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POC 48 113 AVOXIMETER

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Location Med Training

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Comments for version 1.0
Initial version

New SOP for Cath Lab, Reviewed for approval.

Format changes only.

Reviewed by A. Hankerson

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/31/2024	1.0	Eugene Pearlman	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	3/27/2024	3/31/2024	Indefinite

AVOXIMETER

POC 48 113

Lt. Col. Luke Weathers, Jr
VA Medical Center
Memphis, TN 38104

Service Line(s):
Pathology and Laboratory Medicine Service

Signatory Authority:
Chief, Pathology and Laboratory Medicine Service

Effective Date:
March 14, 2024

Recertification Date:
March 31, 2029

Responsible Owner:
Kimberly Ballard
Ancillary Testing Coordinator

1. PURPOSE AND AUTHORITY

a. The AVOXimeter 1000E analyzer is a moderately complex battery-operated bedside whole blood oximeter that performs individual point of care measurements of oxyhemoglobin saturation (%HbO2) and total hemoglobin concentration (THb) on freshly drawn or heparin or EDTA anticoagulated whole blood samples. Oxygen content [O2 mL/dL] of the blood sample is automatically calculated from the %HbO2 and the THb measurements.

b. Safe performance of right heart or transeptal cardiac catheterization requires proper placement of catheters into the appropriate cardiac chambers. The operator relies primarily on comparing pressure wave forms and oxygen saturation determination. For example, a transeptal catheterization involves puncturing the interatrial septum with a needle placed from the right femoral vein. Thus, the needle passes from the right atrium, through the interatrial septum, into the left atrium. As the pressure wave forms in right and left atria can be quite similar, the only way to determine that the needle has passed into the left atrium is measurement of oxygen saturation (which should increase from approximately 70% (right atrium) to > 90% (left atrium)). If, for example, a transeptal puncture was attempted, and a blood sample drawn for oxygen saturation showed a sat of 40% when right atrial saturation was 70% that would indicate a course of the needle into the coronary sinus and would mandate immediate withdrawal of the instrument to prevent cardiac tamponade.

c. Another Cardiac Catheterization use of oxygen saturations is to detect and identify anatomic defects within the heart. To quote from Grossman's text, "The commonest abnormality, atrial septal defect, is sometimes hard to detect by catheter position alone, since the catheter appearance in the left atrium or ventricle may be indistinguishable from its course during the usual right heart catheterization. Measurement of pressure and blood oxygen saturation, together with hand injection of radiographic contrast…should allow the operator to sort out the anatomy".

d. The AVOXimeter 1000E is to be used in the cardiac catheterization laboratory to provide a quick measurement of oxygen saturation of a small sample of whole blood during cardiac catheterization procedures. It will provide saturation measurements in approximately ten seconds.

2. ASSIGNMENT AND RESPONSIBILITY

a. **Chief of P&LMS.** Overall responsible for ensuring the laboratory has an effective communication system.

b. **Ancillary Testing Coordinator.** Responsible for implementing a comprehensive procedure for performing testing on this instrument, conducting operator assessments, and providing any training.

c. **Ancillary Testing Specialist.** Aiding operators, performing training, required troubleshooting of instruments and other duties as needed by Ancillary Testing Coordinator.

d. **All Staff members.** All authorized users are physicians, RN (registered nurse), RT (radiologic technician), MIT (Cath Lab) and have been trained in the proper procedure for handling sample and performing patient testing using this procedure.

3. DEFINITIONS

a. **PPE.** Personal Protective Equipment i.e. gloves, face shield, goggles, lab coat, etc.

b. **QC.** Quality Controls, to be performed monthly and or every new lot of test kits.

c. **Waived Test.** Complexity of the test whereas the interpretation, performance and sampling of the test is of low risk.

4. SPECIMEN INFORMATION

a. Specimen Collection The AVOX cuvette requires 50 ul of blood to measure blood oxygen saturation, however in order to prevent air bubbles, at least 1 ml blood is suggested to draw. The physician will be responsible for drawing the specimen.

b. Patient Identification: The patient's armband name and social security number must be checked and match patient name and social security number on the patient's chart.

c. Types of specimens: Do not use samples that contain excessive volumes of anticoagulant or are diluted with saline**.** A plain syringe with no anticoagulant can be used if the sample is to be tested **immediately.**

(1) Mix well.

(2) Do not expose the sample to air. This will cause inaccurate results of O2.

(3) Avoid hemolysis.

(4) Samples should be tested within 5 minutes of collection.

d. Since only one patient procedure is performed at a time, labeling specimen is not necessary. The specimen does not leave the room where patient is drawn and analyzed.

5. MAINTENANCE

a. There is no scheduled maintenance.

b. The instrument should be routinely examined for the presence of blood on the exterior surfaces and cleaned when visibly contaminated using a water-dampened cloth.

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

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

6. SPECIAL SAFETY PRECAUTIONS

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

b. Operate the instrument on a site away from drafts and bright lights.

c. Follow proper infection control guidelines for handling all specimens and related items.

