Avoximeter® 1000E
Whole Blood Oximeter

Implementation Guide

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Introduction

Introduction

The validation studies described in this section are dependent on requirements approved and dictated by the Laboratory Medical Director and the Accrediting Organization for implementing a new lab instrument or assay. Please consult your local governing agency on best practices when validating diagnostic medical equipment, as such best practices may not be reflected in the descriptions set forth in this section.

The Centers for Medicare and Medicaid Services (CMS) administers the Clinical Laboratory Improvement Amendments (CLIA) which regulates all facilities that perform testing on materials derived from the human body for providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

Many private agencies have emerged to promulgate standards for laboratory best practices. In addition, these agencies perform site-visits or inspections to the facility to observe and document compliance of laboratory standards. Currently, these agencies include: The College of American Pathologists (CAP), The Joint Commission (TJC - The Joint Commission on the Accreditation of Healthcare Organizations - or formerly known as JCAHO), and the Commission on Laboratory Accreditation (COLA). These inspecting agencies also offer services to U.S. military hospital laboratories. State governments have a strong role in laboratory standards as well. While the Center for Medicare and Medicaid Services (CMS) regulates laboratory performance by way of the Clinical Laboratory Improvement Act (CLIA) at a national level, each individual State Department of Health (DOH) may modify those regulations and hold the testing facilities in their State to these guidelines that also may be more stringent.

CMS has directed that upon purchasing any new analyzer, immediate testing for patient management is not permitted. Regardless of manufacturer's claims or warranties, a series of quality assurance steps must be conducted to validate instrument performance and ensure analytes are reported with accuracy and precision. These implementation procedures are both essential from a Regulatory perspective and are necessary to assure diagnoses and therapeutic maneuvers remain consistent based on results analyzed from values produced from the new instrument.

Before a new analyzer is used for reporting patient results, the validation and verification of instrument performance must be completed and approved by the Medical Director named on the facility's CLIA license, issued by each State DOH. If the instruments are operating under the Clinical Laboratory's CLIA license, the laboratory Medical Director is required to approve the validation process once completed.
If any department holds their own independent license to perform testing, they must comply with the standards set by the accrediting organization identified on the CLIA application.

Quality Assurance/ Quality Management System (QA/QM) is a sequential integration of policies and processes that transform a physician's order into laboratory information. The objectives of the QA/QM process are to provide quality accurate diagnostic test results and reduce the potential for medical error that wastes resources and harms patients.

A sound QA/QM System and adherence to regulatory compliance guidelines is essential in providing accurate results yielding quality patient care.

To assist in achieving these objectives, Accriva has developed several tools to assist the Point of Care Coordinator (POCC) when implementing new Methods. These tools include: Operator Training documents and Instrument Validation guides.

The Operator Training documents are designed to allow the POCC to adapt the information to reflect their unique testing environment.

Pre-Implementation Checklist

Facility _____

Name _____

Task	Action Required	When Completed
Receipt of Avoximeter 1000E	Each instrument is functional and has a matched set of Optical filters	
Bio-Med Inspection	Assure that the Bio-Med inspection has been completed	
Supplies	Order a sufficient amount cuvettes for validation and training	
Linearity Material	Order linearity material from approved source.	
Liquid Quality Controls (LQC) Material	Order sufficient amounts of LQC material for validation and training from approved source	
Designation of Key Operators	Select individuals that will have advanced training to assist in training	
Training Area	Designate training areas for each Unit away from any patient treatment areas	
Individualized Quality Control Plans (IQCP)	The IQCP templates information has been provided	
Training Materials	The Skills Checklist, the Training Checklists and the Written Test have all been approved by the appropriate individuals for use	
Training Log Sheets	Training Log Sheets are available	
Additional Equipment for Training is available	Equipment: Gloves in various sizes, gauze, surface protectors, syringes and safety transfer needles, Bio-hazard disposal containers, “Sharps” containers, sterilizing wipes, and non-hazardous waste disposal units	

Operator Training and Competency Certification

Overview

Initial training is required by all US-based regulatory bodies. This should entail a complete review of the department's Policy and Procedures Manual with respect to the instrument and all applicable testing.

