
PROCEDURE: RADIOMETER ABL™ 80 OPERATING PROCEDURE

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PRINCIPLE: The ABL 80 analyzer is used for measurements of pH, blood gas and hemoglobin status in arterial, venous and capillary blood samples.

There are four different measuring principles employed for the electrodes in the ABL 80 analyzer.

- **Potentiometry:** The potential of an electrode chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation).
- **Amperometry:** The magnitude of an electrical current flowing through a sensor chain is proportional to the concentration of the substance being oxidized or reduced at an electrode in the chain.
- **Conductometry:** specific impedance of a sample as measured by two conducting electrodes held at a constant voltage is directly proportional to the conductive properties of that sample.
- **Spectrophotometry:** Light passes through a cuvette containing a hemolyzed blood sample. The specific wavelengths absorbed and their intensity generates an absorption spectrum used to calculate oximetry parameters.

The optical system is based on a 138-wavelength spectrometer (spectrophotometer) with a measuring range of 467-672 nm. The spectrometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.

CLINICAL SIGNIFICANCE:

Traditional pH and blood gas analysis establishes the acid-base status of blood by measuring pH, $p\text{CO}_2$ and occasionally ctHb , and gives partial information concerning the oxygen status of blood by measuring $p\text{O}_2$.

SPECIMENS:

Arterial/Venous: A minimum of **125 μL** whole blood must be collected anaerobically in an air-tight syringe, which contains sodium or lithium heparin as an anticoagulant. The sample must be analyzed within 45 minutes of collection.

Capillary: A minimum of **125 μL** whole blood must be collected anaerobically in heparinized capillary tubes. A metal flea must be inserted into the sample as a means of mixing with a magnet before the sample is analyzed. The sample must be within analyzed within 45 minutes of collection.

The exclusive use of heparin as an anticoagulant is recommended by RADIOMETER.

Patients are identified at the beginning of the procedure, just like in the O.R. Patient labels are used to scan the patient ID in the ALB80. Each syringe is not labeled.

REAGENTS:

1. **Solution Pack**

When stored between 12- 25°C Solution Pack Ref 944-252 is stable until expiration date on the pack. When stored at higher temperatures, up to 32°C, Solution pack is stable for 2 weeks if unopened.

After installation of the solution pack it is stable for 30 days on the analyzer or usage prompts the user to install another solution pack. When the ABL80 prompts the user to change the solution pack the ABL80 will not let the operator continue with patient testing until a pack is changed and it passes a system check.

Quality management of the system is accomplished using a solution pack that contains multiple levels of precision tonometered electrolyte solutions packaged in gas tight disposable pouches. The solution pack provides the necessary fluids for the calibration and quality control of all measured parameters.

Each solution pack contains a smart chip that provides information to the system regarding the status of the solution pack. The analyzer automatically reads this information when the solution pack is installed onto the analyzer and writes additional information to the smart chip during use. This information includes the following:

- Serial number of the pack
- Lot number for each of four solution pouches
- Install by date (The last day this solution can be installed onto any analyzer)
- Installation date (The date this solution pack was installed onto an analyzer)
- Number of allowable days in use
- True values for each parameter
- Quality control assigned values and acceptable ranges for each parameter
- Number of cycles for each pouch
- Version of software

The solution pack contains five pouches:

Four pouches contain NIST traceable solutions with various concentrations of tonometered gasses as well as dyes as required for oximetry measurements.

Fifth pouch collects all liquid waste both from the internal solutions and all external solutions including the biohazard of bodily fluids from patient samples. The waste pouch contains an additive, This combines with the liquid waste to form a gel. The gel limits spillage and provides an Added level of safety.

After use solution pack must be disposed of in biohazard waste.

2. **Sensor Cassette**

When stored between 5-25°C Sensor cassettes Ref 945-703 is stable until the expiration date on the cassette.

After installation of the sensor cassette it is stable for 30 days or until the sensor has been used for 100 specimens, the system will prompt the user to change the sensor cassette, and the system will not let the operator continue with patient specimens until the cassette is properly installed and a system check passes.

The sensor cassette is designed for use with whole blood or quality control solutions. The sensor cassette contains a low volume, flow-through cell. All the measuring sensors for pH and blood gas are contained in a multi-use disposable cassette assembly. The cassette flow cell also contains a reference electrode for the potentiometric sensors and an integral temperature sensor and heating element for precise temperature control.

