Wake Forest™
Baptist Medical Center

Point-of-Care Testing
AVOX 1000E
Education Module

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- This presentation does not include all information regarding AVOX testing. It only highlights information.

- For complete information, refer to the AVOX procedure

- The document can be found on the WFBH Intranet—Departments—Point of Care Testing

AVOX Support

- AVOX/ITC Technical Support 1-800-631-5945
- WFBH Clinical Engineering
- Clinical Laboratory Point-of-Care Testing Coordinators
  - Angie Thayer 713-4136
  - Ray Dyer 713-4137
  - Liz Gregory 713-0377
- Contact your site manager

Safety

- Always wear gloves when handling analyzer or samples
  - Including patient testing and performing QC
- Disinfect when contaminated with blood AND between EVERY patient
  - Routine external cleaning is recommended for infection control purposes
- When performing liquid QC, protect fingers. Carefully, break open ampule.

Basic Principle of AVOX 1000E

- The AVOX 1000E test device is used to measure:
    - Fractional oxyhemoglobin (%HbO2)
    - Total hemoglobin (THb) concentration
- Blood samples are injected into a sealed, single-use disposable cuvette that is inserted into the sample chamber.
- The AVOX 1000 E illuminates the sample at multiple wavelengths, records the optical density of the sample at each of the wavelengths, and computes the results.

AVOX 1000E Components

- Analyzer
- Cuvettes
- Orange and Yellow Quality Control Filters
- Liquid Quality Control Materials

Analyzer

AVOX 1000E Analyzer

- To Power ON the Analyzer:
    - Press the Enter/On key
    - Confirm that Self-Test was OK
    - The analyzer indicates that it is ready to analyze samples by displaying “READY”
- Troubleshoot if a Self-Test FAILS
    - Do NOT use the device for patient testing until failure is resolved

