

Cooximetry by Avoximeter 1000E
Department of Clinical Laboratories
The Ohio State University Wexner Medical Center

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Point of Care Testing	Procedure	11/25/2008	POC-6 Revision 11

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Approval*:
Point of Care Chemistry Division Director University Hospital Laboratory Medical Director OSUWMC East Hospital Laboratory Medical Director

Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1. PRINCIPLE

- 1.1. The AVOXimeter 1000E measures total hemoglobin and oxyhemoglobin from a whole blood sample. Specific and multiple wavelengths are utilized to measure these analytes. Oxyhemoglobin is the hemoglobin reversibly bound to oxygen; most of the oxygen in blood is transported in this form. Determination of total hemoglobin and oxyhemoglobin concentration is used to assess oxygen transport status in diagnostic Cath Lab procedures.

2. SCOPE OF DOCUMENT:

- 2.1. This document applies to all Point of Care personnel performing cooximetry testing by the Avoximeter at UH Cath Labs and OSUWMC East Hospital Cath Lab locations.

3. RESPONSIBILITY:

- 3.1. The POCT coordinators and manager are responsible for maintaining this document and ensuring biennial review. The laboratory medical director is responsible for establishing and approving all changes before activating the document.

4. SPECIMEN COLLECTION:

- 4.1. All institutional policies and procedures should be followed in the collection of blood samples. Universal precautions must be followed when collecting and handling blood specimens.
- 4.2. Verify patient identification using at least 2 identifiers.
- 4.2.1. During a surgical procedure patient is identified per OSU timeout.
- 4.3. Specimen Type: Whole blood collected in syringe, heparin or EDTA.
- 4.4. Handling Conditions:
- 4.4.1. Test fresh whole blood specimens as quickly as possible following sample collection.
- 4.4.2. Samples should be collected from an arterial line, an arterial puncture, or venipuncture.
- 4.4.3. When drawing blood samples with a syringe from a saline-filled catheter withdraw the saline first with a separate syringe and make sure that only whole blood is sampled.
- 4.4.4. Care should be taken to prevent the introduction of air into the sample when it is drawn. Expel all air bubbles from the syringe and cap or seal the end of the syringe until ready to test.
- 4.4.5. Sample size for the AVOXimeter 1000E is 50 μ L.
- 4.4.6. A freshly collected sample is optimal. Prior to analysis the sample should be free of any air bubbles and mixed by rolling the syringe between the palms of both hands for 10 seconds. Invert the syringe and repeat mixing. Expel a small amount of blood sample onto an absorbent surface.
- 4.5. Unacceptable specimens: Clotted specimens cannot be analyzed and require recollection.

5. REAGENTS/SUPPLIES:

5.1. Equipment:

- 5.1.1. Avoximeter 1000E cooximeter.
- 5.1.2. The Avoximeter 1000E must be used at room temperature 15-30°C (59-86°F).
- 5.1.3. There are no humidity requirements for the AVOX 1000E.

5.2. Supplies:

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5.2.1. Avoximeter 1000E cuvettes

- A. The cuvettes are packaged with a desiccant in the plastic bag. The Cuvette Path Length is printed on the label of the plastic bag. The cuvettes are sensitive to humidity and temperature:

5.2.1.A.1. Store cuvettes in a closed bag at room temperature 15-30°C (59-86°F).

5.2.1.A.2. Cuvettes are stable as long as the indicator on the desiccant is blue.

5.2.1.A.3. Documentation of room temperature including minimum and maximum temperatures must be recorded in each area of testing and must be available upon request.

5.2.1.A.3.1. If a minimum/maximum thermometer is used to perform continuous monitoring of temperature between daily temperature readings or following a laboratory downtime (e.g. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.

5.2.2. Quality control samples

- A. Control Solutions: Level 1 and Level 3 from RNA Medical™ (CVC 223)

- B. The assayed controls are for monitoring Avox performance in the measuring of total hemoglobin and hemoglobin fractions (oxyhemoglobin/carboxyhemoglobin).

5.2.2.B.1. Store control solutions in the refrigerator at 2-8°C.

5.2.2.B.2. The control is a purified hemoglobin solution which has been treated with compressed air and precise concentrations of carbon monoxide.

5.2.2.B.3. Any expired control solutions must be discarded.