Documentation of training can be accomplished by the operator participating in a written test after review of the Procedure. The Skills Checklist is a detailed list of the skills necessary to successfully manage testing.

Further competency is certified with the Competency Assessment.

Other indicators of competency are the successful testing of LQC and participation in Proficiency Testing events.

Continued competency certification is also an annual requirement and the same steps can be utilized to satisfy this regulation.

These generic documents are designed to be modified by each site to conform to the site's requirements.

Available As Word Documents:

- (3a) **Skills Checklist**
- (3b) **Written Test**
- (3c) **Answer Key for Written Test**
- (3d) **Competency Assessment**
- (7a) **Optical Filter Log**
- (7b) **Weekly LQC Log**

Skills Checklist

Employee Name _____ Operator ID _____

(PRINT)

Employee Signature: _____ Date: _____

(SIGNATURE)

Evaluator: _____ Date: _____

(SIGNATURE)

Skill

Basic Operation	**Performance Acceptable?**
1 Instrument is powered “On” by pressing the “Enter/On” key	Y / N
2 Attaches syringe to cuvette correctly	Y / N
3 Does not touch the light path section	Y / N
4 Examines cuvette for bubbles	Y / N
5 Can manually enter Patient Identification (PID)	Y / N
6 Can recover old patient data	Y / N
7 Records results according to policy	Y / N

Skills Checklist (Continued)

Skill	Performance Acceptable?
Filter Checks	
1 Can describe the function of the filter check	Y / N
2 Knows required time interval for filter checks	Y / N
3 Knows where filter check parameters are located	Y / N
4 Know procedure if filter checks fail	Y / N
Liquid Quality Control (LQC)	
1 Knows to follow LQC manufacturer's instructions in handling LQC material	Y / N
2 Knows there are 3 levels of LQC	Y / N
3 Knows where the acceptable ranges for LQC are located	Y / N
4 Understands that all levels of LQC must be in range before instrument can be used for patient testing	Y / N
5 Understands the purpose of LQC performance	Y / N
6 Knows the frequency of LQC performance	Y / N
7 Knows LQC cannot be stored at room temperature	Y / N

Skills Checklist (Continued)

Skill		Performance Acceptable?
Cuvettes		
1	Knows cuvettes must be stored in their sealed bag	Y / N
2	Understands the humidity indicator must be blue	Y / N
3	Knows what steps to take if humidity indicator is pink or white	Y / N
4	Knows the Cuvette Pathlength changes from lot to lot of cuvettes	Y / N
5	Knows how to check Pathlength	Y / N
6	Can successfully change Pathlength	Y / N

Competency Exam

Name (Printed): _____ Date: _____

Signature: _____ Operator ID: _____

Department: _____

Multiple Choice: Circle best answer(s) to complete each statement.

1. The Yellow and Orange Optical QC Filters need to be performed:

a. Every 8 hours of patient testing
b. Weekly
c. Monthly
d. Daily

2. Liquid Quality Control (LQC) should be performed:

a. Weekly
b. Daily
c. Monthly
d. When a new shipment of cuvettes and/or controls is received

3. The test cuvettes:

a. Have a Pathlength assigned to each lot
b. Must be stored in sealed bag with a desiccant
c. Can only be used once

Competency Exam (Continued)

4. If the desiccants' color indicators (located in the bag of cuvettes) are _____, the cuvettes are OK to be used.

a. Red
b. Blue
c. Pink
d. Peach

5. Each time a new bag of cuvettes is opened, the Pathlength must be verified.

a. True
b. False

6. When filling a cuvette with a patient sample or LQC, it is important to:

a. Avoid air bubbles
b. Avoid overfilling
b. Hold the cuvette by the top collar

7. When inserting a cuvette into the analyzer, it is important to:

a. Use a single smooth motion
b. Keep the fabric vent patch to the left
c. Leave the syringe attached to the cuvette

8. With regards to sample collection and anticoagulant usage which of the following is acceptable:

a. The sample(s) can be drawn in a heparinized blood gas syringe
b. The sample(s) can be collected in a green-top tube (sodium- or lithium- heparin) or a purple/lavender top tube (EDTA)
c. The sample(s) must be collected anaerobically

Competency Exam (Continued)