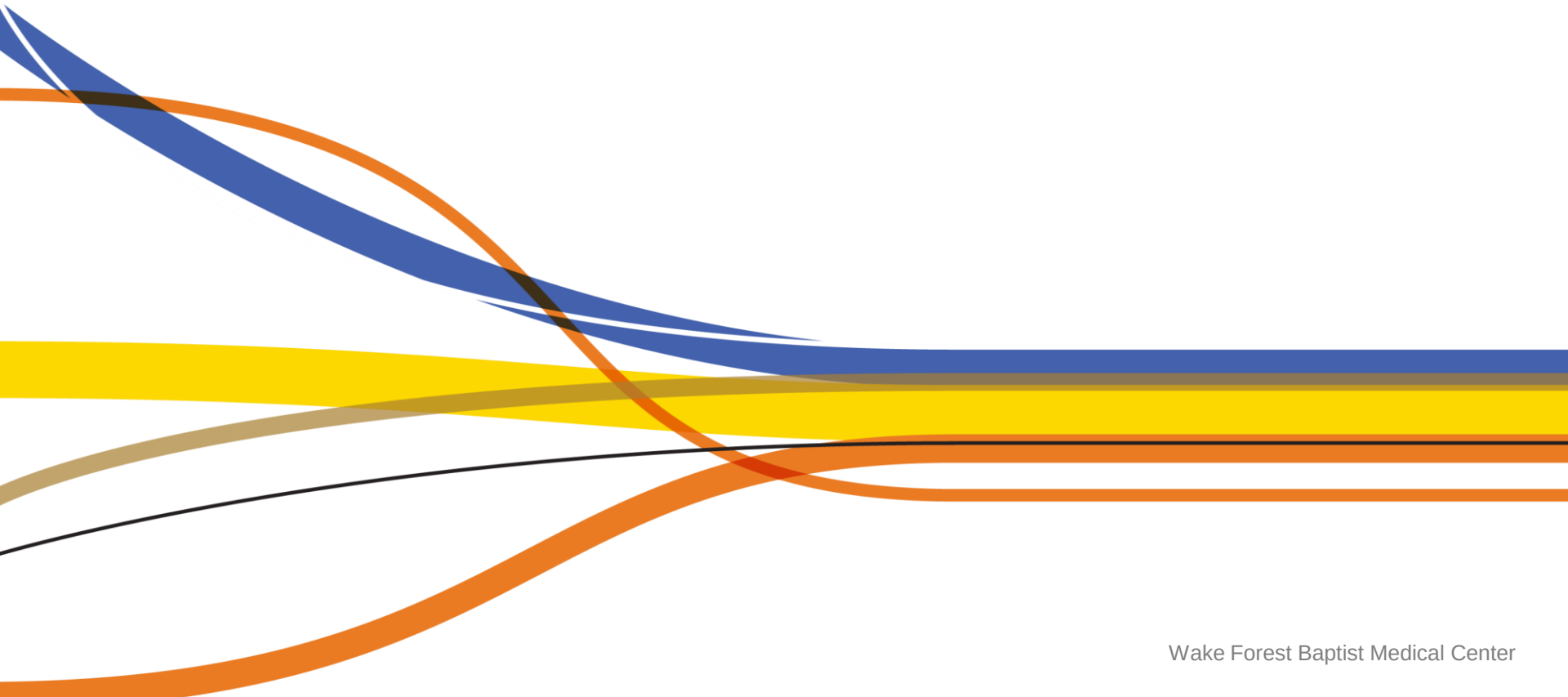
Cuvettes

AVOX Cuvettes

- **SINGLE USE** AVOX Disposable Cuvettes (P/N C-100B)
- Stored at room temperature (15-30°C) in tightly sealed bag with desiccant.
- 1 required per sample
- **DO NOT USE FOR PATIENT TESTING IF DESICCANT INDICATOR IS PINK!!! Patient results may be inaccurate.**

- **The CORRECT cuvette path length must be entered into the analyzer prior to Patient or Quality control (QC) testing.**

Quality Control



Quality Control Responsibility

- If you perform patient AVOX testing, you are responsible for ensuring the required QC has been performed on the analyzer and AVOX cuvettes, PRIOR to testing patient samples.

- Everyone who performs patient testing must also perform daily QC and liquid QC sometime during the year.

- NEVER use an analyzer or cuvettes for patient testing if required QC checks are not within acceptable limits.

Quality Control Documentation

- Document ALL QC values on the QC logs, including QC failures. This helps track on-going problems.

- The daily QC log MUST have QC values or “Not in Use” (NIU) documented for each day.

- If you document NIU, you must sign/initial next to NIU.

Quality Control

- **Daily:**
  - The AVOX 1000E is checked for calibration accuracy and optics cleanliness with the use of Quality Control Filters.
- **Weekly:**
  - The instrument and cuvettes are checked for accuracy and calibration stability using 2 levels of Liquid Quality Control
- **Semiannually**:
  - The AVOX 1000E is compared against the Clinical Laboratory Co-Oximeter every 6 months and linearity is verified by testing a linearity kit.

Quality Control Filters

- Verifies performance of AVOX analyzer
  - Confirms the AVOX is calibrated
  - Assesses the status of the optical system
  - If blood has contaminated the optics, the readings from the QC filters will not fall within the acceptable ranges.
- The QC filters are device specific
  - Do NOT interchange between analyzers
- QC filters must be tested each day of patient use
- All QC results should be documented on the AVOX QC log

Procedure: Quality Control Filters

- Verify that the serial numbers match between QC filters and AVOX analyzer.
- Wipe off the cuvette-shaped yellow and orange optical filters.
- Observe that the “READY” message is displayed and insert the QC filter into the AVOX.
- Wait until readings appear on the display.
- Record results on the provided logs *and review for acceptability*.
- Repeat with second QC filter.
- Record second filter results *and review for acceptability.*
- If BOTH THb and BOTH %HbO2 readings are within specified ranges, the AVOX **passes** both the Quick Cal Check and the Test for Spilled Blood.

Quality Control Filters—Unacceptable Values

- If any one of the four values are outside of the specified range, the AVOX fails quality tests and can NOT be used for reporting patient results until the problem has been resolved.
- **Remedial Action:**
  - Verify QC filters are clean and match the instrument used.
  - Repeat filter testing
  - Contact Clinical Engineering for assistance

Liquid Quality Controls (LQC)

- RNA Medical QC 253 Liquid QC Levels 1 and 3
- Stored at 2-8 C until expiration date
- Avoid freezing and temperatures above 8 C.
- Do NOT need to equilibrate to room temperature prior to use
- Call 1-800-533-6162 for order information.

