Wake Forest Baptist Medical Center	Oxyhemoglobin and Total Hemoglobin Measurement Using the AVOXimeter 1000E Analyzer PRO-POCT-LAB-21	**Dept:**	Point of Care Testing
		Effective Date:	12/2003
		Revised Date:	07/2020
		Contact:	Point of Care Testing Compliance
Greg Pomper, MD, **Clinical Laboratory Medical Director, Point of Care Testing**		**Date Approved**	
Signature/Date: **Signature on File**			

I. General Procedure Statement:

The Clinical Laboratory at Wake Forest Baptist Medical Center (WFBMC) is responsible for oversight of explicitly identified non-waived laboratory testing performed in clinical areas by non-lab personnel. Specific testing sites have been identified and included under the CLIA certificate of the WFBMC Clinical Laboratories for a highly complex lab. Testing policies and procedures must meet all regulatory guidelines established by CLIA and other accrediting agencies, as applicable.

This is to ensure that all testing is performed according to manufacturer's recommendations and that each employee follows the same quality control and patient testing procedures. All AVOX testing should have a documented physician order or follow approved protocols.

The AVOX 1000E test device is used to measure the fractional oxyhemoglobin (%HbO2), the total hemoglobin (THb) concentration, and the oxygen content in a sample of whole blood. Examples of situations where the physician may use the AVOX results are: 1) To help in identifying any possible cardiac shunts, 2) Verify oxygenation status of patients, and 3) Measurement of total hemoglobin (THb) in patient samples.

A. Scope:

This document establishes procedures and guidelines for assuring quality of Point of Care Testing (POCT) results obtained from the AVOXimeter 1000E test device. Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.

1. Responsible Department/Party/Parties:

a. Procedure Owner: Clinical Laboratory Point of Care Testing Compliance Manager

b. Procedure: Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.

c. Supervision: The Medical Director for Point of Care Testing shall supervise the person(s) performing activities outlined in this document.

d. Implementation: Each applicable POCT site manager is responsible for ensuring compliance with processes stated in this document.

II. Definitions:

A. Point of Care Testing (POCT): Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.

B. Non-Waived Test: Tests of moderate or high complexity as designated by the FDA.

C. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all laboratory testing performed on humans.

D. College of American Pathologists (CAP): Accrediting agency for the WFBMC Clinical Laboratory. Point of Care sites included on the CLIA certificate of the Clinical Laboratory are accountable to standards set forth by CAP.

E. Quality Control (QC): Processes to ensure the test system is performing as expected.

F. Quality Assurance (QA): A system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.

G. Quality Improvement (QI): Activities implemented to improve the quality of processes.

H. Proficiency Testing (PT): Unknown samples sent to a lab/test site by a Centers for Medicare and Medicaid Services (CMS) approved PT program.

I. Technical Limits/Reportable Range/Analytical Measurement Range (AMR): The range at which the analyzer has been verified to obtain accurate results. Each method-specific analyte has a specific reportable range.

J. Normal (Reference) Range: The range of values for the average patient population.

K. Erroneous: Containing error, mistaken, incorrect, wrong.

L. Analyzer/Device: For the purposes of this document, refers to AVOX 1000E instrument.

M. Functional Oxygen Saturation: The oxygenated hemoglobin divided by the sum of the oxygenated hemoglobin and the de-oxygenated hemoglobin. Carboxyhemoglobin, methemoglobin, sulfhemoglobin or other dyshemoglobins are not part of the equation and, as a result, can introduce error if they are present. The AVOX 1000E does not report functional hemoglobin.

N. Fractional Oxygen Saturation (%HbO2): The fraction of the total hemoglobin (THb) that is oxygenated. Fractional O2Hb is sometimes referred to as FO2Hb. Although the AVOX 1000E does not report the fractions of carboxy-and methemoglobin, they are measured and used in the measurement/calculation of % HbO2.

O. Calibration Verification: Assaying materials of known concentration in the same manner as patient samples to validate the instrument or test system's calibration throughout the reportable range.

P. Linearity: Achieved when measured results are directly proportional to the concentration of the analyte in the test sample, within a given range.

