# Organization(s):

[ ]  North Carolina Baptist Hospital (NCBH)

[ ]  Lexington Medical Center (LMC)

[ ]  Davie Medical Center (DMC)

[ ]  Wilkes Medical Center (WMC)

[x]  High Point Medical Center (HPMC)

[ ]  Wake Forest Health Network (WFHN)

[ ]  Wake Forest University Health Sciences (WFUHS)

[ ]  Wake Forest University School of Medicine

[ ]  NCBH Outpatient Endoscopy

[ ]  Wake Forest Baptist Imaging, LLC (WFBI)

# Purpose

The purpose of this procedure is to properly utilize the ITC AVOXimeter 1000E. The AVOXimeter 1000E is a battery-operated bedside whole blood oximeter that measures total hemoglobin concentration (THb), and automatically measures oxygen content and saturation on freshly drawn or heparin or EDTA anticoagulated whole blood samples. Determination of total hemoglobin and oxygen saturation is used to assess oxygen transport status in diagnostic cardiac cauterization procedures.

# Scope

This procedure is limited to staff in the cardiac catheterization lab that have gone through training and have demonstrated competency in the use of the AVOXimeter 1000E and is intended for use in the adult Right Heart Procedures. It is the responsibility of the Cath Lab supervisor or manager to prevent use by non-authorized staff.

# Principle

Analysis is accomplished by injecting the sample into a disposable cuvette and inserting the cuvette into the instrument. The ITC AVOXimeter 1000E then illuminates the sample with multiple wavelengths, records the optical density of the samples at each of the wavelengths, and computes the results. In less than 10 seconds, the total hemoglobin concentration, oxygen content (O2), and oxygen saturation are displayed on the instrument.

# Definitions

1. ***Procedure***: A process or method for accomplishing a specific task or objective.

1. ***WFBH***: Wake Forest Baptist Health (WFBH) is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Wake Forest Baptist Imaging, LLC (WFBI), NCBH Outpatient Endoscopy, Wake Forest Health Network (WFHN), and Premier Surgery Center.

# Procedure Guidelines

1. Reagents, Equipment, & Materials
2. AVOXimeter 1000E
3. AVOXimeter 1000E cuvettes
4. Quality Control samples
5. Optical Filters
6. Gauze
7. Heparinized Syringes (for patient samples)
8. Syringes (for controls)
9. Gloves
10. AVOXimeter 1000E cuvettes are packaged with a desiccant in the plastic bag. The cuvette path length is printed on the label on the plastic bag. The cuvettes are sensitive to humidity. Keep the bag sealed when not in use.
	1. Store the cuvettes in a closed bag at room temperature (15-30ºC or 59-86ºF).
	2. Cuvettes are stable as long as the desiccant’s indicator is blue.
	3. Do not use cuvettes for patient testing if the desiccant indicator is pink or white. Patient results may be inaccurate.
	4. If all the spots appear pink or white contact manufacturer.
		* + 1. Technical Support: 800-955-9525 (available after hours, weekends and holidays)
11. RNA Medical Controls: QC 253 Full Range Co-Oximeter Controls, Level 1 and 3 Bovine based hemoglobin solutions.
	1. Store control solutions in the refrigerator at 2-8ºC. The expiration date is written on each box.
	2. Any expired control solutions should be discarded.
	3. If control solutions have turned brown in color, they should be discarded.
12. RNA Medical Co-Oximeter Calibration Verification Controls
	1. Every 6 months, 5 levels of control are run to confirm instrument linearity.
13. Specimen Requirements and Interfaces
14. Standard precautions must be followed when collecting and handling blood specimens.
15. Collect blood samples from the catheter.
16. 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.
17. 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.
18. Sample size for the AVOXimeter 1000E us 50ul.
19. 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 outstretched palms of both hands for 10 seconds. Invert the syringe and repeat mixing. Expel a small amount of the blood sample into an absorbent surface and discard.
20. Calibration
21. The ITC AVOXimeter 1000E is factory-calibrated and employs highly stable state-of-the-art light sources. It is capable of maintaining its calibration for at least 2 years. Should recalibration be required, contact the POCT Manager at extension 12421, who will arrange for service.
22. Proper calibration also requires entry of the correct cuvette path length by the user.
23. Analyzing the Optical QC filters will verify the calibration and confirm that the optics are clean.
24. Additionally, analyzing liquid QC samples verifies the calibration, checks the cuvette storage conditions, and the function of the cuvettes.
25. Quality Control
26. Two levels of the optical QC filters (yellow and orange) should be analyzed daily.
27. One level minimum aqueous control per week. Run levels 1 and 3.
28. Optical QC Filters
29. Calibration is checked every 8 hours of patient testing with the use of two factory calibrated optical filters (yellow and orange). These filters are treated just like a sample cuvette. Each filter is marked with the serial number of the instrument for which it is intended and the range of acceptable values.
30. The optical filters cannot be interchanges with filters from another AVOXimeter 1000E.
31. Insert one of the QC filters into the AVOXimeter 1000E.
32. Enter and/or verify Operator ID.
33. Record results and testing intitials on the Quality Control Log.
34. At the ‘READY’ prompt, repeat the steps for the second control filter.
35. Verify the results are within established control ranges. Acceptable ranges for filters:

|  |  |  |
| --- | --- | --- |
| **Total Hb** | **Range** | **%O2 Hb** |
| Yellow QC Filter | 7.7 to 8.3 g/dl | 93.5% to 96.5% |
| Orange QC Filter | 16.4 to 17.6 g/dl | 37.2% to 40.8% |
|  |  |  |

1. If results are not within range, repeat the test. Most of the time contamination of the optics is responsible for these ‘out of range’ readings.
2. If acceptable results are not obtained with repeat testing, contact

Trimedx and/ or review the AVOX 1000E Operators manual for detailed instructions on how to disassemble the unit and clean the optics.

The POCT Manager should be notified as well at extension 12421.

1. Do not use the instrument if the controls are out of range.
2. Liquid Quality Control
3. Remove Level 1 and Level 3 liquid QC ampules from the refrigerator. Do NOT warm controls before testing.
4. Shake the first control sample for approximately ten seconds.
5. Restore liquid to the bottom of the ampule with gentle tapping. If foam or small bubbles are present, allow ampule to stand until these have come to the surface.
6. With fingers protected, carefully snap open the ampule.
7. Contents should be sampled as soon as the ampule is opened. Using a 1-3ml un-heparinized syringe, slowly draw liquid into the syringe.
8. Insert syringe tip into the cuvette syringe port. Always hold the test cuvette by the black cap. Hold cuvette down at a 45º angle and inject the sample into the cuvette until the sample reaches the vent patch. Leave syringe attached to the cuvette.
	1. **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. Contamination of the optics usually happens because of over-filling the cuvettes.
9. Check that no air bubbles are present in the sample light path. If air bubbles are present in the light pathway, discard cuvette.
10. Holding the cuvette by the black cap, insert it into the instrument within 30 seconds of filling it.
	1. **NOTE:** A delay of analysis greater than 30 seconds may yield erroneous results.
11. Record the result on the Quality Control Log. Repeat steps for both levels of liquid QC.
	1. **NOTE:** If a result is outside of the range limits, this represents an unsuccessful quality control test. Follow these steps if this situation occurs:
12. Verify that the cuvette path length is correct for the cuvettes in use.
13. Check the desiccant’s indicator in the cuvette package.
14. Repeat the test with a new ampule. If the results are within range, proceed with patient testing.
15. If results are still outside the range limits, contact the POCT Manager at extension 12421. **DO NOT USE THE INSTRUMENT.**
16. Verification/ Entry of Cuvette Path Length
	1. Each lot of cuvettes has a unique path length that MUST be entered into the instrument when using the lot of cuvettes. **Failure to enter the correct path length will give false patient results.**
	2. Verify that the cuvette path length is correct for the cuvettes in use. The path length for the cuvette lot is found on the label of the cuvette packaging.
17. Press the **Main Menu** key.
18. Press 1 to select **Calibration** and press **Enter.**
19. Press 3 to select **Cuvette Pathlength** and press **Enter.**
20. Use the back arrow, **←**, to move the cursor and erase the displayed path length. If verifying path length, press **Cancel** to return to each previous screen.
21. Enter the correct path length using the numerical keypad.
22. At the **OK** prompt, press **YES** to enter the path length into the analyzer’s memory.
23. Patient Testing Procedure
	* + 1. Verify the patient’s identification using 2 forms of patient identifiers.
			2. Roll the syringe containing the blood sample between hands periodically inverting the syringe to fully mix the sample. The sample must be mixed for one entire ten second interval just prior to injection into the cuvette.
24. **NOTE:** Poorly mixed samples or those containing clots may cause inaccurate results.
25. Expel a small amount of sample from the syringe. Always hold the test cuvette by the black cap. Hold cuvette down at a 45º angle and inject the sample into the cuvette. Inject sample into the cuvette until the sample reaches the vent patch. Leave the syringe attached to the cuvette.
	1. **NOTE:** Over injection of blood will cause the vent patch to bulge outward. If this happens, pull back slightly on the syringe plunger just until the patch flattens.
26. Check that no air bubbles are present in the sample light path.
	1. Air bubbles will yield erroneous results. If air bubbles are present in the light pathway, discard cuvette.
27. Holding the cuvette by the black cap, insert the cuvette into the slot of the instrument’s front panel.
28. Insert the cuvette within 30 seconds of filling.
	1. **NOTE:** A delay in analysis of greater than 30 seconds may yield erroneous results.
29. Record patient results while cuvette is still in the analyzer. If the display turns off before the result is recorded, stored patient results may be retrieved by pressing the **Main Menu** option. Select **Stored Data**, and **Newest Sample**.
30. Limitations
	* + 1. Sodium or lithium heparin is the anticoagulant of choice. Citrate is known to change the pH of the blood and cause errors in spectrophotometer measurements. Similarly, fluoride/ oxalate should be avoided.
			2. Excessive volumes of anticoagulant lead to dilution errors.
			3. The presence of carboxyhemoglobon, methemoglobin or significant amounts of deoxyhemoglobin will result in a lower oxygen saturation and oxygen content than expected. If the presence of such non-oxygen carrying hemoglobin(s) is suspected samples should be sent to the Laboratory for complete co-oximetry testing.
31. Procedure Notes & Interferences
32. Never re-use a test cuvette once it has been inserted into the analyzer.
33. Do not remove the syringe from the cuvette until testing is complete and the cuvettes have been removed from the analyzer.
34. Discard cuvettes with trapped air bubbles and check for blood clots from patient specimen prior to injection. If samples are not analyzed immediately, the sample should be mixed prior to analysis by rolling the syringe and repeating the mixing process. Invert the sample syringe and allow air bubbles to rise, tapping the syringe if necessary. Expel a small amount of blood sample into an absorbent surface until air has been removed. A sample with clots or bubbles may yield erroneous results.
35. Results & Reporting
36. Reportable Ranges