9. To access patient and or QC results after the cuvette is removed:

a. Use the "Main Menu" key

b. Use the "Computer" key

c. Call the POCT office

10. The Avoximeter 1000E displays:

a. Total Hemoglobin (*t*Hb), Reduced Hemoglobin (HHb) and Oxygen Content (O_2ct)

b. Oxyhemoglobin (%O_2Hb) and Total Hemoglobin (*t*Hb)

c. Oxyhemoglobin (%O_2Hb), Total Hemoglobin (*t*Hb), Met-Hemoglobin (MetHb) and Carboxyhemoglobin (COHb)

c. Oxyhemoglobin (%O_2Hb), Total Hemoglobin (*t*Hb), and Oxygen Content (O_2ct)

11. Which key do you use to check the battery power?

a. "Main Menu", then "Battery"

b. "Computer" then "Time, Date, Temp"

c. "Stored Data"

c. "CANCEL"

Grader Name (Printed): _____

Grader Signature: _____ Date: _____

Answer Key for Competency Exam

1. **A**
2. **A, D**
3. **A, B, C**
4. **B**
5. **A**
6. **A, B, C**
7. **A, B, C**
8. **A, B, C**
9. **A**
10. **C**
11. **B**

Competency Assessment Checklist

Competency Period: **6-month** **12-month** **Annual** **Remedial**

Employee Name:_____ Unit:_____

How Competency is measured:

1. Direct observation of routine patient testing including: patient preparation, specimen collection, labeling, handling, processing and testing
2. Monitoring the recording and reporting of test results including critical values as applicable
3. Review of intermediate test results or worksheets, QC records, proficiency testing results, and preventative maintenance records
4. Direct observation of instrument maintenance and function checks, if applicable
5. Assessment of test performance through testing of previously analyzed specimens, internal blind testing, or external proficiency testing samples.
6. Evaluation of problem-solving skills

Method Of Competency Assessment	Performance Acceptable?
1. Direct Observation of patient test performance	
a. Correctly examines Patient sample for identification and labeling	Y / N
b. Correct sample collection: heparinized syringe: mixes well	Y / N
c. Cuvette handling: handle by black cap: keep syringe attached	Y / N
d. Loading of cuvette: check for bubbles; inserts cuvette correctly	Y / N
e. Analysis of sample by instrument	Y / N
f. Instrument display messages	Y / N
g. Results on screen until sample is removed	Y / N
h. Reading results	Y / N
i. Printing / recording / reporting of results	Y / N

Competency Assessment Checklist (Continued)

Method Of Competency Assessment	Performance Acceptable?

2. Monitoring the recording / reporting of test results

a. Actions for Critical values — Y / N

b. Retrieve patient or QC results — Y / N

3. Key Operators: Review by Policy

a. Reviews Patient test results — Y / N

b. Quality Control (QC) results — Y / N

c. Proficiency Testing (PT) results — Y / N

d. Maintenance — Y / N

(If any unacceptable performance or problems, documentation of resolution):

_____

4. Direct observation of instrument maintenance and required daily / weekly QC

a. Changing cuvettes lots; entering correct Pathlength — Y / N

b. Running QC Optical Filter (Yellow & Orange) every 24 hours and recording results per procedure — Y / N

c. Running LQC per protocol; logging in results per procedure — Y / N

5. Assessment of test performance (complete one of the following)

a. Comparison of test result from #1 above with previous run or duplicate run and record - Optional: attach report or tape and the comparison data; [OR] — Y / N

b. Analyze LQC and record - Optional: attach LQC values along with acceptable range; [OR] — Y / N

c. Proficiency testing sample and record – Optional: attach copy of PT sample analyzed by this employee along with PT report showing 100% acceptable score — Y / N

Competency Assessment Checklist (Continued)

Method Of Competency Assessment **Performance Acceptable?**

6. Assess problem-solving skills

a. Instrument error messages **Y / N**

b. Questionable patient results **Y / N**

c. Checking the current path length in the instrument **Y / N**

d. Optical filter failure or LQC failure **Y / N**

e. Operator lock-out resolution **Y / N**

f. Written Exam completion (At least 85% must be scored) **Date Completed:** _____

Score: _____

LQC range (Level 1 or 2 or 3 from package insert)

Level 1 or 2 (Circle one) Acceptable Ranges

THb % HbO_2

Operator Results:

THB %HbO_2

Proficiency Testing Acceptable Ranges:

THb %HbO_2

Operator Results:

THb %HbO_2

Employee Signature: _____ **Date:** _____

Evaluator's Signature: _____ **Date:** _____

Evaluator's signature above indicates the employee has demonstrated abilities necessary for the quality performance of these tasks, at an acceptable level (unless otherwise indicated in the Notes section).