Each sensor cassette contains a smart chip that provides information to the system regarding the type and status of each sensor cassette. The analyzer automatically reads this information when the cassette is installed onto the analyzer. While in-use the analyzer also records additional information on the smart chip. Information recorded in the smart chip includes:

Lot Number
Serial Number
Parameter Panel
Number of tests allowed
Number of tests remaining
Install by Date (The last day this sensor cassette can be installed onto an analyzer)
Installation Date (The date this cassette was first installed onto the analyzer)
Analyzer serial number (The analyzer onto which this cassette is currently installed)
Expiration Date (Date this sensor cassette will expire once installed)

QUALITY CONTROL:

Radiometer QUALICHECK5+ System control solutions are identified as follows:

S7730 – red S7740 – yellow S7750 - blue

- The information pertaining to the ampoule level, i.e. solution type, lot number, and expiration date, is bar coded on the package insert for easy entry.
- Store ampoules at room temperature.
- All three levels of control material are run at the beginning of each day by trained point of care trained personnel when performing patient tests on that day.
- Ranges for the Quality Control will display on the ABL80 and warn the operator if out of range.
- Quality Control results are entered in the Cerner Lab system for review weekly by the SLCH Point of Care staff.
- Quality Control is reviewed and signed monthly by the Laboratory Medical Director or designee.
- Ranges were established for the current Radiometer lot by running 20 days of Quality control material.
- Ranges were imputed in the ABL80 after review by the Laboratory Medical Director or designee.
- Ranges out of 2SD's will warn the operator to repeat the quality control level.
- Quality Control out of range after repeating, contact the SLCH Point of Care/Core lab before proceeding with patient testing.
- Instrument failures contact the SLCH Point of Care/Core lab

ABL80 Main Menu

The main menu consists of several sections.

The **top** of the screen consists of the title bar area. It displays the status of the analyzer to the user and provides access to additional information including:

- Status message
- System status traffic light
- Data Log button
- Parameter Bar

The **center** section of the screen displays the User logged onto the system.

The **bottom** section of the screen displays the following elements:

- Menu Button
- Logoff button
- Tutorials
- Power status
- Time of the Day

Analyzer Status

- **Status Traffic Light**
Provides a color coded indicator and message to the user of the current status of the analyzer with regard to sample analysis availability. Press the icon to display all related system messages. Press Close or the Menu button to close this window.
Green Light: The analyzer is ready for sample analysis.
Yellow Light: The analyzer is ready for sample analysis but there are one or more conditions soon to occur which will cause the sample analysis to be unavailable.
Red Light: Sample analysis is unavailable due to one or more analyzer conditions.
- **Data Logs**
Provides quick access to the data logs stored in the analyzer. All patient samples, calibrations and Quality control results, as well as other stored information, can be accessed by pressing this icon.
- **Menu**
Provides access to all available navigation menu options. The options available depend on the Security settings established in the system.
- **Logoff**
Appears only when a user is logged onto the analyzer. It provides the ability to manually log the user off of the system.
- **Tutorials**
Provides instructional video, text and audio for a variety of basic operations.

Calibration

With the ABL80 FLEX QC automatic quality control system, the calibration process includes the measurement of three solutions with different analyte concentrations. These three measured values are used in different combinations of two points each to establish three two-point calibration lines for each analyte. One calibration line is consistently used to report sample results. The other two calibration lines are used to evaluate system linearity. When the calibration system fails the system will not allow the user to perform sample analysis.

- **Sensor calibration** is the process of relating sensor electrical outputs to known analyte values.

Traditionally, the calibration line slope (sensitivity) of each sensor is derived from the electrical values end points obtained by measuring two solutions with different analyte concentrations.

- **tHb Calibration:** Calibrates the photometer.
- **System Cycle:** Calibration is performed during a System Cycle.

- **Schedule** A Two Point Calibration is performed every 4 hours. A System cycle is performed every 30 minutes, this is a one point calibration. With every blood sample analysis a System check with a one point calibration is performed. This specialized System check is termed an analysis check. tHb is performed every 3 months.
- **Drift** The system is configured to display a drift value for any parameter whose drift falls outside of the acceptable drift criteria between system cycles.

The calibration results from each system cycle can be viewed in the system cycle data logs. It is also recorded in the event log.

To Review Calibration:

Select Menu/ Data/ Logs/ System Cycle. Highlight the desired record and press the system cycle detail button to view the results. To view the calibration results press the calibration tab.

Results that are out of range will be identified with an arrow up or down to signify out of range.

tHb Calibration Procedure

- Select Menu/Utilities/tHb Calibration
- Press the scan button, and scan the tHb calibration barcode for the ABL80FLEX Co-Ox analyzer, located on the S7770 package insert. If the scanner is not available you may manually enter the barcode using the numeric keypad provided.
- The system will complete a blank calibration then prompt the user to aspirate the calibration solution.
- Carefully open an ampoule of S777- tHb Calibration solution.
- Raise the sample inlet probe. Guide the inlet probe fully into the calibration ampoule solution, ensuring the tip of the inlet probe is fully immersed in the QC solution.
- Press Aspirate. When the sample aspiration is complete, the analyzer provides a message and two short beeps.
- Remove the ampoule and lower the inlet probe.
- The system will proceed to perform the tHb calibration. Once complete, the analyzer will display the calibration results.
- The results screen displays a value for the cuvette factor. The cuvette factor expresses the ratio of the effective light path of the analyzer cuvette to that of a reference cuvette determined by Radiometer.
- The Fcuv acceptable range is 0.80 – 1.20.
- If the calibration result is not acceptable, the system will retain the prior Fcuv and inform the user of this calibration failure.
- Following a successful tHb calibration, the system will automatically initiate a system cycle.
- Performed by Point of Care staff.

