food and Drug Administration. Available from: https://www.fda.gov/media/109582/download. Accessed 10/19/23..

Pre-analytical Stage: Sources of Error and Mitigations

Stage	Source of Error	Mitigation
Pre-analytical **All processes performed prior to testing a specimen**	• Test system access by unauthorized/untrained users	• Configurable operator access • User ID/password requirements • Operator lockout
	• Patient identification • Specimen labeling	• Bar-code readers for positive patient identification and specimen labeling
	• Specimen collection Examples: air bubbles, clots, hemolysis	• Easy-to-use companion collection devices • Blood collection training guides/videos • Ability to test samples immediately after drawing
	• Specimen integrity • Specimen storage and stability • Specimen transportation	• Bedside and near patient testing that mitigates risk of sample degradation
	• Specimen processing	• Education and training guides for specimen processing

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Analytical Stage: Sources of Error and Mitigations

Stage	Source of Error	Mitigation
Analytical All processes performed during testing of a specimen	Reagent stability	• Systems with room-temperature stability Or: • Staff training in quality processes for inventory storage and access
	Test system calibration error	• Automatic calibration with failsafes and error messages to prevent testing when failures occur
	Failed quality control	• Failsafes and error messages to prevent testing when failures occur
	Selection of correct sample type	• Sample type selection required by operator
	Reagent lot expiration	• Bar-coded reagents that enable automatic checks for lot expiration Or: • Implementing and training staff on quality processes for inventory storage and access

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Analytical Stage: Sources of Error and Mitigations

Stage	Source of Error	Mitigation
Analytical All processes performed during testing of a specimen	• Internal system operating error	• Electronic internal QC monitoring throughout test process • External QC • Failsafes and error messages to prevent testing if failures occur • IQCP
	• Operator error	• Training guides, videos, and competency assessment • Guided instructions on display screen
	• Insufficient sample volume/incorrect sample introduction	• Automatic sensor with audible and visual messages • Failsafes and error messages to prevent testing if failures occur
	• Test result out of range	• Administrator rights to set analyte reference ranges • Flag out-of-range results
	• Test result in critical range	• Administrator rights to set critical results • Analyzer that can flag and document critical results in record

1. Identifying and mitigating potential variables in point-of-care testing. Siemens Healthcare Diagnostics Inc. Order No. POC-21-NAM-2215 · Digital only · 03.2021 · © Siemens Healthcare Diagnostics Inc., 2021

Post-analytical Stage: Sources of Error and Mitigations

Stage	Source of Error	Mitigation
Post-analytical All processes performed after test analysis	• Undocumented or incorrectly documented result Example: transcription error	• Results displayed on and stored in instrument with associated patient/QC information, plus ability to recall results • Connectivity for secure transmission of results and associated information to data management system
	• Delayed reporting of critical results	• Connectivity for secure transmission of results and associated information to data management system
	• Confirmation of result transmission	• Flag errors in result transmission

1. Identifying and mitigating potential variables in point-of-care testing. Siemens Healthcare Diagnostics Inc. Order No. POC-21-NAM-2215 · Digital only · 03.2021 · © Siemens Healthcare Diagnostics Inc., 2021

Quality by Design

IQCP: The Individual Quality Control Plan (IQCP) is designed to mitigate risk associated with non-waived testing, except pathology and subspecialties, in each laboratory and to provide an effective quality control program

There are three parts to a complete IQCP:

1. Risk Assessment (RA)
2. Quality Control Plan (QCP)
3. Quality Assessment (QA)

System design can help address risk mitigation in all areas

The five components of the RA

1. **Specimen:** Patient preparation, specimen collection, specimen labeling, specimen storage and stability, transportation, processing, acceptance, and rejection
2. **Test System**: Inadequate sampling, detection of sample errors, interferences, mechanical or electronic failure detection, optics, barcodes, calibration, internal or external controls, temperature, LIS, and result reporting
3. **Reagent:** Shipping, storage conditions, preparation, and expiration dates
4. **Environment:** Temperature, humidity, ventilation, light, noise or vibration, utilities, and space
5. **Testing Personnel**: Education, experience, training, competency, and staffing numbers

1. https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/iqcp-workbook.pdf. Accessed 10/19/23.