The employee's signature indicates the employee is confident with the performance of this procedure, is in agreement, and that all statements are truthful in fact.

Validation Studies

Overview

The following information represents the common procedures as specified by the Accrediting Organizations (AOs) for initial validation of each instrument:

- Trueness/Precision
- Method Correlation between the “Old” method and the Avoximeter 1000E
- **Optional:** Reference Interval (Normal Values) Studies
- Linearity Studies
- **Optional:** Completion of an IQC Plan to reduce the frequency of LQC to weekly. Please contact Accriva Technical Support for the IQCP templates for the Avoximeter 1000E.

For continued compliance

- Six-month Instrument Correlation: correlating all instruments performing the same testing
- The Medical Director of each Facility may specify more studies to validate instrument performance.

Trueness & Precision Study Protocols

Testing Method

Operators should be familiar wit the technique required to manage the Liquid Quality Control (LQC) material prior to performing this test.

1. **The process should be done across several days (i.e., 5 days) and by multiple operators to accommodate different techniques and environments.**
2. **The suggested process involves testing LQC material at all 3 levels twice per day for a total of 10 results for each level.**
3. **The data collected can be analyzed by Accriva upon request. A template to be electronically sent must be completed entirely or will be returned for correction.**

Procedure

1. **Order the LQC material from the recommended source.**
2. **Prepare the LQC material as directed by the manufacturer.**
3. **Perform the Filter check prior to testing the LQC material.**
4. **Confirm cuvette Pathlength is correct.**
5. **Test cuvettes are to be stored in the same area as the Avoximeter 1000E.**
6. **Test the LQC material.**
7. **Record results as directed by policy.**
8. **Data analysis:**
   a. Trueness:
   $\%O_2Hb$ ± 1%;
   *t*Hb (> 10g/dL) ± 0.45%;
   *t*Hb (<10 g/dL) ± 0.35%

   b. Precision:
   $\%O_2Hb$ ± 0.5%
   *t*Hb ± 0.3%

Optional: Data Submission to Accriva

Technical Support is available for data analysis templates or any assistance:

- Email: **ilsd_techsupport@ilww.com**
- Phone number: **1-800-579-2255**

Optional Reference Interval Studies (Normal Values Range)

Overview

The Reference Interval has to be established prior to using the new method to report patient results.

The Reference Interval study must be performed to determine the range for healthy individuals and this range must be included on the result reports.

As the Reference Interval for Normal Donors is well-established in a number of journals and text books, the site may use these as Reference Ranges and include the the sources in their Procedures.

CMS/ CLIA “Brochure #2 Verification of Performance” and CLSI Document C28 both suggest that as few as 20 individuals may be sufficient to verify the reference interval.

The final decision for the total number of individuals to be tested will be made by the Medical Director.

Method Correlation Protocol

Pre-evaluation

Prior to initiating the Clinical Correlation, review the following:

- Be familiar with the operation of the Avoximeter 1000E and review the Operator's Manual.
- Insure both the Avoximeter 1000E and the method currently in use are operating correctly by checking Quality markers such as Daily Quality Control (QC) or maintenance records.
- Read all package inserts.
- Review this entire protocol before beginning a test.

NOTE: Only Avoximeter 1000E cuvettes can be used with the Avoximeter 1000E.