5.2.2.B.4. If control solutions have turned brown in color, they must be discarded.

5.2.2.B.5. New QC lots are tested once for acceptability when distributed to the testing facility. Data is stored on the L Drive

5.2.2.B.6. Documentation of refrigerator temperature including minimum and maximum temperatures must be recorded in each area of testing and must be available upon request.

5.2.3. RNA Medical Brand CVC 223 CO-Oximeter Calibration Verification Controls.

- A. CVC 223 is a purified bovine hemoglobin solution that has been saturated with carbon monoxide or treated with precise concentration of carbon monoxide.

5.2.4. Optical filters (orange and yellow).

5.2.5. Gauze or other absorbent surface.

5.2.6. Syringes and plastic dispense tips or needles for liquid QC.

5.2.7. Disposable gloves, gown and other required personal protective equipment (PPE).

6. SPECIAL SAFETY PRECAUTIONS:



WARNING: BODY FLUID PRECAUTION

Blood is a body fluid capable of transmitting infectious diseases. Universal precautions for the prevention of the transmission of blood borne pathogens must be in effect at all times.

- 6.1. **Universal precautions must be followed when collecting and handling blood specimens.**
- 6.2. Personal protective equipment: wear gloves and gown throughout the specimen collection and testing process.
- 6.3. Splash shield or other PPE device to protect the eyes and mucosal linings.
- 6.4. Use gauze or splash barrier when uncapping specimen.

7. CALIBRATION/PROGRAMMING/MAINTENANCE:

7.1. Calibration:

7.1.1. Calibration is performed by the manufacturer and is stable for two or more years.

7.2. Calibration Verification is performed by:

7.2.1. Analyzing the Optical QC Filters. This will verify the calibration and confirm that the optics are clean. Two optical filters (yellow and orange) must be performed every 24 hours of patient testing.

7.2.2. Analyzing liquid QC samples. This will verify the calibration, the cuvette storage conditions, and the function of the cuvettes. A minimum of two levels of liquid QC material will be analyzed weekly.

7.2.3. CAUTION: Liquid QC verifies the calibration only if the optics are clean

7.3. Programming:

7.3.1. Each lot of cuvettes has a unique pathlength that **MUST** be entered into the instrument when using the lot of cuvettes. **FAILURE TO ENTER THE CORRECT PATHLENGTH WILL GIVE FALSE PATIENT RESULTS!**

7.3.2. Verify that the cuvette pathlength is correct for the cuvettes in use. The pathlength for the cuvette lot is found on the label of the cuvette packaging.

- A. Press the Main Menu key.
- B. Press 1 to select “Calibration” and press Enter
- C. Press 3 to select “Cuvette Pathlength”, and press Enter
- D. Use back arrow (<=) to move cursor and erase displayed pathlength. If verifying pathlength, press Cancel to return to each previous screen.
- E. Enter the correct pathlength using the numeric keypad
- F. At “OK” prompt, press YES to enter the pathlength into the analyzer’s memory.

7.4. Maintenance:

7.4.1. Cleaning of the AVOXimeter surface should be performed as needed to remove dust and any blood spills

7.4.2. Clean the exterior of the unit with isopropyl alcohol

7.4.3. **DO NOT** immerse the unit in any liquids.

7.4.4. **Cleaning of the optical detector-once a year (record on monthly Avox QC log).**

- A. Materials needed:
 - 7.4.4.A.1. # 0 Phillips screwdriver
 - 7.4.4.A.2. 5 mm nutdriver
 - 7.4.4.A.3. ¼ inch nutdriver
- B. Disconnect the ITC AVOXimeter 1000E from the AC Adapter