III. Principle:

Blood samples are injected into a sealed, single-use disposable cuvette that is inserted into the sample chamber. The AVOX 1000 E then illuminates the sample at multiple wavelengths, records the optical density of the sample at each of the wavelengths, and computes the results. Fractional Oxyhemoglobin (%HbO2), Total Hemoglobin, and Oxygen Content in the sample are measured according to Beer's Law and the following calculations:

A. % HbO2 = O2Hb / (Hb + O2Hb + COHb + MetHb) x 100

B. THb = O2Hb + Hb + MetHb + COHb

C. O2 = 1.39 x THb x %O2Hb / 100.

IV. Procedure:

A. Equipment

1. AVOX 1000E Test Device

2. SINGLE USE AVOX Disposable Cuvettes (P/N C-100B). One cuvette required per sample.

a. **The CORRECT cuvette path length must be entered into the analyzer prior to patient or quality control (QC) testing. Refer to Cuvette package insert (XI. Attachments C).**

b. Stored at room temperature (15-30°C/59-86°F) in tightly sealed bag with desiccant/**humidity indicator card. Usage and Handling:**

- The color-change indicator cards react when exposed to humidity by changing from "blue" to "lavender" to "pink" depending upon the relative humidity of the environment.
- The concentration of the active humidity indicator is lower in the indicator spot of 10% than in the indicator spot of 40%.

- The color change is not as dramatic in the lower range as compared to the higher range.
- The lower range may appear almost "white" when the humidity has exceeded the range for that indicator.
- If the 30% indicator appears almost "white", this means the indicator has been exposed to very high humidity or free water. If this occurs:
    - Immediately inspect the package and do NOT use for patient testing.
        - Contact manufacturer Technical Support as listed below.
    - "Lavender" is the color of the current relative humidity within the immediate environment of the sealed bag.
    - If all spots are "Pink" then the relative humidity is greater than the highest percentage indicated as the card's detection limits.
    - If all spots are "Blue" then the relative humidity is less than the lowest percentage indicated by the card.
    - Note: If all of the spots appear "Pink" or "White", contact manufacturer. Technical Support:
        - Toll-free in the U.S: 800-955-9525 (available after hours, weekends, and holidays)

- Disposal of Humidity Indicator Cards – the cards can be disposed as common waste and do not require disposal in a Biohazard Waste container. Discard any card that shows a "circle overrun" or color that is beyond the black border of each circle as these cards may not read accurately.

c. DO NOT USE CUVETTES FOR PATIENT TESTING IF DESICCANT INDICATOR IS PINK or WHITE!!! Patient results may be inaccurate.

- To reverse moisture exposure, store the cuvettes with a new desiccant pouch for 24 hours in a tightly sealed container.

3. 5 cc syringe with blunt needle or safety needle

4. Gloves—ALWAYS wear gloves whenever collecting samples, testing QC or patient samples, or handling the AVOX analyzers.

5. Face Protective Equipment—is provided at user site

6. Tissues or 4X4 gauze

7. AVOX 1000E Quality Control (QC) filters (Two levels: yellow and orange which are **analyzer specific)**

8. RNA Medical QC 253 Liquid QC Levels 1 and 3 (Refer to QC 253 package insert – XI. Attachments C)

a. Stored at 2-8 C until expiration date.

b. Avoid freezing and temperatures above 8C.

c. Call 1-800-955-9525 for order information

9. Cuvettes and QC materials should be marked with the date they are received.

B. Reagents

There are no reagents with this system.

C. Specimen Collection and Specifications

1. Patient Preparation: None required

2. Specimen Type: 50 μl of fresh whole blood, analyzed within 3 minutes of collection, if sample is not hemolyzed.

3. Instructions for Sample Collection:

a. Prior to collecting any blood sample, the patient's identity should be verified by using at least 2 patient identifiers. Per current policy, the patient full name and date of birth are the primary identifiers. Medical record number can also be used as a patient identifier. Follow all WFBMC policies, as applicable.

b. If testing is performed away from the patient's bedside, the blood sample should be identified at the AVOX test device so there is no question as to the sample identity. (Label syringe with patient ID label)

c. Whole blood samples, which are obtained from an indwelling catheter, should be collected after sufficient waste has been drawn to clear the line (approximately 5 mL). Patient results may be compromised if catheter lines are not adequately cleared prior to sample collection.

d. As applicable, testing site departmental guidelines should be followed for specimen collection procedures.

e. In the **Cardiac Cath Lab**, the physician will collect the blood sample and give to the Cath Lab staff to perform sample testing on the AVOX device. Sample testing should be performed within 3 minutes of collection.

f. If testing will be delayed more than 3 minutes, the sample collection syringe should be heparinized.

(1.) Place a ***small drop*** of heparin into the syringe(s).

(2.) Push the plunger forward to remove any excess heparin. The syringe is now ready to collect the blood sample.

(3.) Due to the small volume of blood, care should be taken to evacuate all excess heparin from the syringes. Results can be affected by too much heparin.