Quality by Design: epoc® Blood Analysis System

epoc Blood Analysis System

Key features and benefits:

- Handheld, portable blood analysis system
- Full test menu (13 analytes) on a single, room temperature-stable test card
- Calibration completed before blood sample is introduced (no wasted sample)
- Automated quality assurance
- Low sample volume: requires only 92 µL blood sample
- Comprehensive results ready for wireless transmission in less than 1 minute

1. epoc System Manual with epoc NXS Host. Rev.:04. 2023-04. © 2023 Siemens Healthcare Diagnostics, Inc.

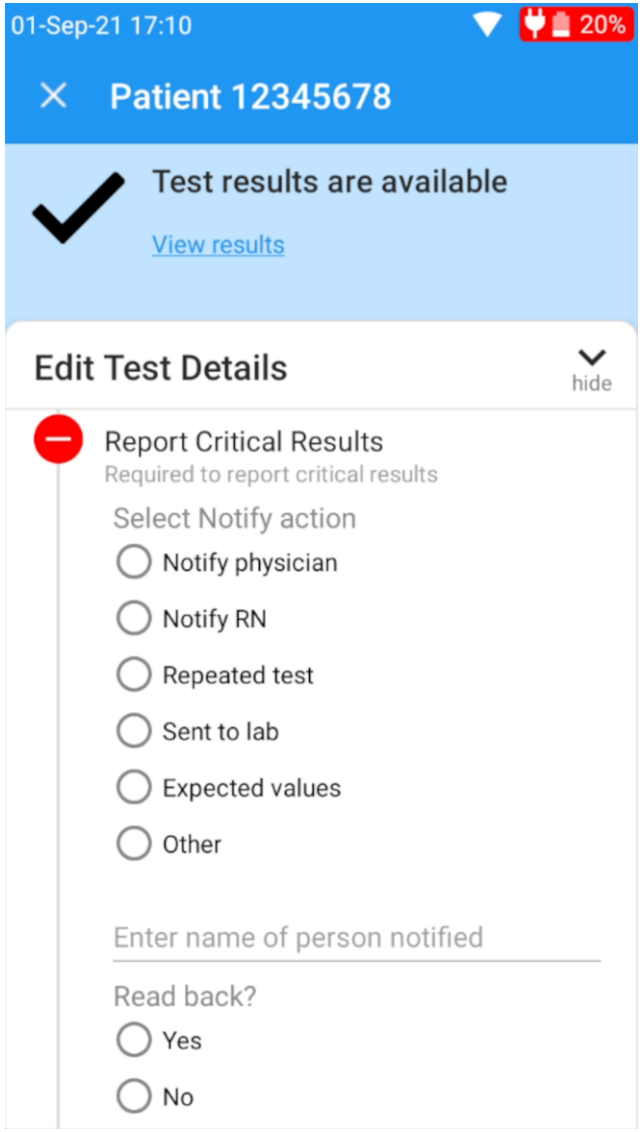
Quality by Design: epoc® Blood Analysis System

Patient-side testing	Allows for improved sample integrity (no transport) and minimizes potential for pre-analytic errors
Room temperature stabile Test Cards	Mitigates test card integrity and expiration due to time and temperature of storage conditions
13-measured analytes on 1 Test Card	Minimizes blood loss due to testing; provides complete panel of results in minutes
Automated Quality Assurance	Achieved with a built-in barcode reader, system integrity checks, and test card calibration. Initialization: • epoc Reader electronic QC test every time the Reader connects with an epoc Host. • QC tests are performed by the epoc Reader on the card and on the operator process after card insertion during initialization.
	In-calibration: • QC tests performed to assess the card and sensors' conformance during the calibration interval before sample is introduced.
	During sample measurement: • QC tests performed to monitor the operator procedure and sample integrity during and after sample introduction.
Built in barcode and bar code reader	Adds traceability: Checks card expiration and links lot number to test results & related patient data.
Built-in animated visual prompts	Guides user through the test process, mitigating user error.

1. epoc System Manual with epoc NXS Host. 51015950. Rev.:04. 2023-04. © 2023 Siemens Healthcare Diagnostics, Inc.