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- C. Remove the four screws from the bottom of the instrument, using the #0 Phillips screwdriver.
- D. Holding the upper and lower covers together, place the instrument in the upright position, with the keypad to your right.
- E. Slowly and carefully lift the upper cover, keeping it parallel with the lower part of the instrument, until the upper cover is free of the rear panel.
- F. Locate the cable that runs from the battery pack to the main circuit board (see operators manual for more detail). Disconnect the cable from the J302 connector on the main circuit board.
- G. Tilt the upper cover backward to fully expose the main circuit board and small circuit board on the lower part of the instrument.
- H. Locate the flat keypad cable that runs from the keypad to the main circuit board. Disconnect the cable from the **Keyboard (J101)** connector on the main circuit board.
- I. Locate the flat LCD cable that runs from the LCD to the main circuit board. Disconnect the cable from the **Display (J102)** connector on the main circuit board.
 - 7.4.4.I.1. Grasp on the connector at the end of the cable. Gently rock the connector in an upward direction to remove it.
- J. Locate the flat cable that runs from the black optical unit to the main circuit board. Disconnect the cable from the **J203** connector on the main circuit board.
- K. Locate the coaxial cable that runs from the black optical unit to the small circuit board. Disconnect the cable from the **J1XX** connector on the small circuit board.
- L. The upper cover containing the black optical unit can now be rested on a table with the front panel facing down.
- M. Using the 5mm nutdriver, remove the four nuts (and washers, if applicable) that secure the black optical unit to the front panel. Then remove the black optical unit from the instrument.
- N. Using the ¼ nutdriver, remove the four screws and four nuts that secure the two halves of the black optical unit. Take care when separating the two halves of the optical unit. Do not lose the small torsion spring or the shutter door. Set them aside in a safe place for reassembly.
- O. Clean the exposed detector with gauze pads dampened with detergent. Do not use abrasives. Dry the detector surface, making sure that it is clean and free of debris. Remove any other debris inside the optical unit.
- P. Reassemble the two halves of the optical unit, making sure that the shutter door and torsion spring are installed correctly (the two door ribs will face forward). One leg of the spring fits into a hole in the door slot, the other leg rests behind the shutter door. Bolt the optical unit back together.
- Q. Place the optical unit back on the front panel. Using the 5mm nutdriver, secure the black optical unit to the front panel with the four nuts (and washers, if applicable).
- R. Position the upper cover (containing the black optical unit) in an upright position over the lower part of the instrument, with the keypad to the right.
- S. Connect the coaxial cable from the optical unit to the **J1XX** connector on the small circuit board.
- T. Connect the flat cable from the optical unit to the **J203** connector on the main circuit board.
- U. Connect the flat cable from the LCD to the **Display (J102)** connector on the main circuit board.
- V. Connect the flat cable from the keypad to the **Keyboard (J101)** connector on the main circuit board.
- W. Connect the cable from the battery pack to the **J302** connector on the main circuit board.

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- X. Slowly and carefully lower the upper cover onto the lower part of the instrument, ensuring that the metal rear panel slides into the center slot at the rear of the upper cover.
 - 7.4.4.X.1. Ensure that the cables are not snagged or crimped between components when lowering the upper cover onto the lower part of the instrument.
 - Y. Using the #0 Phillips screwdriver, secure the bottom of the instrument to the upper cover with the four screws.
 - Z. Connect the AC adapter and turn on the instrument. The self –test should run and the “READY-Insert Cuvette” screen should be displayed.
 - 7.4.4.Z.1. If the self-test fails or an error message is displayed, the most likely cause is improper reassembly or incorrect connections. Should this occur, disconnect the AC adapter and confirm that all connections have been made properly. Should the problem persist, contact IL Technical Support.
- AA. Reset the time and date.
- 7.4.5. Replacing the battery(as needed, record on Avox monthly QC log)**
- A. Materials needed:
 - 7.4.5.A.1. # 0 Phillips screwdriver
 - 7.4.5.A.2. Diagonal cutting pliers
 - 7.4.5.A.3. Replacement battery with cable (E4-BATP)
 - 7.4.5.A.4. Securing cording (packaged with replacement battery)
 - B. Steps B through L of the Cleaning the Optical Detector procedure must be performed before moving to the first step of replacing the Battery below.
 - C. Using diagonal cutting pliers, cut the plastic ties that secure the battery to the frame.
 - 7.4.5.C.1. Be sure to cut only the white plastic ties that are wrapped around the battery and secure it to the lower cover. Do not cut the blue and white power cables that are connected to the top battery.
 - D. Remove the battery, being careful not to snag any components when pulling the cable out from underneath the main circuit board. If the battery well contains tape, remove the tape.
 - E. Remove the liner from the tape on the bottom of the new battery, and place the new battery in the battery well with the tape side down, ensuring that the blue and white cables are facing up, then route the new plastic ties (packaged with the replacement battery) underneath the battery well.
 - F. Secure the new battery in the battery well, using the new white plastic ties.
 - 7.4.5.F.1. When securing the battery to the battery well, be sure that the plastic ties are routed underneath the battery well. Cut the excess length from the plastic ties using the diagonal cutting pliers.
 - G. Thread the blue and white battery cable of the new battery under the main circuit board.
 - H. Re-connect the cables, replace the upper cover of the AVOXimeter, connect the AC adapter, and turn on the instrument as outlined in steps R through Z of the Cleaning the Optical Detector procedure. The self-test should run and the Ready-Insert Cuvette screen should be displayed.
 - 7.4.5.H.1. Be sure to connect the blue and white battery cable last.
 - 7.4.5.H.2. The new battery is not charged. To ensure adequate charge, leave the instrument connected to the AC adapter for a minimum of eight hours.
 - 7.4.5.H.3. Tests can be run while the instrument is charging.