4. Sample Precautions/Interferences/Sample Rejection Criteria:

a. See section on Limitations of Procedure for additional information

b. Cuvettes exposed to moisture (desiccant indicator is pink or white) can affect results and should not be used.

c. Over-filled cuvettes should be avoided.

d. Cuvettes should be inserted into AVOX analyzer within 30 seconds of filling.

e. ONLY Fresh whole blood samples should be used for testing.

f. Air contamination will adversely affect results.

g. Excess heparin or saline dilutes and falsely lowers the hemoglobin of the sample. Allowing the sample to be diluted with saline could possibly oxygenate the sample. Inaccurate results could be obtained.

h. Air Bubbles can cause the %HbO2 (oxyhemoglobin) fraction of the sample to be elevated by 1-2%. Always point the syringe and cuvette at a downward 45-degree angle to prevent oxygenation of the sample. Visible air bubbles should be evacuated before the sample is capped.

i. Delayed sample testing: %HbO2 measurements are most accurate if performed within 10 minutes of specimen collection. If samples are not tested within 10 minutes of collection, a new sample should be collected.

j. Clotted samples should not be used for %HbO2 monitoring on the AVOX device. If a sample will not be analyzed within 3 minutes, the syringe should be coated with heparin to prevent clotting.

k. Samples that have settled out and the red cells have separated from the plasma can give erroneous results. Samples should be well mixed prior to sample analysis.

l. Specimens drawn with other anticoagulants besides sodium or lithium heparin **should NOT** be used for testing on the AVOX. Citrate is known to change the pH of the blood and cause errors in spectrophotometric measurements. Similarly, fluoride/oxalate should be avoided.

m. Lipid (fat) particles in a blood sample may distort the normal light scattering, causing erratic readings.

5. Sample Handling:

a. All samples should be treated as biohazardous substances.

b. Gloves should be worn when handling or collecting blood specimens and during sample analysis.

c. When testing is complete, the sample syringe and cuvette should be discarded in an appropriate biohazard container.

D. Interfering Substances

Refer to above section, Sample Precautions, for interfering substances. Also refer to the AVOX 1000 E Operator's Manual for additional details.

E. Sample Analysis for %HbO2/THb

1. Review QC logs to ensure instrument is ready for use.

2. Gloves should be worn during sample collection and analysis.

3. Face shield protection is provided in each test site.

4. 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".

5. Verify that the correct cuvette path length is programmed in the AVOX. If not, refer to section Cuvette Calibration for details.

6. Check the desiccant indicator to ensure it has not turned pink or white.

- **If the indicator is pink or white,** the cuvettes have been exposed to moisture. Do not use for patient testing.
- If the desiccant indicator is blue, open the sealed bag to remove cuvettes.
  - **a. Immediately reseal bag**.
  - **b**. Do not touch the sampling area (the clear surface) of the disposable cuvettes.
  - **c.** Handle cuvettes by black cap.

7. Collect the sample as defined in section Sample Collection.

8. Evacuate any air bubbles that may be in the sample.

9. If necessary, gently tap the syringe to knock any air bubbles loose.

- ***Immediately cap the sample to prevent air contamination***

10. Keep the syringe containing blood tightly sealed and roll syringe between palms to keep red blood cells and plasma well mixed for at least 10-15 seconds.

11. Remove the cap from the end of the syringe.

12. Squirt out the first few drops of sample to verify no clots are present and to get the well mixed portion of the sample.

13. 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.

14. 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.

15. <u>Caution:</u>

a. Never force blood into the cuvettes. If the sample does not flow easily, discard the cuvette and use another one.

b. When filling the cuvette, do not use excessive pressure or cause the vent patch to bulge outward.

c. Cuvettes must be kept dry at all times. Verify that the desiccant indicator is NOT pink or white. **Do not use if the indicator is pink or white**. Before analyzing samples, take cuvettes from the Ziploc bag. Only take as many as needed for immediate use. Promptly re-seal the zip-lock bag containing cuvettes and desiccant.

16. Observe cuvette closely, make sure that the light path at the widest portion of the sample chamber is completely filled with blood and that blood reaches the air vent at the opposite end of the cuvette. Proper technique for filling cuvettes is illustrated in the AVOX 1000E Operator's Manual.

17. Note: If any blood is on the exterior surface of the cuvette, wipe it off with gauze to avoid contamination of the instrument optics. If sample volume allows, it is best to fill another cuvette and discard any cuvette that has a contaminated exterior.

18. With syringe still attached to the cuvette, hold the cuvette firmly by its black cap, and insert the cuvette into the sample chamber.

a. Do not depress the plunger while the syringe is in the instrument.

b. The filled cuvette should be inserted in the AVOX analyzer within 30 seconds of fill.

c. DO NOT INJECT THE BLOOD INTO THE INSTRUMENT'S SAMPLE CHAMBER.