Liquid QC

- Two levels of Liquid controls are performed to verify performance of AVOX analyzer and test cuvettes.
- LQC is tested:
  - Weekly on all AVOX analyzers
  - On each new shipment of cuvettes
  - Whenever the cuvette path length is changed in an analyzer
  - Whenever analyzer or cuvette performance is in question
  - Post analyzer repair or calibration--prior to use for patient testing.
- Liquid QC performance should be rotated among all users.
- All LQC results should be documented on the AVOX liquid QC log
- Acceptable ranges can be found on the lot specific insert that comes with each box of AVOX liquid QC.

Procedure: Liquid QC (LQC)

- The LQC should be tested immediately after removal from refrigerator.
- Hold ampule at the top and bottom (with forefinger and thumb) and gently invert to mix the solution.
- Restore the QC material to the bottom of the ampule and let sit for about a minute.
- Using finger protection, CAREFULLY break open the ampule of control solution and **SLOWLY** withdraw 0.2 to 0.3 ml into a 1 ml syringe. Use a blunt needle.
    - **EXTREME CARE SHOULD BE USED IN OPENING THE QC AMPULES.** To avoid accidental sharps exposure, the ampule top should be covered with gauze, tissue, or a protective plastic sleeve when opening.
- **Avoid getting air bubbles in the syringe or AVOX results may be adversely affected.**
- Remove blunt needle from the syringe. Discard the needle in a biohazard sharps container.
- Immediately place an AVOX cuvette on the syringe.
- Fill the cuvette according to illustrations in the AVOX Operator's/Service Manual.
- Observe the "READY" message is displayed and insert the Control filled cuvette, with syringe attached, into the AVOX.
- Record results on the AVOX Liquid QC log and review for acceptability. If all readings are **within** the specified ranges, the AVOX **passes** the liquid QC check.

Liquid Quality Control—Unacceptable Values

- DO NOT perform patient testing if any QC value is outside of acceptable tolerance limits.
    - All QC values should be recorded for an accurate audit trail

- Remove the device AND cuvettes from patient use and proceed with troubleshooting procedures

Liquid Quality Control: Troubleshooting Procedures

- If a QC result is outside of acceptable limits, verify the following:
  - Correct cuvette path length is programmed in the analyzer
  - Confirm desiccant indicator is blue in the cuvette package
  - Ensure liquid controls have been stored and handled appropriately
- Repeat the same level of liquid control using a new ampule and a new cuvette from the **same box of cuvettes**
- If repeat results are **within acceptable limits**, then the analyzer and cuvettes may be used for patient testing
- If repeat results are still outside of acceptable limits, contact Clinical Engineering for assistance

Cuvette Calibration

- Each time a new bag of cuvettes is opened, the AVOX cuvette path length must be updated and/or verified.

- Instructions can be located in the AVOX procedure and inside the cuvette box lid

- Prior to patient use and after entering a new cuvette path length in the AVOX analyzer, both levels of QC filters and liquid QC must be tested to verify analyzer/cuvette performance

Bi-Annual Analyzer Comparison

- Must be completed by user site on each AVOX analyzer:
    - Each 6 months
    - After analyzer repair
- Two patient samples are tested to validate comparability of results with the Clinical Laboratory Cooximeter.
- Results are documented and submitted to the Clinical Lab for review.
- If patient comparison results do not match, remove analyzer and cuvettes from use until issue is resolved.
- Call ITC Technical Support at 1-800-631-5945 for assistance

Bi-Annual Linearity Verification

- Must be completed by user site on each AVOX analyzer:
    - Each 6 months
    - After analyzer repair
- A linearity kit is used and is intended to challenge the full reportable range for both THb and %HbO2.
- If linearity verification fails, remove analyzer and cuvettes from use until issue is resolved.
- Call ITC Technical Support at 1-800-631-5945 for assistance

Documentation

- Accurately document patient and quality control values.
- Cuvettes and QC materials should be marked with the date they are received. When supplies are opened and put into use, they should be logged on the appropriate log. All records are kept a minimum of two years.