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

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

7. EQUIPMENT/ FORMS

a. AVOXimeter 1000E instrument

b. AVOXimeter 1000E cuvettes

c. Syringe

d. Power Supply and Adapter

e. Optical Quality Control filters

f. Kimwipes or gauze

g. Disposable gloves

8. REAGENTS

a. **Supplies**

(1) RNA Medical CO-Oximeter Controls (Ref. QC2531 and QC2533)

(2) RNA Medical CO-Oximeter Calibration Verification Set (Ref. CVC223)

b. **Handling and Storage**

(1) The cuvettes are maintained at room temperature (15-30°C) in sealed bag with Humidity Indicator Cards.

(2) 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. How to read the Humidity Indicator Multiple Spot Card:

(a) The concentration of the active humidity indicator is lower in the indicator spot of 10% than in the indicator spot of 40%.

(b) The color change is not as dramatic in the lower range as compared to the higher range.

(c) The lower range may appear almost “white” when the humidity has exceeded the range for that indicator. Cuvettes storage must be re-evaluated.

(d) 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.
- Contact the Ancillary Testing Coordinator or ITC Technical Support as listed below.

(e) "Lavender" is the color of the current relative humidity within the immediate environment of the sealed bag.

(f) If all spots are "Pink" then the relative humidity is greater than the highest percentage indicated as the card's detection limits. Cuvettes storage must be re-evaluated.

(g) If all spots are "Blue" then the relative humidity is less than the lowest percentage indicated by the card.

(h) Disposal of Humidity Indicator Cards – the cards can be disposed as common waste and do not require disposal in a Biohazard Waste container.
Note: 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.

(i) Store controls/verifications at 2-8℃. Do not freeze.

(j) Kits are stable until expiration dates marked on the outer packaging and container.

(k) Kits are only to be used with ID NOW instrument and should not be opened until ready to be used on the instrument.

9. QUALITY CONTROLS

a. Daily Optical Filter Checks

(1) Press the "Enter/On" key if the Avoximeter 1000E is not already "On".

(2) Wait for the display to read "READY … Insert Cuvette" message on-screen.

(3) Clean the filter with clean gauze prior to use.

(4) Insert the filter into the Avoximeter 1000E.

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

(6) 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%

b. Weekly Quality Controls/ LQC

(1) Turn on the Avoximeter 1000E by pressing the “Enter/On” key.

(2) Wait for the self-test to complete.

(3) Follow manufacturer’s directions for handling the material.

(4) Remove the material by using a clean syringe (no anticoagulants).

(5) Connect the filled, plastic syringe to a new disposable cuvette.

(6) Hold cuvette downward at a 45° angle and express QC material into cuve Fill a test cuvette with the liquid control and insert into the analyzer. When the display reads, “Is this liquid QC?”, press “Yes”. When the display reads, “Do you wish to enter level & lot numbers?”, press “Yes”. Select Level (1, 2, or 3 as appropriate), press “Enter”. When the display reads “Lot Number:”, Press “2”, then “Enter”. Input Lot number from the ampule, then press “Enter”. If the displayed Lot number is correct, press “Enter” again. Input Operator ID. Results will display and print out.

Caution: Never force material into cuvette. If cuvette does not fill easily, discard it and use a fresh cuvette.

(7) Confirm that the light path at the widest portion of the sample chamber is free of debris or air bubbles. Ignore bubbles outside of the light path.

(8) Holding the black cap, insert cuvette into front panel slot on the instrument.

(9) Always orient vent patch to the left side when inserting cuvette into the instrument.
Note: Do not depress plunger while syringe is in the instrument.

(10) The Avoximeter 1000E will report the results of the sample within 10 seconds.

(11) Record the results of the QC as directed by site policy.

(12) Each manufacturer will provide the ranges for the LQC material.
<u>If the LQC fails:</u>

- Check the expiration date and repeat with fresh material.
- If the failure persists, check the path length setting and confirm the value matches the printed path length on the bag of cuvettes currently in use.
- If the failure persists, report the failure. No patient testing is allowed until the problem is resolved.

10. EQUIPMEMT CALIBRATION AND MAINTENANCE

a. Semi-annual Patient Correlation:

(1) At least two times per year run three patients using the AVOXimeter 1000E and compare results to Pulmonary Function Laboratory blood gas instrumentation or other method per pathology lab director policy.

(2) Document the correlation study results.

b. Semi-annual Calibration Verification:

(1) Run RNA Medical Calibration Verification Set.

(2) If results are out-of-range compared to the package insert, re-run test. If still out of range, contact technical support.

(3) Document the results.

c. New lot # of Controls

(1) Run all levels of new lot # of controls. Compare results to package insert. Record results on QC log.

(2) If results are out-of-range compared to the package insert, notify Point-of-Care Testing Coordinator.

11. PROCEDURES

a. **General Procedure: Sample Preparation**

(1) If the sample was not infused into the cuvette immediately after blood draw, mix the whole blood sample by rolling the syringe between the palms of the hands.

(2) Remove all the air out of the syringe and remove 0.2 mL blood to the gauze.

(3) Connect the syringe containing the sample to an unused cuvette. Hold the cuvette by means of the finger grip on the black cap. DO NOT touch the clear portion of the cuvette. Firmly holding the syringe and cuvette at a 45-degree, downward angle, fill the cuvette by GENTLY pressing the syringe plunger.

