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48667.311 AVOXimeter 1000E – CO-Oximetry

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Version History

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3.0	Approved and Current	Major revision	3/05/2021	3/11/2021	Indefinite

Linked Documents

- 48667.312 AVOXimeter 1000E Optical QC Log
- 48667.313 AVOXimeter 1000E Quiz
- 48667.314 AVOXimeter Initial Orientation Training Form
- 48667.315 AVOXimeter 1000E Liquid QC Log
- 48667.336 AVOXimeter 1000E 6 Methods of Competency

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AVOXimeter 1000E – CO-Oximetry

Purpose

Whole blood oximeters directly measure the following hemoglobin species: oxyhemoglobin (O_2Hb), reduced hemoglobin (HHb), carboxyhemoglobin (COHb), and methemoglobin (MetHb) with the use of multi-wavelength spectrophotometry.

The AVOXimeter 1000E reports the measured total Hemoglobin (tHb) and $\%O_2Hb$ as a fractional measurement, and then calculates the values of oxygen content (ctO_2), functional oxygen saturation (SO_2) and oxygen capacity.

Invasive cardiologists use such measurements chiefly for two purposes: 1) to detect intracardiac and great-vessel shunts and, 2) to compute cardiac output by the Fick Principle.

Principle

According to Beer's Law, if several light-absorbing compounds are present in a solution, the concentration of each compound can be deduced if the compounds differ in their optical absorbance and if optical density is measured at as many wavelengths as there are compounds present. For example, if three compounds X, Y, and Z are present and if the optical density (OD) is measured at three different wavelengths (λ), the result is a set of simultaneous equations whose total number will equal the number of unknown concentrations.

The total hemoglobin concentration measured by the AVOXimeter 1000E uses oxyhemoglobin (O_2Hb), deoxyhemoglobon (or reduced hemoglobin-HHb), carboxyhemoglobin (COHb) and methemoglobin (MetHb), in the calculation, but the COHb and MetHb results are not displayed:

$[tHb] = [O_2Hb] + [HHb] + [MetHb] + [COHb]$.

Similarly, the percentage of oxyhemoglobin reported by the AVOXimeter 1000E is the *fractional* saturation.

$$\% O_2Hb = \frac{[O_2Hb] \times 100}{[O_2Hb] + [HHb] + [MetHb] + [COHb]}$$

NOTES:
1. For more in-depth discussion of the Theory of Measurement, refer the AVOXimeter 1000E Operator's Manual.
2. Only total hemoglobin and O2 saturation results have been verified and approved for use at SFGH.

Safety

Universal precautions should be observed through all phases of the testing procedure.

Testing Personnel

- Qualified Licensed Registered Nurses (RNs)
- Testing personnel are required to take the initial training and competency assessment. Competency assessment (using 6 methods) must be completed after initial training and before technical duties are performed, six months after completion of initial training and annually thereafter.

Specimen

A. Specimen and Cuvette

The AVOXimeter 1000E requires a minimum sample volume of 50 µL whole blood.

1. Verify patient identification with two identifiers (patient's name and date of birth) before drawing the blood sample. Observe universal precautions; wear gloves and other personal protective equipment as appropriate.
2. Specimen labeling is not required if the sample is run in the presence of the patient and only one sample is run at a time. If there is the potential for specimen mix-up, the specimen must be labeled with patient's full name and medical record number.
3. To obtain accurate measurements, collect blood samples in a sodium or lithium heparinized plastic syringe. Collect and handle the specimens according to medically-accepted sterile techniques.
4. When drawing blood samples with a syringe from a saline filled catheter, withdraw the saline first and make sure that only whole blood is sampled.
5. Roll the tightly sealed syringe between your palms to keep the red blood cells and plasma well mixed. Poorly mixed samples or those containing clots may cause inaccurate results.
6. When handling cuvettes, hold them only by their black caps.
7. Always fill cuvette prior to inserting it into the instrument.
8. Always store cuvettes in the sealed bag with a desiccant pouch or erroneous results may occur. Check the desiccant prior to using cuvettes to ensure that the color indicator has not changed from blue to pink. If the color indicator has changed, do not use cuvettes until a new desiccant pouch can be added to the bag. Prior to use, verify desiccant color indicator is blue.
9. When filling a cuvette, do not use excessive pressure or cause the vent patch to bulge outward. If the vent patch protrudes, discard the cuvette. To avoid contaminating the optics, never insert a cuvette with a protruding vent patch into the instrument.
10. If the sample in the cuvette is poorly mixed or contains clots, then discard the cuvette to prevent erroneous results.