Total Hemoglobin results are reported from the clinical lab complete blood count.

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| --- | --- |
| Oxygen Saturation | 0 to 100% |

1. Normal Ranges
	* + - 1. Oxygen Saturation

|  |  |
| --- | --- |
| Inferior Vena Cava | 77%-89% |
| Superior Vena Cava | 67%-87% |
| Right Atrium | 74%-86% |
| Right Ventricle | 71%-87% |
| Pulmonary Artery | 73%-83% |
| Pulmonary Artery Wedge | 93%-99% |
| Radial Artery | 95%-99% |
|  |  |

1. All results are given verbally to the attending physician immediately after obtaining results and are also documented in the EMR and Hemodynamic System.
2. Maintenance
3. Cleaning of the AVOXimeter 1000E surface should be performed as needed to remove dust and any blood spills.
4. Clean the analyzer’s exterior with isopropyl alcohol.
5. Staff Education and Competency
6. Each operator using AVOXimeter 1000E becomes competent through training provided by the POCT Manager or designated Super Users. Competency is re-assessed annually for the Moderately Complex test. First time users, competency is re-assessed after 6 months and yearly thereafter.
7. Corrective Action
8. If any one of the Daily QC filter 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. See below for Remedial Action:
9. Verify QC filters are clean and match the instrument used.
10. Most likely the cause of failure is blood or other debris obscuring the light detector.
11. Repeat filter testing before referring to the AVOX 1000E Operator’s Manual for optics cleaning.
12. If acceptable results are not obtained with repeat testing, contact Trimedx and/or review the AVOX 1000E Operator’s Manual for detailed instructions on how to disassemble the unit and clean the optics.
13. 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.
14. If the calibration verification fails (any of the liquid QC values falls outside of acceptable range), re-calibration of the AVOX 1000E may be required. See below for Remedial Action:
	1. Verify that the correct cuvette path length is programmed in the analyzer.
	2. Check the desiccant indicator in the cuvette package.
	3. Ensure liquid controls have been stored and handled appropriately.
	4. Repeat the same level of liquid control using a new ampule and a new cuvette from the same box of cuvettes.
	5. If repeat results are within acceptable limits, then the analyzer and cuvettes may be used for patient testing.
	6. If repeat results are still outside of acceptable limits, perform troubleshooting procedures.
	7. Contact manufacturer Technical Support at 1-800-955-9525 (available after hours, weekends, and holidays) or call Trimedx for assistance if the remedial action steps do not resolve the problem.