Integrated patient safety

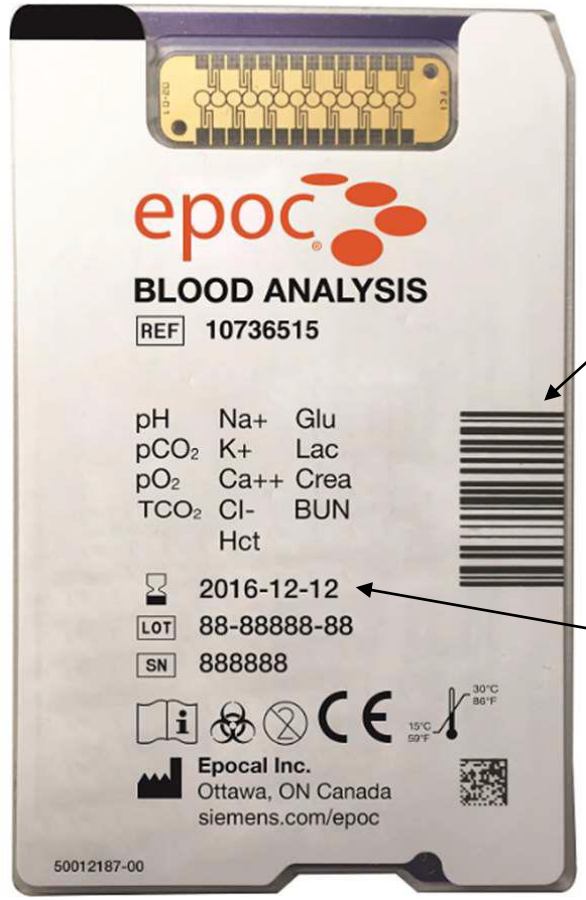
- Sample remains at patient-side and is NOT taken to another location for processing
- Immediate testing at the bedside allows for improved sample integrity and minimizing potential for pre-analytic errors
- Customized reference ranges and critical values by patient sample type
- Optional critical value alerting and reporting at the time of test with color coded display



1. epoc System Manual with epoc NXS Host. 51015950. Rev.:04. 2023-04. © 2023 Siemens Health Diagnostics, Inc.

Process Improvement

- Single, room temperature storage, always ready test card with lot information barcoded directly on the card
  - The epoc Reader will reject any Test Card past the Use By date on the Test Card.
- Error messages that encompass all phases of testing
  - Message types include: environment, card handling errors, sample handling errors, user actions, expired cards, quality control lockouts, user access lockouts, etc.
  - For each message, the description indicates reason why the message occurred and an appropriate response is provided.
- On board, animated user tutorials for sample injection, card insertion, and card removal



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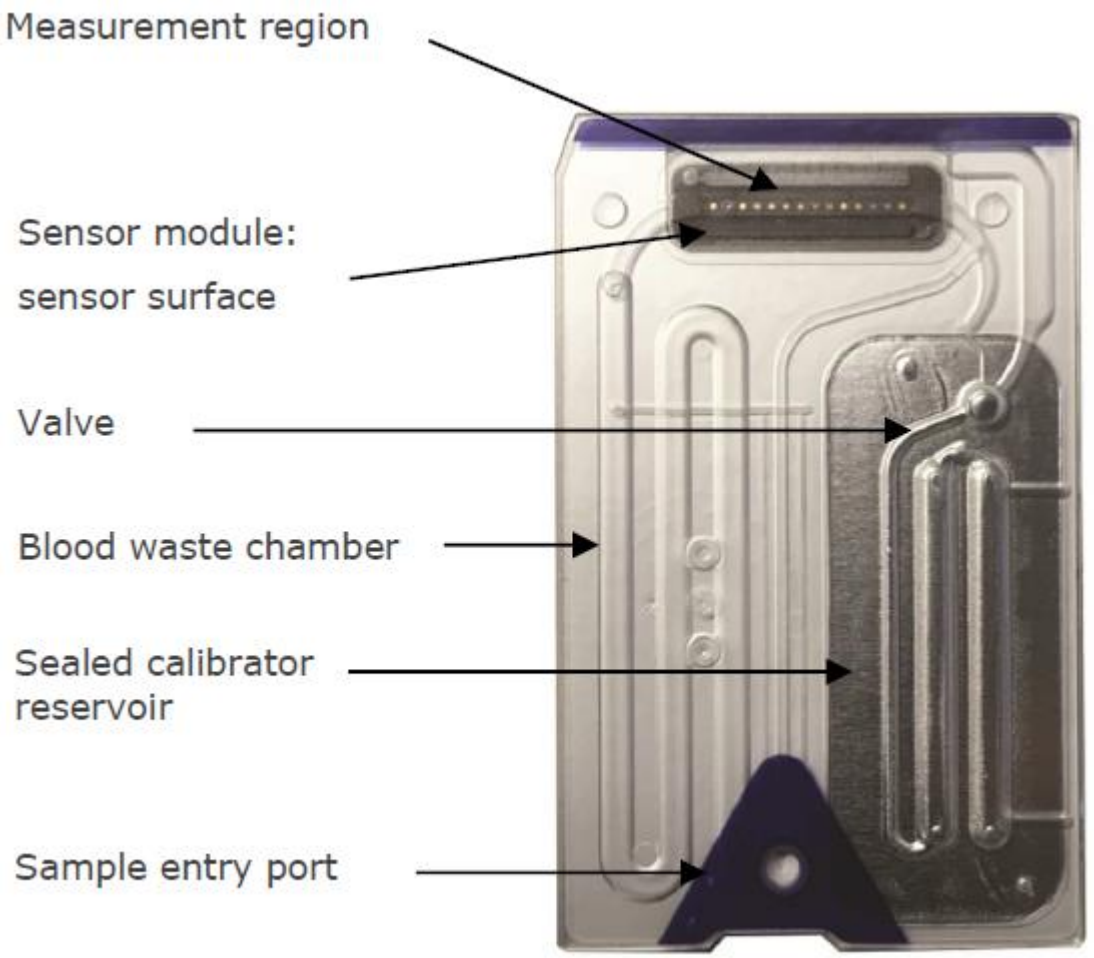
Calibrations