B. Acceptable Sample Types/Anticoagulants

1. Lithium or sodium heparin

C. Specimen Storage

Sodium or Lithium heparinized anticoagulated blood samples for blood gas measurements can be collected and kept in plastic syringes for up to 30 minutes at room temperature.

When drawing blood samples with a syringe from a saline filled catheter, withdraw the saline first and make sure that only whole blood is sampled.

D. Unacceptable Specimens

1. Specimens with visible clotting or debris accumulation.
2. Specimens collected using excessive amount of anticoagulant.
3. Specimens collected using oxalated, fluoride or citrated anticoagulants.
4. Specimens with air contamination as samples must be collected and stored anaerobically.
5. Specimens contaminated with any solutions.

Equipment/ Materials/ Reagents

A. Equipment

1. AVOXimeter 1000E
2. AC Transformer unit (battery charger)
3. Quality Control filters PN E-QCYO
4. Printer model: RP-D10 by SEIKO PN: AVOXPRNT
5. Printer paper PN AVOXROLL
6. Operator’s Manual

B. Materials

1. Whole Blood sample (minimum volume - 50 µl)
2. Full Range Co-oximeter Controls (Levels 1, 2 and 3) by RNA Medical PN QC253
3. Biohazard waste disposal container
4. Co-Oximeter Calibration Verification Controls by RNA Medical PN CVC 223

C. Reagents

1. AVOXimeter disposable cuvettes - ITC catalog Number: PN C100B

D. Reagent Storage

1. The cuvettes are maintained at Room Temperature (15-30ºC or 59-80ºF).

Note: Always keep cuvettes in sealed bag with Humidity Indicator Cards.

E. Humidity Indicator Cards: 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.

1. 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.

   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:

      1) Immediately inspect the package.

      2) Contact 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 then the highest percentage indicated as the card’s detection limits.

   g. If all spots are “Blue” then the relative humidity is less than lower than the lowest percentage indicated by the card.

   Note: If all of the spots appear “Pink” or “White”, contact ITC Technical Support:
   Toll-free in the U.S: (800) 631-5945.
   Outside the U.S: 001.732.548.5700
   e-mail: techsupport@itcmed.com

1. 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.

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

Quality Control

Upon power-up, the AVOXimeter 1000E executes a self-test to confirm the proper operation of its light sources. If the self-test fails, the instrument will assist you in diagnosing the problem.

The optical check is performed **daily prior to patient testing** and when the performance of the analyzer requires verification.

Note: Optical filters are matched to each AVOXimeter 1000E instrument and cannot be interchanged for testing on any other AVOXimeter instruments.

For additional help, notify POCT staff. You may also consult the "Troubleshooting" section of the operator's manual or contact ITC:
Call toll free in the U.S. (800) 631.5945
Outside the U.S: 001.732.548.5700.
Contact by e-mail: www.techsupport@itcmed.com

Notes:
- The initial calibration of the AVOXIMETER 1000E is set at the factory.
- Recalibration is required only if the daily functional checks with the yellow and orange filters do not meet the established specifications.
- The most frequent cause of error messages or erroneous reading is not loss of calibration, but contamination of the optical detector with blood or other debris. The optical filters are used to quickly and conveniently determine whether the optics have been contaminated and to verify that the calibration has not changed.
- These procedural checks not only verify that the instrument is properly calibrated, but also confirm the optical detector is not contaminated by any debris.

A. Calibration

Required for each new lot number of cuvettes and consists of changing the Path length in the instrument.