Test Population

1. **A sufficient number of samples must be obtained to span the entire normal and therapeutic range.**
2. **EP-09 recommends a total of 40 patient samples.**
3. **CLIA recommends 20 - 40 patient samples (42CFR.493.1281).**

Instrument Preparation

1. **Cuvettes are stored at room temperature inside the closed bag with the desiccant. The desiccant indicators must be blue and not pink.**
2. **Confirm the Pathlength entered into the instrument matches the Pathlength on the cuvette bag.**
3. **Perform the reference instrument QC and the Avoximeter 1000E QC (Optical filters, and approved Liquid Quality Control (LQC) material).**

Method Correlation Protocol (Continued)

Test Procedure and Blood Collection

1. Collect whole blood samples in a sodium or lithium heparinized syringe.
2. If the sample was not infused into the cuvette immediately after blood draw, thoroughly mix the whole blood sample by gently rolling the syringe between the palms of the hands.
3. Connect a syringe containing the sample to an unused cuvette.
4. Hold the cuvette by means of the finger grip on the black cap.
5. Firmly holding the syringe and cuvette at a 45-degree angle, fill the cuvette by gently pressing the syringe plunger.
6. Stop filling the cuvette when the sample reaches the vent patch.
7. Do not continue to fill the cuvette and cause the vent patch to bulge.
8. Verify that the light path area is free of bubbles.
9. Remove any blood from the exterior of the cuvette before placing the cuvette (with syringe still attached) into the test chamber.
10. The instrument will immediately start analyzing the sample and display the result.

When comparing the Avoximeter 1000E to another Avoximeter 1000E system

1. Immediately fill the appropriate Avoximeter cuvette using the blood sample remaining in the syringe.
2. Conduct the test immediately.

When comparing the Avoximeter 1000E to another Oximetry Test method

1. Follow the manufacturer's recommended instrument preparation.
2. Test Avoximeter 1000E first if the reference method samples directly from the syringe to prevent contamination.

Method Correlation Protocol (Continued)

Recording Results on Templates from Accriva

1. Record Avoximeter 1000E results in the appropriate column.
2. Record the corresponding results generated by the reference instrument in the appropriate column.
3. Once requisite number of sets of data points distributed over the entire clinical range have been collected, either:

   Contact Accriva Diagnostics for data analysis support:

   - Phone: **1.800.579.2255**
   - By email: **ilsd_techsupport@ilww.com**

   [OR]

   Analyze the data by using an internal program.

Monthly Optical QC Summary (Daily Filter Check)

Month: _____ **Year:** _____ **SN:** _____

	Orange Filter		Yellow Filter			
Date	**%O_2Hb**	***t*Hb g/dL**	***t*Hb g/dL**	***t*Hb g/dL**	**QC Passed?**	**Initials**
	37.2- 40.8	**16.4-17.6**	**93.5- 96.5**	**7.7- 8.3**		
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Summary:

	%O_2Hb	*t*Hb	%O_2Hb	*t*Hb
Mean				
SD				
% CV				

Reviewed by: _____ **Date** _____

Weekly LQC Log

Facility: _____

Month: _____ **Year:** _____ **Avoximeter 1000E SN:** _____

QC Lot Numbers _____ _____ _____ EXP. DATE: _____

		Level 1	Level 2	Level 3	Check if QC OK (within range)
O_2Hb Range (%)	MIN				
	MAX				
*t*Hb Range (g/dL)	MIN				
	MAX				
WEEK 1					
DATE:		O_2Hb:	O_2Hb:	O_2Hb:	
Pathlength:		*t*Hb:	*t*Hb:	*t*Hb:	
WEEK 2					
DATE:		O_2Hb:	O_2Hb:	O_2Hb:	
Pathlength:		*t*Hb:	*t*Hb:	*t*Hb:	
WEEK 3					
DATE:		O_2Hb:	O_2Hb:	O_2Hb:	
Pathlength:		*t*Hb:	*t*Hb:	*t*Hb:	
WEEK 4					
DATE:		O_2Hb:	O_2Hb:	O_2Hb:	
Pathlength:		*t*Hb:	*t*Hb:	*t*Hb:	
WEEK 5					
DATE:		O_2Hb:	O_2Hb:	O_2Hb:	
Pathlength:		*t*Hb:	*t*Hb:	*t*Hb:	
Initials:					

COMMENTS: *If the LQC Lot Changes, start a NEW Weekly Log*
Document ALL LQC Failures in the CORRECTIVE ACTION Log

Reviewed by: _____ **Date** _____