19. Observe the LCD display. Do not disturb the AVOX. Results should display within 10 seconds.

20. Record the %HbO2/THb results on the departmental specific flow sheet and remove the sample from the sample port. Results should be documented with the date, time, sample site, testing personnel, and analyzer serial number.

21. After the AVOX reports the results of the sample, withdraw cuvette and dispose of it. Record the results before removing the cuvette from the analyzer. The results are not displayed once the sample is removed. **Do not leave the cuvette in the instrument after the result is displayed and recorded.**

22. Measure additional samples, as needed.

23. Discard used cuvettes and syringes in an appropriate biohazard container.

24. Cuvettes should not be re-used.

25. Cuvettes should be kept clean, dry and free of contamination.

F. Calculations

N/A (See the AVOX 1000E Operator's Manual if analyzer is to be used for Hemodynamic Computations)

G. Reporting Results

1. See Sample Analysis section.

2. Cath Lab staff will not always report THb results from the AVOX 1000E. If a physician requests THb results, the result will be documented on the departmental specific flow sheet or department electronic record.

3. Respond according to departmental specific guidelines.

4. Reference Ranges (Normal Range):

a. % HbO2: Varies by site sampled. See Appendix A.

b. THb: Varies by age. See Appendix A.

5. Critical Values:

a. Critical values represent an emergency condition and must be reported immediately to the patient's physician. AVOX test results performed in the Cardiac Cath Lab are reported directly to the physician. WFBMC policy should be followed for read back of critical values.

b. There are no defined critical values for **%HbO2.**

c. THb Critical Values: < or = 6.0 g/dL and > or = 20.0 g/dL. If a critical THb value is reported by the AVOX, the provider must be notified and results documented, even if provider did not request a THb.

d. Unexpected critical values should be verified by appropriate repeat testing. Analyzer and cuvette performance should be verified by performing liquid QC and daily QC filter checks.

6. Reportable Range:

a. %HbO2: 0-100%

b. THb: 4-25 g/dL

c. 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."

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

H. Clerical Errors

If an error is discovered in identifying a patient sample or in reporting the results, the patient's physician should be notified immediately and repeat testing performed. Documentation on the site-specific patient care flow sheet should be clear as to the action that was taken.

I. Limitations of Procedure

When questionable or unexpected results are obtained, proper instrument and cuvette performance should be verified by performing quality control checks (QC). Appropriate repeat testing by the Clinical Laboratory should be performed when AVOX results are in question.

1. Poor technique and improper instrument settings can cause erratic results.

2. Do not use the AVOX device for patient reporting if all QC values are not within acceptable limits. Follow appropriate troubleshooting procedures as outlined in the AVOX 1000E Operator's Manual.

3. Cuvettes with smudges, bubbles, fingerprints, or blood smears can cause erroneous or erratic results and should be avoided.

4. Do not remove the sample before a reading is completed.

5. DO NOT reuse cuvettes.

6. DO NOT force the sample into the cuvette. Obtain a new sample and cuvette, as necessary.

7. Total hemoglobin readings may be affected if the proper cuvette optical path length is not correctly entered into the AVOX.

8. Total hemoglobin readings may be affected if the cuvettes are not stored in an air tight container with a desiccant pouch.

J. Records

Quality control records, maintenance and troubleshooting records should be kept current and updated at all times. QC records are kept for 2 years by the Clinical Laboratory and AVOX user site. Maintenance and troubleshooting records are reviewed and stored for the life of the instrument, plus 2 years. Record retention will be adjusted, as necessary, to be in compliance with regulatory authorities. When analyzers are not used for patient testing, it is acceptable to document "not in use" (NIU) on the QC records. QC documentation must be complete with QC values or NIU and testing personnel initials.

V. Quality Control/Quality Assurance (QA) Procedures:

GLOVES SHOULD BE WORN WHEN PERFORMING ANY MAINTENANCE OR QC PROCEDURE ON THE AVOX DEVICE.

A. Maintenance/Troubleshooting/QA Activities

1. Daily:

The AVOX 1000E is checked for calibration accuracy and optics cleanliness with the use of Quality Control Filters. See Daily Quality Control Procedures in section below.

2. Weekly:

The instrument and cuvettes are checked for accuracy and calibration stability. See section on Liquid Quality Control for details.

3. Semiannually: Analyzer Comparison and Linearity Verification

The AVOX 1000E is compared against the Clinical Lab's Co-Oximeter every 6 months and linearity is verified by testing a linearity kit. See Appendix B for the procedure.

4. As Needed: Between every patient use and when visibly soiled, clean the analyzer exterior with WFBMC-approved disinfecting agent.