1. Press the "Enter/On" key if the AVOXimeter 1000E is not already "On".

2. When instrument displays "Ready … Insert Cuvette" on-screen, press the "Main Menu" key

3. Select Option "1" to reach the Calibration Menu.

4. Press "Enter/On" key.

5. Select "3. Cuvette Path length" on the Calibration Menu.

6. Press the "Enter/On" key.

7. The current path length will be displayed with a cursor next to the 3 digits.
8. To change the number, press the "←" key to erase the current digit(s).
9. Enter the path length value as printed on the bag of cuvettes currently in use.
10. Confirm the value is correct then press the "Enter" key.
11. A screen will be displayed that will ask the operator to "Press Y" (to keep the entered value) or "N" to Change (to another value).
    a) If "Y" is pressed the message "Cuvette Wavelength Calibration: Complete… Press Any Key" will appear.
    b) If "N" is pressed, the operator will be returned to the screen to allow for re-entry of the path length.
12. Pressing any key will return the operator to the "Calibration Menu" screen.
13. Press "Cancel" twice to return to the "Ready" screen.

B. Storage of the Optical Filters

1. The filters are stored at Room Temperature (15 - 30ºC or 59-80ºF).

Procedure:

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. Verify the results are within the acceptable limits in the table below and document them on the Optical QC Log. See the Quality Control Failures section below for unacceptable results and actions.

Optical Filter	Low tHb	High tHb	Low %O_2Hb	High %O_2Hb
Yellow filter	7.7	8.3 g/dl	93.5	96.5%
Orange filter:	16.4	17.6 g/dl	37.2	40.8%

C. Weekly Quality Control (LQC)

The purpose of QC 253 liquid controls (LQC) is to serve as another means to verify that the AVOXIMETER 1000E system is functioning properly.

All three levels of the liquid control materials are performed on a **weekly** basis and every time there is a **new lot or new shipment of cuvettes prior to patient testing**. QC results should fall within the manufacture's reference range found listed on each lot's package insert.

- QC 253 is sensitive to many instrument related factors that would affect analytical results. Although it is a bovine blood-based material, it does not contain red cells. Therefore, it may not detect certain malfunctions that would affect the testing of human blood.
- This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.
- Extended exposure to temperatures greater than 8 °C will affect product performance.
- If QC 253 has turned brown in color, this change indicates deterioration and the formation of methemoglobin. In such a case, the control is unsuitable for use and should be discarded.

D. Storage of LQC

The expiration date stated on the QC 253 packaging is for product stored refrigerated (2 – 8 ºC). Avoid exposure to freezing and temperatures greater than 8 ºC.

E. Performing Liquid QC

1. Turn on the AVOXimeter 1000E by pressing the "Enter/On" key

2. Wait for the self-test to complete.

3. Prior to analyzing liquid controls, QC lot information must be defined:
    a. Press the Data key, then select #4 Data Management, press Enter/On.
    b. Select #4 Liquid QC Lot Nos. #4, press Enter/On.
    c. Select Level: 1, 2, or 3
    d. Select Lot – The lot numbers defined for the level selected are displayed. Select the Lot number to be changed or deleted. The QC Lot confirmation screen displays the Lot Number selected.
    e. Option 1. Cancel or OK to accept the Lot Number displayed.
    f. Option 2. "Enter New Value" presents a Lot Number entry screen. Enter a new Lot Number from one to seven numeric digits in length or press Enter/On to delete the previous Lot Number. Entry of a new Lot Number requires confirmation. Deletion of a Lot Number automatically shifts the remaining Lot Numbers up one selection on the Select Lot screen. When specifying Lot Numbers, ignore leading letters.

4. The LQC material should be analyzed immediately after removal from the refrigerator. Before use, gently invert the ampul to mix the solution. Tap the ampul to restore the liquid to the bottom.

5. Using safe practices break the glass vial top and discard in a safe container.

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

7. Connect the filled, plastic syringe to a new disposable cuvette.

8. Hold cuvette downward at a 45° angle and express QC material into cuvette until sample fills cuvette up to the vent patch at the opposite end.

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

9. 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.

10. Holding the black cap, insert cuvette into front panel slot on the instrument.

Note: Do not depress plunger while syringe is in the instrument.