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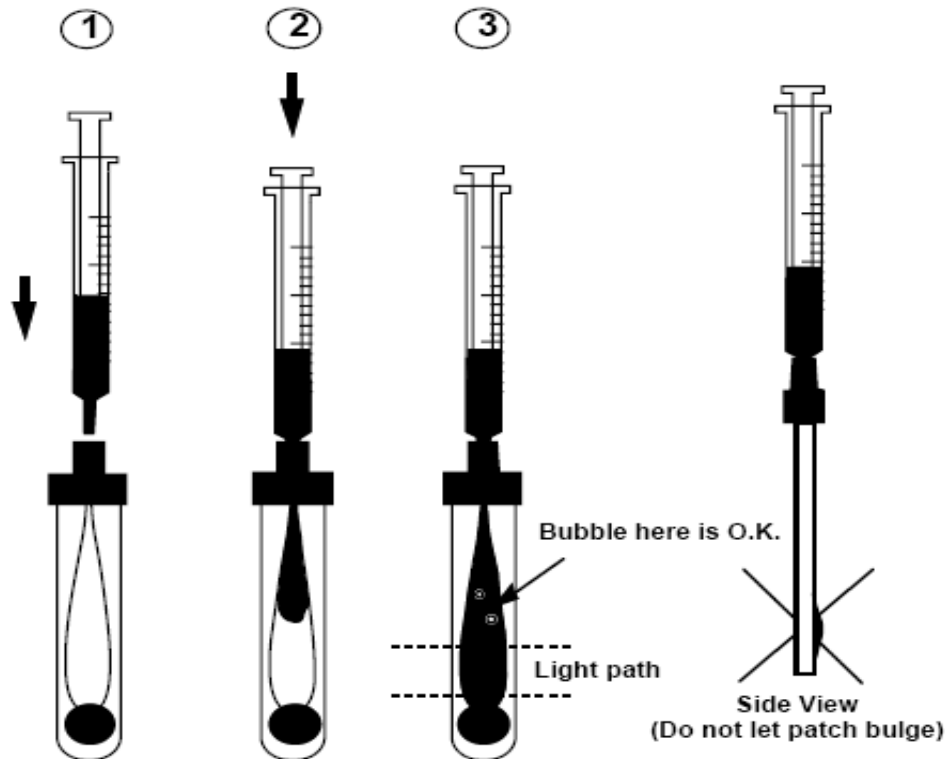
- I. Reset the time and date.
- 7.4.6. Meters may be requested to be returned to the vendor for repairs. If available, loaner meters may be given to the department while their meter is out for repair.
 - 7.4.6.A.1. If a loaner is put in use, QC must be performed prior to patient testing.
- 7.4.7. If the meter fails QC or gives errors upon testing contact the point-of-care testing department at 366-0544 or 685-6610.
- 7.4.8. In the event the point-of-care testing department cannot be reached send samples to the main lab for testing.
- 7.5. Repaired Instrument
 - 7.5.1. Perform a “re-validation testing process,” which includes measuring a combined total of 14 Avox measurements, a combination of Filter QC, Liquid QC, and patient sample correlation as following:
 - A. Correlate 10 patient samples with CCL or Respiratory Therapy blood gas analyzers.
 - B. Measure 1 Liquid QC Level 1
 - C. Measure 1 Liquid QC Level 3
 - D. Measure the Optical Filters (orange and yellow)
- 7.6. **Correlations: See POC Quality Management policy**
- 7.7. Linearity
 - 7.7.1.A.1. RNA Medical Brand CVC 223 CO-Oximeter Calibration Verification Controls are assayed materials used for confirming the calibration and linearity of total hemoglobin and hemoglobin fraction.
 - 7.7.1.A.2. 5 levels of linearity are run, three times each, in the same manner as a patient. Record all values accordingly.
 - 7.7.1.A.3. The expected values are listed in the package insert.
 - 7.7.1.A.4. Record all results in EP Evaluator and give the completed report to the Chemistry Division Director for signature.
 - 7.7.1.A.5. If necessary, refer to the package insert for further details.