Automatic calibrations with each Test Card insertion

- Water-based calibration fluid is contained in a sealed calibrator reservoir
- During the calibration interval (extending for 150 to 175 seconds, depending on environmental thermal conditions) the sensors are heated to 37°C and they wet-up from the dry storage state within the first minute or so, achieving wet up within 60 – 100 seconds.
- Within the card, the function of the calibration fluid is **not the same** as an external quality control fluid with an assigned mean, SD and set pass/fail concentrations.
- Instead, it is used as a single point calibration in every test. The iQC process applied during calibration is described in detail in this section.



1. epoc System Manual with epoc NXS Host. 51015950. Rev.:04. 2023-04. © 2023 Siemens Healthcare Diagnostics, Inc

Quality Control

Overview of Internal QC (iQC)

- Three phases of QC testes performed with the insertion of each Test Card
  1. **Initialization**: An initial battery of tests covering 2 different levels over the dynamic range is performed by the epoc Reader (epoc Reader electronic QC test) every time the Reader connects with an epoc Host.
     - QC tests are performed by the epoc Reader on the card and on the operator process after card insertion during initialization.
  2. **In-calibration:** QC tests performed to assess the card and sensors' conformance during the calibration interval before sample is introduced.
  3. **During sample measurement:** QC tests performed to monitor the operator procedure and sample integrity during and after sample introduction.
- Provides broad spectrum protection against erroneous operation of the system

	Initialization	In-Calibration	Sample
epoc Reader	√	√	√
Cards and test	√	√	√
User procedures	√		√
Sample integrity			√

External Quality Control

Overview of Internal QC (iQC)

- Three phases of QC testes performed with the insertion of each Test Card
  1. **Initialization**: An initial battery of tests covering 2 different levels over the dynamic range is performed by the epoc Reader (epoc Reader electronic QC test) every time the Reader connects with an epoc Host.
     - QC tests are performed by the epoc Reader on the card and on the operator process after card insertion during initialization.
  2. **In-calibration:** QC tests performed to assess the card and sensors' conformance during the calibration interval before sample is introduced.
  3. **During sample measurement:** QC tests performed to monitor the operator procedure and sample integrity during and after sample introduction.
- Provides broad spectrum protection against erroneous operation of the system

	Initialization	In-Calibration	Sample
epoc Reader	√	√	√
Cards and test	√	√	√
User procedures	√		√
Sample integrity			√

Enhanced Quality Control Features

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Improved QC Workflow using electronic Value Assignment Datasheets (eVADs)