5. Troubleshooting: See the troubleshooting section of the AVOX 1000E Operator's Manual for illustrations and details. All instrument errors and corrective actions should be logged on the AVOX 1000E Daily QC log in the problem log section.

******NOTE: After any analyzer maintenance, calibration, or repair and prior to patient use, both levels of QC filters and liquid QC must be tested to verify analyzer/cuvette performance. In addition, analyzer comparison and linearity verification should be completed, per instructions in Appendix B.***

6. Calibration Verification:

Calibration is verified daily with the optical filters and also weekly with the liquid QC.

B. Daily Quality Control Procedures--Quick Cal Check and Test for Spilled Blood

1. Every day of patient use:

a. The operation and calibration of the AVOX 1000E is verified every day of patient testing with the use of two optical filters supplied with every AVOX analyzer.

b. Each filter is marked with the serial number of the instrument for which it is intended and the range of acceptable values. **Do not use the filters from another instrument.**

c. These filters are treated just like a sample cuvette.

d. The QC readings of the filters are recorded on the AVOX 1000E Daily QC Log.

e. Note: In addition to confirming that the AVOX is calibrated, the filters also assess 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. Consult the AVOX 1000E Operator's Manual for detailed instructions on how to disassemble the unit and clean the optics. Call manufacturer Technical Support at 1-800-955-9525 for assistance, if needed (available after hours, weekends, and holidays).

f. QC Filter Procedure

(1.) Verify that the serial numbers match between the QC filters and the AVOX analyzer.

(2.) Wipe off the cuvette-shaped yellow and orange optical filters.

(3.) Observe that the "READY" message is displayed and insert the QC filter into the AVOX.

(4.) Wait until readings appear on the display.

(5.) Record results on the AVOX 1000E Daily QC Log and *review for acceptability*.

(6.) Repeat with second QC filter.

(7.) Record second filter results on the AVOX 1000E Daily QC Log and *review for acceptability.*

g. 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.

Compare your readings with the following table:

Optical Filter	*Low tHb*	*High tHb*	*Low %O2Hb*	*High %O2Hb*
Yellow filter	**7.7**	**8.3 g/dl**	**93.5**	**96.5%**
Orange filter:	**16.4**	**17.6 g/dl**	**37.2**	**40.8%**

h. If any one of the four values is outside its specified range, the AVOX fails these tests and can NOT be used for reporting patient results until the problem has been resolved.

- **Remedial Action:**

  (1.) Verify QC filters are clean and match the instrument used.

  (2.) The most likely cause of failure is blood or other debris obscuring the light detector.

  (3.) Repeat filter testing before referring to the AVOX 1000E Operator's Manual for optics cleaning.

  (4.) If acceptable results are not obtained with repeat testing, contact Clinical Engineering and/or review the AVOX 1000E Operator's Manual for detailed instructions on how to disassemble the unit and clean the optics.

  (5.) Additional quality checks must be performed if the unit is disassembled. Consult manufacturer Technical Support and the Clinical Laboratory Point of Care Testing department for guidance.

  (6.) Manufacturer Technical Support: 1-800-955-9525 (available after hours, weekends, and holidays).

******ALL QC VALUES and TROUBLESHOOTING ACTIONS SHOULD BE RECORDED FOR AN ACCURATE AUDIT TRAIL******

C. Liquid QC (Calibration Verification)

1. Two levels of Liquid controls are performed:

a. Weekly on all AVOX analyzers to verify calibration stability and the accuracy of the cuvettes.

b. On each **new shipment and lot number of cuvettes**

c. Whenever the **cuvette path length is changed** in an analyzer.

d. Whenever analyzer or cuvette **performance is in question**.

e. Post analyzer repair or calibration--prior to use for patient testing.

f. Liquid QC testing should be rotated among all users.

2. If this calibration verification fails (any of the QC values falls outside of acceptable range), re-calibration of the AVOX 1000E may be required. See below for Remedial Action.

3. The AVOX analyzer and cuvettes cannot be used for patient sample testing until all quality control values are within acceptable limits.

4. If all readings are **within** the specified ranges, the AVOX **passes** the liquid QC check.

5. The liquid QC should be tested immediately after removal from the refrigerator.

6. Before use, hold the ampule at the top and bottom (with forefinger and thumb) and invert gently to mix the solution. Restore the QC material to the bottom of the ampule. Let the ampule sit for about a minute to ensure there are no micro bubbles present.

7. 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 safety needle or a blunt needle.

a. *NEVER manually re-cap needles*!

b. EXTREME CARE SHOULD BE USED IN OPENING THE QC AMPULES.

c. To avoid accidental sharps exposure, the ampule top should be covered with gauze, tissue, or a protective plastic sleeve when opening.