8. QUALITY CONTROL:

- 8.1. Optical QC filters: Two optical filters (yellow and orange) must be performed every 24 hours of patient testing:
 - 8.1.1. Insert one of the QC filters into the AVOXimeter 1000E meter. **NOTE:** The optical filters cannot be used interchangeably with those of another AVOXimeter 1000E.
 - 8.1.2. Enter/Verify Operator ID.
 - 8.1.3. Record results and testing initials on the Quality Control Log.
 - 8.1.4. At “READY” prompt, repeat steps for second control filter.
 - 8.1.5. Verify that the results are within established control ranges. If results are not within range, repeat test. If QC continues to be out, notify the Point-of-Care Coordinator. **Do not use the instrument if the controls are out of range.**
 - 8.1.6. **All corrective action must be documented for quality control failures immediately on the QC log.**
- 8.2. LIQUID QC: A minimum of two levels of liquid QC material will be analyzed weekly:

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- 8.2.1. Remove Level 1 and Level 3 liquid QC ampules from the refrigerator. Do NOT warm controls before testing.
- 8.2.2. Shake the first control sample approximately ten seconds
- 8.2.3. Restore liquid to the bottom of the ampule with gentle tapping. If foam or small bubbles are present, allow the ampule to stand until these have come to the surface.
- 8.2.4. With fingers protected, carefully snap open the ampule.
- 8.2.5. Contents should be sampled as soon as the ampule is opened. It is necessary to transfer liquid from the ampule to a syringe. Use an 18-20 gauge needle on a 1-3 mL **non-heparinized** syringe. Insert the needle to the bottom of the ampule and slowly draw liquid into the syringe.
- 8.2.6. Remove the needle and insert the syringe tip into the cuvette syringe port. Always hold the test cuvette by the black cap. Hold cuvette down at a 45° angle and inject the sample into the cuvette. Inject sample into the cuvette until the sample reaches the vent patch. Leave syringe attached to the cuvette. **NOTE:** Over-injection of QC material will cause the vent patch to bulge outward. If this happens, pull back slightly on the syringe plunger just until the patch flattens.
- 8.2.7. Check that no air bubbles are present in the sample light path. If air bubbles are present in the light pathway, discard cuvette.
- 8.2.8. Holding the cuvette by the black cap and with the vent patch side of the cuvette to the left, insert it into the instrument within 30 seconds of filling it. **NOTE:** A delay of analysis greater than 30 seconds may yield erroneous results.
- 8.2.9. Press “**YES**” at the “Liquid QC?”
- 8.2.10. Press “**YES**” at the “Enter Lot Number.”
- 8.2.11. Select Lot number and press “**ENTER.**”
- 8.2.12. Enter/Verify Operator ID.
- 8.2.13. Record result on the Avox Quality Control Log. Repeat steps for both levels of liquid QC. **NOTE:** If a result is outside the range limits, this represents an unsuccessful quality control test.
 - A. Verify that the cuvette pathlength is correct for the cuvettes in use.
 - B. Check the indicator on the desiccant pack in the cuvette package for acceptability.
 - C. Repeat the test with a new ampule. If the results are within range proceed with patient testing.
 - D. If results are still outside of range limits, contact the Point-of-Care Coordinator. **DO NOT USE INSTRUMENT.**
 - E. **All corrective action must be documented for quality control results immediately on the QC log.**