- An eVAD file is a single file stored on the epoc Host that contains:
  - All current ranges and expiration dates for all valid quality control (QC) fluids, calibration verification (CV) fluids, and sensor configuration version
- QC Workflow Steps:
  1. Scan the lot barcode from the liquid quality control bottle
  2. Run the QC or CV test
  3. epoc Host will automatically indicate Pass/Fail

Improved QC Compliance using schedules and lockouts

- The QA Schedules and Lockout feature provides the following capabilities: Three verification types that can help enforce QA schedules during blood testing: **Lock, Ask, and Disabled**
- QA Schedules can be configured to require a certain number of QC fluid levels or specific QC fluid levels to help meet the compliance requirements of your institution.
- Each department can have its own QA Schedule to help enforce compliance through device QC lockout on a periodic schedule (fixed, hourly, weekly, monthly, etc.)

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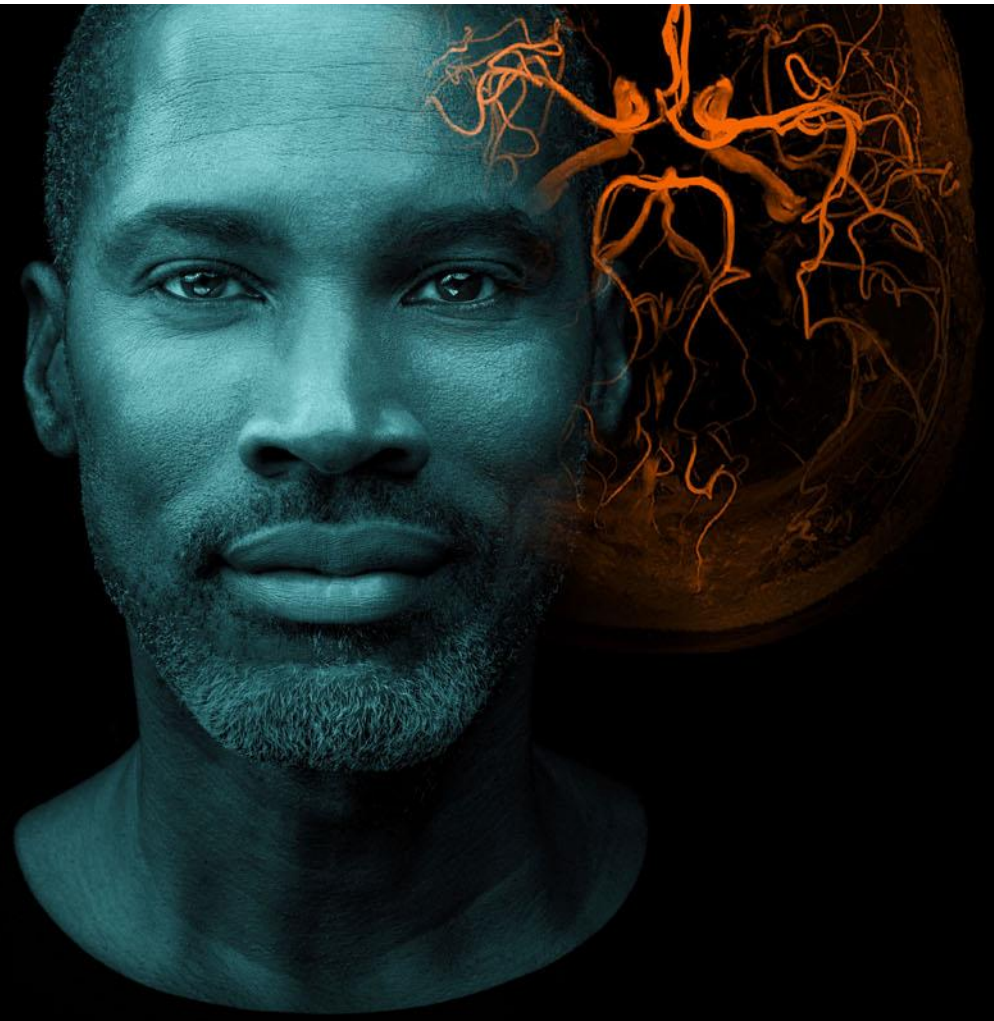
UniPOC Demonstration

Chad Juhl, Senior Informatics Sales Specialist



Thank You!

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