Syringe and Capillary Samples

Before an analysis, the blood sample should be ready in the syringe or capillary tube and free from air bubbles. The specimen must be mixed thoroughly to ensure accurate hematocrit and hemoglobin values. Also, the analyzer must be in the Ready mode before an analysis can be started. Always wear gloves when performing blood gases or AC T's in the Cath lab.

1. Ensure the analyzer is ready to accept a patient sample.
2. Traffic light is displaying a green light.
3. The desired parameters are available and appear in the parameter bar as green.

4. Scan User ID badge, only trained Cath lab staff are able to scan as a trained operator.
5. Select the Blood Drop for analysis of a patient sample, or from the menu button analysis.
6. Slide the handle up to the first position. For Capillary specimens slide the handle to the first position and continue pulling the handle up and forward to lock it into the second position for capillary sampling.
6. Guide the inlet probe into the sample. Ensure the tip of the inlet probe is fully immersed in the sample. Scan the patient label for patient ID entry.
7. Select sample type from the selections: Arterial, Venous, Capillary, Mixed Venous and Other
8. Patient Type: Select from the drop down selections: IVC, RA etc.
9. Results will print when the analysis is completed.

Patient Result Screen/Troubleshooting

The result displays all the selected parameters along with the measured value for each and a reference range

Flags

*** The Final result is outside of the measuring range of the analyzer.

!! Possible air was identified in either the sample or the flush during analysis. Repeat specimen.

? One or more errors have been identified related to oximetry results. All related results are flagged with a question mark. Repeat specimen. Specimen may also be sent to the Core Lab for analysis.

Sample Information

Scan the account number, Patient ID, First and Last name, Birth Date by scanning in the information in the required field. The required fields are set up by the Point of Care Coordinator and the testing location.

MAINTENANCE:

Daily: Please use a bleach wipe/sani wipe when visible blood is present on the ABL80 to wipe off the instrument.

Weekly: Point of Care personnel does data deletions, the status of the solution pack, sensor cassette, quality control and the completion of weekly inventory.

Record this maintenance on the ABL80 Maintenance log.

As Necessary:

- Solution Pack or Sensor cassette needs to be replaced due to depletion or 30 days.
- Paper change when needed.
- The analyzer continuously monitors the status of system components, which require replacement. An overview of the current status of these items can be obtained from the Data Logs, System Information which also enables you to view the status of the sensor cassette and the solution pack.

Quarterly:

tHb Calibration performed by the Point of Care personnel.

CALCULATIONS:

Refer to Section 12 of the Operators Manual for all detailed equations of all parameters.

Measured Parameters

<u>Symbol</u>	<u>Unit</u>	<u>Measuring Range</u>	<u>Reportable Range</u>
pH	-	6.500-8.000	6.500-8.000
pCO ₂	mmHg	10.0 - 100.0	10.0-100.0
pO ₂	mmHg	10.0 - 500.0	10.0-500.0
ctHb	g/dL	0.0 - 27.7	1.0-27.70
sO ₂	%	0.0 - 100.0	0.0-100.0
FO ₂ Hb	%	0.0 - 100.0	0.0-100.0
FCOHb	%	0.0 - 100.0	0.0-100.0

REFERENCE RANGE:

Arterial

OxyHemoglobin:	90-95%
Carboxyhemoglobin:	<3%
Hemoglobin:	14.5-22.5 (0-1 Week)
	10.0-18.0 (1 Week-1 Month)
	9.0-14.9 (1-6 Months)
	10.5-13.5 (6 Months-2 Years)
	11.5-13.5 (2-6 Years)
	11.5-15.5 (6-12 Years)
	13.8-17.2 (12 Years-Adult Male)
	12.1-15.1 (12 Years-Adult Female)

Arterial

pH	7.35 - 7.45
pCO ₂	32 - 48 mmHg
pO ₂	83 - 108 mmHg
tCO ₂	20 – 30 mmol/L

Critical Values

Carboxyghb Art:	>10%
Oxyhemoglobin	< or = 60%
Hemoglobin	< or = 7.5 g/dL
pH	<7.20 or >7.60
pO ₂ Venous	<15

All patient specimens assayed in the Cardiac Cath Lab results are given directly to the physician in the Cath lab at the time of analysis. Measuring ranges print on the Cath lab printout.

Results that do not match the clinical picture a specimen should be sent to the Core Lab for verification.

Results are entered in Cerner by Core Lab Staff and verified by Point of Care Staff for accuracy.

LIMITATIONS OF PROCEDURE: For a complete list of potential interfering substances refer to Section 6 of the Reference Manual for ABL80.

AMR Ranges are checked twice a year by CAP Linearity survey and signed by the Medical Director.

Patient comparisons are run quarterly using the ABL80 (A) and (B) and the Radiometer 800's in the Core lab. Results must be \pm 2SD's of the closest Quality Control Range.

Quality Control is signed by the Laboratory Medical Director monthly.

REFERENCES:

Operator's Manual for ABL80 series. Radiometer/Copenhagen, Radiometer America 2008.

Reference Manual for ABL80 series. Radiometer/Copenhagen, Radiometer America 2008.



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Annual Review: Medical Director/Designee

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