8. Avoid getting air bubbles in the syringe or AVOX results may be adversely affected.

9. If used, re-sheath the safety needle and carefully remove needle from the syringe. Discard the needle in a biohazard sharps container.

10. Immediately place an AVOX cuvette on the syringe.

11. Fill the cuvette according to illustrations in the AVOX 1000E Operator's Manual.

12. Observe that the "READY" message is displayed and insert the Control-filled cuvette, with syringe attached, into the AVOX.

13. Wait until readings appear on the display.

14. Record results on the AVOX 1000E Liquid QC log and review for acceptability.

15. Repeat above steps with the second level of liquid control.

16. After the AVOX reports the results, withdraw the cuvette and dispose of it. Do not leave the cuvette in the instrument after results are displayed and recorded.

17. DO NOT perform patient testing if all QC values are not within acceptable limits.

18. ***All QC values should be recorded for an accurate audit record. ***

19. Remedial Action

If a QC result is outside of acceptable limits, verify the following:

a. Verify that the correct cuvette path length is programmed in the analyzer.

b. Check the desiccant indicator in the cuvette package.

c. Ensure liquid controls have been stored and handled appropriately.

d. Repeat the same level of liquid control using a new ampule and a new cuvette from the same box of cuvettes.

e. If repeat results are **within acceptable limits**, then the analyzer and cuvettes may be used for patient testing.

f. If repeat results are still outside of acceptable limits, perform troubleshooting procedures.

g. Contact manufacturer Technical Support at 1-800-955-9525 (available after hours, weekends, and holidays) or call Clinical Engineering for assistance if the remedial action steps do not resolve the problem.

D. Calibration

1. Instrument Calibration

The AVOX is calibrated at the factory and ready for use. The AVOX employs highly stable state-of-the-art light sources. Factory tests and extensive clinical use indicate that the AVOX easily maintains its calibration readings for two or more years. The most frequent cause of error messages or erroneous reading is not loss of calibration but contamination of the optical detector by spilled blood or other debris. AVOX Systems does not recommend re-calibration unless indicated by calibration verification or QC failures. Calibration verification is performed using the daily QC filters and two levels of liquid controls.

2. Cuvette Calibration

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

a. While the AVOX displays "READY", press the Main Menu key.

b. Select Option 1 to reach the Calibration Menu and Enter.

c. Select 3 for cuvette path length and Enter.

d. Observe the number displayed. If it matches the new cuvette path length, press Enter and skip to step j.

e. When prompted, enter the AVOX path length value from the bag of cuvettes by backspacing (use the ← key) over the current value shown and type in the new path length indicated on the bag of cuvettes.

f. Press Enter.

g. The next screen displayed "Value (s) OK? [Y/N]" will be confirmation of the result entered. Press Yes or No as needed to confirm or correct.

h. Once the number entered is confirmed as correctly entered, the AVOX will store a new calibration constant in non-volatile memory and use it in subsequent analyses.

i. The message **"Cuvette Path length Calibration: Complete Press any key**" is displayed.

j. Press the Cancel key repeatedly to return to the sample analysis "READY" screen.

k. ******NOTE: Prior to patient use, after entering a new cuvette path length in the AVOX analyzer, both levels of QC filters and liquid QC must be tested and within acceptable limits to verify analyzer/cuvette performance.***

E. Semi-Annual Patient Comparison and Linearity Verification--See Appendix B for details

1. Semi-annually, the user site is responsible for performing and documenting analyzer comparison and linearity verification on each AVOX analyzer.

a. Two patient samples and a linearity kit are tested semi-annually.

b. The linearity kit is intended to challenge the full reportable range for both THb and %HbO2.

c. A patient sample is tested to validate comparability of results with the Clinical Lab Cooximeter.

d. Results are documented and submitted to the Clinical Lab POCT office for review.

4. The Clinical Lab's CO-Ox instrument will be used as the reference method for %HbO2 and THb results.

5. If patient comparison results do not match or linearity verification fails, re-calibration of the AVOX 1000E is required. (Call manufacturer Technical Support at 1-800-955-9525 for assistance in re-calibration - available after hours, weekends, and holidays).