11. The AVOXimeter 1000E will report the results of the sample within 10 seconds.

12. Record the results of the QC in the Liquid QC Log.

13. Verify that the results are within the acceptable range. See the Quality Control Failures section below for unacceptable results and actions.

F. Quality Control Failures

1. If the daily filter check fails:

   a. Clean the filter and repeat the test.

   b. If the failure persists, this may be an indication of a blood spill inside of the instrument and will require cleaning – please refer to the Operator's Manual for detailed cleaning instructions.

2. If the LQC fails:

   a. Check the expiration date and repeat with fresh material.

   b. 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.

   c. If the failure persists, report the failure to the Super User and/or POCT Clinical Lab Scientist and remove the instrument from use until the reason for the failure is resolved.

Note: LQC failure may require contacting ITC for troubleshooting:
Call toll free in the U.S. (800) 631.5945
Outside the U.S: 001.732.548.5700.
Contact by e-mail: www.techsupport@itcmed.com

d. Do not use instrument for patient testing if QC fails.
e. Document all QC results on the Liquid QC Log.

WARNING! Even if the AVOXimeter 1000E's readings with liquid QC materials fall within the acceptable ranges specified on the insert sheet supplied with the liquid QC materials, the AVOXimeter 1000E can still give spurious readings on whole blood if blood or other debris has gotten onto the light detector. To rule out this possibility, perform the Optical QC Procedure with the yellow and orange filters.

Patient Testing

A. 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.

Note: If cuvette does not fill easily, do not force blood into the cuvette but discard and use a fresh cuvette.

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.

Note: Do not overpressure the cuvette or cause the vent patch to bulge outward.

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

Note: Do not depress plunger while syringe is in the instrument or remove the syringe.

9. If the AVOXimeter 1000E displays the previous MRN, you must acknowledge that it is the correct MRN or change it. Otherwise, the analyzer will prompt the user to enter the MRN. NOTE: If a different user is performing or if the analyzer is starting up, the analyzer will automatically prompt for a MRN to be entered with

no choice to select the previous one. **ALWAYS VERIFY THAT THE CORRECT MRN IS BEING USED ON YOUR PATIENT TEST.**

10. The AVOXimeter 1000E will report the results of the sample within 10 seconds:

Sample #1			
tHb	O2Hb	COHb	MetHb
17.0	39.7	56.6	1.1
g/dL	%	%	%

Not reportable COHB METHB

11. Results will automatically print in a summarized format. To print in long format, simply press the PRINT button. Report the results in the electronic medical record (EMR).

12. Remove the cuvette and syringe from the instrument.

13. Dispose of the used cuvette in a biohazard waste container.

14. To analyze the next sample, obtain a fresh cuvette from the bag next to the instrument, and repeat the previous eleven steps.

Results

A. Reference Range

	All Whole Blood Samples	
Analyte	Male	Female
THB (g/dL)		
>18 yrs	13.3 - 17.7	11.7 - 15.7
12 – 18yrs	13.0 - 16.0	12.0 - 16.0
OSAT	95 - 99 %	

B. Reporting Results

1. Upon test completion, record results in the electronic medical record (EMR).

C. Critical Results

THB >30d: <7g/dL or >20g/dL

D. Reportable Range

Analyte	
Total Hgb (g/dL)	5.0-25.0
O2 Saturation (%)	25-100

E. Unexpected Results

1. All results should be evaluated with respect to the patient's condition and medications.

2. Any result that does not reflect the expected result should be repeated immediately.

Proficiency Testing

Each institution must be enrolled in a Proficiency Testing (PT) program as part of Quality Management. Receiving, distribution, handling, preparing the PT material, and reporting results to the issuing agency will be directed by the institutional policy. Under no circumstances will any PT samples be referred to another facility for testing or confirmation of the results. Notify POCT and the issuing agency if there is a delay in receipt or damage to the testing material.

Linearity

- Commercial linearity kits (CVC 223 CO-Oximeter Calibration Verification Controls, 5 Levels, distributed by RNA Medical) are used to verify linearity and reportable ranges of total and percent oxyhemoglobin twice annually. It may be necessary to run additional linearity samples to ensure the reportable range can be adequately verified.
- Linearity results are reviewed and approved by the Division Chief of the Hematology Laboratory and the Laboratory Director.