(4) **NOTE**: Never force the sample into the cuvette. If a cuvette does not fill easily, discard it and use a new one.

(5) Continue to fill cuvette until the sample reaches the vent patch at the opposite end. DO NOT fill the cuvette to point where the vent patch bulges.

(6) **NOTE: DO NOT insert a cuvette with a protruding vent patch into the test chamber**.

(7) Remove any blood or debris from the exterior of the test cuvette before inserting it into the test chamber.

(8) Verify that the light path area of the cuvette is free of air bubbles. If there is air bubbles within the light path area, use a new cuvette and repeat step 2-6.

b. **Patient Testing Procedure**

(1) Turn on the Avoximeter 1000E by pressing the “Enter/On” key and

(2) Wait for the self-test to complete.

(3) Thoroughly mix the syringe containing the patient’s sample by rolling between the hands for at least 10 – 15 seconds.

(4) Connect the blood-filled, plastic syringe to a new disposable cuvette.

(5) Hold cuvette downward at a 45° angle and express blood into cuvette until sample fills cuvette up to the vent patch at the opposite end.

(6) Confirm that the light path at the widest portion of the sample chamber is free of debris or air bubbles. Ignore bubbles outside of the light path.

(7) Remove any blood on the cuvette's exterior surface before inserting cuvette into the cuvette slot on the front of the instrument.

(8) The Avoximeter 1000E will report the results of the sample within 10 seconds.

(9) Report the results as designated by this policy.

(10) Remove the cuvette and syringe from the instrument.

(11) Dispose of the used cuvette according to policy.

NOTE: If the User ID and Patient ID are not input prior to inserting the cuvette into the test chamber, the analyzer will default to QC mode.

c. **Limitations.**

(1) Exposure of the cuvettes to excessive humidity may result in a loss of accuracy. Always keep cuvettes in sealed bag with desiccant.

(a) No interference observed from bilirubin, hemolysis, carboxyhemoglobin.

(b) Methemoglobin: <1% O_2Hb <0.2 g/dl THb
(THb = 16 g/dL)
(MetHb <10%)
(7.1< pH < 7.8)

12. ENTRY OF RESULTS

a. Enter patient's SSN and USER ID, AVOX will print out patient's tHB and O2HB result if printer is attached,, manually record results, or result will automatically transmit to patient's chart if interface connectivity is available.

b. Enter the patient's HB and Sat O2 to Maclab then the printout copy needs to scan to CPRS.

c. Report results directly and immediately to the practitioner.

d. **Linearity/ Reportable Range/ AMR**

(1) %HbO2 is 0% - 100%

(2) tHb is 4 – 25 g/dL

e. **Critical Values**: No critical values are indicated for this application of (%HbO2) or (tHb)

f. **Hüfner's Number**
Hüfner's number is the volume of oxygen that can be carried by one gram of hemoglobin and is used to calculate the oxygen content of a sample. Although Hüfner's number is generally assumed to be 1.39 mL/g of Hb, facilities may use a different value and may wish to set the Avoximeter 1000E to match other instruments in the facility.

(1) Press the "Enter/On" key if the Avoximeter 1000E is not already "On".

(2) In the "Main Menu" screen, select "1. Calibration" and press "Enter"

(3) In the next screen, select "4. Hüfner's Number".

(4) The screen will display "1.39" and will only allow change to the last digit of Hüfner's Number.

(5) If the entry is correct, press "1 – OK" then "Enter".

(6) If the entry is not correct, press "2 – Re-enter".

(7) Follow the steps as outlined in #3 and #4.

(8) After accepting the reset Hüfner's Number, pressing the "Enter" key will return the operator to the "Calibration" screen.

(9) Press "Cancel" twice to return to the "Main Menu".

13. REFERENCES

a. VHA Directive 1106.1, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 24, 2024, http://vaww.lab.med.va.gov/References_Directives_and Regulations_P.asp

b. Package Insert, RNA Medical Controls, (F1011 Rev. 10/2010)

c. Package Insert, RNA Medical Calibration Verification Set, (H1231 Rev. 4/2012

d. AVOXimeter 1000E Operator's Manual, (AP1001, 11/2007)

e. Grossman, Cardiac catheterization and Angiography, 3rd Edition, page 66.

14. APPENDICES

None

15. REVIEW

This SOP will be reviewed at least every 2 years, when there are changes to the government document that need to be made and any regulatory requirement for frequent review.

16. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of March 2029. In the event of contradiction with national policy, the national policy supersedes and controls.

17. SIGNATORY AUTHORITY

Dr. Eugene Pearlman
Pathology and Laboratory Medicine Service, Chief

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This SOP is available in Media Lab: https://www.medialab.com/lms/admin/ad_tab_doc_frameset.aspx?leftdest=todo&oid=44462549&o=3d523f5ddaf473e01ca4a390d42c48e6&docid=1442508&dochash=6973f6026869ac33edd1619d5325ba72&revisionid=2450038&revhash=a042552061c2a60bc57e0615633f51cf