F. Operating Precautions

1. This instrument should not be used in the presence of flammable agents or anesthetics.

2. To protect against fire, only use power supply with the model provided by the manufacturer.

3. Do not allow blood, water, or other liquids to enter the instrument itself.

4. Blood exposed to the cuvette should NOT be returned to the patient. Cuvettes are NOT sterile.

5. Do not attempt to use this instrument outside the recommended temperature range: 15C-30C (59F-86F).

6. Do not place this instrument in air currents or thermally unstable surroundings.

7. Do not warm the cuvettes in your hand.

8. Leave the syringe attached to the cuvette during testing.

9. Do not re-use the cuvettes; discard after each use.

10. Always keep cuvettes in sealed bag with an active desiccant.

11. For proper calibration and calibration verification, use only the controls recommended by the manufacturer. Controls from other sources may yield erroneous results.

12. To minimize the hazard of electrical shock, connect the power supply to a properly grounded outlet only.

13. Do not leave a cuvette in the Avoximeter 1000E. Remove the cuvette and syringe as soon as the sample has been analyzed and the result recorded.

14. Operate the instrument at a site away from drafts and bright lights.

15. Do not use strong solvents to clean the surfaces.

16. Do not allow any fluid to enter the cuvette slot.

VI. Proficiency Testing:

Non-waived Point of Care AVOX Testing that is not considered our primary test method and is also covered by the same CLIA certificate as the Main Clinical Laboratory, CLIA ID 34D0664386, does not subscribe to a proficiency testing program. However, this AVOX testing does participate in semi-annual comparison testing with the clinical laboratory to verify performance of the AVOX test method.

Sites not included on CLIA ID 34D0664386 must participate in a CMS-approved proficiency testing program. Users should follow instructions provided with the survey samples. Current accrediting and regulatory standards are followed. The proficiency samples are rotated among different users. There is no communication between the Clinical Laboratory and POCT sites, regarding specific result values, until after the proficiency provider submission deadline. If proficiency survey sample results fail, the problem is investigated and resolved as necessary; for example, re-training, instrument performance evaluation or survey sample handling. Follow-up and corrective actions are documented.

Samples will be handled as follows:

i. All PT samples in the kit should be tested on the Same Day.

ii. One staff member should test All samples that come in the survey kit (referenced as PT event).

iii. Testing of PT events should be rotated among testing personnel each calendar year, as available.

iv. A goal, but NOT a requirement, is to follow this rule: At least one PT event-- per year-- per staff member when possible. Managers will keep track of personnel testing PT to make sure that one person is not always performing the PT.

v. One analyzer should be used to test ALL samples that come in a survey kit (referenced as PT event).

vi. A PT event should be handled in the same manner as a patient sample, so analyzer selection should be consistent with a patient sample in the workflow. The analyzer used for proficiency testing is not assigned. The analyzer used is at the discretion of the testing staff member, when this is the workflow for patient samples.

VII. Employee Training and Competency:

Employee training documentation is completed upon training on the AVOX system. Each user of the AVOX system should be trained prior to using the device for patient testing and should maintain updated competency records. During the first year of an individual's duties, competency must be assessed at least semiannually. After the first year of using the AVOX 1000E test system, competency is assessed annually.
Current regulatory standards will be followed. Any user that fails to meet the competency requirements will need to be re-educated for use of the system. The Clinical Laboratory Point of Care Testing office and user site manager maintain training and competency records.

VIII. Product Information:
Manufacturer Technical Support: 1-800-955-9525 (available after hours, weekends, and holidays)

IX. Review/Revision/Implementation:

A. Review Cycle: Each 2 years

1. All new policies/procedures/guidelines and those that have major revision must be reviewed/signed by the CLIA Laboratory Medical Director.

2. Review/sign-off can be completed by the designated section Medical Director in the following circumstances:

a. Biennial review

b. Minor document revisions

B. Office of Record: Clinical Laboratory, Point of Care Testing Compliance

X. Related Policies/Procedures/Guidelines:

A. Non-Waived Point of Care Testing (POCT) Quality Management Plan and Quality Control/Quality Assurance Procedures

B. Understanding of Responsibilities Between Testing Sites and the Clinical Laboratory for Point of Care Testing

XI. Attachments:

A. Appendix A
Total Hemoglobin Reference Ranges (Normal Values)

B. Appendix B
AVOX 1000E 6-Month Analyzer Comparison/Linearity Verification Procedure

C. Other Associated Forms and Documents

- Cuvette package insert
- RNA Medical Liquid QC 253 package insert
- RNA Medical Calibration Verification Controls CVC 223 package insert
- AVOX 1000E Daily QC Log
- AVOX 1000E Liquid Quality Control Log
- AVOX Competency Observation Form
- AVOX 1000E 6-Month Analyzer Comparison Form
- AVOX 1000E Calibration Verification/Linearity/AMR Log

XII. Revision Dates:
Effective: 12/1/03
Revised:
12/05
07/08
3/2013—procedure renumbered with this version-- numbering changed from PPB-NCBH-LAB-775-21 to PRO-POCT-LAB-21
06/2016
07/2018