Analyzer handling prior to sending to Clinical Engineering

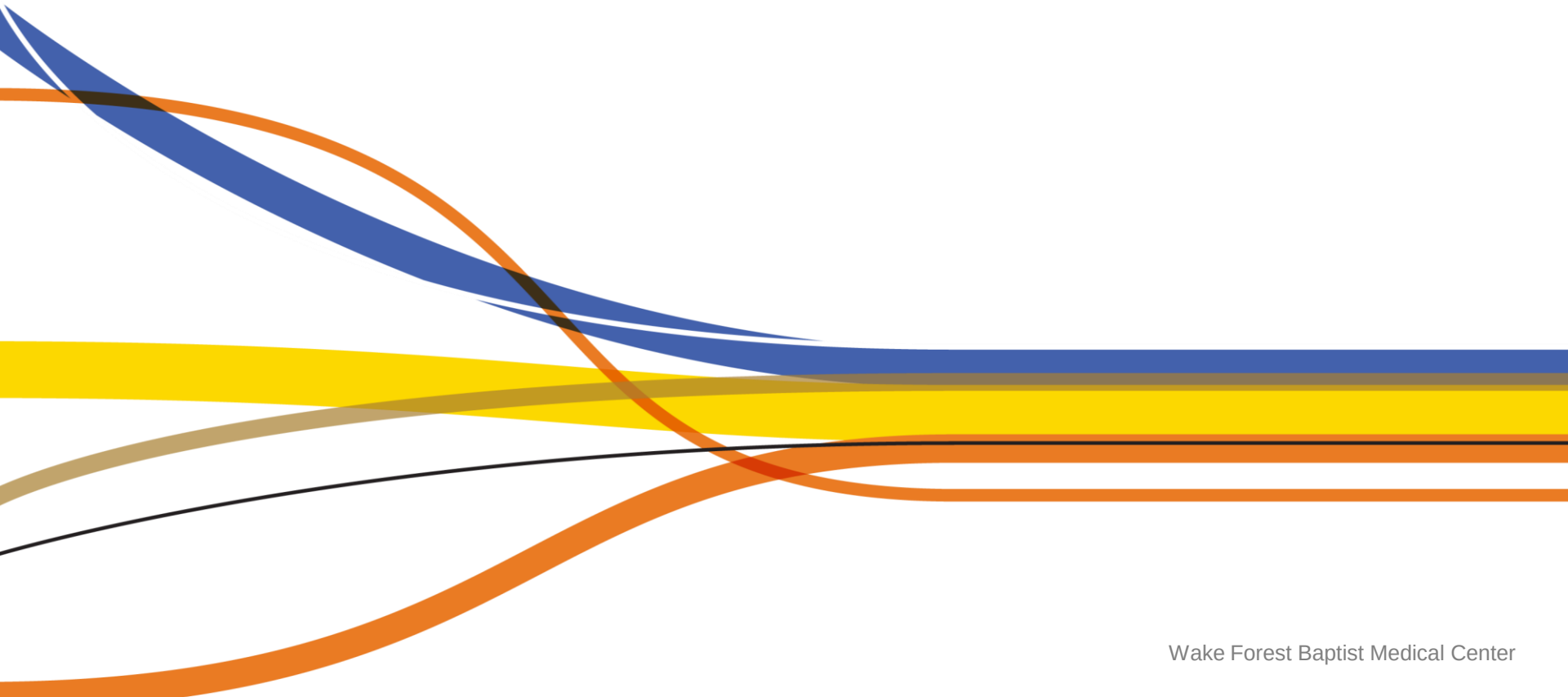
- Clean the outside of the analyzer with Caviwipe or approved bleach wipe.

- Ensure there are NO blood/body fluids on the device.

Analyzer Re-Implementation Post Repair

- If an analyzer goes to Clinical Engineering or ITC Tech Support for check or repair, ALL of the following MUST be completed PRIOR to patient use:
  - Perform BOTH levels of QC filters
  - Perform BOTH levels of liquid QC
    - ALL QC results must be within acceptable limits
  - Perform patient sample comparison with the Clinical Laboratory cooximeter and with the other AVOX device.
    - All values must be within acceptable tolerance limits
  - Test Linearity Kit
    - All values must be within acceptable limits
- All actions should be clearly documented

Sample Requirements



Sample Requirements

- **<u>ONLY</u> <u>FRESH</u> <u>whole blood</u> should be tested on the AVOX**

- Arterial or venous blood is acceptable

- 50 μl of fresh whole blood-analyzed within 3 minutes of collection.