Procedural Notes

A. Battery

The AVOXimeter 1000E can be powered either from its internal batteries or from the wall transformer that serves as a battery charger or AC adapter. Ni-Cad batteries suffer from a "memory effect" if they are charged before being completely discharged. To get the best use, allow the batteries discharge completely before charging them. If a screen message says "Battery Critical — Connect Charger", connect the charger and leave it connected for a minimum of 4 hours.

1. Check the status of the battery by pressing the "Computer" key.

2. Select Option "3. Time, Date, Battery".

3. Select Option “3. Battery Status”.

4. The second and third lines of the display show a battery status message such as “High, OK, Low, or Critical”.

B. Stand-by Mode

The Standby Delay can be set for 10 to 180 minutes:

1. Press the “Computer**”** key.

2. Select “Device Settings”.

3. Select Standby Delay and enter the time as specified by policy.

4. Default time is 60 minutes (1 Hour).

C. Automatic Power Down

1. The AVOXimeter 1000E will shut itself off completely if it has been in Standby Mode for 240 minutes (4 hours).

2. This function is not adjustable.

D. To Add New Users

1. Press the DATA button.

2. Select the User & Patient ID and then the ENTER button.

3. Select “Enter User ID” and then the ENTER button.

4. Enter the QA User ID number and then the ENTER button.

5. Select “OK” and then the ENTER button.

6. Select “Require User ID” and then the ENTER button.

7. Select “OK” and then the ENTER button.

8. Select “Add User” and then the ENTER button.

9. Enter the user ID number and then the ENTER button.

10. Select “OK” and then the ENTER button.

Limitations

A. Substances tested for possible interference:

Bilirubin: no interference

Hemolysis: no interference

Carboxyhemoglobin: no interference

Methemoglobin: (tHb = 16g/dl) (MetHb <10); (7.1< pH < 7.8)	<1% O_2Hb	< 0.2 g/dl tHb
Fetal hemoglobin: (tHb = 13.5 g/dl) (HbF <100%)	< 1% O_2Hb	< 0.45 g/dl THb

B. Operating Precautions

- This instrument is intended for use by persons trained in health care delivery and should be used only by authorized personnel.
- Operator should be thoroughly familiar with the information in this procedure before using the instrument for diagnostic purposes.
- This instrument should not be used in the presence of flammable agents or anesthetics.
- For continued protection against fire, replace power supply only with the model provided by ITC.
- Do not allow blood, water, or other liquids to enter the instrument itself.
- Blood exposed to the cuvette should not be returned to the patient as cuvettes are not sterile.
- Do not attempt to use this instrument outside the recommended temperature range: 15°C - 30°C (59°F - 86°F).
- Do not place this instrument in air currents or thermally unstable surroundings.
- Do not warm the cuvettes in your hand.
- Hold the cuvette by the black cap only.
- Leave the syringe attached to the cuvette during testing.
- Do not re-use the cuvettes; discard after each use.
- Always keep cuvettes in sealed bag with an active desiccant.
- For proper calibration and calibration verification, use only the controls recommended by ITC. Controls from other sources may yield erroneous results.

- Operator should take appropriate precautions when handling potentially infectious blood samples.

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

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

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

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

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 non-corrosive disinfectant wipe is recommended:

- Do not use strong solvents to clean the surfaces.

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

References

AVOXimeter 1000E Operators and Service Manual, U.S. Patent No. 5,430,542; 6,262,798; 6,519,025, ITC, 11/2007

Full Range Co-oximeter Control (RNA Medical) Package Insert, RNA Medical Division of Bionostics, Inc., 7 Jackson Road, Devens, MA 01434 (BIOMKT-0013, Rev. C 8/2011)

CVC 223 CO-Oximeter Calibration Verification Controls Package Insert, RNA Medical, Division of Bionostics, Inc., 7 Jackson Road, Devens, MA 01434 (BIOMKT-0007, Rev. C 8/2011)