Review Date	Revision(s)	Signature
07/2020	Changed name of department throughout document; changed Tech Support phone # - multiple places; added reference ranges for HbO2% - Appendix A; added pkg inserts for cuvettes, controls QC 253 and linearity material CVC 223; added Review/revision box; minor formatting changes; added Tech Support contact info "available after hours, weekends, and holidays"	

XIII. References

A. AVOX 1000E Operator's Manual, Whole-Blood Oximeter, International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ 08820. AP1001 11/07

B. RNA Medical Liquid QC 253 package insert, RNA Medical, 7 Jackson Road, Devens, MA 01434 BIOMKT-0013 Rev C 8/2011.

C. RNA Medical Calibration Verification Controls CVC 223 package insert, RNA Medical, 7 Jackson Road, Devens, MA 01434 BIOMKT-0007 Rev C 8/2011.

Appendix A
Reference (Normal) Ranges Hemoglobin and Fractional Oxyhemoglobin (%HbO2)

Analyte	Units	Reference Range (Normal Range)
Hemoglobin	g/dL	18y 14-18
MALE		12y 13-16
		6y 11.5-15.5
		2y 11.5-13.5
		6m 10.5-13.5
		3m 9.5-13.5
		2m 9-14
		1m 10-18
		14D 12.5-20.5
		7d 13.5-21.5
		1d 14.5-22.5
		0d 13.5-19.5
Hemoglobin	g/dL	18y 12-16
FEMALE		12y 12-16
		6y 11.5-15.5
		2y-7d same as male
		1d 14.5-22.5
		0d 13.5-19.5
%HbO2	**%**	50-65 (Venous – IVC, RA, RV)
		60-70 (Mixed Venous)
		95-100 (Arterial)

Appendix B
6-Month Analyzer Comparison/Linearity Verification Procedure

I. General Procedure Statement:

Linearity verification is used to confirm that the calibration of the test system has remained stable for the full reportable range. Analyzer comparison is used to verify that results reported by the AVOX correlate to results reported by the Clinical Laboratory co-oximeter.

II. Principle:

Semi-annually, arterial and venous blood specimens are compared against the Clinical Laboratory Co-oximeter analyzer to verify correlation between the two different testing methodologies. Also, a linearity kit is used to verify analyzer linearity for full analytical measurement range (AMR). This validation is performed on all AVOX analyzers in use. These quality checks will also be completed post analyzer repair, after analyzer re-calibration, and any other time performance is in question.

III. Procedure:

A. Equipment/Supplies

1. At least 1 cc of arterial blood
2. At least 1 cc of venous blood
3. RNA Medical Linearity Kit CVC 223
   a. Stored 2-8°C until expiration date
   b. Avoid freezing and temperatures above 8°C
4. Syringes (at least 3 cc) with blunt or re-sheathable safety needles
5. Paper towels, tissues, or 4x4 gauze
6. AVOX Disposable Cuvettes
7. AVOX 1000E analyzer

B. Procedure--Patient Sample Comparison

1. Perform required daily optical QC filter checks and record results on AVOX 1000E 6-Month Analyzer Comparison form.
2. Obtain a fresh venous heparinized blood sample with the % HBO2 in the 50 - 75% range. If possible, try to get total hemoglobin (THB) in the upper end of the reportable range.
3. Obtain an arterial heparinized blood sample with the % HBO2 in the 85 - 100% range. If possible, try to get the total hemoglobin (THB) in the lower range of the reportable range.
4. Test both samples on all AVOX analyzers and then test specimens on the Clinical Laboratory co-oximeter. Keep samples well mixed and tightly capped.
5. Measure and Record the AVOX %HBO2 and THB results of both samples on the AVOX 1000E 6-Month Analyzer Comparison form.
6. Submit results to the Point of Care Testing Compliance department for review.

C. Procedure--Linearity Verification

1. Follow linearity kit package insert for handling instructions.
2. Test all 5 levels on each AVOX in triplicate. It is acceptable to use the same sample for triplicate testing, provided sample integrity is maintained and no air contamination occurs.

Document results on the AVOX 1000E Calibration Verification/Linearity/AMR log and verify that all values are within package insert ranges that are specifically listed for the AVOX 1000E analyzer.

D. Acceptable Limits

1. **Patient split samples** must match the Clinical Lab +/- 1 g/dL for THB and +/- 3% HBO2 saturation.
2. **Linearity readings** must fall within the package insert acceptable limits.
3. If any values are not within acceptable limits, patient testing should be suspended on the specific AVOX device until resolution is made.