# References

1. AVOXimeter 1000E Operator’s and Service Manual, 2007
2. AVOXimeter 1000E Compliance Guide, Rev. 3.98
3. AVOXimeter 1000E Procedure Manual NCCLS format

# Revision Dates

12/09

4/15

8/19

6/21

10/22

3/23

5/24

**Attachment A**

**AVOXimeter 1000E QC LOG**

**Serial Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\*EQC must be performed every 8 hours (when in use)**

**\*\*Wet QC must be performed weekly.**

 **Level 1 and Level 3- Make Copies of the information sheet and submit to POCT Manager monthly.**

**Revision: 5/24/2023 VJB**

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| --- | --- | --- | --- | --- | --- |
| **Date/Time** | **Yellow Filter****O2% 93.5-96.5** | **Yellow Filter****Hgb 7.7-8.3g/dl** | **Orange Filter****O2% 37.2-40.8%** | **Orange Filter** **Hgb 16.4-17.6g/dl** | **Initials** |
| **Week 1 Date:****Cuvette Lot:** | **Level 1 Lot #:** | **Result** | **Level 3 Lot #:** | **Result** | **Initial/Date:** |
| **Exp date:**  | **Exp date:**  |
| **O2 Range:**  |  |
| **O2 Range:** |  | **Hgb Range:** |  |
| **Hgb Range:**  |  |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
| **4** |  |  |  |  |  |
| **5** |  |  |  |  |  |
| **6** |  |  |  |  |  |
| **7** |  |  |  |  |  |
| **Week 2 Date:****Cuvette Lot:** | **Level 1 Lot #:** | **Result** | **Level 3 Lot #:** | **Result** | **Initial/Date:** |
| **Exp date:** | **Exp date:** |
| **O2 Range:**  |  | **O2 Range:**  |  |
| **Hgb Range:** |  |
| **Hgb Range:** |  |
| **8** |  |  |  |  |  |
| **9** |  |  |  |  |  |
| **10** |  |  |  |  |  |
| **11** |  |  |  |  |  |
| **12** |  |  |  |  |  |
| **13** |  |  |  |  |  |
| **14** |  |  |  |  |  |
| **Week 3 Date:****Cuvette Lot:** | **Level 1 Lot#:** | **Result** | **Level 3 Lot #:** | **Result** | **Initial/Date:** |
| **Exp date:** | **Exp date:** |
| **O2 Range:**  |  |
| **O2 Range:**  |  | **Hgb Range:** |  |
| **Hgb Range:** |  |
| **15** |  |  |  |  |  |
| **16** |  |  |  |  |  |
| **17** |  |  |  |  |  |
| **18** |  |  |  |  |  |
| **19** |  |  |  |  |  |
| **20** |  |  |  |  |  |
| **21** |  |  |  |  |  |
| **Week 4 Date:****Cuvette Lot:** | **Level 1 Lot #:** | **Result** | **Level 3 Lot #:** | **Result** | **Initial** |
| **Exp date:** | **Exp date:** |
| **O2 Range:**  |  |
| **O2 Range:**  |  | **Hgb Range:** |  |
| **Hgb Range:** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date/Time** | **Yellow Filter****O2% 93.5-96.5** | **Yellow Filter****Hgb 7.7-8.3g/dl** | **Orange Filter****O2% 37.2-40.8%** | **Orange Filter** **Hgb 16.4-17.6g/dl** | **Initials** |
| **22** |  |  |  |  |  |
| **23** |  |  |  |  |  |
| **24** |  |  |  |  |  |
| **25** |  |  |  |  |  |
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| **27** |  |  |  |  |  |
| **28** |  |  |  |  |  |
| **29** |  |  |  |  |  |
| **30** |  |  |  |  |  |
| **31** |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Week 5 Date:****Cuvette Lot:** | **Level 1 Lot #:** | **Result** | **Level 3 Lot#:** | **Result** | **Initial/ Date:** |
| **Exp date:** | **Exp date:** |
| **O2 Range:**  |  | **O2 Range:**  |  |
| **Hgb Range:** |  | **Hgb Range:** |  |