Sample Considerations—Samples Collected from In-Dwelling Lines

- Always adequately “clear” line prior to collecting a sample for AVOX testing

- Inaccurate results will be given if samples are contaminated/diluted.

Patient Testing

AVOX Orders/Documentation

- All AVOX testing should have a documented physician order.
- All AVOX results should be documented in the permanent patient record.
  - Results should include:
    - AVOX result with units of measure
    - Testing personnel
    - Date of testing
    - Time of testing
- A clear audit trail should be maintained correlating patient results with quality control results for the analyzer and cuvettes that were used for patient testing.

Patient Identity

- Follow WFBH policy for verification of patient identity—Use 2 patient identifiers at the patient bedside

- Ensure sample identity throughout entire testing and reporting process

Testing a Patient Sample—

- Review QC logs to ensure instrument is ready for use.
- Gloves should be worn during sample collection and analysis.
- Turn on the AVOX by pressing the Enter/On key and confirm that the self-test was successful. The instrument indicates that it is ready to analyze samples by displaying the “READY SCREEN”.
- Verify that the correct cuvette path length is programmed in the AVOX.
- Open the sealed bag to remove cuvettes. **Immediately reseal bag**. Do not touch the sampling area (the clear surface) of the disposable cuvettes.
- Handle cuvettes by black cap.

Testing a Patient Sample--continued

- Evacuate any air bubbles that may be in the sample
- Immediately cap the sample to prevent air contamination and keep tightly sealed
- Roll syringe between palms to keep red blood cells and plasma well mixed
- Remove the cap from the end of the syringe.
- Squirt out the first few drops of sample to check for clots and to get the well mixed portion of the sample.
- Attach the cuvette to the Luer tip of the syringe, point the cuvette downward at a 45º angle, and observe the sample chamber of the cuvette. **DO NOT INJECT THE BLOOD INTO THE INSTRUMENT'S SAMPLE CHAMBER**.
- Press the plunger gently and fill the cuvette. Stop injection of the sample as soon as blood reaches the air vent. Do not allow any air bubbles to adhere to the internal surface of the cuvette.

Performing Patient Testing -- Continued

- With syringe still attached to the cuvette, hold the cuvette firmly by its black cap, and insert the cuvette into the sample chamber. **Do not depress the plunger while the syringe is in the instrument.**
    - **The filled cuvette should be inserted in the AVOX analyzer within 30 seconds of fill.**
- Observe the LCD display. Do not disturb the AVOX. Results should display within 10 seconds.
- Record the %HbO2 results in the patient record and remove the sample from the sample port and discard in an appropriate biohazard container.

Caution

- **<u>Caution:</u>**
    - Never force blood into the cuvettes. If the sample does not flow easily, discard the cuvette and use another one.
    - When filling the cuvette, do not use excessive pressure or cause the vent patch to bulge outward.

Results

Result considerations

- Unexpected and unexplained results should be verified by another test method.

- Problems should be reported to the Clinical Laboratory Point-of-Care Testing Coordinator 3-4136

Reportable Range

- %HbO2: 0-100%
- THb: 4-25g/dL
- THb results <4 or >25 will give an ERROR on the AVOX analyzer. Results outside of this range should be reported as “Out of Instrument Range.”

- If values outside of this range are required, samples can be sent to the Clinical Laboratory for testing.

Limitations of Method

Factors affecting results

- **The following factors can affect result reliability:**
  - **Cuvettes exposed to moisture (desiccant indicator is pink)**
  - **Over-filled cuvettes**
  - **Delay inserting cuvettes into the AVOX analyzer**
  - **Air contamination**
  - **Excess heparin or saline—Diluted samples**
  - **Certain medications**

Factors Affecting Results--Continued

- **The following factors can affect result reliability:**
  - **Air Bubbles**
  - **Delayed sample testing**
  - **Clotted samples**
  - **Samples that have settled out and the red cells have separated from the plasma**
  - **Lipid (fat) particles**

Quality Concerns

- Any concerns regarding reliability of AVOX testing should be reported to the site manager and to the Clinical Lab Point of Care Testing Coordinator.

- If the employee feels that their concerns are not adequately addressed by WFBH management, the College of American Pathologists (CAP) can be contacted at 1-866-236-7212.

Congratulations

- You have completed the AVOX 1000E education module.

- Please note that this module does not replace the AVOX procedure

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