9. TEST PROCEDURE:

- 9.1. To turn on the instrument press ENTER/ON, the instrument starts and performs a series of self-tests. (The ENTER/ON button is also used to shut down the instrument if necessary).
- 9.2. Patient testing can only be done if all quality control has been completed and control results are within acceptable limits.
- 9.3. Roll the syringe containing the blood sample between hands and periodically invert the syringe to fully mix the sample. The sample must be mixed for a full ten-seconds just prior to injection into the cuvette. **NOTE:** Poorly mixed samples or those containing clots may cause inaccurate results.
- 9.4. Expel a small amount of sample from syringe. Always hold the test cuvette by the black cap. Hold cuvette down at a 45° angle and inject the sample into the cuvette. Inject the sample into the cuvette until the sample reaches the vent patch. Leave syringe attached to the cuvette. **NOTE: Over-injection of blood will cause the vent patch to bulge.** If this happens, pull back slightly on the syringe plunger just until the patch flattens.
- 9.5. Check that no air bubbles are present in the sample light path. **NOTE:** Air bubbles will yield erroneous results. If air bubbles are present in the light pathway, discard cuvette.
- 9.6. Holding the cuvette by the black cap, insert it into the slot of the instrument's front panel.
- 9.7. Insert the cuvette within 30 seconds of filling with the vent patch to the left. **NOTE:** A delay in analysis of greater than 30 seconds may yield erroneous results.
- 9.8. Enter/Verify the Operator ID number using the numeric keypad and press "ENTER."
- 9.9. Enter the patient identification number using the numeric keypad (All patient ID numbers must be 9 digits). Verify the number on the screen and press "ENTER."

9.10. Record patient results in the medical records while the cuvette is still in the analyzer. The Avoximeter is connected to the hospital network by a Lantronix adapter, results will cross to the EMR when testing is completed.

NOTE: If the display turns off before the result is recorded, stored patient results may be retrieved by pressing the “Main Menu”. Select “Stored Data”, and “Newest Sample.”

10. CALCULATIONS:

10.1. N/A

11. REPORTING RESULTS:

11.1. Results are recorded in the patient’s medical record automatically as the test is completed.

11.1.1. In the event of a system downtime results are stored in the meter and can be retrieved if needed.

11.2. Refer to master test list for reference intervals.

11.3. Refer to master test list for Analytical measurement range (technical range).

11.4. Refer to master test list for reportable range (reportable range).

11.5. Refer to Critical Results/ Critical Value policy for critical values

11.5.1 Notification of Critical results is documented in the patient’s medical record during the procedure.

12. INTERPRETATION OF RESULTS

12.1. Samples with results outside of the range should be confirmed with a repeat sample.

12.2. If any result is critical the operator must take the appropriate corrective action.

13. LIMITATION OF PROCEDURE:

13.1. **Never reuse a test cuvette once it has been inserted into the analyzer.**

13.2. Do not remove the syringe from the cuvette until testing is complete and the cuvette has been removed from the analyzer.

13.3. Discard cuvettes with trapped air bubbles and check for blood clots in patient specimen prior to injection. Before analyzing the sample, the syringe should be mixed by rolling the syringe between the outstretched palms of both hands for 10 seconds. Invert the syringe and repeat mixing. Invert the sample syringe and allow air bubbles to rise (tap syringe if necessary). Expel a small amount of blood sample into an absorbent surface until all air has been removed. A sample with clots or air bubbles may yield erroneous results.

13.4. Common sources of sampling errors:

13.4.1. Sample not freshly drawn.

13.4.2. Introduction of room air.

13.4.3. Sample was not well mixed.

13.4.4. Air bubbles or clots present in the light path.

13.4.5. Type of anticoagulant used.

13.4.6. Overfilling of cuvette.

13.4.7. Failing to insert the cuvette into the analyzer in less than 30 seconds.

14. REFERENCES:

- 14.1. Blood Gas and pH Analysis and Related Measurements; Approved Guideline. NCCLS C46-A, Vol. 21, No. 14. 2001
- 14.2. AVOXimeter 1000E Operator's and Service Manual, Rev. 7.04
- 14.3. AVOXimeter 1000E Compliance Guide, Rev. 3.98
- 14.4. AVOXimeter 1000E Procedures Manual NCCLS format (.pdf) Download from website at www.avoxsystems.com (12/21/2004)

15. RELATED DOCUMENTS

- 15.1. Refer to QPulse System or Document Detail Report for related laboratory Policies, Procedures and Master Forms